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The International Comparative Legal Guide to:

Product Liability 2009

A practical insight to cross-border Product Liability work

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EDITORIAL

Welcome to the seventh edition of *The International Comparative Legal Guide to: Product Liability*.

This guide provides the international practitioner and in-house counsel with a comprehensive worldwide legal analysis of the laws and regulations of product liability.

It is divided into two main sections:

Seven general chapters. These are designed to provide readers with a comprehensive overview of key product liability issues, particularly from the perspective of a multi-jurisdictional transaction.

Country question and answer chapters. These provide a broad overview of common issues in product liability laws and regulations in 37 jurisdictions.

All chapters are written by leading product liability lawyers and we are extremely grateful for their excellent contributions.

Special thanks are reserved for the contributing editors, Ian Dodds-Smith of Arnold & Porter (UK) LLP and Michael Spencer QC of Crown Office Chambers, for all their assistance.

Global Legal Group hopes that you find this guide practical and interesting.

The *International Comparative Legal Guide* series is also available online at www.iclg.co.uk

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Recent Developments in European Product Liability

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Introduction

The Product Liability Directive, 85/347/EEC ("the Directive") lays down common rules governing liability for defective products in the European Union ("EU"). It imposes strict liability on the producer of a defective product for damage caused by the defect. A product is defective if it does not provide the safety that consumers generally are entitled to expect taking account of all of the circumstances, including the product's get up and presentation and its expected use.

This article discusses recent developments in European product liability law, including the European Commission's Third Report on the Directive and European caselaw. The European Court of Justice ("ECJ") has recently provided guidance on the interpretation of when a product is "put into circulation" for the purposes of the Directive and has also been asked to address how the 10-year 'longstop' period under Article 11 of the Directive is applied. This article also addresses other EU developments including the proposed Consumer Rights Directive and proposals regarding collective consumer redress that could significantly change the legal environment for bringing product liability claims in the EU.

The European Commission's Third Report on the Application of the Directive

The report, which was published on 14 September 2006, describes the outcome of the European Commission's third review of the operation and effect of the Directive in the context of the European product liability framework (earlier reviews were published in 1995 and 2001). Overall, the report concludes that the Directive is operating in a satisfactory way and there is currently no need for further amendment. It concludes that there is some evidence that Member States' varying legal traditions have led to differences in interpretation by national courts and disparities in the application of certain aspects of the Directive. While there is scope for further harmonisation (possibly through European caselaw) those disparities did not create significant barriers to trade or distortions to competition within Europe. The Commission identified a number of issues that it will continue to monitor:

- the burden of proof (Article 4) - the Commission found evidence of differences in approach to assessing the burden of proof and that several Member States had sought to redress claimants' difficulties in proving defect/causation (for example, by inferring causation and, therefore, liability from the fact that a product is defective);
- the concept of defect (Article 6) - there was evidence of disparities in the way different national courts approached the assessment of defect;
- the development risks defence (Article 7(e)) - the Commission found that the scope of the defence was uncertain and there was evidence of differences in approach by national courts;
- the minimum damages threshold for property claims (Article 9) - some Member States treated this provision as imposing a deductible on the amount of damages recoverable, while others treated it as a threshold above which claims can be brought (where full damages are recoverable provided the value of the claim exceeds the threshold);
- whether a new regulatory compliance defence should be introduced - some respondents in highly regulated industries argued in favour of the introduction of such a defence; and
- the application of the Directive to novel products - some respondents argued that the Directive was an inappropriate means of dealing with design and information defects in novel products.

When is a Product "Put into Circulation" and How is the 10-year Longstop Period Applied?

Determining when a product has been put into circulation is a key concept which underpins the liability regime imposed by the Directive. The question of whether a product is defective is assessed by reference to information and knowledge available at the time that it is put into circulation. The application of the so-called 'longstop' period pursuant to Article 11 of the Directive is also determined by reference to that date. Article 11 provides that an injured person's rights are extinguished 10 years after the product was put into circulation, and proceedings alleging strict liability under the Directive must therefore be commenced within 10 years of that date. Under Article 7 of the Directive the producer also has a defence if he can show that he did not put the product into circulation.

In the case of *OB v Aventis Pasteur MSD and Aventis Pasteur SA*, (Case C-127/04) the ECJ was asked to consider when a product is put into circulation for the purposes of Article 11 of the Directive. The case concerned the application of the Directive to complex manufacturing and distribution arrangements within an international group of companies. The claimant alleged that he had sustained serious injuries as a result of receiving a defective dose of the Hib vaccine. The vaccine was manufactured in France by Aventis Pasteur SA ("APSA"). It was purchased in fully finished packaged form by Aventis Pasteur MSD ("APMSD"), the UK distributor of the product and holder of the UK marketing authorisation. It was a company owned by a joint venture between Merck Inc and APSA. APMSD supplied the product to the Department of Health which supplied it to a doctor, who in turn, administered the vaccine to the Claimant.

Proceedings were commenced against APMSD on 2 November 2000. The Claimant was informed by APMSD that APSA was the producer of the vaccine and he commenced a separate set of proceedings against it on 7 October 2002. APSA argued that those proceedings were time barred because the vaccine was put into circulation by delivery of the vaccine by APSA to APMSD on 18 September 1992. The Claimant subsequently applied to substitute APSA for APMSD in the first set of proceedings (having previously failed in an application for joinder). The English Court made a preliminary reference to the ECJ asking, amongst other matters, for guidance on when, in these circumstances, a product is put into circulation.

In its decision delivered on 9 February 2006, the ECJ decided that a product is put into circulation when it is taken out of the manufacturing process operated by the producer and enters a marketing process in the form in which it is offered to the public for sale or consumption. The Court declined to follow the Advocate General's opinion which proposed that, in the case of a group of companies, a product was only put into circulation when it left the control of the group. However, the ECJ recognised that where entities in the chain of distribution are closely connected to the producer, it is for the national courts to examine the factual situation and determine whether, in reality, the related entity is involved in the manufacturing process. This is a question of fact and takes no account of whether the related entity has an independent legal personality, or whether the products have been purchased by it and property (ownership) in the products has passed. The focus of the assessment should be whether the related entity carries out an activity that is properly to be treated as a production activity or, in contrast, is simply acting as a distributor of a product manufactured by an associated company.

In the light of this decision, where companies engage in complex intra-group manufacturing and distribution arrangements it will be necessary to examine the contractual position and the activities carried out by each group company to determine when a product is put into circulation. The ECJ's decision suggests that subsidiary companies which are responsible for packaging or repackaging finished goods may be treated as engaged in manufacturing processes and, therefore, that the supply of unfinished products to those companies under intra-group manufacturing arrangements would not amount to 'putting the product into circulation'. Such companies may, therefore, be treated as a producer and sued in their own right by consumers. However, where a subsidiary or associated company is simply a distributor of a finished product in the form that it would be offered for sale to consumers, it is not a producer and the sale or supply of products to that organisation amounts to putting the product into circulation.

The decision provides important clarification of this key legal test. It undermines the argument sometimes adopted by consumers that a product is not put into circulation until it reaches the consumer who claims to be injured by it, and emphasises the importance of commencing proceedings promptly. However, there remain areas of uncertainty. Some consumers have argued that where a product, such as a vaccine, is reconstituted, time does not being to run until the reconstitution because the test only applies to a product "in the form that it reaches the public". It remains important that manufacturers and distributors are able adequately to document their manufacturing and distribution arrangements to prove the date when a product is put into circulation. Manufacturers should consider reviewing their document retention policies to ensure that steps are taken to preserve the evidence necessary to establish a proper case of limitation.

Other aspects of the ECJ's judgment in *O'Byrne* were treated by the English courts as difficult to interpret. There remains doubt as to extent of the harmonisation achieved by the Directive in relation to the discretion of national courts to allow substitution of parties after the expiry of the 10-year longstop. The English courts have recently made a further preliminary reference to the ECJ in the same case seeking clarification of this point and the question referred is:

"Is it consistent with the… Directive for the laws of a Member State to allow substitution of a new defendant to a claim brought under the Directive after the 10 year period for enforcing rights under Article 11… has expired in circumstances where the only person named as a defendant in the proceedings instituted during the 10 year period was someone who does not fall within Article 3 of the Directive."

A decision is unlikely before 2010.

Other European Developments - Proposed Consumer Rights Directive

In October 2008 the Commission published a Proposal for a Directive on Consumer Rights (COM (2008) 614 final). The proposal aims to introduce a single unified set of rules governing consumers' contractual rights in the EU. It will update the existing legal framework in line with advances in modern technology and the increasing use of the internet, while removing inconsistencies in the previous laws and closing gaps. It will consolidate the existing requirements contained in four separate Directives which govern unfair contract terms (Directive 93/13/EEC), consumer sales and guarantees (Directive 1999/44/EC), distance contracts (Directive 97/7/EC) and doorstep selling (Directive 85/577/EEC on contracts negotiated away from business premises). As these Directives laid down minimum standards, individual EU countries have adopted the requirements in different ways, in some instances imposing additional or stricter rules. The result is a patchwork of different laws which the Commission considers is unclear to consumers and confusing for business. In particular, different Member States have different requirements in respect of the length of consumer guarantees and the cooling off period during which a consumer can withdraw from a distance selling contract. The Commission is concerned that these different rules present a barrier to cross-border trade and points to the reluctance of European consumers to purchase products from another country, despite significant differences in price. (For example according to the papers accompanying the proposal, the cost of a digital camera was found to be 54% more expensive in Finland than it was in the UK.) It is therefore intended that the new rules will be a harmonising measure from which Member States cannot derogate.

The proposed Directive applies to contracts for the sale of goods and services between businesses and consumers. All types of contracts are covered including distance contracts and contracts made away from business premises. The proposed Directive aims to lay down EU wide rules covering pre-contractual information, the delivery of goods, the remedies available to consumers who purchase faulty products, unfair contract terms and, in the case of distance and pressure sales, the cooling off period. It also includes new rules relating to the delivery of goods. Under the proposals goods must be delivered to the consumer anywhere in the EU within a maximum of 30 calendar days from agreeing the contract. The trader bears the risk of the goods, including the cost of any deterioration, until delivery takes place. In the case of non-delivery or late delivery a consumer is entitled to a refund as soon as possible, and no later than 7 days from the agreed date of delivery.

Other European Developments - Collective Redress

Possible changes to the procedural rules affecting many product liability claims may have a greater impact on the overall legal environment for such claims than changes to the Directive itself. As

the Commission acknowledged in its Third Report, many of the disparities in the application of the Directive reflect the varying legal traditions and procedural rules in different Member States. In November 2008 the European Commission published a Green Paper on Consumer Collective Redress (COM (2008) 794 final) which sought views on how existing methods of redress in respect of breaches of consumer law could be improved. The Green Paper was developed in the light of a series of studies which have reviewed the effectiveness and efficiency of existing EU collective redress mechanisms, the availability of alternative means of consumer redress (other than court proceedings), and have looked specifically at the problems faced by consumers in obtaining collective redress for infringements of consumer protection legislation.

These reports found that only 13 Member States (Austria, Bulgaria, Denmark, Finland, France, Germany, Greece, Italy, the Netherlands, Portugal, Spain, Sweden and the UK) have collective redress schemes, and that there was considerable divergence in the way those schemes operated and were regulated. Existing collective redress mechanisms had been applied in relatively few cases and the levels of compensation provided to consumers was low. The reports concluded that the efficiency and effectiveness of existing mechanisms could be improved, that they may not provide adequate redress where a group of consumers pursue very low value claims, and the absence of any collective redress mechanism in some countries may leave consumers with no adequate means of obtaining compensation. In the light of these studies the Commission's Green Paper concludes that because of weaknesses in the current EU framework "a significant proportion of consumers who have suffered damage do not obtain redress". It sought views on 4 possible options (which could be combined or pursued independently) to address this problem:

1 No action - taking no immediate action while monitoring the impact of the national and EU systems that are already in place or are about to be implemented (such as the Mediation Directive, which must be implemented by 2011, and the Small Claims Regulation which came into force at the beginning of 2009 and applies to cross-border disputes with a value of €2,000 or less).

2 Co-operation between Member States - this would involve setting up a co-operation scheme which would extend the protection of existing national collective redress systems to consumers from other Member States, and recommend that countries which do not have such a scheme should establish one. The Green Paper concludes that there would, therefore, need to be a cost sharing mechanism as Member States may be reluctant to finance a mechanism for proceedings by non-citizens in circumstances where no equivalent mechanism exists in the citizen's own country. Issues relating to jurisdiction and choice of law would also arise.

3 Mix of policy instruments - this option could include a mixture of binding and non-binding measures such as: promoting collective mediation or arbitration; raising consumers' awareness of existing measures; extending existing small claims procedures to allow mass small claims to be brought; extending the Consumer Protection Cooperation Regulation, for example to include a power to compensate consumers that have been harmed where there has been an intra-Community infringement, or by providing a power to skim-off the profit made by traders who have committed such an infringement; or improving consumer complaint handling systems.

4 Judicial collective redress procedure - introducing a binding or non-binding EU measure that would ensure that a judicial collective redress procedure exists in all Member States. The Green Paper makes clear that the aim of such a mechanism would be to "facilitate meritorious claims and benefit consumers", while discouraging a "litigation industry". In its "Questions and Answers" document which accompanies the Green Paper the Commission makes clear that the introduction of a "US style class action" is not what is envisaged. It identifies a "toxic cocktail" of measures which in combination should not be introduced including contingency fees, punitive damages, extensive pre-trial discovery and opt-out redress mechanisms.

The Green Paper highlights a number of issues that would need to be considered if this option were to be pursued, including how the procedure would be financed, how unmeritorious claims could be prevented and whether the procedure should be 'opt-in' (consumers must commence an action) or 'opt-out' (consumers are treated as parties to a court action unless they specifically opt-out). Although the Green Paper does not say expressly that such a measure would harmonise the current systems in all Member States, the "Questions and Answers" states that such a procedure would introduce "one EU wide system for the Single Market".

The Green Paper's consultation period has now expired, and the Commission is considering the responses received. The Green Paper acknowledges that "there is no easy answer to the problem" of providing EU consumers with adequate redress and concludes that all current redress systems have strengths and weaknesses, and that no single mechanism is ideal for all types of claims. In view of the difficulties inherent in pursuing each of the proposed options it is unclear what, if any, measures will ultimately be introduced.

Collective Redress Benchmarks

The Commission has also consulted on a set of 10 benchmarks which are intended to set the standard for collective redress systems throughout the EU. Once the benchmarks have been finalised, the Commission intends to evaluate whether EU Member States are meeting the benchmarks and, if not, it will consider "what EU action would best meet the needs of European consumers". The benchmarks may, therefore, provide the platform for possible reform in this area. They are:

"1. The mechanism should enable consumers to obtain satisfactory redress in cases which they could not otherwise adequately pursue on an individual basis.

2. It should be possible to finance the actions in a way that allows either the consumers themselves to proceed with a collective action, or to be effectively represented by a third party. Plaintiffs' costs for bringing an action should not be disproportionate to the amount in dispute.

3. The costs of proceedings for defendants should not be disproportionate to the amount in dispute. On the one hand, this would ensure that defendants will not be unreasonably burdened. On the other hand, defendants should not for instance artificially and unreasonably increase their legal costs. Consumers would therefore not be deterred from bringing an action in Member States which apply the "loser-pays" principle.

4. The compensation to be provided by traders/service providers against whom actions have been successfully brought should be at least equal to the harm caused by the incriminated conduct, but should not be excessive as for instance to amount to punitive damages.

5. One outcome should be the reduction of future harm to all consumers. Therefore a preventative effect for potential future wrongful conduct by traders or service providers concerned is desirable - for instance by skimming off the profit gained from the incriminated conduct.

6. The introduction of unmeritorious claims should be discouraged.

7. Sufficient opportunity for adequate out-of-court settlement should be foreseen.

8. The information networking preparing and managing possible collective redress actions should allow for effective "bundling" of individual actions.
9. The length of proceedings leading to the solution of the problem in question should be reasonable for the parties.
10. Collective redress actions should aim at distributing the proceeds in an appropriate manner amongst plaintiffs, their representatives and possibly other related entries."

Consumer organisations and business groups' views on the benchmarks expressed during the consultation differed on many of the key issues. Whilst the majority of consumer organisations considered the Commission's initiative to be constructive and useful, industry representatives criticised the proposed benchmarks since they appeared to them to be focused only on consumers' interests and failed to balance fairly the interests of consumers in having better access to justice with the interests of the economy and the judiciary in ensuring adequate safeguards are in place to prevent unmeritorious claims. Whilst there was broad agreement over certain benchmarks, for example that the length of the proceedings should be reasonable, other benchmarks have attracted considerable criticism. For example, industry are strongly opposed to Benchmark 5 on the basis that any collective redress mechanism should focus on compensating consumers for the damages they have suffered, rather than adopting a punitive approach. Similarly, industry strongly disagree with Benchmark 10 which suggests that compensation awarded as a result of a collective redress action could be distributed to legal professionals or third parties.

The outcome of the Commission's consultation on the collective redress benchmarks has not yet been published. If the Commission remains minded to continue to pursue this approach it is likely that the existing benchmarks will be amended.

Conclusion

Although the Directive has now been in force for over 20 years there have been relatively few cases on the interpretation of its provisions. The European Commission's Third Report concluded that the Directive was operating in a satisfactory way, but it acknowledged that there were disparities in its application by national courts and there was therefore scope for further harmonisation of national product liability laws within Europe. The ECJ's decision in *O'Byrne* provides helpful clarification on the application of one of the key provisions and concepts underpinning the Directive. However, a number of areas of uncertainty remain. For example:

- the scope of the development risks defence and, in particular, its application to cases involving manufacturing defects; and
- what information may be taken into account in assessing whether a product is defective - whether this includes information and warnings supplied to intermediaries such as health professionals, as well as information supplied directly to consumers.

It is hoped that the Court will, in future, be invited to provide guidance on the interpretation of some of these issues. Meanwhile, a number of new legislative initiatives are being pursued by the European Commission, particularly in relation to consumers' contractual rights and mechanisms for collective redress, that may in future enhance consumers' rights in respect of defective products and make it easier to pursue claims for compensation.

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Arnold & Porter is an international law firm with over 600 attorneys in eight offices in the U.S. and London and Brussels. With more than 80 attorneys engaged in product liability matters, Arnold & Porter is one of the most experienced firms internationally, providing clients with an integrated product liability service on a transatlantic basis.

The European product liability group is a recognised leader in the UK and Europe, with comprehensive experience in handling the defence of claims. Its lawyers have been at the forefront of "group action" litigation, with experience derived from the successful defence of many major multi-claimant cases that have been brought in the UK and elsewhere in the EU over the last 30 years. In the US, the firm has acted both as national counsel for companies and as trial counsel in cases involving personal injury and property damage claims.

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Strategies For Dealing With the Risk of Punitive Damages

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I. Introduction

The concept of punitive damages is well-established in the United States' civil justice system. *See Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 25 (1991); *Exxon Shipping Co. v. Baker*, 128 S.Ct. 2605, 2620 (2008) (stating that "the modern Anglo American doctrine of punitive damages dates back at least to 1763" and explaining that "damages beyond the compensatory was not, however, a wholly novel idea even then, legal codes from ancient times through he Middle Ages having called for multiple damages for certain especially harmful acts."); Schwartz, Victor E. *et al., Selective Due Process,* 82 Oregon L. Rev. 33 (2003). Until well into the Nineteenth Century, punitive damages were available under certain circumstances as additional potential recovery for non-economic damages otherwise unavailable under the narrow concept of compensatory damages prevalent at the time. *See Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 121 S. Ct. 1648, 1686 n.11 (2001). In other words, the original concept of punitive damages in the United States was to make the plaintiff "whole".

In contrast, the modern concept of punitive damages is aimed at punishing a defendant and deterring future "bad" conduct. *Id*. at 1686; *see also Kemp v. AT&T Co.*, 393 F.3d 1354 (11th Cir. 2004) (punitive damages "provide a meaningful deterrent against corporate misconduct"); *Unique Envelope Corp. v. GS Am., Inc.*, 331 F. Supp. 2d 643 (D. Ill. 2004) ("Punitive damages serve the dual purpose of deterrence and retribution"). Indeed, today, "punitive damages, unlike compensatory damages, are not designed to redress the loss of the plaintiffs, but instead are aimed at deterrence and retribution." *Gaskins v. BFI Waste Servs., LLC*, 2005 WL 1667737 (E.D. Va. June 17, 2005).

The standards for imposing punitive damages have also changed through the years. Traditionally, courts only imposed punitive damages for "intentional" conduct. *See* Schwartz, *et al.*, 82 Oregon L. Rev. at 36-37. Since the 1960s, however, with the emergence of mass tort litigation, courts have shown a willingness to award punitive damages for conduct that is less than intentional, e.g., conduct described as "wilful and wanton," or "with a reckless disregard for the safety of consumers." *See id.*

Historically, punitive damages were awarded infrequently. *See* Schwartz *et al.*, 82 Oregon L. Rev. at 33. Today, punitive damages awards are "higher and more frequent in the United States than they are anywhere else." Exxon Shipping, 128 S.Ct. at 2623. Indeed, whereas multi-million dollar verdicts were once unheard of in the United States, several verdicts in the past years have exceeded $1 billion. *See id*. at 36-37. For example, in 2000, a Florida jury awarded $146 billion against the American tobacco companies in a class action lawsuit. In August 2006, a Florida jury ordered a Morgan Stanley broker to pay $1.45 billion to an investor for defrauding him in the sale of his camping gear company. Multi-million dollar punitive damage awards are also becoming increasingly frequent. In February 2008, a Nevada jury awarded $134 million in compensatory and punitive damages to three plaintiffs who claimed that a prescription medication caused their breast cancer. In August 2006, a Louisiana jury awarded $51 million to a plaintiff who claimed his heart attack was caused by a prescription pain medication. All of the foregoing jury awards were appealed and later overturned and/or reduced, however, these examples illustrate the uncertainty of punitive damages.

Not only have the amount of punitive damage awards "skyrocketed" in the past few decades (*see Haslip*, 499 U.S. at 18), the inconsistency in these awards has wrecked havoc on the United States' civil justice system. *See Exxon Shipping*, 128 S.Ct. at 2625 ("The real problem, it seems, is the stark unpredictability of punitive awards."). First, it is difficult to predict whether punitive damages will be submitted for a jury's consideration because there is no "bright-line" rule for determining what evidence is necessary to sustain a claim for punitive damages. As a result, much is left to the court's discretion. Likewise, if a punitive damage claim is submitted to the jury, "[t]he difficulty of predicting whether punitive damages will be awarded by [the] jury in any particular case and the marked trend toward astronomically large amounts when they are awarded, have seriously distorted settlement and litigation processes and have led to wildly inconsistent outcomes in similar cases." *Tort Reform Record*, available online at the American Tort Reform Association website, www.atra.org. A study cited by the Supreme Court in Exxon Shipping revealed that while the median ratio of punitive damages to compensatory damages was 0.61:1, the mean ratio was 2.90:1 with a standard deviation of 13.81 prompting the Court to comment "the thrust of these figures is clear: the spread is great, and the outlier cases subject defendants to punitive damages that dwarf the corresponding compensatories." *Exxon Shipping*, 128 S. Ct. at 2625.

In short, the prospect of punitive damages is a "wild card" that often drives unreasonable settlements, particularly in the context of mass tort litigation. For example, in November 2007, a $4.85 billion class action settlement was reached involving claims for heart attacks related to prescription drugs; in late 2007, a federal judge in New Orleans approved a $330 million settlement between Murphy Oil Corporation and residents of a New Orleans suburb flooded by crude oil during Hurricane Katrina.

Responding to the growing concern that punitive damages were "run[ning] wild," (*Haslip*, 199 U.S. at 18), the United States Supreme Court has given substantial attention to the topic during the past ten years. *See State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 417 (2003) (stressing a concern about the "imprecise manner in which punitive damages systems are administered); *see also Exxon Shipping*, 128 S.Ct. 2605; *Philip Morris USA v. Williams*, 127 S. Ct. 1057 (2007); *Cooper Indus., Inc. v.*

Leatherman Tool Group, Inc., 532 U.S. 424 (2001); *BMW of N. Am. Inc. v. Gore*, 517 U.S. 559 (1996), *Honda Motor Co. v. Oberg*, 512 U.S. 415 (1994); *TXO Prod. Corp. v. Alliance Res. Corp.*, 509 U.S. 443 (1993); *Haslip*, 499 U.S. 1 (1991). According to a prominent commentator, "[t]he Supreme Court's jurisprudence since the late 1980s demonstrates the Court's concern that punitive damage awards should not be assessed without constraints on jury discretion." Schwartz *et al.*, 82 Oregon L. Rev. at 38.

Any discussion of punitive damages jurisprudence in the United States must begin with the three main United States Supreme Court decisions, which set forth the current standards for the imposition of punitive damages. These three decisions are *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996) ("*Gore*"); *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 ("*State Farm*"); and *Philip Morris USA v. Williams*, 127 549 U.S. Ct. 1057346 (2007) ("*Williams*"). In these three cases, the Supreme Court attempted to reign in punitive awards by setting some due process guidelines for courts and juries to follow. Specifically, in Gore, the Supreme Court set forth three "guideposts" to be used in determining whether to award punitive damages and, if so, in what amount. In *State Farm*, the Court expounded further on the Gore guideposts. In *Williams*, the Court clarified the types of conduct for which a jury could impose punishment.

This article discusses the Supreme Court's opinions in *Gore*, *Campbell*, and *Williams*, (see Endnote 1) and their progeny and offers practical strategies and suggestions for counsel defending cases that involve punitive damages. Further, this article explores questions yet unanswered concerning punitive damages.

II. *BMW Of North America v. Gore*

In *BMW v. Gore*, 517 U.S. 559 (1996), the plaintiff alleged that BMW committed fraud by failing to disclose minor cosmetic repairs to cars that were being sold as new. *Id.* at 563. The flawed paint job on the plaintiff's new BMW sedan was so minor that he never noticed it. The repair was brought to his attention months later when he brought the car to a detailer for cleaning. The plaintiff sued BMW seeking compensatory and punitive damages on the theory that BMW's failure to disclose the re-painting constituted "gross, oppressive or malicious" fraud under Alabama law.

At trial, an Alabama jury awarded the plaintiff $4,000 as compensatory damages. *Id.* at 565. The jury also awarded $4 million in punitive damages, which it apparently calculated by multiplying Dr. Gore's damage estimate ($4,000) by 1,000, i.e., the number of cars BMW allegedly sold throughout the country under its nondisclosure policy. *Id.* at 564.

On appeal to the Alabama Supreme Court, BMW contended that its out-of-state conduct was permissible under the law of other states and, therefore, could not serve as a basis for a punitive damages award. *Id.* at 565. The Alabama Supreme Court agreed, holding that the jury should not have been permitted to consider sales by BMW outside of Alabama. *Id.* at 566. The court then reduced the punitive damages amount to $2 million, reasoning that this amount was "constitutionally reasonable." *Id.*

In a 6-3 decision, the United States Supreme Court overturned the Alabama Supreme Court, holding that even the reduced punitive award was "grossly excessive" in violation of due process. The Court began its analysis by noting that "[t]he Due Process Clause of the Fourteenth Amendment [to the United States' Constitution] prohibits a state from imposing a 'grossly excessive' punishment on a tortfeasor." *Id.* at 568. The Court established three "guideposts" for assessing whether a particular punitive damage award exceeds the constitutional limit: (1) the degree of reprehensibility of the defendant's misconduct; (2) the disparity between the actual or potential harm suffered by the plaintiff and the punitive damage award; and (3) the difference between the punitive damage award and the civil penalties authorised or imposed in comparable cases. *See id.* at 574-75. Applying the first two guideposts, the Court in Gore set aside the $2 million punitive damage award as "grossly excessive" and, therefore, unconstitutional as compared with the $4,000 of harm suffered by plaintiff. *Id.* at 586.

III. *State Farm v. Campbell*

State Farm v. Campbell, 538 U.S. 408 (2003) is a "watershed" case in the Supreme Court's punitive damage jurisprudence. The American media hailed the decision as "a major victory in the long-running effort to shield corporate defendants from unconstrained jury awards" (*New York Times*) and "a big win for business interests concerned about ballooning legal judgments" (*Wall Street Journal*). Likewise, the National Association of Manufacturers heralded it as "an important breakthrough in our continuing efforts to make judges more aware of the fact that elements of our judicial system are out-of-control."

In *State Farm*, insurance company investigators determined that the plaintiff, Curtis Campbell, was responsible for causing a car accident resulting in death to one individual and severe injuries to two others. *Id.* at 412-13. Campbell's insurer, State Farm Mutual Automobile Insurance Company, contested liability, refused a settlement offer within the policy limits, and told Campbell that State Farm would represent his interests at trial. *Id.* A jury found Campbell 100% at fault and returned a judgment for $185,849. State Farm refused to cover the liability in excess of the policy limit. Based on the foregoing, Campbell initiated a bad faith action against the insurance company.

At trial, State Farm's motion to exclude evidence of alleged similar conduct involving other insureds that occurred in unrelated cases outside of Utah was denied. *Id.* at 412. Campbell thus introduced evidence that State Farm's decision to take the case to trial was the result of a twenty-year national scheme to meet its financial goals by capping payouts on claims. The Utah jury awarded Campbell $2.6 million in compensatory damages and $145 million in punitive damages, which the trial court later reduced to $1 million and $25 million respectively. Both parties appealed.

On appeal, the Utah Supreme Court sought to apply the three guideposts set forth in Gore. *Id.* at 415. Purporting to apply these factors, the Utah Supreme Court re-instated the $145 million punitive award, basing its decision on the following factors: (1) State Farm's "reprehensible conduct" as evidenced by the nationwide scheme to cap payouts; (2) State Farm's "massive wealth"; (3) the statistical probability that State Farm would only be punished in one out of every 50,000 cases; and (4) the fact that State Farm could have faced excessive civil and criminal penalties, including suspension of its license and disgorgement of profits. *Id.*

The United States Supreme Court analysed the Gore guideposts and reversed the decision of the Utah Supreme Court, finding that the case was "neither close nor difficult" and that it was an error to reinstate the jury's $145 million punitive award. *Id.* at 1521.

A. The first Gore guidepost: the degree of reprehensibility of the defendant's conduct

According to the Supreme Court, the first guidepost is "the most important indicium of reasonableness" of a punitive award. *State Farm*, 538 U.S. at 419. The Court held that it "should be presumed that a plaintiff has been made whole for his injuries by compensatory

damages." Thus, punitive damages are justified only if "the defendant's culpability, after having paid compensatory damages, is so reprehensible as to warrant the imposition of further sanctions to achieve punishment or deterrence." *Id.* The reprehensibility of a defendant's conduct should be determined by considering whether: (1) the harm caused was physical or economic; (2) the conduct evinced "an indifference to or a reckless disregard of the health or safety of others;" (3) the target/victim of the alleged conduct was financially vulnerable; (4) the conduct was repeated or isolated; and (5) the harm was the result of "intentional malice, trickery, or deceit." *Id.* at 419.

Applying these factors, the Court concluded that "a more modest punishment for this reprehensible conduct could have satisfied the State's legitimate objectives, and the Utah courts should have gone no further." *Id.* at 419. The Court was troubled that the award was based on State Farm's nationwide policies, rather than its conduct toward Mr. Campbell, noting that the case had been used "as a platform to expose, and punish, the perceived deficiencies of State Farm's operations throughout the country." *Id.* This was improper, because a state "cannot punish a defendant for conduct that may have been lawful where it occurred.... Nor, as a general rule, does a State have a legitimate concern in imposing punitive damages to punish a defendant for unlawful acts committed outside of the State's jurisdiction." *Id.* at 420. In rejecting the plaintiff's argument that evidence of lawful out-of-state conduct was relevant to demonstrate State Farm's motive against its insured, the Court held that "[l]awful out-of-state conduct may be probative with it demonstrates the deliberateness and culpability of the defendants' action in the State where it is tortious, but that conduct must have a nexus to the specific harm suffered by plaintiff." *Id.* Accordingly, the jury must be instructed that "it may not use evidence of out-of-state conduct to punish a defendant for action that was lawful in the jurisdiction where it occurred." *Id.* at 421.

Perhaps even more significant to the United States Supreme Court was the fact that the jury awarded punitive damages to punish conduct that "bore no relation" to the plaintiff's harm. *Id.* at 422. The Court specifically rejected this as a basis for a punitive award. *Id.* "A defendant's dissimilar acts, independent from the acts upon which liability was premised, may not serve as a basis for punitive damages." *Id.* "A defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavoury individual or business." *Id.* Thus, "[d]ue process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties' hypothetical claims against a defendant under the guise of a reprehensibility analysis.... Punishment on these bases creates the possibility of multiple punitive damages awards for the same conduct." *Id.*

B. The second *Gore* guidepost: the disparity between the actual or potential harm suffered by plaintiff and the punitive damages award

Although the Court refused to "identify concrete constitutional limits on the ratio between harm, or potential harm, to the plaintiff and the punitive damages award" (*id.* at 424), it did set forth some parameters. Specifically, "few awards exceeding a single-digit ratio between punitive and compensatory damages, to a significant degree, will satisfy due process." *Id.* at 425. Moreover, "[s]ingle digit multipliers are more likely to comport with due process, while still achieving the State's goal of deterrence and retribution." *Id.*

In support of its holding, the Court cited the following: (1) the 4:1 ratio cited in Gore; (2) its earlier decision in *Pacific Mutual Life Insurance Company v. Haslip*, 499 U.S. 1, 23-24 (1991), wherein the Court held that a ratio of more than 4:1 "might be close to the line of constitutional impropriety;" and (3) a long history of "sanctions of double, treble, or quadruple damages to deter and punish." The concept of a single-digit ratio was "not binding," rather "instructive" and "must be based upon the facts and circumstances of the defendant's conduct and the harm to the plaintiff." Greater ratios "may comport with due process where a particularly egregious act has resulted in only a small amount of economic damages." And a lesser ratio, "perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee" when substantial compensatory damages are awarded." *Id.* at 425-26.

Turning to the facts before it, the Court held that there is a presumption against a 145:1 ratio. *Id.* The award was further found to be excessive because: (1) the compensatory award was substantial; (2) the harm was economic, not physical; and (3) the compensatory award was likely based on a punitive element. *Id.* at 425-26. The Court specifically rejected the Utah Supreme Court's rationale that State Farm would be "punished in only the rare case." *Id.* at 426. Such rationale "had little to do with the actual harm sustained" by the plaintiff. *Id.* Moreover, the "wealth of a defendant cannot justify an otherwise unconstitutional punitive damages award." *Id.* at 427.

C. The third *Gore* guidepost: the difference between the punitive damages awarded by the jury and the civil penalties authorised or imposed in comparable cases

The Court began its brief analysis of this guidepost by noting that, in the past, it had looked to criminal penalties that could be imposed. *Id.* at 428. The Court stated that, although criminal penalties continue to have some relevance regarding the seriousness with which a state views the wrongful action, such penalties have "less utility" in determining the amount of a punitive award. *Id.* Indeed, "great care" should be taken to prevent juries from assessing criminal penalties in civil trials, which lack the "heightened protection" of a criminal trial. *Id.* For this reason, "the remote possibility of a criminal sanction does not automatically sustain a punitive damages award." *Id.* (See Endnote 2.)

Applied to the facts of the case, the Court determined that the most relevant civil penalty under Utah law was a $10,000 fine for fraud, "an amount dwarfed by the $145 million punitive damages award." *Id.* at 428. Finally, the Court rejected the Utah Supreme Court's speculation about potential civil penalties such as State Farm's loss of licence or disgorgement of profits because such penalties were based upon evidence of out-of-state and dissimilar conduct. *Id.*

IV. *Philip Morris v. Williams*

Gore and *State Farm* provided needed guidance to lower courts; however, the Supreme Court left many unanswered questions. For example, neither *Gore* nor *State Farm* involved product liability. Accordingly, courts had not uniformly applied *State Farm* in the personal injury context.

In February 2007, the Supreme Court addressed some of the questions left unanswered by *Gore* and *State Farm*. The case, *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), arose out of the smoking related death of Jesse Williams. *Id.* at 349. His estate brought a lawsuit for negligence and deceit against Philip Morris, the manufacturer of Marlboro cigarettes. *Id.* The jury found for the plaintiffs and awarded compensatory damages of $821,000 and punitive damages of $79.5 million. *Id.* at 350. The verdict was reduced to $32 million by the trial judge but then reinstated to $79.5 million by the Oregon Court of Appeals. *Id.*

The United States Supreme Court vacated and remanded the case for reconsideration in light of State Farm. *Id.* On remand, both the Oregon Court of Appeals and the Oregon Supreme Court determined that the

$79.5 million punitive damages award was not excessive. *Id.* at 351-52. Philip Morris sought *certiorari* asking the court to consider: (1) whether Oregon had unconstitutionally permitted Philip Morris to be punished for harming non-party victims; and (2) whether the Oregon courts had disregarded "the constitutional requirement that punitive damages be reasonably related to the plaintiff's harm." *Id.* at 352. The Supreme Court granted certiorari to consider those two questions.

After discussing the limits that due process places on punitive damages, the Supreme Court determined that "the Constitution's Due Process Clause forbids a State to use a punitive damages award to punish a defendant for injury that it inflicts upon non-parties or those whom they directly represent, i.e., injury that it inflicts upon those who are, essentially, strangers to the litigation." *Id.* at 353. The Court recognised that allowing punitive damages to punish for harm caused to others would "add a near standardless dimension to the punitive damages equation" and would deny the defendant the "opportunity to defend against the charge." *Id.* at 354. Furthermore, it would magnify the risks of "arbitrariness, uncertainty, and lack of notice." *Id.* The Court stated that it could "find no authority supporting the use of punitive damages awards for the purpose of punishing a defendant for harming others." *Id.* The Court also held that consideration of potential harm in the punitive damages analysis must be limited to the potential harm to the plaintiff as opposed to potential harm to others. *Id.*

The Court, however, did not go so far as to say that harm to persons other than the plaintiff was never relevant to the punitive damages analysis. Instead, the Court specifically allowed the jury to weigh the harm caused to others when judging the reprehensibility of the conduct that injured the plaintiff. *Id.* at 355. The Court explained that "[e]vidence of actual harm to non-parties can help to show that the conduct that harmed the plaintiff also posed a substantial risk of harm to the general public and so was particularly reprehensible." *Id.*

Williams creates a unique scenario, where evidence of harm to others may be considered in the evaluation of the reprehensibility of the conduct that injured the plaintiff but the jury may not directly punish the defendant for that conduct. No doubt recognising the difficulty posed by this distinction, the Court stressed that "the Due Process Clause requires states to provide assurance that juries are not asking the wrong question, i.e., seeking, not simply to determine reprehensibility but also to punish for harm caused strangers." *Id.* Accordingly, "state courts cannot authorise procedures that create an unreasonable and unnecessary risk of any such confusion occurring." *Id.* at 357.

Because the Court believed that the Oregon Courts had not applied the right constitutional standard, and had not ensured that the jury did not punish for harm to others, the Court remanded the case for further proceedings. *Id.* at 358. The Supreme Court did not reach the issue of whether the Oregon Court had disregarded the constitutional requirement that punitive damages be reasonably related to the plaintiffs' harm.

As *Williams* was a wrongful death product liability case, the United States Supreme Court has resolved any ambiguity about whether the Gore/State Farm factors apply to personal injury/product liability cases. Additionally, the Court has clarified that juries may not punish for harm caused to others, regardless of the state where those others were injured and placed clear limits of the kind of potential harm that may be taken into account. It is still too early to realise the full impact that *Williams* may have, however, it provides an opportunity to challenge state statutes and jury instructions that appear to authorise punitive damages to punish for harm caused to others.

V. Post-*State Farm* And Its Progeny

Gore, *State Farm*, and *Williams* provide much needed guidance to lower courts; however, the Supreme Court has left open many unanswered questions. Since it was handed down six years ago, over 1,000 cases have referenced *State Farm*. The debate over its interpretation continues in state and federal courts throughout the United States. Some courts have strictly applied the *State Farm* factors, while other courts have rendered *State Farm* virtually meaningless by "distinguishing" cases on their particular facts. Significant areas that remain unsettled among lower courts are discussed below.

A. Lower Courts Have Applied Different Interpretations To The Ratio Guideline

In *State Farm*, the U.S. Supreme Court stated that punitive damage awards of 4:1 were at the outer edge of due process reasonableness and that a ratio of 1:1 might be more appropriate if compensatory damages are high. Lower courts have applied different interpretations to the ratio guideline enunciated in State Farm. Some courts have strictly adhered to the admonition that ratios greater than 9:1 should be viewed with extreme caution and some have even insisted that single-digit ratios be scrutinised. Other courts have used creative interpretations of the single-digit ratio guideline and/or simply disregarded the ratio guideline as a mere "suggestion" rather than a requirement. Defence trends and plaintiff trends are identified below.

1. Defence Trends

(a) Single-Digit Ratios Are Not *Per Se* Constitutional And Are Still Subject To A State Farm Analysis

In *Bunton v. Bentley*, 153 S.W.3d 50 (Tex. Dec. 19, 2004), a defamation case, the jury entered a verdict awarding the plaintiff $150,000 for past and future loss of reputation, $7 million for mental anguish and $1 million in punitive damages. *Id.* at 52. The court of appeals reduced the mental anguish award to $150,000 but did not reduce the punitive damages award noting that the defendant did not "complain on appeal of the award of exemplary damages" and "the ratio between the actual damage award, after remittitur, and the award of exemplary damages falls within the parameters set by the United States Supreme Court." *Id.* The Texas Supreme Court affirmed the remittitur of compensatory damages but remanded to the court of appeals for evaluation of whether the punitive damages needed to be adjusted based on the remittitur. *Id.* at 54.

The Texas Supreme Court gave specific instructions to the court of appeals regarding how to conduct the *State Farm* analysis. The court stressed that each of the *Gore/State Farm* guideposts must be reviewed in order to make a determination about the excessiveness of the punitive damages award. *Id.* "These factors are intertwined … and cannot be viewed in isolation; specifically, a reviewing court cannot conclude that a particular ratio is consistent with due process unless that court examines the ratio in light of the other factors and in light of the actual harm to the plaintiff." *Id.* Recognising that the court of appeals had noted that the 3:1 ratio in the case was in line with ratios in other cases, the Texas Supreme Court stressed that "the analysis cannot end there" and instructed the court of appeals to apply the Gore/State Farm guideposts "with care to ensure both reasonableness and proportionality." *Id.* In so ruling, the Texas Supreme Court became one of the first courts to definitively address the trend of "rubberstamping" single-digit ratios. *See* Fey, Laura Clark *et al*., *The Supreme Court Raised Its Voice: Are the Lower Courts Getting the Message?* 56 Baylor L. Rev. 807, 840 (2004). *Bunton* provides strong authority for the proposition that courts cannot merely rubberstamp a single-digit ratio and must instead conduct a full due process review of each award of punitive damages.

(b) When Compensatory Damages Are High, A Lower Ratio Is Appropriate

In *Boerner v. Brown & Williamson Tobacco Co.*, 394 F.3d 594 (8th

Cir. Jan 7, 2005), the Eighth Circuit ordered a remittitur of a $15 million punitive damages award that was supported by $4 million in compensatory damages. *Id.* at 603. Although the punitive damages award presented only a single-digit ratio, the court determined that, given the substantial compensatory damages, due process required a ratio closer to 1:1 and remitted the award from $15 million to $5 million. The court ordered the remittitur despite finding that the defendant's conduct was highly reprehensible and "shown to relate directly to the harm suffered." *Id.*

Boerner is significant because it demonstrates a faithful application of the Supreme Court's instruction that lesser ratios are appropriate when compensatory damages are substantial. The Eighth Circuit started with the proposition that when compensatory damages are high, "caution is required." *Id.* The court then noted that the factors that could justify a higher ratio, "such as the presence of an 'injury that is hard to detect' or a 'particularly egregious act [that] has resulted in only a small amount of economic damages'" were absent. *Id.* Boerner gives defendants an additional tool for arguing that a 1:1 ratio is appropriate in cases involving substantial compensatory damages.

Like *Boerner*, *Williams v. ConAgra Poultry Co.*, 378 F.3d 790 (8th Cir. 2004) suggests that a 1:1 ratio is appropriate under certain circumstances. In *Williams*, plaintiff brought a race discrimination action against his former employer. The jury awarded $600,000 in compensatory damages and $6 million in punitive damages. The court remitted the punitive award to $600,000 (i.e., the amount of the compensatory award) noting the U.S. Supreme Court's admonition that "when compensatory damages are substantial, then a lesser ratio, perhaps only equal to compensatory damages" is appropriate. *Id.* at 799. The court went on to conclude that "six-hundred thousand dollars is a lot of money" and, therefore, due process required a 1:1 ratio. *Id.*

Similarly, in *Bach v. First Union Nat. Bank*, the Sixth Circuit determined that, on the facts of the case before it, a 1:1 ratio was the maximum ratio that could survive due process. 486 F.3d 150, 156 (6th Cir., 2007). The jury had initially awarded $400,000 in compensatory damages and $2,628,600 in punitive damages for a 6.6:1 ratio. *Id.* at 152. Citing the relatively low reprehensibility of the tort (only one of the reprehensibility factors was met) and commenting that the 6.6:1 ratio was "alarming" the 6th Circuit remanded with instructions to hold a new trial on punitive damages or enter a remittitur. *See* 149 Fed. Appx. 354 (6th Cir. 2005). On remand, the district court rejected First Union's argument for a 1:1 ratio stating "had the Sixth Circuit thought a 1:1 ratio was appropriate in this case, it surely would have said so." 2006 WL 840381 at *4. The District Court then remitted punitive damages of $2,228,600 for a 5:1 ratio, the plaintiffs accepted the remittitur and the defendants appealed. 486 F.3d at 153.

On appeal, the parties agreed at oral argument that if the court found the award to be unconstitutionally excessive, it should set a constitutional maximum award to guide the District Court. *Id.* at 155. The Sixth Circuit agreed and determined that there were no facts to "justify a departure from the general principle that a plaintiff who receives a considerable compensatory damages award ought not also receive a sizeable punitive damages award absent special circumstances." *Id.* at 156. Accordingly, the court concluded that "$400,000, the amount of compensatory damages, constitutes an appropriate limit on punitive damages in this case." *Id. See also Bridgeport Music, Inc. v. Justin Combs Pub.* 507 F.3d 470, 490 (6th Cir. 2008) (applying Bach to a 9.5:1 ratio and concluding that, when there is "large compensatory damages award of $366,939, a substantial portion of which contained a punitive element, and the low level of reprehensibility of defendants' conduct, a ratio of closer to 1:1 or 2:1 is all that due process can tolerate").

Some courts have even been willing to consider ratios that are less than 1:1. In *Adidas America, Inc. v. Payless Shoesource, Inc.*, the United States District Court for the District of Oregon ordered a remittitur of a punitive damages award from $137 million to $15 million. 2008 WL 4279812 at *16 (D. Or. Sept. 12, 2008). The District Court began its analysis of the ratio guideline by commenting that the jury had awarded $30.6 million in compensatory damages and therefore the initial ratio of punitive to compensatory damages was only 4.5:1. *Id.* at *15. The District Court then cited State Farm for the proposition that where compensatory damages are substantial, a lesser ratio, perhaps only equal to compensatory damages, can reach the outermost limit of the due process guarantee." *Id.* The District Court stated that it believes the $30.6 million compensatory damages award was substantial and stated that, given other factors in the case including that "there was no physical harm or disregard for a person's health or safety, there were no lost sales, Adidas suffered no economic harm that jeopardised its business in any way, and, even though Payless acted wilfully, it did not do so for the entire period addressed here," "even a 1:1 ratio between compensatory and punitive damages is too high." *Id.* at *16. The court then stated that "I realise that going below a 1:1 ratio is unusual but such awards have been improved if there is only economic harm." *Id.* (citing *Motorola Credit Corp. v. Uzan*, 509 F.3d 74 (2d Cir. 2007).

2. Plaintiff Trends

(a) The Ratio Guideline Is A Mere "Suggestion"

Some lower courts read the *State Farm* single-digit ratio guideline as a suggestion rather than a requirement. *See, e.g., Hangarter v. Provident Life and Accident Ins. Co.*, 373 F.3d 998, 1014 (9th Cir. 2004) ("*State Farm's* 1:1 compensatory to punitive damages ratio is not binding, no matter how factually similar the cases may be."); *Boeker v. Phillip Morris, Inc.*, No. B152959 (Cal. Ct. App. Apr. 1, 2005) (the single-digit ratio language in *State Farm* is "instructive, but not binding").

Mathias v. Accor Economy Lodging, Inc., 347 F.3d 672 (7th Cir. Oct. 21, 2003) is perhaps the most commonly cited example wherein a court treats *State Farm* as a "suggestion" rather than a requirement. In an opinion written by Judge Richard A. Posner, the United States Court of Appeals for the Seventh Circuit affirmed a judgment reflecting an award of $5,000 in compensatory damages and $186,000 in punitive damages for injuries resulting from bedbug bites occurring at the defendant's hotel. The defendant argued that, under *State Farm*, four times the compensatory damages (i.e., $20,000) was the maximum the jury could have constitutionally awarded each plaintiff in punitive damages. *Id.* at 674. The Seventh Circuit disagreed, initially noting that the Supreme Court did not "lay down a 4:1 or single-digit ratio rule - it said merely that 'there is a presumption against an award that has a 145:1 ratio.'" *Id.* at 676. The court went on to ignore many of the basic tenants enunciated in *State Farm*.

The court relied on some of the following facts in holding that the punitive award, which was 37.2 times greater than the compensatory award, was not excessive: (1) unlike in *State Farm*, where the plaintiff was awarded $1 million in compensatory damages, in the present case, although "defendant's behaviour was outrageous.... the compensable harm done was slight and at the same time difficult to quantify because a large element of it was emotional." (2) The defendant "may well have profited from its misconduct because by concealing the infestation it was able to keep renting rooms." (3) The defendant might have "postponed the instituting of litigation to rectify the hotel's misconduct" by telling guests the bugs were ticks instead of bedbugs. (4) "[T]he award of punitive damages in this case thus serves the additional purpose of limiting the defendant's ability to profit from its fraud by escaping detection and (private) prosecution. If a tortfeasor is 'caught' only half the time it commits torts, then when he is caught he should be punished twice as heavily in order to make up for the times he gets away." *Id.* at 677.

Likewise, courts are sometimes willing to uphold large ratios in cases

where the court perceives that the defendant's conduct is particularly reprehensible. *See Willow Inn, Inc. v. Public Serv. Mut. Ins. Co.*, 2003 WL 21321370 (E.D. Pa. May 30, 2003), aff'd 399 F.3d 224 (3d Cir. 2005) (upholding a 75:1 ratio in part because of "aggravating" factors "associated with particularly reprehensible conduct," including the following: (1) target of the conduct was financially vulnerable; (2) misconduct was repeated rather than a single instance of malfeasance; and (3) the defendant's conduct was intentional).

(b) Ratio Guidelines May Not Apply In Cases Involving Violations Of Constitutional Rights And/Or When Compensatory Damages Are Minimal Or Difficult To Quantify

Dunn v. Village of Put in Bay, Ohio, 2004 WL 169788 (N.D. Ohio Jan. 26, 2004) is a Section 1983 excessive force case involving a police officer's use of pepper spray. In *Dunn*, the District of Ohio upheld a punitive damages award of $23,422 based on a compensatory damages award of $1,577. The court determined that the use of pepper spray to apprehend a "non threatening suspect … for an act of alleged vandalism was egregiously reprehensible and showed 'callous indifference' to the plaintiff's Fourth Amendment rights. *Id.* at *2. The court recognised that the 15:1 ratio of punitive damages to compensatory damages raised due process concerns but determined that case fell within the Supreme Court's allowance for higher ratios in cases where "a particularly egregious act has resulted in only a small amount of economic damages." *Id.*

Dunn is an excellent example of how courts tend to deal with cases involving a violation of constitutional rights. Courts in these cases tend to allow greater than single-digit ratios. *See* Fey, *et al.*, 56 Baylor L. Rev. at 840; *see also Williams v. Kaufman County*, 352 F.3d 994 (5th Cir. 2003) (upholding a 150:1 ratio in civil rights case involving illegal strip searches by county sheriff); *Madeja v. MPB Corp.*, 821 A.2d 1034 (N.H. 2003) (upholding a 35:1 ratio in sexual harassment case); *Romanski v. Detroit Entertainment, L.L.C.*, 428 F.3d 629 (6th Cir. 2005) (remitting a $875,000 punitive damages award to $600,000 in a §1983 false imprisonment case, as compensatory damages were only $279.05, the post-remititur ratio was 2150:1); *Santamaria v. Dallas Independent School District*, 2007 WL 1073850 (N.D. Tex. April 10, 2007) (upholding a 100:1 ratio in a case involving *nominal* damages and explaining "as the instant case concerns the ratio between punitive and nominal damages, *Campbell's* discussion of the proper ratio between punitive and compensatory damages is inapposite to our consideration today") (emphasis in original).

Similarly, courts sometimes allow greater ratios in cases involving small and/or hard-to-quantify damages. *See*, e.g, *Kunz v. DeFelice*, 538 F.3d 667, (7th Cir. 2008) (citing *Exxon Shipping* and *BMW* for the proposition that "heavier punitive awards have been thought to be justifiable... when the value of injury and the corresponding compensatory award are small." and upholding a 9:1 ratio.); *Willow Inn, Inc. v. Public Serv. Mut. Ins. Co.*, 2003 WL 21321370 (E.D. Pa. 2003), aff'd 399 F.3d 224 (3d Cir. 2005) (upholding 75:1 ratio in bad faith action where compensatory damages were only $2,000).

B. Some Lower Courts' Interpretation of "Potential Harm" Allows Significant Room For Large Punitive Damage Awards

A pro-plaintiff trend among lower courts is to use the United States Supreme Court's language regarding "potential harm" to justify an otherwise unconstitutional award. For example, in *In re Exxon Valdez*, 296 F. Supp. 2d 1071 (D. Ala. 2004), *vacated on other grounds by*, 472 F.3d 600 (9th Cir. 2006), *opinion amended and rehearing denied*, 490 F.3d 1066, *certiorari granted*, 128 S.Ct. 492 (2007); *opinion on appeal vacated on other grounds by Exxon Shipping v. Baker*, 128 S.Ct. 2605 (2008), the District of Alaska relied on an expensive reading of potential harm when setting a $4.5 billion punitive damages award based on a $513 million compensatory damages award. While the district court reduced the punitive damages award from $5 billion to $4.5 billion (and the Ninth Circuit subsequently reduced to the award to $2.5 billion), the case demonstrates how a court can disregard the spirit of *Gore* and *State Farm* to uphold a large punitive damages award.

The district court relied heavily on the expansive concept of potential harm when analysing the *Gore/State Farm* guideposts. With regard to reprehensibility, rather than focusing on the actual harm caused by the accident (which was substantial in its own right) the court considered the harm that could have resulted had the ship sunk, had the entire cargo of oil spilled or had the oil slick ignited. *Id.* at 1094-95. While the Ninth Circuit subsequently reduced the punitive damages award to $2.5 billion (a 5:1 ratio) because of evidence that Exxon had taken steps to mitigate the harm caused, the court specifically endorsed the district court's potential harm analysis. 472 F.3d at 616. ("[T]aking into account the potential harm to the crew and rescuers punishes Exxon for the same conduct that harmed the plaintiff."). *See also Krysa v., Payne*, 2005 Mo. App. LEXIS 1680 (Mo. Ct. App. Nov. 15, 2005) (approving a 27:1 ratio because the defendant's conduct (sale of a defective truck) had the "potential" to cause even greater harm than it actually caused);

Exxon Valdez was decided just months before the Supreme Court issued its decision in *Williams*. When courts rely heavily on potential harm (vs. actual harm), the ratio guidepost can become virtually meaningless, which results in large punitive damage awards. However, Williams has clarified that consideration of potential harm is not unlimited, rather it is limited to potential harm to the plaintiff. *Williams*, 127 S. Ct. at 1063 ("We have made it clear that the potential harm at issue was harm potentially caused to *the plaintiff*.").

While the *Exxon Valdez* case was ultimately resolved by the United States Supreme Court's decision in *Exxon Shipping* that punitive damages in maritime cases are limited to a 1:1 ratio, the majority of the court did not criticise or discuss the District of Alaska's discussion of potential harm. Justice Ginsburg in her dissenting opinion made clear that she believed the court had not fully considered the potential harm that could have resulted had the oil spill been worse. 128 S.Ct. at 2639 (Ginsberg J. dissenting) ("Horrendous as the spill from the Valdez was, millions of gallons more might have spilled as a result of Capt. Hazlewood's attempts to rock the boat off the reef."). It remains to be seen whether lower courts will gravitate to Justice Ginsburg's position on potential harm.

After *Williams*, some courts have attempted to limit potential harm. In *Kauffman v. Maxim Healthcare Services, Inc.*, the United States District Court for the Eastern District of New York indicated that consideration of potential harm should be limited to situations where there was an unsuccessful scheme to cause additional damages and should not apply in situations where a plaintiff's efforts to mitigate damages limited the total harm. 509 F.Supp.2d 210, 219 (E.D.N.Y. 2007) ("The fact that the plaintiff might have been less successful at mitigating his damages is not a basis of 'potential harm'"). As the court explained "there would be no reason for requiring a plaintiff to mitigate damages if the ultimate result would effectively produce a windfall rather than compensation for injuries sustained." *Id.*

C. There Is Confusion Among Lower Courts Regarding The Role Of The Wealth Of The Defendant

In *State Farm*, the Supreme Court sent mixed messages regarding what role defendants' wealth should play in assessing punitive damages. *See* Fey *et al.*, 56 Baylor L. Rev. at 848. In one respect, the Supreme Court suggested that wealth was not relevant to determining whether a punitive damages award is constitutional. Indeed, the Court specifically indicated that a consideration of a defendant's wealth

"bear[s] no relation to the award's reasonableness or proportionality to the harm" and that "[t]he wealth of a defendant cannot justify an otherwise unconstitutional punitive damage award." *State Farm*, 538 U.S. at 427. The Court followed this language, however, with language from Justice Breyer's concurring opinion in *Gore* which suggested the consideration of a defendant's wealth was neither unlawful nor inappropriate. *See id*. at 427-28 (wealth "provides an open-ended basis for inflating awards when the defendant is wealthy….that does not make its use unlawful or inappropriate; it simply means that this factor cannot make up for a failure of other factors") (citing *Gore*, 517 U.S. at 591 (Breyer, J., concurring).

Add to the confusion the fact that many state and federal courts had long accepted wealth as an appropriate factor. *See* Fey *et al*., 56 Baylor L. Rev. at 849. For these reasons, lower courts have not reached a consensus regarding whether a defendant's wealth should be considered and, if so, to what extent. Some courts have questioned whether wealth can play any role in setting the amount of punitive damages. *See*, e.g., *Hayes v. Wal-Mart Stores, Inc.*, 294 F. Supp. 2d 1249, 1251 (E.D. Okla. 2003) ("[T]he use of a defendant's net worth may be in doubt."); *McClain v. Metabolife Int'l Inc.*, 259 F. Supp. 2d 1225, 1229 (N.D. Ala. 2003) ("[T]his court is not sure whether the financial impact on a defendant is a thing to be considered."); *see also Romo v. Ford Motor Co.*, 6 Cal. Rptr. 3d 793, 801 (Cal. Ct. App. 2003) (noting that *State Farm* shifted the focus away from "the defendant's wealth or general incorrigibility").

By contrast, a majority of lower state and federal courts continue to find that a defendant's wealth is relevant. *See, e.g., Lowry's Reports, Inc. v. Legg Mason, Inc.*, 302 F. Supp. 2d 455, 461 (D. Md. 2004) ("[T]he jury's consideration of [the defendant's] wealth was a correct application of the deterrent role of statutory damages."); *Dewick v. Maytag Corp*., 324 F. Supp. 2d 889, 889 (N.D. Ill. 2004) (Illinois law "continues to teach that evidence as to a defendant's net worth, and arguments based on that evidence, are appropriate to place before a jury that is asked to award punitive damages."); *Hollock v. Erie Ins. Exch.*, 842 A.2d 409, 419 (Pa. Super. Ct. 2004) (noting that governing state law called for a consideration of defendant's wealth); *Stroud v. Lints*, 790 N.E.2d 440, 446 (Ind. 2003) ("The defendant's wealth is ordinarily cited as a reason to escalate a punitive award, and that is consistent with the goal of deterrence."); *Seltzer v. Morton*, 154 P.3d 561, 597 (Mont. 2007) ("a defendant's financial condition is logically one of the essential factors to consider in determining an amount of punitive damages that will appropriately accomplish the goals of punishment").

Indeed, the defendant's wealth can play a central role in upholding a punitive damages award. In *Romanski*, the fact that the defendant was a casino that brought in approximately $1 million dollars a day was a large factor in the Sixth Circuit allowing a punitive damage award of $600,000. 428 F.3d at 649-50. The Romanski court explained that "we must take into account the casino's wealth to ensure that the punitive damages award will further the interests it is designed to advance." Id. at 647. The court then set punitive damages at $600,000 which constituted 60% of the casino's daily revenue commenting that "[i]t cannot be seriously contended that this is an insignificant amount for the casino." *Id*. at 649-50.

While decisions that rely as heavily on wealth as Romanski are rare in post-*State Farm* cases, there remains a great deal of confusion and disagreement about the proper use of the defendant's wealth in calculating punitive damages.

VI. Opportunities To Limit / Dispose Of Punitive Damages Post-State Farm

Although courts are bound to apply the guideposts announced in *Gore* and *State Farm*, many "gray areas" remain. For example, "reprehensibility" is a broad concept left to interpretation by trial courts. Likewise, there is no "bright line" rule regarding ratios. Lower courts are also left to decide which civil penalties are most "comparable" to the case at bar and whether and to what extent a defendant's wealth should be considered. Because so much of the United States Supreme Court's jurisprudence regarding punitive damages is open to interpretation, it is up to defence counsel to educate the trial judge about the restrictions imposed by *State Farm* and its progeny. As a practical matter, defence counsel should consider opportunities throughout the litigation to ensure that the holding and rationale of *State Farm* at its progeny is understood and applied during trial.

In addition, during all stages of the case, it is essential that defendants keep in mind potential constitutional challenges because a court may decline to apply portions of *State Farm* if the appellate record has not been properly preserved. *See e.g., Henley v. Phillip Morris, Inc.*, 9 Cal. Rptr. 3d 29, 71 (Cal Ct. App. 2004) ("Unlike the defendant in *Campbell*, however, defendant made no attempt to anticipate the Supreme Court's direction by objecting to the evidence or seeking a limiting instruction.").

In addition to the due process limits imposed by *State Farm*, *Exxon Shipping* serves as a reminder that defence counsel should be prepared to raise any limits on punitive damages that may be available *in addition* to those found in the Constitution. It is not at all clear that the Supreme Court would have limited punitive damages in *Exxon Shipping* to a 1:1 ratio had it reviewed the case solely under due process principles. In addition to the 1:1 ratio limit for cases involving maritime law, various state laws impose limits on punitive damages. *See Exxon Shipping*, 128 S. Ct. at 2622-23 (discussing statutory and common law punitive damages restrictions in various states including Nebraska, Louisiana, Massachusetts, Washington, New Hampshire, Michigan, Connecticut, Virginia, Ohio, Alaska, Missouri, Alabama, North Dakota, Colorado and Oklahoma). In addition to blanket restrictions on punitive damages, some states have restricted punitive damages in certain types of cases. *See, e.g.*, N. J. Stat. Ann 2A:58C-5 (permitting no punitive damage awards in a product liability case against a pharmaceutical manufacturer whose product was approved through the United States Food and Drug Administration's process, unless there is evidence that the manufacturer withheld information from the Food and Drug Administration during the approval process).

A. Affirmative Defences

In assessing potential affirmative defences to a claim for punitive damages, the facts of the particular case, the jurisdiction in which the case is pending, and the state's substantive law should all be taken into consideration. One goal is to preserve the defence's arguments regarding the constitutionality of punitive damages. Typically, defendants should consider an affirmative defence stating that an award of punitive damages would violate defendant's procedural and substantive due process rights and equal protection rights (see *State Farm*; First, Fifth, Sixth, Eight, and Fourteenth Amendments to the United States Constitution and similar Articles of state Constitutions). In addition, the affirmative defences should specifically include and cite to any state statutes or case law that might be relevant in determining the availability or amount of punitive damages.

B. Bifurcation

Bifurcation is a procedural device whereby different issues are tried sequentially, "with the presentation of proof on the trailing claims or issues contingent upon the outcome of the previously considered questions." Landsman, Stephan *et al*., *Be Careful What You Wish For: The Paradoxical Effects of Bifurcating Claims for Punitive Damages*,

1998 Wis. L. Rev. 297, 299. In federal court, bifurcation is governed by Federal Rule of Civil Procedure 42(b). Rule 42(b) provides that "[t]he court, in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy, may order a separate trial of any claim... or of any separate issue." F.R.C.P. 42(b). Many states have similar rules regarding bifurcation. Other states' rules of civil procedure provide that a party is entitled to bifurcation of punitive damage issues as a matter of right. *See, e.g.*, Mo. Rev. Stat. § 510.263(1) ("All actions tried before a jury involving punitive damages shall be conducted in a bifurcated trial before the same jury if requested by any party.").

Some states (e.g., Minnesota) completely bifurcate any punitive claim. In those states, the jury first determines whether the defendant is liable for compensatory damages. Then, if compensatory damages are awarded and if the judge determines that punitive damages will be submitted to the jury, a separate trial (in front of the same jury) is held to determine whether punitive damages will be awarded and, if so, in what amount. Other states (e.g., California) only bifurcate the amount of punitive damages.

In states that allow complete bifurcation, *State Farm* may have an impact on the scope of evidence presented in Phase I. In those states, bifurcation offers defendants "significant protection from prejudice arising out of the misuse of information relevant only to the punitive damage decision." Landsman, Stephan *et al.*, 1998 Wis. L. Rev. at 335. Specifically, the jury should not hear evidence that is only relevant to punitive damages. This would arguably include all "bad company" evidence and evidence regarding the defendant's net worth.

State Farm will have less of an impact in states where the effect of bifurcation is only to defer evidence regarding the amount of punitive damages until Phase II. In those states, evidence relevant to whether punitive damages should be awarded is not deferred until Phase II. Accordingly, the evidence relevant to punitive damages that is heard during the first phase is generally similar to the evidence presented in the second phase. A defendant may not gain much, if anything, in the way of excluding evidence by bifurcating under these circumstances.

There are other potential risks and benefits associated with a bifurcated trial. On the "benefit" side, research suggests that defendants increase their likelihood of winning on liability in a bifurcated trial. *See* Landsman, Stephan *et al.*, 1998 Wis. L. Rev. at 316. There are also risks associated with bifurcation. For example, some commentators have suggested that defendants who lose on liability "substantially increase the risk that punitive damages will be assessed against them if the case is bifurcated." *Id.* at 335. Research further suggests that "not only does the incidence of punitive liability increase, but the size of the punitive award grows substantially if the case is bifurcated." *Id.*

Because there are potential risks and benefits to bifurcation, the particular facts and circumstances of each case, and the effect of bifurcation in a particular jurisdiction, must be weighed prior to making this important decision.

C. Motion to strike punitive damages

Before trial, defence counsel should consider moving to strike the plaintiff's claim for punitive damages on grounds that, under *State Farm*, the admissible evidence cannot support a claim for punitive damages. A constitutional challenge to a state's punitive damages statute may also be appropriate under *Williams*. *See Moody v. Ford Motor Co.*, 506 F. Supp. 2d 823, 849n. 14 (N.D. Okla. March 20, 2007) (commenting that, under *Williams* "[t]here is the possibility that section 9.1 may be facially unconstitutional, but the issue has not been addressed by the Oklahoma Supreme Court or the Oklahoma Legislature"). In addition, counsel should consider a motion to strike on grounds that plaintiff has failed to allege the appropriate standard of conduct for imposition of punitive damages. For example, if a state only permits punitive damages in cases involving "clear and convincing evidence" of conduct that is "wilful and wanton," counsel should set forth that language and law as an affirmative defence.

D. Motions in Limine

A pre-trial motion *in limine* is an opportunity to educate the court about the parameters established by State Farm. The main objective is to limit introduction of evidence on the issue of punitive damages, including for example: (1) the defendant's business or sales practices in states other than the state where the case is pending; (2) the defendant's overall net worth; (3) arguments by counsel for a punitive damage award that will "send a message"; (4) evidence unrelated to the plaintiff's alleged harm; (5) statements urging the jury to punish defendant for conduct that is lawful; and (6) statements urging the jury to punish for harm caused to persons other than the plaintiff.

E. *Voir dire*, opening statement, and closing argument

It is important to educate the jury at every stage of the trial. In most cases, they are the decision makers regarding whether to award punitive damages and, if so, in what amount. *Voir dire*, opening statement, and closing argument are significant opportunities to convey the defence themes. Throughout the trial, defence counsel should stress that a plaintiff is "made whole" by compensatory damages and, accordingly, no plaintiff is entitled to punitive damages as a matter of right. *State Farm* clearly delineated between punitive damages and compensatory damages noting that they serve different purposes. Specifically, compensatory damages are intended to compensate the plaintiff for his loss, whereas punitive damages are "aimed at deterrence and retribution." *State Farm*, 538 U.S. at 416. If the facts permit, defence counsel may want to consider the argument that punitive damages are not necessary because: passage of time; the company has instituted a change in policy; or there has been a change in ownership of the business. *See* Fey *et al.*, 56 Baylor L. Rev. at 857.

F. Jury instructions

Jurors must be properly instructed regarding the scope of evidence they may consider in determining whether to assess punitive damages. It is essential to inform jurors that assessment of punitive damages is not required and should not be assessed simply because the defendant has sufficient assets to pay such an award. Potential elements of a punitive damages jury instruction include: (1) a punitive damage award is not required; (2) punitive damages should not be awarded as a result of anger, passion, or prejudice, or to re-distribute wealth; (3) plaintiff has the burden of establishing entitlement to punitive damages by clear and convincing evidence establishing that defendant acted intentionally or with actual malice; (4) no punitive damages may be assessed for lawful conduct; (5) discretion should be used in determining the amount of any punitive damage award; (6) any punitive damage award must bear a reasonable relationship to the harm suffered by plaintiff (the Ninth Circuit refused to require a reasonable-relationship instruction in *White v. Ford Motor Co.*, 500 F.3d 963, 973-74 (9th Cir. 2007) because the reasonable relationship requirement only relates to ascertaining the permissible constitutional ceiling for a punitive damages award which is a legal question and, therefore, is not for the jury to consider; despite this ruling, the authors believe it is appropriate to request such an instruction); (7) the defendant cannot be punished for conduct outside the state; (8) there must be a nexus between the conduct of the defendant and the harm suffered by the plaintiff; and (9) punitive damages may not be

awarded for harm caused to persons other than the plaintiff. *See* White, 500 F.3d at 793 (reversing punitive damages award and remanding for new trial on punitive damages where jury had not been instructed that it could not impose punitive damages for harm caused to third parties); *Merrick v. Paul Revere Life Inc. Co.*, 500 F.3d 1007, 1018 (9th Cir. 2007) (same); *Bullock v. Philip Morris USA, Inc.*, 159 Cal. App. 4th 655, 696 (Cal. App. 2008) (same).

Jury instructions should also address the issue of the defendant's wealth. Specifically, if the court determines that defendant's financial condition is admissible, defendants should propose jury instructions that limit its use. For example, a jury should be instructed that they cannot use the defendant's wealth as a basis for rendering an excessively high punitive damage award and that the defendant's wealth cannot justify an otherwise unconstitutional punitive damages award.

G. Post-trial motions

If a jury awards punitive damages, defence counsel should be alert to reversing the award by filing a timely post-trial motion to preserve an appeal. Examples of post-trial motions are: a motion for new trial; a motion for judgment N.O.V. (notwithstanding the verdict, i.e., asking the court to set aside the jury's verdict); and/or a motion for remittitur (i.e., to reduce the amount of the punitive award). Arguments may include the following: (1) the jury failed to follow the jury instructions in awarding punitive damages; (2) the evidence submitted was insufficient to support the punitive damage award; (3) the trial court failed to properly apply *State Farm* in denying defendant's motion for new trial and/or remittitur of the punitive damage award; (4) the trial court admitted or failed to admit certain evidence in violation of *State Farm*; (5) the punitive award is too large to satisfy the due process requirements of *State Farm*; (6) the state's punitive damages statute is unconstitutional because it allows the jury to impose punishment for harm caused to persons other than the plaintiff; and (7) the jury instructions did not advise the jury that it could not impose punishment for harm caused to persons other the plaintiff.

When arguing that a punitive damages award should be reduced because it is unconstitutionally excessive, counsel should be careful to brief the applicability of each *Gore/State Farm* guidepost. In *Seltzer v. Morton*, the Montana Supreme Court declined to review an award of punitive damages under State Farm when the defendants argued that the award was unconstitutionally excessive but did not brief each of the guideposts. 154 P.3d 561, 602 (Mont. 2007) ("[B]ecause of the Defendants' failure to provide analysis in challenging the amount of the punitive damages verdicts against Morton and Gladwell, as required by M.R. App. P. 23(a)(4), we will not consider the issue, and we simply affirm those awards.") (citations omitted).

VII. Conclusion

Historically, courts have not provided juries with specific guidelines upon which to base an award of punitive damages and, if so, in what amount. This has led to wildly inconsistent verdicts. Consequently, the fear of astronomical punitive damages awards has skewed the evaluation of litigation and fuelled unreasonable settlements.

State Farm, *Gore*, and *Williams* provide valuable insight regarding the relevant factors to be considered in awarding punitive damages. They present new opportunities to dispose of and/or limit punitive damage claims. Read broadly, *State Farm* suggests that punitive damages are not favoured and may not be appropriate in many cases. Further, *State Farm* also suggests that, in cases where punitive damages are submitted to the jury, restrictions must be imposed to ensure that the award comports with due process.

As a practical matter, many questions remain unanswered by the Supreme Court. Concepts such as "reprehensibility," "ratio," "comparable penalties," and the role of the wealth of the defendant are left open to interpretation by trial courts. Lower courts have been grappling with these unanswered questions and have interpreted the Supreme Court's punitive damages jurisprudence differently - some courts follow the letter and spirit of the opinions, while other courts skirt the directives by limiting the holdings of *Gore*, *State Farm*, and *Williams* to their specific facts.

While no "bright line" rules exist in the context of punitive damages, defence counsel should urge that *State Farm* and its progeny operate to prevent, or at least limit, punitive damage awards.

Endnotes

1 The Supreme Court's most recent decision on punitive damages is *Exxon Shipping Co. v. Baker*. *Exxon Shipping* will likely not have as significant an impact on punitive damages as *Gore*, *State Farm* and *Williams* because the decision was based on federal maritime law as opposed to constitutional due process. 128 S.Ct. at 2626 ("Today's inquiry differs from due process review because the case arises under federal maritime law, rather than the outer limit allowed by due process; we are examining the verdict in the exercise of federal maritime common law authority, which precedes and should obviate any application of the constitutional standard."). Indeed, several lower courts have shown reluctance to follow *Exxon Shipping* because of its statements that it was applying maritime law. *See, e.g., Green v. Denny's Corporation*, 2008 WL 4328221 (S.D. Ill. Sep. 18, 2008) ("*Exxon* is of limited applicability by its own terms."); *Valarie v. Michigan Department of Corrections*, 2008 WL 4939951at *1, (W. D. Mich. Nov. 17, 2008) ("This court concludes that the Exxon punitive damages ratio does not apply here.").

2 Despite State Farm's language that criminal penalties are less relevant in a punitive damages analysis, some lower courts still look to criminal penalties. *See Kunz v. DeFelice*, 538 F.3d 667, 680 (7th Cir. 2008) (Upholding a $90,000 punitive damages award against a police officer who beat an arrestee and rejecting the argument that fines for the defendants' conduct would have ranged between $2,500 and $25,000 because a conviction for aggravated battery could result in 2-5 years of imprisonment).

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The EU General Product Safety Regime

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The regulation of the safety of consumer products in the EU has changed fundamentally since 15 January 2004, the date for the implementation of the General Product Safety Directive (*2001/95/EC*) (the Directive). The Directive marked the end of the "silent" recall of consumer products in the EU, imposing onerous new obligations on suppliers of consumer products to EU markets.

The Directive, which has been implemented in all EU Member States, has had a significant impact, as evidenced by the substantial increase in the number of recalls and other notifications of dangerous products since it came into effect. The greatest number of recalls has been of toys, electrical products, childcare articles and motor vehicles. Producers and distributors have had to implement changes to their systems and processes for managing potential safety risks, and they have witnessed greater publicity being given to product safety issues in their industries.

This article:

- Considers the key features and provisions of the Directive.
- Summarises European Commission (the Commission) guidance on the notification obligation.
- Provides practical advice on risk management and product recalls in particular.

(References to Articles are to Articles in the Directive unless otherwise stated.)

General Product Safety

The first directive on general product safety (*92/59/EEC*) was adopted in 1992 and introduced into the EU the concept of a "general product safety obligation" (the "1992 Directive"). Its purpose was to ensure a consistent, high level of safety in respect of consumer products throughout the EU; however, it did not have much of an impact in the Member States, and was criticised for not going far enough to ensure consumer safety (particularly at an enforcement level), and for lack of clarity of several of its provisions.

These criticisms culminated in the revised Directive, which replaced the 1992 Directive and took the regulation of product safety in the EU to a new level. The Commission's objectives in revising the 1992 Directive were to provide for increased transparency, more active market surveillance, more effective enforcement measures and simpler rules for rapid intervention to remove dangerous products from the market, all with a view to furthering the primary aim of ensuring a high level of consumer protection and the proper functioning of the internal market.

The Directive is intended to cover all products that are supplied to consumers, to the extent that an aspect of their safety is not regulated by other sector-specific safety regulations. This means that all consumer products in the EU are fully covered either by the Directive, or by sector-specific safety regulations, or by a combination of the two.

Key Changes to the Safety Regime Brought About by the Directive

The revised Directive introduced several significant changes to the way the safety of products is regulated.

- Producers and distributors have additional obligations to conduct market surveillance and monitor risks.
- Producers and distributors are required to notify national authorities of product risks.
- Producers have an obligation to recall dangerous products.
- The range of products covered by the regime is wider.
- The application of the regime to "borderline" industries has been clarified.
- National authorities have increased powers and obligations to enforce product safety laws and prosecute those who fail to meet their obligations.
- National authorities have powers to initiate product recalls of their own accord.
- National authorities have powers to share information with each other and with the public.

Key provisions

The safety regime under the Directive is built around the "general safety requirement" (*Article 3(1)*). A product that does not meet the definition of a safe product is considered "dangerous" (*Article 2(c)*).

What is a safe product?

A "safe product" is any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons. The following points in particular should be taken into account:

- The characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance.
- Its effect on other products, where it is reasonably foreseeable that it will be used with other products.
- The presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other

indication or information regarding the product.

- The categories of consumers at risk when using the product, in particular, children and the elderly.

(*Article 2(b).*)

The Directive imposes a number of obligations on producers and distributors to reduce the risk of dangerous products being placed on the EU market. In particular, producers must:

- Place only safe products on the market (*Article 3(1)*).
- Provide consumers with relevant information to enable them to assess risks inherent in the product (*Article 5(1), paragraph 1*).
- Have systems to enable them to be informed of the risks that a product might pose (*Article 5(1), paragraph 3(a)*).
- Have systems to enable them to take appropriate action to avoid risks (which might include being able to trace marketed products) (*Article 5(1), paragraphs 2 and 4(a)*).
- Keep distributors informed of any sample testing or other monitoring activities (*Article 5(1), paragraph 4(b)*).
- Where appropriate: carry out sample testing of marketed products; keep a register of complaints; and adequately investigate complaints (*Article 5(1), paragraph 4(b)*).
- Notify the competent authorities immediately a marketed product is known or should be known to pose unacceptable risks (*Article 5(3)*).
- Recall dangerous products in the appropriate circumstances. If they fail to do so, producers can be ordered by the authorities to recall products (*Articles 5(1) and 8(1)(f)*) (see the section on "Product recalls" below).

Distributors are required to assist in compliance with the applicable safety requirements by:

- Keeping and making available whatever documents are necessary for tracing the origin of products (*Article 5(2)*).
- Passing on information on product risks (*Article 5(2)*).
- Co-operating with the action taken by producers and the competent authorities (*Article 5(4)*).
- Notifying the competent authorities immediately a marketed product is known or should be known to pose unacceptable risks (*Article 5(3)*).

Definitions

A "producer" is defined as any of the following:

- A manufacturer established in the EU or an own-brander (that is, someone who places his name or trademark on the product so as to present himself as a producer) (*Article 2(e)(i)*).
- An EU representative of the manufacturer, if the manufacturer is not established in the EU or, if none, the importer of the product (*Article 2(e)(ii)*).
- Other professionals in the supply chain, in so far as their activities may affect a product's safety (*Article 2(e)(iii)*).

A "distributor" is defined as any professional in the supply chain whose activity does not affect the safety properties of a product (*Article 2(f)*).

Scope

Under the previous regime, the obligation to put safe products on the market related only to products intended for consumer use, or likely to be used by consumers, including second-hand products (with some exceptions).

The Directive extends to all products that are made available to consumers, including ones that it is reasonably foreseeable may be used by consumers even if not intended for them (such as products that might be expected to "migrate" from the professional to the consumer market, for example, laser pens). It also extends to products used by consumers in the course of a service being provided to them (for example, sun beds used in sports clubs) (*Article 2(a)*).

"Borderline" industries

The Directive does not extend to products that are subject to a separate comprehensive product safety regime under EC law (*Article 1(2)*). In practice, the only products beyond the scope of the Directive are food and pharmaceuticals.

Several industries are subject to partial safety regulation, such as those involved in the manufacture and supply of toys, cosmetics, motor vehicles, electrical products, personal protective equipment, construction equipment, machinery, and medical devices.

The Commission has published two guidance documents which, between them, offer guidance on the relationship between the Directive and the legislation affecting these products. This guidance, while it is of some assistance, does not deal with a number of the issues relevant to those industries, nor does it give much guidance on how the Directive might operate in respect of other regulated industries ("*Guidance Document on the Relationship Between the General Product Safety Directive (GPSD) and Certain Sector Directives with Provisions on Product Safety", November 2003, http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/guidance_gpsd_en.pdf and "Guidance Document on The Relationship Between the General Product Safety Directive (GPSD) and Certain Sector Directives with Provisions on Product Safety - Second Chapter", November 2005, http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/gpsd_2ndchapiter_en.pdf*).

Notification obligation

Under the Directive, producers and distributors must notify the competent authorities "immediately" they know, or ought to know, that a product they have marketed poses unacceptable risks (*Article 5(3)*). It is generally an offence not to comply with this requirement (*see the section on "Penalties" below*).

Significantly, the Directive imposes the notification obligation on distributors as well as on producers. This means that producers could find themselves in a situation where the distributors of their products notify the authorities of alleged defects in their products, without necessarily first telling the producers. Similarly it has the potential to create strain on commercial relationships in the event the producer and distributor take different views on whether a particular product safety issue should be notified.

The broader implications of the notification requirement will be obvious to those who have experience with the regime under the consumer product safety legislation in the US where there is a similar, but not identical, obligation to notify the authorities if producers discover that a product they have marketed presents unacceptable risks. In fact, the notification obligation under the Directive is more onerous than its US equivalent because:

- The safety threshold for reporting product risks is likely to be, in most cases, much lower.
- The enforcement mechanisms will be decentralised and inevitably subject to inconsistent application as between various Member States.
- There is less adequate protection of any confidential information supplied by manufacturers (*see the section on "Information sharing" below*).

National authorities

Under the Directive, national authorities are under an obligation to

take positive steps to ensure adequate market surveillance of consumer products (*Article 9(1)*). National governments need to ensure that their enforcement authorities have sufficient resources to enable them to fulfil this obligation.

National authorities are also specifically empowered to initiate product recalls. Although a product recall is to be considered a last resort, national authorities are required to take into account the "precautionary principle" when assessing what action should be taken (*Article 8(2)*).

National authorities must also give consumers and other interested parties an opportunity to submit complaints, and these complaints must be followed up as appropriate (*Article 9(2)*).

Information sharing

National authorities must share information about "serious risks" with the Commission (*Article 12*). The Commission is empowered to share that information with other Member States, through the EU emergency system for the rapid exchange of information (RAPEX), and even with their counterpart organisations in other countries. The Commission and the Consumer Product Safety Commission in the US have already agreed guidelines for sharing information about specific product safety risks that are notified to either of them and they now routinely share information with each other about dangerous products and product recalls that come to their attention. Also, due to the increased number of notifications being of products that are of Chinese origin, in May 2006 it was agreed between the Commission and Chinese government that RAPEX information concerning Chinese products would be made available to the Chinese government to enable it to take immediate follow-up steps.

The authorities can also make the information provided by producers and distributors available to the public, other than where the information is covered by "professional secrecy" and does not need to be disclosed to protect consumers. The public will also have a right to gain access to the information provided to the regulatory authorities, particularly as it relates to product identification, the nature of the risk and the measures taken (*Article 16*).

The Commission routinely publishes on its website information about products posing serious risks that are notified to it by Member States under the Directive (http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm).

Penalties

The penalties for breach of the Directive vary under the implementing legislation of the different Member States. For example, penalties in the UK are fines of up to £20,000 and/or 12 months' imprisonment for the more serious offences, such as a breach of the general safety requirement, and fines of up to £5,000 and/or three months' imprisonment for other offences. In other countries, penalties can include fines of up to €2 million, and forced businesses closure.

Commission Guidance On Notification

The notification obligation in particular presents difficult challenges for producers and distributors when they are confronted with an unexpected safety risk presented by products they have marketed (*see the section on "Notification obligation" above*). This is when the adequacy of systems put in place to ensure safety will come to be scrutinised and when management will be faced with the question of whether the legal obligation to notify authorities, and possibly then take corrective action, has been triggered (*see the sections on "Risk management" and "Product recalls" below*).

In recognition of that, the Commission published guidelines intended to give producers, distributors and national authorities some guidance on how the notification obligation is to operate in practice ("*Guidelines for the notification of dangerous consumer products to the competent authorities of the Member States by producers and distributors in accordance with Article 5(3) of Directive 2001/95/EC*", *http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/notification_dang_en.pdf*) (guidelines).

Immediate notification

The Directive does not indicate what "immediately" means in the context of the notification obligation (*see the section on "Notification obligation" above*). The guidelines offer some assistance:

"*The [Directive] requires that the competent authorities be informed immediately. A company must therefore inform them without delay, as soon as the relevant information has become available, and in any case within 10 [calendar] days since it has reportable information, even while investigations are continuing, indicating the existence of a dangerous product. When there is a serious risk companies are required to inform the authority(ies) immediately and in no case later than three [calendar] days after they have obtained notifiable information.*

In an emergency situation, such as where immediate action is taken by a company, the company should inform the authorities immediately and by the fastest means."

These time limits can be difficult to apply in practice, particularly if information about the nature and extent of the risk is still emerging. It will not always be clear whether the product poses risks that are incompatible with the general safety requirement. This might be the case, for example, where a company has received one isolated report of a safety incident, or a potential risk is identified but there is no more than a theoretical possibility of the risk materialising.

Risk assessment

To help identify risk in this context, the guidelines set out a "methodological framework" for risk assessment. This framework suggests an approach based on a systematic evaluation of the following factors:

- Severity of injury.
- Overall probability of injury.
- Type of person at risk (especially vulnerable people).
- Adequacy of warnings/obviousness of hazard.

The guidelines include a risk assessment matrix incorporating the results of the evaluation of the interaction of these factors, and indicate on that basis whether notification is required.

The Commission has stressed that these guidelines will not necessarily apply in all cases. In fact, they have, since their introduction, been the subject of much criticism and have proven to be unworkable in many situations. As a result, the Commission has been consulting on a new and revised methodology, which is expected to be published later this year and which will hopefully offer producers and distributors a more practical approach for analysing product risks.

The key lesson highlighted by the guidelines is that every potential safety risk arising in respect of marketed products needs to be considered carefully on its facts, with proper input from experts experienced in both the technical aspects of the risk assessment and the legal obligations under the new regime.

Pan-European notification

If the potentially unsafe product has been marketed in more than one Member State, the producer or distributor is faced with the prospect of having to give a notification "immediately" to the national authorities in up to 25 Member States (*see the sections on "Co-ordinate notification action" and "Guidance for Pan-European notification" below*).

Although not envisaged in the Directive or fully reflected in the implementing legislation in any Member State, the guidelines suggest a procedure whereby a producer or distributor may notify only the authority in the Member State in which they are established, provided either the risk is notified as being a "serious risk" or is otherwise considered a serious risk by the receiving authority, or that authority has agreed with the producer or distributor to notify the authorities in the other Member States.

As this procedure has not been given full effect in the implementing laws in the Member States, if a producer or distributor chose to use this single notification procedure, rather than directly contacting the authorities in each Member State, it could give rise to a breach of the Member State's local laws on notification. Some national enforcement authorities have indicated that they would accept this single notification procedure as satisfying the notification obligation. However, whilst businesses may be able to discharge their obligations in most Member States by following the single notification procedure, rather than informing each Member State authority directly, they should nevertheless be advised of the practical risks in following this "short-cut".

The main risk, from a practical perspective, of following the single notification procedure arises from the fact that, whilst it offers the possibility of a centralised process for notification, there is no current procedure for centralised enforcement. If the producer does not make the effort to establish direct contact at a local level with the authorities who will be making decisions about enforcement, the enforcement authority may initiate its own investigation in the local market. Often this will involve the authorities directly contacting customers and local distributors, and they will make decisions about enforcement based on whatever information such investigations may reveal. This makes it impossible for a producer dealing with a pan-European safety issue to have any confidence in its ability to control the issue in the various countries, which could have damaging implications for the reputation of the producer, and could undermine the key objectives of any corrective action being undertaken.

The Commission has been considering options for introducing a technical solution to enable pan-European communications to take place more effectively, quickly and reliably. In this regard the Commission has been in the process of setting up a new internet application - Business Application - to enable producers and distributors to send the notification form to the competent authorities of all EU Member States via the Internet. The Business Application system is to become operable on 4 May 2009 and guidance was published by the Commission in April on preparation and submission of the form: http://ec.europa.eu/consumers/safety/rapex/docs/manual_form_business_app.pdf. The form is available in five languages, namely English, French, German, Italian and Spanish. If the notification is to be sent to any Member States that do not work in one of those languages, the producer or distributor will need to prepare and attach relevant translations. It should also be noted that this system still will not include any provision for enforcement decisions, and will therefore not release prudent producers and distributors of the need to establish a direct local point of contact with the enforcement authority in each country.

Risk Management

Effective risk management is crucial to ensuring that as far as possible products are safe, and that a company responds effectively under the Directive to any safety problems that arise after the product has been put into circulation. A risk management system should cover all stages of the production process including design, manufacture, production, testing (including equipment testing), packaging, storage, distribution and post-marketing surveillance.

There are a number of important steps that manufacturers or suppliers should take as part of a basic risk management system to help meet the new Directive's requirements.

Product safety review team

A product safety review team should be set up to co-ordinate a comprehensive risk management programme. The members of such a team should be drawn from all relevant sections of the organisation. The team should meet regularly and have authority to take any necessary action.

The review team's main function would be to ensure that the basic product safety procedures are maintained and that problems are dealt with effectively.

The review team would need to review safety and quality control procedures, devise a product recall plan, and, in the event of a safety problem, be in a position to assess the scale and seriousness of the risk and respond accordingly. This will involve ensuring that internal and external advisers with appropriate experience can be quickly called in to deal urgently with potential risks that might arise. The review team will also need to nominate individuals as contact points for the regulators, and keep comprehensive information on distributors, retailers and customers of each product should a recall be required.

Terms and conditions

The law permits a degree of flexibility as to the terms on which manufacturers, distributors and retailers may apportion risk among themselves in relation to product liability issues. Appropriately drafted warranties and indemnities can go a considerable way towards achieving this and at the same time assist in mounting an appropriate defence in proceedings. Systems should therefore be in place to ensure that a company's terms of business are properly incorporated into contracts and are assessed and reviewed periodically.

Post-market surveillance

Producers must ensure they take adequate steps to monitor the safety of their products, even after they have been marketed (*Article 5(1)*). This may include systems for sample testing of marketed products, maintaining a register of consumer complaints, and establishing systems to ensure good communication of information about potential risks between the producer and distributors.

Instructions and warnings

Companies must ensure that instructions and warnings are communicated effectively to consumers whether by labelling, package inserts or other means. This may involve warning product users of newly identified risks after the product has been sold. The style of packaging as well as its physical characteristics can affect

the safety of a product, as can the nature of any advertising material or marketing tactics.

Documents

The management of documents is vital to controlling product liability risks. Claims cannot be properly defended without good records to show that the company acted responsibly. Companies also need to be able to provide the authorities with relevant information in order to discharge their obligations under the Directive and other regulations. It is crucial to have accurate records showing who did what, when they did it, and how problems were identified and dealt with. Written procedures should be drawn up to cover all aspects of the company's functions that relate to product safety. These need regular reviewing and updating. It is important to keep a record of outdated procedures and also of the reason for any change in procedures.

A retention policy to ensure that documents are kept for an appropriate period is equally important. Retention of documents may enable companies to defend product liability claims effectively, but documents that show the company in a bad light can be devastating. It should be assumed that any document created may be discovered in product liability proceedings. Staff should therefore think carefully about the words they choose when creating documents, so as to avoid exaggeration or speculation and to limit scope for misinterpretation. This is particularly true of e-mail correspondence as, all too often, ideas and comments are set down in e-mails that would never be recorded in more formal documents.

Insurance

A company will require insurance cover for product liability risks. The scope and terms of insurance policies must be carefully examined. Insurance can be obtained to cover the cost of a recall, but it is not usually included in a standard product liability policy. The definition of "products" should also be reviewed to make sure it is wide enough to cover instructions, labels and warnings.

Investigation capabilities

If a problem is suspected, it will usually be necessary to carry out further testing and other technical investigations on the product. Such investigations will enable a manufacturer to assess whether:

- A replicable defect exists in the product, or whether the problem was a one-off.
- Injury or damage to other consumers is foreseeable.
- Any particular consumers are at risk.

The information collected will help inform a decision on what action to take and, in particular, on whether to recall the product (*see the section on "Product recalls" below*). It may be necessary to use external testing houses: it is useful to have established contacts with these in advance of any problem arising.

Risk audits

An excellent way of monitoring and assessing the effectiveness of a risk management system is by undertaking a thorough product liability audit. The systems in place should be checked regularly to ensure that they continue to cover all potential problems with the product and any new requirements imposed by the regulators or authorities. Written records should be kept of all audits that can then be used if necessary in the future to show that the company acted responsibly.

Dealing with the media

Product safety problems are invariably of great interest to the media. It is rare that they are reported in an objective and balanced way: the desire to get a story out as quickly as possible, the inherent difficulties of accurately reporting on the nature and magnitude of risks, and the inclination of journalists to over-dramatise a story, all contribute to inaccurate and misleading reporting. This can lead to consumers being unnecessarily alarmed and can cause damage to the reputation of a company.

It is always useful to have established relationships with key media outlets so that if the company needs to get certain messages across, it can use these outlets to do so. However, above all it is important to be in a position to brief the media at the earliest opportunity and, for this purpose, to have a briefing pack with the essential details about the nature of the problem and how the company proposes to deal with it. There also needs to be a group of experienced staff who can deal with any follow-up questions from the media.

Product Recalls

The Directive has changed the way in which product recalls and other corrective actions must be approached by producers and distributors in the EU. Perhaps most importantly, there are the practical issues related to the need to notify and work with the authorities in all Member States where the product has been marketed (*see the section on "Notification obligation" above*). The following are some practical tips that may be useful to consider:

Plan effectively

The first indication of a potential risk usually occurs well before all facts are available. Any decision on what action to take should ideally be made following a proper and thorough investigation into the true nature and extent of the risk. Due to the strict nature of the notification obligation, and the tight timeframe in which it is intended to operate, this may not always be possible. However, a producer or supplier will be better able to control the management of the risk (and avoid having to undertake what might ultimately prove to be overly cautious corrective action) if it can quickly marshal its internal team and external advisers to start dealing with the issue promptly (*see the section on "Risk management" above*).

Co-ordinate notification action

In view of the comments made above in respect of the single notification procedure, prudent businesses will want to ensure that they make direct contact at a local level in each country in which notification is required (*see the sections on "Pan-European notification" and "Guidance for Pan-European Notification" above*). The notifications should take place simultaneously in each affected Member State. Information about product risks can be communicated swiftly among national authorities through the RAPEX system. It could be embarrassing for a producer or distributor, and lead to unnecessary conflict with the authorities, if some national authorities first learn of a risk affecting products in the markets for which they are responsible from another source, particularly where it becomes apparent that authorities in other Member States have been notified earlier.

It is also important that consistent information be communicated to the authorities in all the relevant countries to avoid any suggestion that the same risk is being handled differently in different markets. In some cases, different steps may be justified, due to differing

market conditions, consumer behaviour, or modes of distribution of the product, but any discrepancies must be capable of ready justification.

For the same reasons, the flow of information during the course of the corrective action must be controlled. Some national authorities may raise questions or request further information about the risk or the proposed action. The nature of such responses in each Member State should be carefully managed to ensure a consistent flow of information.

Get the balance right

When making initial notifications to authorities about a potential product risk or proposed corrective actions, the authorities will need sufficient information to enable them to determine the adequacy of the producer's proposed actions. However, the provision of too much detail can result in misunderstandings and can prompt unnecessary inquiries from authorities, with the risk that the taking of corrective action can be delayed, particularly if the information is highly technical and needs to be translated.

Maintain good relations with the authorities

Complications can, and regularly do, arise in pan-European recalls when the authorities take inconsistent views of the way in which the potential risk ought to be dealt with. This can become particularly problematic if some authorities are not satisfied with corrective actions proposed by the producer or distributor. It is often necessary to enter into negotiations with local authorities in an effort to satisfy them that the steps proposed, which are also being undertaken in other countries, are appropriate to deal with the perceived risk. This is why it is important to ensure a good relationship with local authorities from the outset.

Since the Directive came into force, national safety authorities have become more experienced in dealing with product risks notified to them, and are becoming much more interventionist in relation to how corrective action should be handled in their countries. Generally, however, if the local authorities can see that the recall action is being undertaken carefully and professionally and that the producer or distributor is willing to be open and prompt in its communications with the authorities, there is much less risk that the authorities will seek to substitute their judgment for that of the producer or distributor.

Protect confidential information

One of the difficulties with the Directive is that, unlike in the US, it is not possible to ensure that information given to the authorities will remain confidential (*see the section on "Information sharing" above*). Indeed, the authorities are given the power and encouragement to make such information available to the public unless it is covered by "professional secrecy", which is taken, in at least some countries, to mean trade secret. This is an important consideration when deciding precisely what information to provide to the authorities. In certain situations it may be possible to agree a mechanism to protect confidential information, for example, where its release could put the producer or distributor in breach of their legal obligations in other countries.

Guidance For Pan-European Notification (Assuming Single Notification Procedure Not Adopted)

1. Develop a master "notification pack"

- Select language for documents in master pack: this will usually be English.
- Get the right balance of information, having regard to:
  - legal obligations of disclosure;
  - confidentiality concerns; and
  - the need to provide adequate information about the risk and proposed corrective action, but not so much, and not presented in such a way, as to lead to unnecessary questions from authorities.
- Emphasise the international scope of action to minimise the risk of an individual national authority seeking to modify proposed strategy.

2. Line up a network of experienced local counsel in each country

- Select local counsel with relevant experience and expertise.
- Brief local counsel to be ready to respond when necessary.
- Request advice from local counsel on any particular requirements of national authorities.

3. Prepare to notify national authorities

- Send notification pack to local counsel for translation.
- Ensure local counsel can be contacted and are available to notify national authorities as soon as instructed.

4. Notify national authorities simultaneously using local counsel

- Maintain centralised control over responses to enquiries from national authorities. Ensure consistency of information provided to national authorities (allowing for differences in the level of detail).

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He regularly advises clients on product safety issues such as risk management systems, media handling, labeling, contractual terms and conditions, product recalls, crisis management and liaison with EU and national authorities. In recent years he has advised several international product suppliers on EU-wide product recalls under the General Product Safety Directive.
John was appointed by the European Commission to lead the team that carried out a major study on the Product Liability Directive and its possible reform and is a member of the Working Group established by the Commission to monitor and review product liability developments.

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Update on U.S. Product Liability Law

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Introduction

Federal preemption has been called "the fiercest battle in products liability law today". [See Endnote 1.] This year, the United States Supreme Court decided one of the most significant preemption cases of recent memory in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009). The *Wyeth* Court held that certain failure-to-warn claims before it were not preempted by federal law, but left open the door for preemption in future cases. In the wake of *Wyeth*, whether preemption applies to the circumstances of a given case is apt to be an intensively litigated issue.

Although no other recent decisions garnered the same attention as *Wyeth*, there have been several important developments in U.S. product liability law during the past year. They include key decisions on the admissibility of expert testimony on causation and issues relating to liability for allegedly defective warnings. Many of these developments arose in litigation involving prescription drugs. This is not surprising, as it is estimated that approximately one-third of all pending U.S. product liability cases are against prescription drug companies. [See Endnote 2.] However, important developments occurred outside of the prescription drug context as well.

This chapter provides an update on each of the following hot topics in product liability law:

- Preemption.
- Admissibility of Expert Testimony on Causation.
- Heeding Presumption/Proximate Cause in Failure-to-Warn Cases.
- Potential Liability of Non-Manufacturers for Failure-to-Warn.
- Removal of State Court Actions to Federal Court/CAFA.
- *Forum Non Conveniens*.
- Settlements.

Preemption

Federal preemption is based on the Supremacy Clause in the United States Constitution, which establishes that the U.S. Constitution, federal laws, and treaties are "the supreme Law of the Land". [See Endnote 3.] Where state law conflicts with federal law, state law "must yield". [See Endnote 4.] In deciding whether preemption is warranted, courts determine whether Congress intended to displace state law in enacting the federal law. [See Endnote 5.] Preemption may be expressed in an explicit provision of federal law or implied from the application of the federal regulatory regime. [See Endnote 6.]

Litigation involving FDA-approved pharmaceuticals and medical devices has become a flashpoint for preemption questions, in part because a broad system of FDA regulation exists alongside the states' tort regimes. Two U.S. Supreme Court cases addressing the preemptive scope of FDA regulation-*Riegel v. Medtronic*, 128 S. Ct. 999 (2008) (holding that certain state law tort claims were expressly preempted by the Medical Device Amendments to the FDCA), and *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008) (affirming judgment below by an equally divided court without reaching preemption of Michigan statute relating to fraud-on-the-FDA)-were discussed in last year's Update on U.S. Product Liability Law. [See Endnote 7.] *Riegel* and *Kent* set the stage for *Wyeth v. Levine*, the most closely watched and potentially far-reaching of the three recent preemption cases. 129 S. Ct. 1187 (2009).

In a 6-3 decision, *Wyeth* held that federal law did not impliedly preempt the specific state law tort claims at issue given the limited regulatory and litigation record. *Id.* at 1204. Plaintiff Diana Levine, a professional musician, developed gangrene, which required amputation of her right forearm after she was administered Wyeth's anti-nausea medication Phenergan using the "IV push" method. *Id.* at 1191-92. Phenergan "causes irreversible gangrene if it enters a patient's artery". *Id.* at 1191. Although Phenergan's labeling "warned of the danger of gangrene and amputation following inadvertent intra-arterial injection", Levine claimed that this warning was not strong enough, particularly given the emerging evidence of additional amputations caused by IV push. *Id.* at 1191-92.

Wyeth argued that Levine's state law tort claims were preempted on two grounds: (1) it would have been impossible for Wyeth to comply with its putative duty under Vermont law to modify Phenergan's labeling without violating federal law; and (2) Levine's state tort action created "an unacceptable 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress' because it substitutes a lay jury's decision about drug labeling for the expert judgment of the FDA". *Id.* at 1193-94 (citations omitted). The Supreme Court rejected both arguments based on the limited record before it. The Court concluded that compliance with both federal and state law was not "impossible" given the application of FDA's "changes being effected" (CBE) regulation to the case. *Id.* at 1196-97.

The Court underscored that Wyeth had "offered no . . . evidence" that FDA would have rejected stronger warnings, amended pursuant to the CBE regulation, about the dangers of using the IV push method. Id. at 1198. To the contrary, the record showed that "FDA had *not* made an affirmative decision to preserve the IV-push method", and had given no more than "'passing attention to the issue'" of how strong the warning should be. *Id.* at 1199 (emphasis

added). The record also contained data that the Court found both Wyeth and FDA could have analysed, but did not-including "at least 20 incidents prior to [plaintiff's] injury in which a Phenergan injection resulted in gangrene and an amputation". *Id.* at 1197. The Court therefore concluded that Wyeth had not presented "clear evidence" that FDA would not have approved a stronger warning about the risks of the IV-push method, nor had Wyeth shown that allowing Levine's claim would frustrate the achievement of Congress's and the Agency's goals. *Id.* at 1198, 1204.

Although the Supreme Court rejected Wyeth's preemption defence in the specific circumstances and on the limited record at issue, the Court did not categorically reject conflict preemption defences in future cases involving prescription drugs. Instead, the Court separately analysed the two types of implied conflict preemption-impossibility and frustration of congressional purpose-and found, after a detailed factual review, that neither applied in Levine's case. The Court acknowledged that in another case, with different facts, preemption may be warranted. *See, e.g., id.* at 1204. The standards after *Levine* are whether there is "clear evidence" that FDA "would not have approved" the "stronger warning" plaintiffs seek to impose, *id*. at 1198-99, or whether imposition of such a state law requirement would "frustrate the achievement of congressional objectives", *id*. at 1204. *Wyeth* suggests a number of ways in which such a showing may be made in future cases. In the wake of *Wyeth*, the lower federal courts will have to determine whether FDA's specific regulatory actions in a given case meet these standards.

Accordingly, although some plaintiffs' counsel have hailed *Wyeth* as a landmark decision upholding the role of state tort law in regulating prescription pharmaceuticals, preemption remains a potential defence for prescription drugs and other types of products. Indeed, several post-*Wyeth* decisions have held that state law was preempted. [See Endnote 8.] The Third Circuit may be the first of the federal courts of appeals to apply *Wyeth* in the prescription drug context. The Supreme Court recently issued an order granting certiorari, vacating, and remanding *Colacicco v. Apotex, Inc.*, 521 F.3d 253 (3d Cir. 2008)-which upheld preemption of certain failure to warn claims-for further consideration in light of *Wyeth*. See *Colacicco v. Apotex, Inc.*, No. 08-437, 2009 WL 578682 (Mar. 9, 2009). Under the Supreme Court's practice, such a "GVR" order is not a "final determination on the merits". *Tyler v. Cain*, 533 U.S. 656, 666 n.6 (2001) (rejecting reliance on such an order). Thus, on remand, the appeals court may reach the same preemption result as it did before *Wyeth*. *See, e.g., U.S. v. Levy*, 416 F.3d 1273, 1279-80 (11th Cir. 2005). It remains to be seen whether, as some have predicted, *Wyeth* will lead to "a flood of new lawsuits" against prescription drug manufacturers [see Endnote 9] and will have "significant implications beyond drug manufacturing". [See Endnote 10.]

In addition, *Wyeth* related solely to implied preemption, and has no direct bearing on express preemption. In fact, following the Supreme Court's express preemption decision in *Riegel*, there have been dismissals of several cases involving medical devices that underwent FDA's premarket approval process, and one judge dismissed an entire Multidistrict Litigation (MDL) [see Endnote 11] proceeding involving defibrillator leads based on *Riegel*. [See Endnote 12.] The courts may not, however, have the final word on express preemption. Some members of Congress have advocated legislation to supersede *Riegel*. [See Endnote 13.]

Admissibility of Expert Testimony on Causation

In most states, expert testimony is required in a product liability action for the plaintiff to satisfy his or her burden of proof on the issue of whether the product caused the alleged injury. Moreover, in pharmaceutical and toxic torts cases, a plaintiff generally is required to show by expert testimony both that exposure to a substance can cause a particular injury (general causation), and that such exposure was a cause of his or her individual injury (specific causation). [See Endnote 14.] The standards for admissibility of expert testimony were defined by the U.S. Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). *Daubert* directs federal district courts to serve as gatekeepers, ensuring that all proffered scientific expert testimony is "not only relevant, but reliable". *Id*. at 589.

A *Daubert* ruling excluding expert testimony on general or specific causation can substantially impact a product liability case. In the past year, federal courts have issued important rulings on the admissibility of expert testimony in each of these contexts.

General Causation. In the Human Tissue Products MDL, [see Endnote 15] plaintiffs who received human allografts processed from "stolen" human tissue alleged product liability claims against companies who processed the tissue, based on plaintiffs' alleged contraction of or fear of contracting infectious diseases from the allografts. *In re Human Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644, 651 (D.N.J. 2008). Certain defendant companies moved for exclusion of plaintiffs' proposed expert testimony on general causation, and requested summary judgment. The defendants argued that none of the alleged viruses could survive the allograft sterilisation process and storage at room temperature for a prolonged period of time. *Id*. at 652. Limiting the inquiry to whether tissue stored for thirty days or more could possibly transmit the relevant viruses, the court found that none of the plaintiffs' general causation experts was able to offer reliable scientific testimony on the matter. Specifically, the court found that no directly relevant studies existed, and that three of the proffered experts failed to explain how their conclusions could be reliably extrapolated from the in vitro, animal, or marginally related epidemiological studies upon which they relied. *Id*. at 667, 671, 676. The proposed testimony of the fourth general causation expert was excluded because it had "no basis in any specific medical literature and [wa]s merely based upon his belief". *Id*. at 679. The court therefore granted summary judgment in favour of defendants on all claims relating to the transmission of the relevant viruses through unprocessed tissue stored at room temperature for thirty days or more. *Id*. at 690-91.

Specific Causation. In two cases set for trial in the Seroquel MDL, [see Endnote 16] the court granted summary judgment to defendant AstraZeneca after excluding testimony from the plaintiffs' specific causation experts. In the first case, the plaintiff's expert opined that plaintiff's treatment with Seroquel was a "substantial factor" in her weight gain and diabetes. *Guinn v. AstraZeneca Pharms. LP*, No. 6:07-cv-10291-Orl-22DAB, 2009 WL 428917, at *6 (M.D. Fla. Jan. 30, 2009). The court held that the expert's testimony did not satisfy *Daubert's* reliability requirement. *Id*. at *3. The court concluded that the plaintiff's expert was "unable to identify any mechanism by which Seroquel causes weight gain and, further, could not articulate even an average amount of weight gain that could be attributed to Seroquel." *Id*. at *5. Moreover, the plaintiff's expert admitted that plaintiff had "numerous pre-existing health conditions" and that these conditions alone could have caused plaintiff to develop diabetes. *Id*. at *6.

In the second case, the plaintiff offered two witnesses to establish specific causation-an endocrinologist and a psychiatrist. *Haller v. AstraZeneca Pharms. LP*, No. 6:07-cv-15733-Orl-22DAB, 2009 WL 428915, at *3 (M.D. Fla. Feb. 6, 2009). The court concluded that the endocrinologist's testimony failed to meet the reliability and relevance prongs of *Daubert*, noting that there were "so many

Daubert problems associated with [his] opinions that it is difficult to know where to begin", *id*. at *18, and that "the underpinnings of his opinion . . . changed in direct response to AstraZeneca's motion practice." *Id*. at 20. Likewise, the psychiatrist's specific causation testimony was excluded because, as a psychiatrist, he was unqualified "to express a diabetes causation opinion". *Id*. at *24. Moreover, the court found that the psychiatrist's opinion suffered from "many of the relevance and reliability concerns" raised by the endocrinologist's testimony. *Id*.

As these recent cases demonstrate, defendants are well advised to explore flaws in expert opinions on general and specific causation, via depositions or testimony at *Daubert* hearings. A favourable *Daubert* ruling can lead to the dismissal of some, if not all, of plaintiffs' claims. In addition, as discussed further below, it can set the stage for settlement.

Heeding Presumption/ Proximate Cause in Failure-to-Warn Cases

As mentioned above, causation is a fundamental element for proving a product liability claim. In addition to proving medical causation in certain types of product liability litigation, the plaintiff also must prove that the alleged defect in the product was a proximate cause of the plaintiff's injury. Where the alleged defect is a failure to warn, the plaintiff typically must establish that had a different warning had been given, the injury would have been avoided. [See Endnote 17.]

Several state courts have held that, in order to meet this burden of proving proximate causation, plaintiff may rely upon a rebuttable presumption that had an "adequate" warning been given, the plaintiff would have heeded it. This is often referred to as a heeding or "read-and-heed" presumption. [See Endnote 18.] If a heeding presumption applies, the burden shifts to the defendant to prove that the plaintiff would not have heeded an adequate warning. [See Endnote 19.] Courts have found support for adopting the use of such a presumption in comment j to Section 402A of the Restatement (Second) of Torts (1965). [See Endnote 20.]

Case law on the heeding presumption continued to develop during the past year. In *Boyd v. Lincoln Electronic Co.*, 902 N.E.2d 1023 (Ohio Ct. App. 2008), a former boilermaker welder asserted product liability claims against manufacturers of welding rods, wire, and consumables. *Id*. at 1025. The court held that the plaintiff could rely on the heeding presumption to defeat summary judgment even though it was undisputed that the plaintiff did not read warnings that manufacturers began placing on welding-rod containers starting in 1967. *Id*. at 1025-26, 1032-34. The court concluded that the heeding presumption was not *per se* rebutted by evidence that the plaintiff did not read any warnings accompanying the product, because plaintiff presented evidence that he did not ever see the warnings due to their placement on the welding rod containers. *Id*. at 1032-34. Plaintiffs in other cases will likely use this rationale to try to argue around evidence that they did not read warnings that were provided.

Several courts also considered application of the heeding presumption in the prescription drug context. The proximate cause analysis differs in this context because most states have held that the "learned-intermediary doctrine" applies in prescription drug cases. Pursuant to this doctrine, the manufacturer's duty to warn runs to the prescribing physician, who acts as a learned intermediary for the patient. [See Endnote 21.] Therefore, to establish proximate causation in a prescription drug case, plaintiff must prove that the allegedly "inadequate" warning affected the physician's decision to prescribe the drug, thereby injuring plaintiff. [See Endnote 22.]

In the past, efforts to apply a heeding presumption in prescription drug cases have met with some success. [See Endnote 23.] Recently, however, several courts have rejected this argument in the context of antidepressant litigation.

In *Ackermann v. Wyeth Pharmaceuticals*, 526 F.3d 203, 212-14 (5th Cir. 2008), the prescribing physician submitted a declaration stating that he would have considered or heeded a different warning had one been provided, but that it would not have changed his decision to prescribe the antidepressant Effexor to the decedent or his treatment of the decedent. *Id.* at 210. The plaintiff argued that she could overcome this evidence by relying upon a "read-and-heed" presumption under Texas law. *Id*. at 212. The Fifth Circuit Court of Appeals rejected this argument. First, the court noted that comment j had been superseded by the Restatement (Third) of Torts: Product Liability § 2. Second, the court concluded that, pursuant to Texas law, plaintiff bore the burden of showing that the allegedly inadequate warning was a proximate cause of injury. Third, the court expressed doubt that Texas courts would apply a "read-and-heed" presumption in learned intermediary cases, because it would not serve the purpose of excusing the plaintiff from making self-serving assertions about whether he or she would have followed the warning, as it is the doctor -not the plaintiff- who testifies about whether a different warning would have changed the prescribing decision. For all of these reasons, the court held that the read-and-heed presumption does not apply to Texas cases involving learned intermediaries. *Id*. at 212-14.

Likewise, several other courts recently have held that a heeding presumption does not apply where the prescribing physician testifies that he or she would have taken the same course of treatment even if a different warning had been provided about antidepressants. [See Endnote 24.] These courts did not apply a bright-line rule that the heeding presumption cannot apply in prescription drug cases (as the *Ackermann* court did), but instead based their rulings upon the facts of the case at hand.

We anticipate that defendants will continue to argue against application of the heeding presumption in prescription drug cases, particularly where there is evidence from the treating physician that a different warning would not have led to a different prescribing decision. Whether such attempts will be successful depends upon the facts of the case and applicable state law.

Liability of Non-Manufacturer for Failure-to-Warn

Although negligence and strict liability failure-to-warn claims are among the most common product liability suits filed against pharmaceutical manufacturers today, plaintiffs generally cannot maintain such claims against name-brand prescription drug manufacturers where the plaintiff ingested only the generic form of the medication. This is because product liability laws require plaintiffs to show that the defendant manufactured the product in question. To circumvent this basic requirement, plaintiffs who consumed generic drugs often look to the theory of negligent misrepresentation to attempt to assign liability to name-brand manufacturers. While this theory has not had much traction in the past, [see Endnote 25] the recent ruling in *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (Cal. Ct. App. 2008), may have given negligent misrepresentation claims against name-brand manufacturers more bite. [See Endnote 26.]

Previously, there were two seminal cases on this issue: *Foster v. American Home Products Corporation*, 29 F.3d 165, 169, 171 (4th Cir. 1994) (applying Maryland law), and *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 522 (E.D. Penn. 2006). In both cases,

plaintiffs based their claims on a foreseeability argument that proceeded as follows: (1) federal laws require generic drugs to be biologically equivalent to the name-brand counterpart and require generic manufacturers to use the same labeling as previously approved for the name-brand drug; (2) pharmacists are authorised by statute to fill prescriptions for name-brand drugs with the generic equivalent, unless the prescribing physician expressly forbids a substitution; (3) therefore, it is foreseeable that either a prescription for a name-brand drug, written in reliance on the name-brand product information, would be filled with a generic, or that a prescription for the generic would be written in reliance on the name-brand labeling. [See Endnote 27.]

Although the courts in *Foster* and *Colacicco* stated their holdings differently, both focused on the fact that plaintiffs cannot circumvent product liability laws by using the theory of negligent misrepresentation. Because the basis of plaintiffs' claims was injury due to a product, the courts reasoned that plaintiffs must show that the defendant manufactured the product. The courts held that there was no foreseeability, and therefore no duty to warn, because the name-brand defendant did not manufacture the product.

While the plaintiff in *Conte* proceeded on essentially the same legal argument as the plaintiffs in *Foster* and *Colacicco*, the *Conte* court drew a line between product liability law and negligent misrepresentation law. The court reasoned that liability depends not on whether the defendant manufactured the product, but whether the defendant, in disseminating product warnings, should foresee that patients might take a generic version of a drug pursuant to a prescription written in reliance on the name-brand maker's information. [See Endnote 28.]

The *Conte* court based its foreseeability analysis on the general rule in California that "all persons have a duty to use ordinary care to prevent others from being injured as a result of their conduct". 168 Cal. App. 4th at 103. The court also looked to Sections 310 [see Endnote 29] and 311 [see Endnote 30] of the Restatement (Second) of Torts involving misrepresentation, as well as two non-product liability related negligent misrepresentation cases in which the courts also looked to foreseeability. [See Endnote 31.] Based on these rules and on the record, the court found "the conclusion inescapable that Wyeth knows or should know that a significant number of patients whose doctors rely on its product information for Reglan are likely to have generic metoclopramide prescribed or dispensed to them". *Id*. at 107. The court held that "Wyeth owes a duty of due care to those people it should reasonably foresee are likely to ingest metoclopramide in either the name-brand or generic version when it is prescribed by their physicians in reliance on Wyeth's representations". *Id*.

Although the *Conte* court opened a new avenue for liability against name-brand manufacturers, the court may have ventured out on a legal limb by itself. At least two subsequent cases addressing the issue have found brand-name manufacturers not liable under these facts. [See Endnote 32.] Indeed, the court in *Moretti v. Wyeth*, No. 2:08-CV-00396-JCMGWF, 2009 WL 749532 (D. Nev. Mar. 20, 2009) squarely rejected the *Conte* decision, noting that "every other court that has considered this issue has rejected" liability. [See Endnote 33.] Despite this, plaintiffs are likely to argue that the *Conte* court got it right and other courts should follow its lead in the future. Therefore, branded drug manufacturers may face an increasing number of claims by users of generic counterparts, particularly in California and other states that have not rejected the theory of liability recognised in *Conte*.

Removal of State Court Actions to Federal Court/CAFA

In the U.S. legal system, the plaintiff chooses whether to file a complaint in state or federal court. In certain instances, defendants can force plaintiffs to litigate their claims in federal court by filing a notice of removal. The notice of removal, in effect, removes jurisdiction over the action from the state court and places it in the federal court. In a product liability case, it can be beneficial for defendants to remove state court actions to federal court, particularly where a state court forum has a reputation for being "plaintiff-friendly" or where an MDL proceeding has been established in federal court to coordinate pretrial proceedings for all cases relating to a particular product so that defendants can avoid duplicating pretrial efforts in multiple courts.

Removal is governed by statute, 28 U.S.C. § 1441 *et seq.*, and requires a defendant to establish that a federal court would have had subject matter jurisdiction over the action if it had been originally filed in federal court. Generally, subject matter jurisdiction is conferred on federal courts where the action (a) raises an issue of federal law, or (b) there is diversity of citizenship among the parties. *See* 28 U.S.C. §§ 1331, 1332. In product liability cases, the most common basis for removal is diversity of citizenship among the parties, which requires the defendant to show (a) that the plaintiff (or plaintiffs) is a citizen of a different jurisdiction than each of the defendants, (b) that none of the defendants properly joined and served in the action is a citizen of the state in which the action was filed, and (c) that at least $75,000 is at stake for an individual action (referred to as "the amount in controversy"). *See* 28 U.S.C. §§ 1332, 1441. Inventive plaintiffs who prefer to litigate in state court have developed tactics to avoid the removal of their cases to federal court, *e.g.*, by naming a non-diverse defendant such as a doctor or local distributor.

In 2005, the U.S. Congress passed legislation that broadened the subject matter jurisdiction of federal courts in certain class and mass actions. The Class Action Fairness Act of 2005 (CAFA), Public Law 109-2, 119 Stat. 4 (2005), conferred jurisdiction on federal courts over class actions and mass actions with over 100 class members or plaintiffs where (a) any class member or plaintiff is diverse from any defendant, and (b) the aggregate amount in controversy exceeds $5 million.

Given the relative youth of CAFA, much of the law construing its provisions is unsettled. As in the context of a traditional removal, the plaintiffs' bar has begun to develop strategies to avoid removal based on the broadened jurisdiction conferred by CAFA. For example, instead of filing a lawsuit on behalf of several hundred plaintiffs, counsel have filed substantively identical lawsuits, each naming less than 100 plaintiffs, to avoid qualifying as a mass action. In *Tanoh v. Dow Chemical Co.*, No. 09-55138, 2009 WL 826404 (9th Cir. Mar. 27, 2009), plaintiffs filed seven lawsuits, with 99 named plaintiffs each, alleging identical claims seeking recovery for injuries purportedly resulting from exposure to the defendant's pesticide product. The defendant removed the seven cases, contending that the division of claims was an improper gaming of the system contrary to the intent of CAFA. The Ninth Circuit rejected this argument.

In addition to manipulating the number of plaintiffs named in a suit, plaintiffs have avoided removal under CAFA by expressly disclaiming recovery for amounts at or above the $5 million minimum amount in controversy. [See Endnote 34.] However, where several cases are consolidated (for example, because they assert identical or substantially similar facts and causes of action), each of which disclaims recovery of $5 million or more, courts have

concluded that the amounts in controversy must be aggregated. [See Endnote 35.] Thus, when a defendant is faced with multiple identical or substantially identical claims in which the CAFA jurisdictional minimum is not met, the defendant may decide to seek a consolidation of those claims and, if successful, remove the consolidated action.

Another strategy defendants may employ where a complaint disavows recovery for amounts at or above $5 million, or is silent as to the amount in controversy, is to contend that the allegations contained in the complaint place the jurisdictional minimum at issue. Defendants should beware, however, that a federal court's willingness to consider extrinsic evidence that the minimum amount in controversy is met depends on the jurisdiction. [See Endnote 36.]

Removal under CAFA is not a guarantee that the case will remain in federal court throughout the proceedings. Some courts have concluded that an action properly removed under CAFA may cease to be properly in federal court at some point during the proceedings. In *Muehlbauer v. General Motors Corp.*, No. 05 C 2676, 2009 WL 874511 (N.D. Ill. Mar. 31, 2009), for example, the defendant properly removed a class action alleging a class in excess of 100 members and an aggregate amount in controversy of over $5 million. For each individual class member, however, the amount in controversy was "far below" $75,000. When certification of the class action was denied, the court concluded that subject matter jurisdiction based on CAFA was no longer proper, and held that it did not have diversity jurisdiction because the aggregate amount in controversy of the plaintiffs' individual claims did not exceed the jurisdictional minimum of $75,000. In contrast, other courts have found that where a federal court has subject matter jurisdiction over a class action under CAFA at the outset of the case, such jurisdiction does not abate simply because the federal court denies certification of the class. *See, e.g., Garcia v. Boyar & Miller, P.C.*, 2007 WL 1556961 (N.D. Tex. May 30, 2007).

As consensus has not yet developed on these and other issues, defendants must ensure that they have a clear understanding of the current state of the law regarding CAFA in the jurisdictions in which they are defending against class action or mass action claims.

Forum Non Conveniens

Non-U.S. plaintiffs often file product liability claims in U.S. courts, seeking to benefit from certain procedural mechanisms and substantive law that are unavailable in their home countries. The advantages that encourage non-U.S. plaintiffs to seek redress in U.S. courts include substantial pretrial discovery, perceived generous damages awards (including punitive damages), and jury trials. With the high stakes and expenses associated with mass tort litigation, the U.S. system may also be appealing because of the availability of contingency fee arrangements and the absence of awarding attorneys' fees to the prevailing party automatically.

Defendants may move to dismiss non-U.S. plaintiffs' claims on grounds of *forum non conveniens*. A court may dismiss a case based on *forum non conveniens* where the defendant successfully establishes that: (1) an alternative forum is available and adequate; and (2) the balance of factors related to the parties' private interests and the public interest weighs in favour of adjudication elsewhere. Among the private and public interests a court will often consider are access to witnesses and documents, the ability of the defendant to implead necessary third parties, the interest of a plaintiff's home country in resolving the dispute, and the burden placed on the U.S. court system if the case is not dismissed. [See Endnote 37.]

In the past year, U.S. courts have issued decisions that highlight challenges non-U.S. plaintiffs may encounter when facing motions to dismiss on *forum non conveniens* grounds. One Florida appellate court dismissed a case on *forum non conveniens* grounds where the purportedly available and adequate forum had declined to exercise jurisdiction over the case. *See Scotts Co. v. Hacienda Loma Linda*, 2 So. 3d 1013 (Fla. Dist. Ct. App. 2008). In that case, the defendant moved to dismiss a Panamanian corporation's claims based on *forum non conveniens*. The lower court denied the motion, but the appellate court reversed and required the parties to stipulate that the court would retain jurisdiction if the Panamanian court would not entertain the case based on preemption (or preventive jurisdiction). [See Endnote 38.] Id. at 1014-15. After the reversal, and while the Panamanian corporation sought rehearing and discretionary review in the Florida Supreme Court, Panama enacted a law that would block transfers based on *forum non conveniens*. [See Endnote 39.] *Id*. at 1015. The Panamanian corporation filed its complaint in the Panamanian trial court, including with it "allegations and exhibits sufficient to invite dismissal based on preemption and the blocking statute . . . ." *Id*. at 1016. The Panamanian court did precisely that. *Id*. at 1015-16. The case was subsequently reinstated in the Florida state court, and the defendant appealed such reinstatement. The Florida appellate court reversed the order of reinstatement. *Id*. at 1017-18. Central to its decision was the recognition that a non-U.S. plaintiff whose claims have been dismissed by a U.S. court cannot take steps to render the alternative forum unavailable either by "itself inducing the foreign court to dismiss the foreign action or . . . relying on foreign laws or decisions plainly calculated to preclude dismissal . . . ." *Id.* at 1017-18. Thus, the Florida appellate court concluded that where a court finds an alternative forum available and adequate, the plaintiff must submit to that forum and support that court's exercise of jurisdiction.

Practical considerations may carry significant weight in a court's ultimate *forum non conveniens* analysis. For example, in the Factor VIII or IX Concentrate Blood Products MDL, defendants moved to dismiss the claims of Taiwanese citizens based on *forum non conveniens*. *See In re Factor VIII or IX Concentrate Blood Prods. Liab. Litig.*, 595 F. Supp. 2d 855 (N.D. Ill. 2009). After considering expert testimony from both sides, and determining that Taiwan was an available forum, that Taiwan and California (where the complaints were filed) were on par as to adequacy (or inadequacy), and that on balance, factors favoured dismissal, it ultimately was a practical consideration on which the court's decision hinged. See *id.* at 860, 866, 874. Anticipating that defendants would move to dismiss the case in Taiwan on the basis that the statute of limitations barred the plaintiffs' claims if the district court granted the motion to dismiss, the district court concluded that dismissal would impose unnecessary expense on the plaintiffs where California courts would apply the same limitations law as would the Taiwanese court. *Id*. at 874. Thus, the district court denied defendants' motion to dismiss on *forum non conveniens* grounds.

Timeliness of a defendant's motion to dismiss based on *forum non conveniens* may be another factor that the court considers. In the Vioxx MDL, the court granted a motion to dismiss claims of various non-U.S. plaintiffs based on *forum non conveniens*. *In re Vioxx Prods. Liab. Litig.*, No. 2:05-MD-01657-EEF-DEK (E.D. La. Feb. 10, 2009). [See Endnote 40.] In so doing, the court rejected the plaintiffs' argument that Merck's motion should be dismissed as untimely. [See Endnote 41.] *Id*. at 22. The court noted that there is no precise time period within which a defendant must file a motion for dismissal under the doctrine of *forum non conveniens*. *Id*. at 20. Given the complexity of the Vioxx MDL, the court determined that Merck had filed its motion within a reasonable time. *Id.* at 20-22. The court also rejected a request by U.K. plaintiffs that Merck be required to agree that: (1) the parties would

have a trial by jury in the U.K.; (2) the parties could obtain evidence pursuant to the Federal Rules of Civil Procedure; (3) the parties would be permitted to present testimony at trial in the form of oral, video, and written depositions; and (4) that Merck would identify, produce and authenticate all documents it had produced, authenticated, listed, or offered as exhibits in previous U.S. trials. *Id*. at 23. The court indicated that the U.K. plaintiffs were seeking to circumvent the rules and procedures adopted by the U.K. which reflected its policy judgments. *Id.* at 24. The Vioxx court refused to undermine those judgments and impose conditions on a foreign court. *Id*. at 22-24.

The increasingly transnational nature of litigation will undoubtedly be accompanied by growing efforts of non-U.S. plaintiffs to access U.S. courts and benefit from particular features of the U.S. judicial system. Although *forum non conveniens* motions are often granted, counsel should carefully consider practical considerations, appropriate timing of such motions, and supporting experts and evidence. Defence counsel also should be prepared to counter new attempts to circumvent *forum non conveniens* rulings, such as occurred in *Scotts Co.* and the Vioxx MDL.

Settlements

U.S. product liability proceedings can involve hundreds or even thousands of plaintiffs, creating the risk of large defence costs and substantial potential liability for manufacturers. Manufacturers tackle these risks in different ways. Some take the initial position that they will defend every case, one trial at a time; others choose to settle product liability claims early in the litigation.

Yet, trying every case is not workable as a long-term solution for manufacturers if the proceedings involve hundreds or thousands of plaintiffs. Litigating claims can result in spiraling defence costs and liability awards, which creates uncertainty for the company. As a result, it is not surprising that some defendants decided to pursue settlement last year before a single case was tried in the relevant MDL and state court proceedings.

For example, in the ReNu Contact Lens Solution MDL, Bausch & Lomb began settling claims that its ReNu with MoistureLoc contact lens solution caused infection due to *Fusarium* keratitis before any such cases were tried, but has not been settling any claims of bacterial infection. [See Endnote 42.] Early settlement of *Fusarium* claims likely was driven by the fact that the product had been withdrawn from the market, [see Endnote 43] so the universe of claimants was limited and the running of the statute of limitations defined. In addition, there was evidence that the alleged *Fusarium* infections were caused by the product at issue based on available scientific and epidemiological data, which indicated that ReNu with MoistureLoc contact lens solution was associated with an increased relative risk of *Fusarium*. [See Endnote 44.] On the other hand, settlement of bacterial infections claims could encourage additional filings, as any contact lens user has an increased risk of bacterial infection. Therefore, these claims have not been subject to early settlement.

A significant court ruling also can pave the way for an early settlement before any cases are tried. For instance, last year Pfizer set aside $894 million to settle lawsuits relating to its Cox-2 inhibitors, Bextra and Celebrex. [See Endnote 45.] The settlement followed rulings by the MDL court and New York state court excluding expert testimony that a 200 mg dose of Celebrex could increase the risk of heart attack and stroke. [See Endnote 46.] As 200 mg was the most widely used dosage of Celebrex, this ruling had a significant impact on limiting Pfizer's potential liability, and was one factor leading to the settlement of the majority of Celebrex and Bextra lawsuits before any such cases were tried.

Merck took a different approach in the Vioxx litigation, in which it tried 20 cases before reaching a $4.85 billion settlement with plaintiffs in 2007. [See Endnote 47.] During the past year, the Vioxx settlement continued to progress. Of interest, insurers who paid medical expenses for claimants in the Vioxx settlement had placed liens on the claimants' settlement in an effort to recover their expenses, which is a typical occurrence in the U.S. However, 100 private health insurers agreed to the "Private Lien Resolution Program" that automatically reduces all injury-related liens by 50 percent and places caps on the liens. [See Endnote 48.] This agreement is reported to be the first of its kind in a mass litigation settlement. [See Endnote 49.] Settling parties will likely try to reach similar agreements with lien holders in the future.

Conclusion

2009 likely will be remembered for the *Wyeth* decision, but there were several additional important legal developments that occurred. We expect that, in the next year, product liability litigation will continue to give rise to ground-breaking decisions and evolving legal theories.

Endnotes

1. Adam Liptak, *Drug Label, Maimed Patient and Crucial Test for Justices*, N.Y. TIMES, Sept. 19, 2008 (quoting Catherine M. Sharkey, law professor at New York University), available at http://www.nytimes.com/2008/09/19/us/19scotus.html?n=Top/Reference/Times%20Topics/Subjects/ L/Liability%20For%20Products.
2. Jerry Markon, *High Court Case Looms Large for Drugmakers*, N.Y. TIMES, Nov. 4, 2008, available at http://www.washingtonpost.com/wp-dyn/content/article/2008/11/03/AR2008110300192.html
3. U.S. CONST. art. IV, cl. 2.
4. *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824).
5. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) ("[The] purpose of Congress is the ultimate touchstone of pre-emption analysis.").
6. See, e.g., *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).
7. See S. Gourley & S. Knutson, *Update on U.S. Product Liability Law*, THE INTERNATIONAL COMPARATIVE LEGAL GUIDE TO: PRODUCT LIABILITY 2008, at 23.
8. *Compare, e.g., Bruesewitz v. Wyeth*, No. 07-3794, 2009 WL 792468, at *7 (3d Cir. Mar. 27, 2009) (holding design and warning claims in case involving DTP vaccine expressly preempted by the Vaccine Act), and *Longs v. Wyeth*, No. 1:03-cv-2042, 2009 WL 754524, at *4 (N.D. Ohio Mar. 20, 2009) (holding that plaintiff's pre-FDA approval claims were preempted and distinguishing *Wyeth* on the basis that it focused on the manufacturer's post-approval duty to update warning labels), *with Schrock v. Wyeth Inc.*, No. CIV-08-453-M, 2009 WL 635415, at *3 (W.D. Okla. Mar. 11, 2009) (holding no preemption of warning claims in case involving generic Reglan).
9. See Barry Meier & Natasha Singer, *Drug Ruling Puts Devices in Spotlight*, N.Y. TIMES, Mar. 5, 2009, available at http://www.nytimes.com/2009/03/05/business/05device.html?partner=rss.
10. Adam Liptak, *No Legal Shield in Drug Labeling*, N.Y. TIMES, Mar. 5, 2009, available at http://www.nytimes.com/2009/03/05/washington/05scotus.html.

11. Multidistrict litigation (MDL) is a procedure used to transfer to one federal judge all pending federal civil cases of a similar type filed throughout the United States for purposes of pretrial coordination. See *http://www.jpml.uscourts.gov/* for additional information.

12. *See, e.g., Bausch v. Stryker Corp.*, No. 08 C 4248, 2008 WL 5157940 (N.D. Ill. Dec. 9, 2008) (dismissing strict liability and negligence claims); *Link v. Zimmer Holdings, Inc.*, No. 06 C 5438, 2008 WL 5047677 (N.D. Ill. Nov. 26, 2008) (dismissing strict liability, negligence, and breach of warranty claims); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298 (D. Colo. 2008) (dismissing failure to warn, defective design, negligence, and breach of warranties claims); see also *In re: Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147 (D. Minn. 2009) (dismissing entire MDL).

13. See Barry Meier & Natasha Singer, *Drug Ruling Puts Devices in Spotlight*, N.Y. TIMES, Mar. 5, 2009 (noting that "influential members of Congress plan to introduce a bill soon that would supersede last year's Supreme Court device ruling [i.e., *Riegel*]"), available at http://www.nytimes.com/2009/03/05/business/05device.html?partner=rss.

14. *See, e.g., McClain v. Metabolife*, 401 F.3d 1233, 1237 (11th Cir. 2005).

15. The Human Tissue MDL arose from a criminal enterprise by Biomedical Tissue Services, Ltd. (BTS), and its principle to harvest tissue from human corpses without obtaining proper consents or following appropriate regulations. Defendants include the principles in the criminal operation, the funeral homes who allowed BTS access to the corpses, the companies who processed tissue recovered by BTS, the distributors of the processed tissue products, and the hospitals and medical personnel who transplanted the processed tissue product.

16. Seroquel is an atypical antipsychotic medication indicated for treatment of certain bipolar disorders and schizophrenia. Product liability cases involving Seroquel are coordinated in MDL 1769 before the U.S. District Court, Middle District of Florida. The majority of plaintiffs claim that Seroquel caused them to develop diabetes and/or diabetes-related ailments.

17. *See, e.g., Coffman v. Keene Corp.*, 628 A.2d 710, 716-21 (N.J. 1993); *Reyes v. Wyeth Labs*., 498 F.2d 1264, 1281 (5th Cir. 1974), cert denied, 419 U.S. 1096 (1974).

18. *See, e.g., Coffman*, 628 A.2d at 719-20 (collecting cases in which courts adopted a heeding presumption in failure-to-warn cases).

19. *See, e.g., Reyes*, 498 F.2d at 1281.

20. *See, e.g., Coffman*, 628 A.2d at 716-20. Comment j provides, in relevant part: "Where [a] warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous."

21. *See, e.g., Ackermann v. Wyeth Pharms*., 526 F.3d 203, 207-08 (5th Cir. 2008).

22. *See, e.g., id.* at 208-09; *see also Ebel v. Eli Lilly & Co.*, No. 08-40170, 2009 WL 837325, at *6 (5th Cir., March 30, 2009) (applying Texas law).

23. *See, e.g., Giles v. Wyeth, Inc.*, 500 F. Supp. 2d 1063, 1065-66 (S.D. Ill. 2007) ("Some states apply a heeding presumption in learned intermediary cases. In these states, a court presumes that warnings, if given, will be heeded and followed and that medical practitioners will act competently") (internal quotations omitted).

24. *See Porter v. Eli Lilly & Co.*, 291 Fed. Appx. 963 (11th Cir. 2008) (applying Georgia law to grant summary judgment to defendant where the prescribing physician testified that even if he had read the warning proposed by the plaintiff, he would have still prescribed Prozac to the plaintiff); *Dietz v. SmithKline Beecham Corp.*, No. 4:07-CV-6077-RLV, 2008 WL 5329295 (N.D. Ga. Dec. 9, 2008) (applying Georgia law and relying on Porter, the court granted summary judgment to defendant where the prescribing physician testified that he stood by his decision to prescribe Paxil to the plaintiff and would do so at present despite a new warning for Paxil) But *see Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174, 1182, 1196-99 (D.N.M. 2008) (denying summary judgment to defendant on issue of proximate cause even though prescriber testified he was "confident" that he would have prescribed Prozac to the plaintiff in 2003 even if it had a boxed warning that was later added in 2007).

25. *See Schrock*, 2009 WL 635415, at *5 ("[T]wenty four courts in fourteen different states have rejected the assertion that defendants have a duty to warn about products they did not manufacture."); *Moretti v. Wyeth*, No. 2:08-CV-00396-JCMGWF, 2009 WL 749532, at *4 n.1 (D. Nev. Mar. 20, 2009) (collecting cases that have rejected manufacturer liability in this context).

26. *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (Cal. Ct. App. 2009).

27. *See also id.* at 105.

28. *Id.* at 103.

29. Section 310 provides that an actor who makes a misrepresentation is subject to liability if the actor "intends his statement to induce or should realize that it is likely to induce by action the other."

30. Section 311 provides that one who negligently gives false information to another is liable for harm caused by action taken by the other in reasonable reliance on the information where such harm results "to such third persons as the actor should expect to put in peril by the action taken."

31. *Conte*, 168 Cal. App. 4th at 103-04 (citing *Garcia v. Superior Court*, 789 P.2d 960 (Cal. 1990) (holding that parole officer had a duty of care where parolee kidnapped and shot victim after parole officer told parolee's victim that parolee would "not come looking for her" after his release); *Randi W. v. Muroc Joint Unified School Dist.*, 929 P.2d 582 (Cal. 1997) (School district held liable for misrepresentations about a former employee where employee molested a student in his new employment)).

32. *Schrock*, 2009 WL 635415, at *5; *Moretti*, 2009 WL 749532.

33. *Moretti*, 2009 WL 749532, at *4.

34. *See, e.g., Morgan v. Gay*, 471 F.3d 469 (3d Cir. 2006), cert. denied, 128 S. Ct. 66 (2007) (affirming the remand of a putative class action where plaintiff expressly disclaimed recovery of $5 million or more).

35. *See, e.g., Freeman v. Blue Ridge Paper Prods., Inc.*, 551 F.3d 405 (6th Cir. 2008) (holding that the requested damages of five consolidated actions, each disclaiming damages above $4.9 million, may be aggregated to $24.5 million making removal of the consolidated action proper under CAFA).

36. *Compare Lewis v. Ford Motor Co.*, No. 2:09-cv-00164-WLS, 2009 WL 840233 (W.D. Pa. Mar. 26, 2009) (considering affidavit submitted by defendant and other extrinsic evidence in concluding that more than $5 million was at stake even though the complaint was silent on the amount in controversy), *with Lowery v. Alabama Power Co.*, 483 F.3d 1184 (11th Cir. 2007), *cert. denied*, 128 S. Ct. 2877 (2008), and *Innovative Health & Wellness LLC v. State Farm Mut. Auto. Ins. Co.*, No. 08-60786, 2008 WL 3471597 (S.D. Fla. Aug. 11, 2008) (relying on *Lowery*). *Lowery* was discussed in detail in S. Gourley & S. Knutson, *supra* note 7, at 24-25.

37. *See Gulf Oil Corp. v. Gilbert*, 330 U.S. 501, 508-09 (1947), superseded by statute on other grounds, 28 U.S.C. § 1404.
38. The appellate court described preemption or preventive jurisdiction as "a judicial or legislative basis in Country A for refusing jurisdiction over a case initially filed by a citizen of Country A in Country B." *Scotts Co.*, 2 So. 3d at 1015 & n.2.
39. The Panamanian blocking statute was repealed in early 2008. *See id.* at 1015. It was then reinstated with slightly modified language. *See Paulownia Plantations de Panama Corp. v. Rajamannan*, 757 N.W.2d 903, 908 (Minn. Ct. App. 2008), review granted (Feb. 17, 2009).
40. Available at http://vioxx.laed.uscourts.gov/Orders/O&R021009.pdf.
41. The cases had been filed in 2006 or 2007, and Merck had filed its motion seeking dismissal of such cases based on *forum non conveniens* on May 16, 2008.
42. Transcript of Proceedings, *In re Bausch & Lomb Contact Lens Solution Products Liab. Litig.*, MDL No. 1785, C/A No. 2:06-77777-DCN and *In re: New York ReNu with MoistureLoc Product Liab. Litig.*, Index No. 766,000/07, Sept. 9, 2008, at p. 10-12, available at http://www.renumdllitigation.com/docs/09.09.2008%20-%20Transcript%20-%20NY%20Hearing.pdf
43. FDA Statement, Bausch & Lomb Global Recall of ReNu with MoistureLoc Contact Lens Cleaning Solution, May 15, 2006, http://www.fda.gov/bbs/topics/news/2006/new01371.html
44. *Id*.
45. Stephanie Saul, Pfizer to Settle Claims Over Bextra and Celebrex, N.Y. TIMES, Oct. 18, 2008, available at http://www.nytimes.com/2008/10/18/business/18drug.html.
46. *In re Bextra and Celebrex Marketing Sales Practices and Prod. Liab. Litig.*, 524 F. Supp. 2d 1166 (N.D. Cal. 2007), as discussed in S. Gourley & S. Knutson, *supra* note 7.
47. *See* S. Gourley & S. Knutson, *supra* note 7, at 26-27.
48. *See* http://vioxx.laed.uscourts.gov/ (description of Jan. 30, 2009 court conference); see also http://www.vioxxlienresolution.com/
49. *Vioxx Settlement Liens Limited by Unusual Agreement*, Jan. 25, 2009, available at http://www.wiredprnews.com/2009/01/25/vioxx-settlement-liens-limited-by-unusual-agreement_200901252100.html

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REACH and the Consumer Products Sector - Regulatory and Product Liability Implications of the EU's Chemicals Regime

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Introduction

Nearly two years ago, REACH - the European Union (***EU***)'s comprehensive new regulation on chemicals - came into force across the 27 Member States, after nearly a decade of wrangling, horse-trading and intense lobbying.

REACH is a dramatic overhaul of the EU's regulation of chemical substances and of their use in downstream products. The underlying premise of REACH is that Europe's previous chemical safety regime was not fit for purpose. Of the 100,000 or so substances currently sold in the EU, the vast majority never had to be tested under previous EU legislation. Little formal data on possible human health or environmental impacts was available to national regulators, on whom the burden for testing fell. REACH is intended to fill this information gap by requiring industry to provide the European Chemicals Agency (***ECHA***) with data on the safety and properties of tens of thousands of substances (see inset box: "REACH in a nutshell").

Although its primary impact will be on the chemicals industry, REACH also poses significant challenges for downstream users of chemicals, including manufacturers and importers of consumer products. In particular, the potential product liability implications of the new regime for some such companies should not be underestimated. REACH is, after all, intended to generate new data on chemical hazards: the European Commission (the ***Commission***) has stated that "*it is expected that REACH will generate new data which will help identify another 600 substances of very high concern over the next 11 years*" [see Endnote 1]. The branding of another 600 substances as hazardous that have not been previously classified as such may well, in turn, fuel litigation on both sides of the Atlantic.

In this briefing, we map how REACH may affect EU and international consumer products companies, focusing in particular on their regulatory obligations under REACH and its potential to increase their exposure to product liability and occupational health litigation.

REACH in a nutshell

The REACH Regulation (1907/2006/EC) was adopted on 18 December 2006. It applies to most chemical substances, whether on their own, in preparations (mixtures) or used in products (or "articles"), that are manufactured or used in, or imported into, the EU in quantities of over one tonne per year. Its principal elements are as follows.

Legal entities

All obligations under REACH fall on EU legal entities, as defined under the national law of the EU Member State in which they are active. This means that:

- Companies based outside the EU do not have direct legal obligations under REACH (although the legal entities in the EU that import their products - such as distributors or first tier customers - may well do).
- Where a company in Member State A has a branch office in Member State B, and that branch office manufactures or imports a substance, registration and other obligations under REACH in respect of that substance may well lie with the company in Member State A rather than the branch office. This will, however, depend on whether the national law of Member State B recognises branch offices as having separate legal identity or not.
- Different legal entities in the same corporate group may each have their own, independent obligations under REACH. Although they can informally agree between themselves that one group company will take the lead in ensuring REACH compliance, they cannot legally "contract out" of these obligations.

Registration and pre-registration - "no data, no market"

The central requirements of REACH are that:

- Substances, on their own or in preparations, may not be manufactured in the EU, or imported into the EU, in quantities of over one tonne per year unless they have been registered. This is the principle of "no data, no market" set out in Article 5 of the REACH regulation.
- Substances contained in articles that are manufactured in, or imported into, the EU must also be registered if relevant tonnage thresholds are met and they are intended to be released from the article under normal or reasonably foreseeable conditions of use, as discussed later in this briefing.

Registration requires any legal entity that manufactures a substance in the EU or imports it into the EU to obtain information on the properties of that substance, to assess the risks arising from its use and to establish how those risks can adequately be controlled, before documenting this process in a registration dossier supplied to the ECHA (see below).

The timetable for registering most substances that are currently sold and used in Europe is staggered over an 11-year period according to perceived risk and tonnage:

- Such substances placed on the market in quantities greater than 1,000 tonnes must be registered by 1 December 2010. This deadline also applies to substances which ECHA has determined to be particularly "high risk".
- Such substances placed on the market in quantities of between 100 and 1,000 tonnes must be registered by 1 June 2013.

- Such substances placed on the market in quantities of between 1 and 100 tonnes must be registered by 1 June 2018.

However, in order to qualify for these deadlines, potential registrants of phase-in substances had to provide basic "pre-registration" information to ECHA by 1 December 2008. Pre-registration was required by any legal entity that has REACH registration obligations in respect of most existing substances. This could include manufacturers and importers of articles (where a substance present in the article is intended to be released), as well as of substances on their own or in preparations.

Those that failed to pre-register by 1 December 2008 cannot now legally manufacture or import the relevant substance until they submit a full registration to ECHA. There is evidence that many companies made precautionary pre-registrations with this risk in mind.

All manufacturers/importers who have pre-registered the same substance will automatically form a Substance Information Exchange Forum (***SIEF***), whose aim is to share data over its period of operation. Much of the information that ultimately forms part of the registration dossier for a given substance will come from other SIEF members.

What information is required in the registration dossier?

The registration dossier must include a technical dossier and, for substances manufactured or imported in quantities of ten tonnes or more per year, a chemical safety report (***CSR***) that records and summarises a chemical safety assessment (***CSA***). The CSR records the hazard classification of a substance and the assessment as to whether the substance is persistent, bioaccumulative, and toxic (***PBT***), or very persistent and very bioaccumulative (***vPvB***). The higher the tonnage, the more information on the intrinsic properties of the substance is required.

The CSR also sets out exposure scenarios for the substance in question. Exposure scenarios are sets of conditions that describe how substances should be manufactured or used during their life-cycle. This includes how the manufacturer or importer controls, or recommends control of, exposures of humans and the environment to the substance. The exposure scenarios must include appropriate risk management measures that, when properly implemented, ensure the risks from the uses of the substance are adequately controlled. Exposure scenarios need to be developed to cover all "identified uses".

"Identified uses" are the manufacturers' or importers' own uses, as well as uses that are made known to them by their downstream users. Relevant exposure scenarios will need to be annexed to the SDS that will be supplied to downstream users and distributors. Where a customer does not want to make its use of a substance or preparation known to the supplier, e.g. for reasons of commercial confidentiality, it may have to assume the burden of preparing its own CSR for the use in question.

REACH encourages the submission of existing information wherever possible. New tests are only required when it is not possible to provide the information in any other permitted way and testing proposals may have to be pre-approved by ECHA. The aim is to reduce the amount of testing on animals and avoid unnecessary costs.

Evaluation

The Agency will evaluate a small proportion of the registration dossiers received. It will also evaluate testing proposals made by potential registrants.

Authorisation

Substances classified by the EU authorities as being of very high concern (***SVHC***) and placed on Annex XIV of REACH will be subject to authorisation under REACH. SVHC include PBT and vPvB substances, as well as category 1 and 2 CMR (Carcinogenic, Mutagenic or Reprotoxic) substances. There is no minimum tonnage threshold for authorisation.

At present, ECHA has published a "candidate list" of SVHC listing 18 potential SVHC, and this will be populated further over time. Although the publication of the candidate list has triggered certain obligations for businesses (see below), not all the substances on it will necessarily be placed on Annex XIV and therefore be subject to authorisation. Member State authorities are currently evaluating the substances on the candidate list to determine which of these substances should be placed on Annex XIV, which identified uses of such substances should require authorisation and, for each, what the "sunset date" should be, after which authorisation will be required before use.

Once this system is fully operational, SVHC that appear on Annex XIV will have to receive pre-marketing authorisation before they can be placed on the market on their own, in preparations or in articles. The burden is on the EU manufacturer or EU importer of any such substance to convince ECHA, and ultimately the Commission, that such a substance should receive authorisation. In the case of CMRs, an authorisation will be granted if the applicant can demonstrate that the risk from the use of the substance is adequately controlled. For PBTs and vPvBs, and CMRs where the applicant is unable to meet the "adequate control" test, an authorisation may be granted if the applicant can show that the socio-economic benefits of continued manufacture/use outweigh the risks and that there are no suitable alternatives available.

Restriction

This procedure replaces the current regime for banning or restricting the use of the most hazardous chemicals. REACH prohibits the manufacture, placing on the market or use of an exhaustive list of such substances that will be enumerated in its Annex XVII (which will doubtless be amended over time).

Enforcement

REACH's legal form - a regulation - means that it took effect across the EU on 1 June 2007 without the need for its provisions to be implemented into the law of the Member States (as would be the case with a directive).

Exemptions

Certain substances will fall outside REACH (e.g. radioactive substances) or its registration requirements (e.g. substances used as food additives) or will be deemed to have been registered (e.g. active substances and co-formulants authorised for use in plant protection products). Registration is also not required for substances manufactured or imported at under one tonne/year.

What Regulatory Obligations Will REACH Impose on Consumer Products Companies?

The direct regulatory impact of REACH on consumer products companies and other downstream users of chemicals will vary widely, depending upon the capacity in which any given corporate entity acts in relation to any given substance or preparation.

EU-based manufacturers and importers of substances and preparations

Relatively few consumer products companies manufacture

substances, so most will not need to register on this basis. However, any EU legal entity that imports substances into the EU - on their own or in preparations (mixtures) - will face registration obligations under Article 6 of REACH. Given that common paints, solvents, inks and adhesives will generally be treated as preparations under REACH, these obligations may apply to a variety of consumer products businesses.

"Import" has been expressed by the Commission to mean the physical introduction of a substance, preparation or article into the customs territory of the Community, so a company on the French side of the Franco-Swiss border buying cleaning fluid directly from a company in Geneva would be that preparation's importer. Such businesses will have to think carefully about their supply arrangements if they are to avoid being fixed with potentially burdensome registration obligations under REACH. There is also the possibility that the volume of substances imported into the EEA and EFTA will have to be counted when determining tonnage, for the purposes of registration, authorisation etc.

EU-based manufacturers and importers of articles (products) containing chemicals

EU legal entities that manufacture or import articles containing chemical substances will not have registration obligations, unless the conditions set out in Article 7 of REACH are met:

- The substance in question is intended to be released during normal and foreseeable conditions of use.
- The total amount of the substance present in the articles exceeds 1 tonne per annum per legal entity.
- The substance has not yet been registered for that use.

In May 2008, ECHA published guidance on the registration of substances in articles. However, six EU Member States lodged formal objections to certain of this document's interpretations of the law, and it has also been criticised as being hard to apply in practice. ECHA is now reviewing the document, and this process is expected to be complete by Autumn 2009.

Given the complexity of the applicable provisions and the lack of clarity offered by the guidance in some key areas, it is small wonder that determining the existence and extent of consumer products companies' obligations may involve some difficult judgment calls for the companies concerned. Key areas of difficulty include:

- Should a particular consumer product be classified as a substance, a preparation, an article or as a "special container" for a substance or preparation (this being a new concept described in the ECHA guidance, but not set out in the REACH regulation itself)? As noted, substances and preparations will usually need to be registered, including where they are present in a "special container", but substances in an article will only need to be registered if there is an intentional release.
- At what stage of processing does a raw material (e.g. wool) become an article (e.g. a textile)? REACH defines an article as any object that, during production, is given a special shape, surface or design that determines its function to a greater degree than does its chemical composition.
- In what circumstances is a substance "intended to be released" from an article? For example, a manufacturer's intention may be different from that of a consumer who misuses a product.

EU-based manufacturers and importers of articles (products) that contain substances on the candidate list for authorisation

Article 33 of REACH requires that EU and EEA suppliers of articles which contain substances on the candidate list for authorisation in a concentration above 0.1 per cent (w/w) to:

- provide safe use information (including, as a minimum, the name of the relevant SVHC) to anyone who receives the article, which might include consumers; and
- identify the substance in question and provide safe use information to any consumer who requests it, free of charge and within 45 days of the request being made.

Since the candidate list has now been published, these obligations are now in force.

From 2011, EU and EEA manufacturers and importers of articles containing substances on the candidate list must in addition make a "notification" to ECHA where all the following conditions are met:

- The SVHC is present in the article in a concentration above 0.1 per cent (w/w).

  Our experience of advising clients in relation to compliance with the RoHS Directive and the penta/octa ban (see inset box: "The greening of EU product policy") suggests that this may not be simple to evaluate.
- The total amount in the range of articles produced/imported exceeds 1 tonne per annum per legal entity.
- The manufacturer or importer cannot exclude exposure to humans or the environment during normal or reasonable foreseeable conditions of use and disposal of the article.

  In practice, it may prove extremely difficult for any company to exclude any human health or environmental impact across the whole product lifecycle (e.g. landfill disposal).
- The substance has not already been registered for the use in question.

The purpose of the notification provisions is to allow ECHA and the Commission to take a view on the need for future restrictions on the use of SVHC. However, there is no confidentiality in information so notified, which is therefore likely to come into the public domain.

Consumer products companies who use substances or preparations in the workplace

All consumer products companies with operations in the EU will make use of chemicals in the workplace. They will therefore be treated as "downstream users" of chemicals for the purposes of REACH. These are defined as Community-based legal entities, other than the manufacturer or importer, who use a substance, either on its own or in a preparation, in the course of an industrial or professional activity.

Most downstream users will face limited obligations under REACH. Principally, they will need to satisfy themselves that the substance or preparation they are using has been registered for their intended use, or source it elsewhere if not, and then apply any risk management procedures identified in the materials supplied with it (such as a safety data sheet (SDS)). In addition, all downstream users of a substance are required to:

- report new information they may uncover on, for example the hazards of a particular substance back upstream;
- allow workers and union representatives access to chemical hazard information in relation to workplace chemicals; and
- retain information in relation to any obligation under REACH for at least 10 years.

Consumer products companies based outside the EU

REACH is not intended to have extraterritorial effect. However, non-EU companies must still be mindful of its impact. Take the

example of a US-based product manufacturer that sells its products into the EU. If substances in those products are subject to the registration or notification requirements already described, then responsibility for compliance would fall on the first legal entity to import the product into the EU - which may well be a customer, a third party distributor or some other entity (e.g. an import/export affiliate) that is ill-equipped to manage these requirements.

Article 8 of REACH offers one solution in these circumstances: the appointment by the "non-Community manufacturer" of an "only representative" within the EU, who will then assume the actual importers' duties under REACH. Technically, only a non-EU manufacturer (as opposed to, for example, a US distributor in the same corporate group) can appoint an only representative. An alternative, in these circumstances, would be for the overseas company to re-route and channel its distribution via a trusted, EU-based affiliate or importer, which would then fulfil registration or notification requirements before selling on to other European customers.

What Impact Might REACH Have on Consumer Products Companies' Litigation Risks?

One group that the Commission has ignored in its assessment of the likely benefits of REACH is lawyers. REACH is likely to lead to a surge of legal challenges and even business disputes over the coming years: it is an important piece of legislation for many businesses, but a poorly drafted one. There is plenty of scope within the REACH text for interpretation and disagreement, whether between commercial entities or between regulators and the regulated.

Perhaps more directly relevant to readers of this Guide, however, will be REACH's impact on companies' litigation exposures towards consumers of their products or their own employees. To understand what that impact might be, one must first look at the reasons why REACH was introduced.

An early 2001 meeting of the Environment Council (made up of representatives of EU Member State governments) stated that REACH's aim was to remedy the situation, whereby: "*Man and the environment are potentially exposed from a large number of sources to a large number of chemical substances, the hazardous properties of which have not been identified*" [see Endnote 2]. In 2005, in a speech to the American Chamber of Commerce in Brussels, the EU's Commissioner for the Environment, Stavros Dimas, explained that: "*we have incomplete, or no safety information at all, about 99 per cent of the volume of the chemicals we use… If REACH succeeds in reducing chemicals-related diseases by only 10 per cent, which is a conservative assumption, the health benefits are estimated at more than €50 billion ($64 billion) over 30 years. This means tens of thousands of avoided cases of infertility, cancer, skin diseases, neurological disorders and other illnesses*" [see Endnote 3]. The EU's own detailed consumer polling has indicated that the top environmental issue for European citizens, in terms of the information they feel they lack, is "*the impact on our health of chemicals used in everyday products*" [see Endnote 4].

Consumer concern as to the supposed health effects of chemicals was ably exploited by the environmental NGOs during their lobbying for a tougher REACH regime. By way of example, one particularly dramatic report by Greenpeace and the World Wildlife Fund [see Endnote 5], published shortly before the European Parliament's first formal consideration of the REACH proposal in November 2005, examined the presence of "*known or suspected hazardous chemicals from eight chemical groups… in [human] umbilical cord blood*" [see Endnote 6]. The report, which was filled with suitably emotive imagery of babies, foetuses and pregnant women, noted that "*[i]n recent years, Greenpeace has analysed a range of everyday consumer products for the presence of a number of (potentially) hazardous chemicals and looked for these same chemicals in house dust and rainwater. The results add weight to the suspicion that these chemicals can 'leak' from products*". Examples of chemicals in consumer products identified by the NGOs as being of concern include brominated fire retardants and polyvinyl chloride (PVC) in office computers and other electronic equipment, dichlorodiphenyltrichloroethane (DDT) in food, perfluorocarbons (PFCs) in carpets, textiles, leather, paper and board, phthalates in a variety of PVC products and the antibacterial agent triclosan in sportswear, mattresses and food cutting boards.

Such a climate clearly favours further product liability litigation. There are remarkable similarities between the list of "*toxics*" targeted by the green lobby in Europe and the "top ten" lists of household chemicals that already appear on the websites of US plaintiff lawyers advertising for claims. Those websites contain lurid language concerning the "*nerve deadening chemicals*" supposedly found in air fresheners, the "*known carcinogens*" supposedly found in carpet and upholstery shampoo, the use of antibacterial agents "*tied to liver damage*" in some cleaners, etc. There is already some indication that concerns raised in US chemicals-related product liability and occupational health litigation - which has covered substances and issues as diverse as asbestos, silica, lead paint, off-gases from welding rods, pesticides, benzene, allergens in latex gloves and household products and perfume intolerance - may be finding expression on the other side of the Atlantic. For example, in March 2005, the Dutch courts ordered two consumer associations to withdraw unproven allegations that emissions from household air fresheners could present health risks, in an action brought by an affiliate of a US consumer goods company (*LJN: AS8908, Voorzieningenrechter Rechtbank's-Gravenhage, KG 05/64*).

The worst case scenario is that new testing and modelling conducted under REACH will provide evidence that a substance used for years in a mass market consumer product or in the workplace poses serious human health or environmental hazards that were not previously appreciated. As previously noted, the Commission has itself estimated that 600 substances may be newly classified as SVHC as a result of REACH. Any such hazard data will be packaged by registrants into readily understandable form (registration dossier/CSR) and - with limited exceptions - published on ECHA's website, for all, including activist groups and plaintiffs' lawyers, to access. The risk characterisation requirements for the CSR will also force registrants to go "on the record" as to the potential environmental and human health impacts of their chemicals under conditions of use.

Furthermore, there is a risk that the candidate list for authorisation and, ultimately, Annex XIV will come to represent a "shopping list" for the plaintiffs' bar. The consumer information and labelling provisions set out in Article 33 of REACH (see above) may also allow plaintiff lawyers and other interested parties to identify which SVHC/substances on the candidate list are used in which consumer products.

In the US, where, as noted, plaintiff lawyers have long targeted chemicals and household goods companies in their endless search for the next set of deep pockets, the historic and ongoing litigation concerning products containing asbestos, lead paint and even perfume allergies are unhappy indicators of what might happen next. In Europe, such litigation could provide an interesting test for the development risks/state of the art defence contained in the Product Liability Directive (85/374/EEC), on which the EU's strict

liability consumer protection regime is based. This provides a defence from strict liability where a defendant can show that "*the state of scientific knowledge and technical knowledge at the time when he put the [relevant] product into circulation was not such as to enable the existence of the defect [in that product] to be discovered*" (Article 7(e) of the Product Liability Directive). Conversely, a consumer products company supplies products in the EU at its own risk, from the moment that data on a potential product defect becomes accessible to the global scientific community. REACH is likely to mean that the ability to invoke the development risks defence in respect of a safety issue caused by the presence of a chemical in a product will fall away the moment that data on that issue is published on ECHA's database. This is just one reason why it will become increasingly important for product manufacturers on both sides of the Atlantic to monitor the state of the science as REACH begins to bite.

REACH may also oblige some consumer products companies doing business in Europe to change the formulations of their products and/or the instructions for use that they supply to consumers. The principal risk here is once again for multinationals, whose operations straddle both the EU and more litigious markets such as the US. New product formulations or instructions for use, based on hazard information that may well be readily accessible on ECHA's website, might provide *prima facie* evidence of a "reasonable alternative design" for the purposes of US product liability litigation. Moreover, an argument that "*what is good enough for European consumers should be good enough for Americans*" might play well with a US jury. Ensuring cross-border consistency of product formulation and quality becomes even more important under REACH than it has been in the past.

The Commission has said it hopes that REACH will lessen long term product liability risks, as the use of potentially more hazardous substances declines. That is of course probable. However, for some, the same may not be true of litigation risk in the short to medium term.

How Might REACH Impact Consumer Product Companies' Commercial Relationships?

A more practical challenge posed by REACH for consumer products companies may be in ensuring the continued supply of the substances that they (or their component suppliers) need for product manufacture. The Commission has estimated that REACH will lead to around two per cent of existing chemicals being substituted out or otherwise withdrawn from the market. There are a number of ways in which this may happen:

- REACH may result in EU-wide restrictions on the uses of particular substances.
- Substances on the aforementioned Annex XIV list will be subject to authorisation. Uses which do not receive authorisation will be prohibited.
- A manufacturer or importer may simply decide that the expense and burden of complying with REACH do not justify the continued manufacture of the substance in, or its importation into, the EU. Where demand for a substance for a particular use is small, the manufacturer/importer might similarly decide not to register for that use.
- A manufacturer or importer may fail to pre-register or register where required to do so by REACH.

In most cases, it will clearly be in the commercial interest of manufacturers, importers, distributors of chemicals and their customers to work together to achieve registration and thereby ensure security of supply. Businesses may seek to work out a variety of solutions based on their relative resources and bargaining power (e.g. tying suppliers of key chemicals into long term, fixed price contracts). In the longer term, the negotiation of other terms of commercial contracts may also be influenced by REACH:

- Warranties: customers may attempt to obtain express guarantees from their chemicals suppliers that their substances will be registered, that they will be fit for the buyer's intended use and that any data supplied to ECHA or others will be materially accurate.
- Intellectual property/confidentiality: customers may have to supply sensitive information on end uses to their suppliers, who may then share it with other chemical producers and importers in the context of a SIEF/registration consortium. In such circumstances, the limits of the use of that information would need to be defined.
- Risk allocation: as discussed, REACH may increase some businesses' product liability exposure and apportionment of these risks may be addressed by way of warranties, indemnities or insurance requirements.

Ensuring Compliance and Mitigating Risks

REACH may well be, in the words of The Economist, "*the biggest regulatory behemoth to appear for years*" [see Endnote 7], but it is but one of many pieces of legislation that have changed the regulatory framework for consumer products in Europe (see inset box: "The greening of EU product policy"). Ensuring compliance with this myriad of legislation is an increasing challenge both for EU industry and for overseas businesses who require access to the EU market.

Even now, nearly two years after REACH came into force, exactly how the new regime will work in practice, and its full ramifications, remains unclear. As noted, guidance for industry published only recently is already being revised. Meanwhile, the provisions of REACH are subject to rolling review by the Commission and the European Parliament and further changes to the legislative text are likely in the years to come. There are, however, three important areas of work for consumer products companies who may be affected by REACH.

First, EU consumer products companies which have pre-registered under REACH should ensure that they work to achieve registration for each relevant substance by the applicable deadline. This will involve working with chemicals companies and potentially competing consumer products businesses in SIEF and registration consortia, and separate consideration should be given to how to do this in a way which complies with the law (e.g. from an antitrust perspective) and which ensures fair cost-sharing and the protection of confidential information.

Second, all companies, wherever they are based in the world, should consider whether they can reduce or eliminate their use of chemicals which appear on ECHA's candidate list for authorisation. For many businesses, this will involve no more than continuing existing product stewardship policies. However, the list - which, as noted, will grow over time - is likely to place real pressure on global industry to phase out the use of the substances it contains. Among other things, the list provides environmental NGOs and the plaintiffs' bar a list of targets for future action and Article 33 provides them with the tools to identify the presence of substances on the list in consumer products.

Third, once the REACH regime is fully up and running, it will be important for consumer products companies that do use substances in the workplace and/or in their products to keep abreast of any new information on the hazards of those substances that may appear on the ECHA database or otherwise be generated by REACH. Reacting quickly to any such data is likely to assist the defence of

any future product liability or occupational health litigation related to the substance in question.

The greening of EU product policy

REACH is just one of a large number of legislative initiatives undertaken by the EU since 2000 with the objective of improving the safety of consumer products and lessening their environmental impact. Key measures have included the following:

- 2000's End of Life Vehicles (ELV) Directive (2000/53/EC). The ELV Directive requires that last owners must be able to dispose of their vehicles free of charge from 2007 (and requires producers to pay all or a significant part of the free take-back from this date), sets rising reuse, recycling and recovery targets and restricts the use of hazardous substances in both new vehicles and replacement vehicle parts.
- 2001's revised General Product Safety Directive (2001/95/EC). The GPS Directive obliges producers and distributors of consumer goods to ensure their safety and immediately to notify the authorities and take appropriate corrective action (including recall) when an unsafe product has reached the market.
- 2002's Waste Electrical and Electronic Equipment (WEEE) Directive (2002/96/EC), which is currently under review. The WEEE Directive aims to minimise the impact of electrical and electronic goods on the environment, by increasing re-use and recycling and reducing the amount of WEEE going to landfill. It seeks to do so by making producers responsible for financing the collection, treatment, and recovery of waste electrical equipment, and by obliging distributors to allow consumers to return their waste equipment free of charge. The operation, and possible expansion of, the WEEE regime is being considered by the Commission in 2008.
- 2002's related Directive on Restrictions of the use of certain Hazardous Substances in electrical and electronic equipment (RoHS) (2002/96/EC, as amended by Directive 2003/108/EC). RoHS, which is also under review, prohibits the placing on the market, as from 1 July 2006, of equipment containing more than the specified limits of lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE). The Commission's current consultation on the expansion of RoHS may include another 46 substances, including PVC, within its remit.
- 2003's Directive banning the marketing and use of penta and octa bromodiphenyl ether substances at concentrates above 0.1 per cent by weight (Directive 2003/11/EC).
- 2005's Energy-using Products (EUP) Directive (2005/32/EC). The EUP Directive establishes a legal framework for the setting of eco-design requirements to improve the environmental performance of EUPs throughout their lifecycle. Various Commission studies are currently examining a number of domestic and other products, with a view to establishing priorities for the "daughter directives" that are expected to be published under the EUP Directive.
- 2006's Batteries Directive (2006/66/EC). The Directive imposes a partial ban on the placing on the market of nickel-cadmium batteries and sets new restrictions on the disposal of batteries and accumulators.

Endnotes

1 See the Questions & Answers document at http://ec.europa.eu/enterprise/reach/faq_en.htm (under "Which are the most dangerous substances? How many are there?").

2 European Council. 2001. Conclusions from Environment Council. 7 June 2001.

3 Stavros Dimas, EU Commissioner for the Environment. "Climate Change and REACH". Speech to the American Chamber of Commerce in the EU, Brussels, 19 July 2005.

4 European Commission. April 2005. Special Eurobarometer survey, "The attitudes of European citizens towards environment".

5 "A Present for Life: hazardous chemicals in umbilical cord blood", WWF and Greenpeace, September 2005.

6 Greenpeace press release, "Man made chemicals in Maternal and Umbilical cord blood", 8 September 2005.

7 The Economist. 11-17 November 2006.

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His experience includes advising clients on preparing for compliance with REACH; on product safety and recall issues arising from defective components in consumer products and foods; and on the environmental and products regulation applicable to a wide range of client businesses. He has particular expertise in the interplay between general product and more specific sectoral legislation at an EU level.

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International Electronic Discovery

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Introduction

The discovery of electronic evidence or e-Discovery has become a key focus in product liability litigation both in courts in the US and around the world. Recent amendments to and the creation of e-Discovery law in the form of statutes, cases, and court rules shows that the law is finally catching up with the realities of the Information Age.

e-Discovery or the discovery of electronically stored information (ESI) is generally understood as the act of preserving, collecting, preparing, reviewing, and producing electronic documents and data during civil litigation. Since the vast majority of corporate documents now are kept in electronic form, e-Discovery may very well soon overtake "traditional discovery" in terms of importance, volume and cost to the parties and the courts. The practitioner not only needs to be aware of the applicable rules governing e-Discovery, but also needs to be able to implement best practices when conducting e-Discovery and avoid its pitfalls.

Well into the third year - if not more - of e-Discovery jurisprudence, the law in this area is beginning to take a definite form. It is shaping up to be another challenging element in litigating a case for both the parties and the courts. This article will provide the reader with a very brief, summary overview of major e-Discovery laws, cases, and principles affecting the international product liability practitioner. [See Endnote 1.] In addition, this article will offer the reader practical tips in dealing with e-Discovery on a global scale.

1. e-Discovery is Here and Here to Stay

Pre-trial discovery is an important process in a product liability case in any jurisdiction, but perhaps nowhere more so than in the US where broad discovery demands, loose standards of discoverability, strict time limits for production, and "person most knowledgeable" depositions on factual and now corporate IT issues, etc. can and do dramatically affect the conduct and outcome of any litigation. Until a dispute arises between the parties, discovery in the US remains largely unsupervised by the courts.

a. Discoverability of ESI in the US

In the US, the standard for discoverability is generally that the discovery must be "reasonably calculated to lead to the discovery of admissible evidence" - the information sought need not itself be admissible to be discoverable. *Fed.R.Civ.P. 26(b)(1).* Parties may seek discovery of all information "relevant" to the subject matter of the litigation - a process that has often been described as "casting a fishing net" to see what you "catch". In addition to the broad discoverability standards, a company also faces short and strict time limits for production, generally between only 15-45 days within which to search, organise, evaluate, object to and produce all materials relevant to the discovery requests and demands. In addition to rights of written discovery, US discovery rules give litigants a right to conduct oral questioning under oath of company representatives who have knowledge of the subject matter of the litigation and/or the subject matter of the discovery. Depositions of "persons most knowledgeable" in corporate IT departments, who are subpoenaed to testify about and explain corporate electronic document retention means and methods, policies and procedures, are becoming evermore commonplace.

Given the adversarial nature of US litigation, cases are increasingly fraught with e-Discovery disputes that have to be carefully prepared by the parties and decided by the courts. Until the revisions to the US Federal Rules of Civil Procedure, the enactment of e-Discovery procedural rules in US state courts, binding rules and helpful guidelines regarding e-Discovery practice were few and far between, and e-Discovery was - and in many US state courts still is - often regulated only by case law, which necessarily led to more such disputes arising.

b. e-Discovery Rules in the US Federal Courts

The e-Discovery amendments to the US Federal Rules of Civil Procedure came into force on December 1, 2006. The amendments affect Rules 16, 26, 33, 34, 37 and 45. [See Endnote 2.]

In the context of global products litigation in US federal courts, counsel must meet and confer to resolve e-Discovery issues, including the scope of preservation, the types of technologies involved, and the form of production - in every lawsuit. This means that counsel has an affirmative duty to become intimately familiar with each and every client's manner, methods, processes and procedures for storing and maintaining electronic documents.

e-Discovery best-practices also require the creation and maintenance of an "electronic information system" - primarily via an ongoing document retention policy capable of being suspended on short notice via an appropriate litigation hold.

In addition to the US Federal Rules of Civil Procedure, many US federal courts have enacted local rules specifically governing the discovery of ESI, and others are considering them. Of the 94 US District Courts, at least 41 presently have specific local e-Discovery rules in effect [see Endnote 3] or "Default Standards for ESI". In addition, certain individual courts and judges have their own e-Discovery rules and forms. In 2007, the Federal Judicial Center released its "Managing Discovery of Electronic Information: A Pocket Guide for Judges".

c. e-Discovery Rules in US State Courts

In addition to amendments to the US Federal Rules of Civil Procedure, many US state courts have enacted or are considering e-Discovery statutes, rules and guidelines. As of March 2009, over half of all US states have either court rules or statutes addressing e-Discovery in some form: Alaska, Arizona, Arkansas, California, Connecticut, Idaho, Illinois, Indiana, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Tennessee, Texas, Utah, Virginia and Wyoming. In addition, California, Florida, New Mexico, New York and Washington are evaluating proposed rules. In August 2006, the Conference of Chief Justices of the US state courts issued an updated and detailed "Guidelines for State Trial Courts Regarding Discovery of ESI". In December 2007, the National Conference of Commissioners on Uniform State Laws approved its "Uniform Rules Relating to the Discovery of Electronically Stored Information", which advocates the adoption of e-Discovery rules in all US state courts.

d. e-Discovery Outside of the US

Courts and entities outside of the US have also issued rules and guidelines related to e-Discovery. To date, all common law countries have some form of e-Discovery regulations and provisions. For example in the UK, the October 2005 amendments to the Practice Direction to UK Civil Procedure Rules r31 brought e-Discovery and electronic disclosure to the fore for UK companies involved in litigation and those conducting discovery in the UK. Companies and their legal advisers not only have to examine how electronic documents are created, stored, searched and retrieved in litigation, but they also have to be aware of and follow the guidelines for e-Discovery at the very earliest stages of litigation. UK courts have even interpreted the e-Discovery rules to include the creation and production of reports on ESI.

The Supreme Court of Ireland reached a similar result in *Dome Telecom, Ltd. v. Eircom, Ltd.* (2007) IESC 59. Though the court refused to order the creation of a report on the data in this case, holding the discovery unnecessary and disproportionate, it did hold that "[i]t may … be necessary to direct a party to create documents even if such documents do not exist at the time the order is made".

UK and Irish treatment of a litigant's e-Discovery duties are more expansive than US e-Discovery jurisprudence to date: in the US a litigant need only produce responsive documents and things in its custody and control and need not create evidence for production. [See Endnote 4.] Though, as e-Discovery jurisprudence is becoming more sophisticated, this too is changing.

Canada was a leader in the e-Discovery front. Several Canadian provinces have adopted some form of the well-known "Sedona Principles Governing Electronic Discovery". In fact, the Province of Ontario issued and has been working within the framework of its "Guidelines for the Discovery of Electronic Documents in Ontario" since late 1995. While the principles are issued as guidelines, rather than law, and are therefore not enforceable directly, they do "aid in the enforcement of agreements between parties or provide the basis for court orders" related to e-Discovery. Canadian practitioners have reported that a separate body of e-Discovery law has "mushroomed" in recent years. Current practical considerations in Canada include many of the same issues facing other product liability practitioners around the globe: retention and preservation issues; defining the proper scope of production; shifting the costs of e-Discovery; and gaining access to computer systems and data sources such as hard drives.

The Canadian province of Nova Scotia recently implemented electronic discovery rules modeled on the US e-Discovery amendments to the FRCP. The rules require the parties to "make diligent efforts to become informed" about relevant ESI in their present or past control, and to search for, acquire, and disclose all such data. Nova Scotia Civil Procedure Rule 15.02(1)(a). In addition to this broad preparation and production requirement, the new rules include a new duty to preserve ESI as soon as a party "becomes aware that a proceeding is to be defended or contested." Id. at Rule 16.02(2). Under this provision, a defendant in a Nova Scotia court may be required to create a "litigation hold" before the formal start of litigation. Further, the parties are encouraged to agree on how discovery should proceed even before discovery begins, which will require very early understanding of the relevant ESI relevant to a case. The rules also provide "default provisions" governing discovery in the event that the parties fail to reach such an agreement.

In Australia, the Federal Practice Note on Document Management, Discovery and Electronic Trials came into effect on July 1, 2008. This Practice Note applies to cases where the volume of discovery is reasonably anticipated to exceed 200 documents. It provides a framework for discovery of both paper and electronic documents and is supposed to facilitate the use of technology to increase litigation efficiency. In addition to the Practice Note, the Court also issued the following Related Materials: (a) the Pre-Discovery Conference Checklist (PDCC); (b) the Default Document Management Protocol (DDMP); (c) the Sample Advanced Document Management Protocol; (d) the Pre-Trial Conference Checklist (PTCC); and (e) the On-line feedback forum and email distribution list. On January 29, 2009, Australia implemented further U.S.-style rules for electronic discovery in the Practice Note to The Use of Technology in the Management of Discovery and the Conduct of Litigation. Like the recent rule changes in Canada, the Practice Note requires parties and counsel to meet and confer early in litigation to discuss electronic discovery protocols. The parties should cover the PDCC checklist of topics, including the "strategy for the identification, collection, processing, analysis, review and exchange of Electronic Documents"- including "those contained within databases, proprietary computer systems and other uncommon formats or repositories".

Other - primarily civil law - jurisdictions and the EU have on the books either legislation, binding court rules or guidelines to address the maintenance, storage, transfer and use of ESI in civil litigation. Most limit the information available to parties seeking discovery in litigation, including to protect personal privacy. [See Endnote 5.]

e. e-Discovery in International Arbitration

In addition to the increasing prevalence of e-Discovery in litigation before courts, e-Discovery has also recently been an issue in international arbitration. As is common in most civil law jurisdictions, discovery is significantly more limited in the arbitration context than in US litigation. Generally, the parties will agree to or the arbitral tribunal will decide on the proper scope of discovery. However, since arbitration is not governed by civil procedure rules, many parties anticipating arbitration may not fully preserve all data and information. But since the vast majority of business information is now stored electronically, parties to arbitration are increasingly actively using or seeking the discovery of ESI in their proceedings. To date, however, the rules of the major arbitral organisations do not deal with the issue of e-Discovery. This too is beginning to change. In October 2008, the Chartered Institute of Arbitrators issued its "Protocol for E-Disclosure in Arbitration". While it does not apply to all cases before the Tribunal, the Protocol aims to address the issues surrounding ESI early in a case, including the proper scope, form of production and costs of E-Disclosures. As e-Discovery becomes more

prevalent in arbitration, the international practitioner can expect more bodies to address these issues in their rules and procedural guidelines.

Upon examination of the rules, guidelines and case law, some common themes emerge: (1) the duty of counsel to become familiar with a client's electronic management system; (2) the client's duty to preserve electronic documents, where the term "documents" has a broad definition; (3) how one should go about ensuring preservation; and (4) the necessary balancing in assessing proportionality and costs in the e-Discovery process. In addition, the failure to properly provide e-Discovery often leads to severe sanctions. But perhaps the most pressing issue in international e-Discovery is the conflict between broad rights to discovery in US litigation and significant privacy and other considerations in nearly all of the rest of the world that all counsel need to take into consideration in the face of international e-Discovery.

2. Counsel's Duty to Know: What are We Even Dealing with Here?

The e-Discovery rules, laws, and court decisions handed down to date either expressly or implicitly impose a clear, affirmative duty on the part of counsel to research and understand the details of the corporate client's records management and IT systems as they relate to e-Discovery demands.

For example, even prior to the amendments to the US Federal Rules coming into force, the US District Court for the District of Kansas Electronic Discovery Guidelines state that "counsel should become knowledgeable about their clients' information management systems and their operation, including how information is stored and retrieved. In addition, counsel should make a reasonable attempt to review their clients' electronic information files to ascertain their contents, including archival, backup, and legacy data (outdated formats or media)". Ideally, all of this should occur prior to the beginning of the traditional discovery process, and perhaps even prior to any litigation, especially for in-house counsel.

Counsel's duty to be familiar with their clients' information management systems is a common theme in the rules and guidelines because electronic information is, by its very nature, fragile and transient. In order for counsel to ensure that the company can properly preserve electronic information for production in litigation, counsel must know what the company has, where it is stored, how it is stored, and who is responsible for it.

3. Document Preservation: Okay, But Can a Company Ever Destroy Anything?

When exactly does the duty to preserve ESI arise and under what circumstances a company can destroy potentially relevant and discoverable business records?

The US Court of Appeals for the Fourth Circuit has explained that "[t]he duty to preserve material evidence arises not only during litigation but also extends to that period before litigation when a party reasonably should know that evidence may be relevant to anticipated litigation". *Silvestri v. General Motors Corp.*, 271 F.3d 583, 591 (4th Cir. 2001). This principle also clearly applies to ESI. In *Doe v. Norwalk Community College*, 2007 WL 2066497 (D.Conn. Jul. 16, 2007), the court held that the duty to preserve arose at the latest when the defendant received the plaintiff's demand letter from her attorney, over two months prior to the plaintiff filing her complaint. The court indicated that the duty to preserve and the attendant duty to issue a litigation hold may even have arisen seven months' prior thereto, when the parties first met to discuss the issues related to the lawsuit - the alleged sexual assault of the plaintiff by the defendant's employee, a professor at the College. In the Doe case, the defendant had, pursuant to its "normal practices", "scrubbed" the professor's hard drive after he left the College. In addition, a later forensic search of certain other employee's hard drives revealed that pre-incident e-mails, which the plaintiff alleged would have shown the defendant's actual knowledge of the professor's conduct prior to her incident, had been altered or destroyed - also pursuant to College policy. The College had not issued a litigation hold, nor had it directed key players to search for and/or preserve records relating to the case. The court ultimately granted the plaintiff's request for an adverse inference instruction with respect to the destroyed evidence and awarded Doe her reasonable attorneys' and experts' fees and costs for pursuing the motion and investigating the spoliation of evidence.

Outside of the US, the same principles apply. For example, the Ontario Guidelines provide: "As soon as litigation is contemplated or threatened, parties should immediately take reasonable and good faith steps to preserve relevant electronic documents." The duty to preserve, however, is not absolute. The Guidelines recognise that "it is unreasonable to expect parties to take every conceivable step to preserve all documents that may be potentially relevant". US courts have agreed. The Rambus patent infringement prosecutions illustrate these principles:

A California court laid down some well-reasoned, common-sense rules regarding the destruction of corporate records for business reasons. In *Hynix Semiconductor, Inc. v. Rambus, Inc.*, No. C-00-20905 RMW (N.D.Cal. Jan. 4, 2006), Hynix sought terminating sanctions in a patent infringement suit because Rambus had in place a document retention policy that resulted in the destruction of potentially relevant and discoverable electronic and paper documents. Prior to the case being filed, Rambus developed and began implementing a company-wide, written document retention policy. Under the policy, Rambus destroyed e-mail preserved on backup tapes after three months. Rambus also held several "Shred Days" to enforce compliance with its document retention policy. During the "Shred Days", Rambus instructed its employees to follow the retention policy guidelines and determine what information they should keep and what they should destroy.

Rejecting Hynix's arguments against such a document lifecycle management programme, the court stated: "Rambus' adoption and implementation of its content-neutral Document Retention Policy in mid-1998 was a permissible business decision… [made before reasonably anticipated litigation and] did not constitute unlawful spoliation." The court noted that the document retention and destruction policy and its implementation did not target any specific documents or category of relevant documents. Nor did the court find an intent to prevent the production of relevant documents in the lawsuit. The court noted specifically that one "legitimate consequence of a document retention policy is that relevant information may be kept out of the hands of adverse parties". The court therefore refused Hynix's request for terminating sanctions and held that this destruction of even admittedly highly relevant information during an established, ongoing records retention and destruction programme was permissible absent notice to the company of potential litigation which would involve that specific information.

But not all courts have agreed. In a later patent infringement suit, also involving alleged spoliation by Rambus, the court undertook a detailed analysis of when and under what circumstances the implementation of the same document retention and destruction policy may constitute spoliation, though the court ultimately did not impose sanctions. In *Samsung Elecs. Co., Ltd. v. Rambus, Inc.*, 439 F.Supp.2d 524, 565-74 (E.D. Va. 2006), the court relied on substantial documentation of Rambus's spoliation developed during the *Rambus, Inc. v. Infineon Tech. AG*, 220 F.R.D. 264 (E.D. Va. 2004) and *Hynix Semiconductor, Inc. v. Rambus, Inc.*, supra, cases. The court agreed

with Samsung in this case and found that Rambus had engaged in the spoliation of evidence as part of its plans for litigation against the DRAM industry, including Samsung specifically. The court found that Rambus implemented its content-neutral document retention policy to justify destroying relevant and discoverable patent claims information when Rambus anticipated, or reasonably should have anticipated, litigation with Samsung. The court assured, however, that "neither corporations nor individuals are at risk of a finding of spoliation merely because they adopt or implement a proper document retention policy". But the court also cautioned that "any company that implements a document retention policy during or in anticipation of litigation, and destroys documents relevant to the actual or anticipated litigation, will face and lose a spoliation charge". The court further found Rambus's litigation hold instructing its employees to "not destroy relevant documents" vague and insufficient to satisfy Rambus' preservation obligations in light of several factors, including: the volume of documents destroyed; the extent and types of evidence destroyed after the hold was issued; the failure to specify which documents were relevant to litigation; and the fact that Rambus maintained no records of which documents were destroyed. The court went on to offer guidance on how companies can comply with their preservation duties by modifying document retention policies already in place. The court stated that in issuing a litigation hold, "the company must inform its officers and employees of the actual or anticipated litigation, and identify for them the kinds of documents that are thought to be relevant to it". The court also indicated that the collection and segregation of the relevant documents may also serve to comply with a corporation's duty to preserve. "It is not sufficient, however, for a company merely to tell employees to 'save relevant documents,' without defining what documents are relevant." The court observed that a company cannot "make a document retention programme an integral part of its litigation strategy and, pursuant thereto, target for destruction documents that are discoverable in litigation".

More recently, Rambus has once again suffered a setback in the defense of its document retention policy. In *Micron Tech., Inc. v. Rambus, Inc.*, 2009 WL 54887 (D. Del. Jan. 9, 2009), a bench trial was held on the issue of Rambus' alleged spoliation of relevant documents. The case itself arose from Micron's alleged infringement of Rambus' patents. Micron claimed that Rambus' document retention policy caused relevant documents were destroyed - even as part of its patent litigation strategy. The court agreed. Finding the defendant was an "aggressive competitor", the court determined that litigation was inevitable and reasonably foreseeable since December 1998, near the time when Rambus implemented its document retention policy. The court determined that any document destruction following December 1998 was intentional and in bad faith. As the plaintiff established that the documents that were destroyed were discoverable and relevant to the instant litigation, the court concluded that the plaintiff was prejudiced by the defendant's conduct. The court therefore sanctioned the defendant by declaring the patents in suit unenforceable against the plaintiff. The court found that Rambus "knew, or should have known, that a general implementation of the policy was inappropriate because the documents destroyed would become material at some point in the future". Rambus has indicated an intent to appeal this decision.

What these cases show is that a coherent, pre-litigation document retention policy is one key aspect to winning an e-Discovery battle. Courts have expressly recognised that companies need not keep all documents forever. However, a reasonable, good faith records management programme that is widely and consistently followed, as well as a plan for stopping it when the duty to preserve arises, establish current best practices in this area.

4. The Litigation Hold Letter: How does a Company Ensure Preservation?

Any document retention policy must be designed to account for the case where litigation is anticipated, threatened or filed. At this point, counsel must ensure that any records retention policy in place is stopped to a degree such that evidence and information relevant to the dispute or potential dispute is preserved. It is now widely accepted that in order to accomplish this task, counsel must issue a "litigation hold". But "stopping" an ongoing document destruction programme pursuant to the document retention plan alone may not suffice to meet the legal burden to preserve information under new e-Discovery rules.

A litigation hold is correspondence transmitted to all individuals likely to be in possession of relevant information asking them to preserve all such materials in exception to the company's otherwise applicable records destruction plan. The notice should contain a description of the litigation and the categories of documents that should be preserved, and it should provide instructions on how to preserve those documents. It should also provide information necessary to contact the in-house or external attorney or e-Discovery liaison, who is the client's designated person responsible for managing document preservation in a particular case. The notice should be circulated in different formats and as widely as needed in order to meet the preservation goals, including sending the document by various means, both hard copy and electronic, and perhaps even posting it or publishing it in public company areas.

Best-practices and current case law and rules of court essentially require the issuance of a litigation hold. These documents are, due to notice pleading in the US, often overly-inclusive and must be relatively detailed in order to serve their intended purpose.

a. Sanctions for Failure to Issue a Litigation Hold

In fact, the failure to issue a litigation hold by itself can lead to sanctions - both for the client and counsel. In *Tantivy Communications, Inc. v. Lucent Techs. Inc.*, 2005 WL 2860976 (E.D.Tex. Nov. 1, 2005.), the plaintiff accused the defendant of "hide the ball" discovery abuse during a patent infringement suit. The plaintiff petitioned the court to exclude certain defence evidence as a sanction for this alleged abuse. Specifically, the plaintiff had requested documents and data regarding interoperability testing, including information from the defendant's website. The defendant had responded time and again in written discovery that it knew of no documents in its possession responsive to the plaintiff's requests. The plaintiff discovered during a later employee deposition, however, that the defendant had destroyed arguably responsive documents, including test plans and interoperability contracts - both in paper in electronic form - pursuant to its document destruction policy. Citing the *Zubulake* line of cases, the court stated, "[the defendant] and its counsel are well aware that a party in litigation must suspend its routine document retention/destruction policy and establish a 'litigation hold' to ensure the preservation of relevant documents". Though the court preliminarily withheld ruling on the imposition of specific sanctions, it stressed in its ruling that it would not allow "lawyers or their clients to lay behind the log and disregard their discovery obligations".

Other court decisions indicate that merely sending a litigation hold may not be enough to meet current preservation obligations, i.e. more action may be required of counsel. In a decision known as *Zubulake V* (*Zubulake v. UBS Warburg LLC*, 229 F.R.D. 422 (S.D. N.Y. 2004)), the court held that it is both the in-house and outside counsels' duty to ensure that relevant information is preserved by giving clear instructions to the client to save it and - more importantly - to take

affirmative steps to ensure the client is actually heeding those instructions. At the outset of the litigation, counsel for the defendants instructed UBS personnel to retain relevant electronic information. Despite those orders, some UBS employees deleted relevant e-mails and destroyed electronic backup material in the corporate network. Some other employees never produced relevant information to counsel. As a result, many discoverable e-mails were not produced to the plaintiff until two years into the litigation - and some were lost forever. The *Zubulake* court sanctioned the defendant specifically for the failure of its lawyers in: (1) not specifically giving "litigation hold" instructions and personally requesting retained information from a key employee involved in the dispute; (2) not adequately communicating personally with the employees about what electronic information they retained and how they maintained their computer files; and finally (3) not safeguarding backup material which could have contained deleted e-mails. The very serious discovery sanctions included both monetary fines and a ruling that the jury would be given an adverse inference instruction with respect to deleted e-mails.

More recently, in *Metrokane, Inc. v. Built NY, Inc.*, 2008 WL 4185865 (S.D.N.Y. Sept. 3, 2008), the defendant sought sanctions for the plaintiff's alleged failure to produce e-mails highly damaging to the plaintiff's patent infringement suit. The defendant also argued that the late discovery of these e-mails via production from a third-party hampered its ability to pursue the necessary discovery related to the e-mails. Opposing the motion, the plaintiff vaguely asserted that the defendant failed to demonstrate any misconduct or prejudice and pointed to its lack of a written document retention policy, which the court inferred to mean that the plaintiff's real argument was that the e-mails were no longer in its system. Ultimately, the court found the plaintiff was, at the minimum, negligent since it failed to preserve and produce the e-mails, and the court found that the plaintiff's redaction of certain portions of the e-mails amounted to intentional concealment. Accordingly, the court ordered an adverse jury instruction and awarded attorneys' fees incurred in bringing the motion.

In *Keithley v. Homestore.com, Inc.*, 2008 WL 3833384 (N.D. Cal. Aug. 12, 2008), plaintiffs sought terminating, evidentiary and monetary sanctions due to defendants' alleged spoliation of evidence, which allegedly impacted the plaintiffs' ability to prove patent infringement. The court ultimately held several hearings after extensive briefing of the spoliation issue. The briefing was deemed "a moving target because of defendants' belated production of evidence that it had previously stated was either nonexistent or destroyed". The magistrate initially awarded a monetary sanction of more than US$ 250,000 in fees and costs associated with the defendants' discovery misconduct, and recommended an adverse inference jury instruction. The magistrate judge declined to recommend terminating sanctions. The defendants committed numerous discovery violations and initially contended that a proper document retention policy was in place and followed. The defendants were later forced to admit that there was no written litigation hold in place, which caused the court to note: "The lack of a written document retention and litigation hold policy and procedures for its implementation, including timely reminders or even a single e-mail notice to relevant employees, exemplifies defendants' lackadaisical attitude with respect to discovery of these important documents…. Defendants had a duty to notify and periodically remind technical personnel of defendants' preservation obligation and ensure that they took adequate steps to safeguard the data. At a minimum, defendants were reckless in their conduct …. Had defendants imposed a proper litigation hold in this case, the evidence … would have been preserved. Instead, evidence … was destroyed." The defendants appealed, and the district court upheld the magistrate judge's report and recommendation on sanctions for the egregious discovery abuses. The plaintiffs were allowed to take further depositions and then sought additional sanctions in the amount of US$ 391,903.51, based on the costs associated therewith. The court ultimately awarded a total of US$ 205,507.53. The defendants were also ordered to pay the plaintiffs' lodging expenses incurred during the re-deposition process. See id., 2008 WL 4830752 (N.D.Cal. Nov. 6, 2008), 2008 WL 5234270 (N.D. Cal. Dec. 15, 2008), and 2009 WL 55953 (N.D.Cal. Jan. 7, 2009).

In some cases, courts have gone so far as to order a party to issue a litigation hold. In *Board of Regents of University of Nebraska v. BASF Corp.*, 2007 WL 3342423 (D. Neb. Nov. 5, 2007), the defendants moved the court to compel the plaintiffs to produce all "development" documents. In this patent and licensing litigation, the court had previously ordered the plaintiffs to produce certain development documents that the defendants had requested. The plaintiffs produced nearly 13,000 pages of documents in response thereto, 11,000 of which were produced shortly before the close of discovery. This led the defendants to renew their motion to compel. The e-Discovery violation came to light when one witness testified at deposition that his original search had only covered his hard copy and not his electronic files. This witness also revealed that during and independent of the litigation, the plaintiff had switched from a central archiving system to an "individual user" archiving system for ESI, including e-mail, under which the individual user determined which materials to keep and which to delete. At no point during the litigation did the plaintiff or its counsel explicitly instruct the key players to preserve or search for ESI, nor did they issue a litigation hold. The court found that counsel have a duty to direct their client to conduct a thorough search and to follow up to ensure that all relevant materials in the client's custody and control are produced. The court went on to state that this duty is heightened when under court order to search for and produce discovery. The court issued remedial sanctions, which included re-searching "all of the files, including electronic files" pursuant to the court's orders, having employees and counsel swear to the methods, means and completeness of the searches, offering certain key players for re-deposition, and immediately issuing a litigation hold - all at the plaintiff's sole expense. The court also awarded attorneys' fees and costs associated with the discovery dispute.

Based upon the e-Discovery jurisprudence to date, best practices dictate that counsel issue a litigation hold and supervise the discovery process. This means that counsel for corporate litigants should also personally follow-up with affected personnel to ensure that they comply with the litigation hold and save and produce all discoverable data. In addition, counsel must work with corporate IT personnel to ensure that electronic documents are not destroyed and that they are properly preserved.

b. Production or Discovery of the Litigation Hold

The fear of having the client be required to produce the actual litigation hold letter during discovery should not deter counsel from issuing the hold. In a recent automotive product liability case, *Capitano v. Ford Motor Co.*, 831 N.Y.S.2d 687 (N.Y. Sup. Ct. 2007), the plaintiffs sought production of the defendant's "suspension orders" - the defendant's version of a litigation hold - after determining through other means that the defendant had not produced certain documents during discovery. The plaintiffs claimed that if they had access to the "suspension orders" they would be able to determine if the missing documents in question were intentionally or negligently destroyed, or perhaps secure information which may lead to the discovery of the missing documents. The defendant argued that the suspension orders were not relevant, and even if they were, that they were protected from discovery by the attorney-client privilege and/or attorney work product doctrine. The defendant submitted an Affidavit from an attorney in its legal department who explained that the suspension orders were "communications (a) that are issued by

attorneys in Ford's Office of the General Counsel in connection with certain anticipated or pending litigation or administrative proceedings and (b) that identify attorney-selected categories of documents required to be maintained beyond periods set out pursuant to Ford's records management programme". The attorney further explained that the suspension orders were confidential communications between the attorneys and Ford's representatives, were disseminated to only those employees who deal with Ford's record management programme, and contained the warning that the "suspension orders" were privileged and confidential and that dissemination should be limited to persons working at Ford on a need-to-know basis. The plaintiffs countered by offering the deposition testimony of another Ford attorney who, in an unrelated case, stated that Ford's suspension orders were posted on Ford's intranet communications system and were available to all employees. Based thereupon, the plaintiffs argued that the defendant had waived any attorney-client privilege. Although the court agreed with the plaintiffs that the requested "suspension orders" may lead to the production of admissible evidence and were, therefore, relevant, it denied the motion. The court concluded that the suspension orders were attorney-client privileged communications protected from discovery under N.Y. Civil Practice Law § 4503 (2007). It did not reach the issue of whether the "suspension order" constituted attorney work product.

In another case, a court reached the same result, though it found the "litigation hold" irrelevant but protected. In *Gibson v. Ford Motor Co.*, 2007 WL 41954 (N.D. Ga. Jan. 4, 2007), the plaintiff moved to compel the production of the defendant's "suspension order". The court found that the document did not have to be produced since litigation holds likely constitute an attorney work product, often are overly inclusive, and the documents they list do not necessarily bear a reasonable relationship to the issues in litigation. The court also feared that compelled production could have a chilling effect and "dissuade other businesses from issuing such instructions in the event of litigation" and that "[i]nstructions like the one that appears to have been issued here insure the availability of information during litigation. Parties should be encouraged, not discouraged, to issue such directives".

As e-Discovery jurisprudence develops, however, not all courts are convinced of the privileged nature of "litigation hold" letters. In any case, these privileges are not absolute. In the case In *re eBay Seller Antitrust Lit.*, 2007 WL 2852364 (N.D. Cal. Oct. 2, 2007), the court held that though the defendant need not produce copies of its "document retention notices" (DRNs), the plaintiffs were entitled to inquire into the *facts* as to what the employees who had received the DRNs had done in response. The court found that the defendant met its burden of showing that the contents of the DRNs may be protected by either the attorney-client privilege or the attorney work product doctrine. In this case, the parties had previously agreed to conduct a corporate witness deposition to clarify the defendant's ESI preservation and collection efforts. Nonetheless, the court allowed further discovery on exactly that issue and as to the DRNs. The court ordered the defendant to reveal the names and job titles of the 600 employees who had received the DRNs and found that the plaintiffs were entitled to know what the defendant's employees were *doing* with respect to collecting and preserving ESI. The court also found it appropriate to discover what those employees were *supposed* to be doing. Ultimately, the court held that the plaintiffs were entitled to know what kinds and categories of ESI the defendant's employees were instructed to preserve and collect, and what specific actions they were instructed to undertake to that end. In fact, the court expressed hearty scepticism that the DRNs were privileged at all. In light of its other rulings to conduct further discovery, however, it ultimately did not reach the privilege issue. It remains to be seen how other courts will balance and weigh the privilege issues surrounding the litigation hold letter.

As shown above, the failure to implement proper document retention procedures and programmes can have drastic consequences in litigation in the e-Discovery context. However, the exact scope of the duty to preserve is not entirely clear. Courts and others differ on the types of information subject to preservation and potential production.

5. Data, Data Everywhere: What is a "Document" in e-Discovery?

A "document" in the e-Discovery context clearly includes an e-mail or a word processing document - but what about the associated document properties, i.e. drafts and various versions of the document? The terms active data, ambient data, archival data, backup data, deleted data, distributed data, fragmented data, legacy data, metadata, migrated data, near-line data, off-line data, and residual data are all used to describe ESI or certain aspects of ESI. Some of the above may be discoverable; some may not.

For example, in *In re Flash Memory Antitrust Litigation*, 2008 WL 1831668 (N.D. Cal. Apr. 22, 2008), the court reminded both the parties and counsel of their duty to preserve "documents, data and tangible things", including writings, records, files, correspondence, reports, memoranda, calendars, diaries, minutes, electronic messages, voice mail, e-mail, telephone message records or logs, computer and network activity logs, hard drives, backup data, removable computer storage media such as tapes, discs and cards, printouts, document image files, Web pages, databases, spreadsheets, software, books, ledgers, journals, orders, invoices, bills, vouchers, check statements, worksheets, summaries, compilations, computations, charts, diagrams, graphic presentations, drawings, films, charts, digital or chemical process photographs, video, phonographic, tape or digital recordings or transcripts thereof, drafts, jottings and notes, studies or drafts of studies or other similar such material. Information that serves to identify, locate, or link such material, such as file inventories, file folders, indices, and metadata, is also included in this definition. The court in this case noted that not only did the parties have to take reasonable steps to preserve the relevant information until they agreed to a preservation plan or until the court ordered otherwise, but also ordered the parties to "exercise all reasonable efforts to identify and notify parties and non-parties of their duties, including employees of corporate or institutional parties, to the extent required by the Federal Rules of Civil Procedure".

In the UK, pursuant to the UK Practice Direction 2A1, the definition of a document "extends to electronic documents, including e-mail and other electronic communications, word processed documents and databases. In addition to documents that are readily accessible from computer systems and other electronic devices and media, the definition covers those documents that are stored on servers and backup systems and electronic documents that have been 'deleted'. It also extends to additional information stored and associated with electronic documents known as metadata".

Though the Practice Direction includes a list of factors relevant to determine the final scope of e-Discovery, the definition of "document" under the Civil Procedure Rules has arguably been expanded to include as discoverable information that would not commonly be referred to as a "document": Metadata is fair game [see Endnote 6] - or so it would seem.

But what is metadata? Metadata is fundamentally different from electronic and printed documents. All the information in a paper document is displayed on its face, which is not the case for electronic documents where its history is preserved in metadata. Paper shows what a document says or looks like; metadata can reveal where the documents went and what was done to it there - and by whom. Clients and counsel must be aware of and prepared to confront any embedded

information and they must do so in a timely fashion. While metadata may arguably be relevant in some cases, in most cases it is not.

The seminal metadata production case remains *Williams v. Sprint/United Mgmt Co.*, 230 F.R.D. 640 (D. Kan. 2005) (*Williams I*). In *Williams I*, the court held that "[w]hen the Court orders a party to produce an electronic document in the form in which it is regularly maintained, i.e. in its native format or as an active file, that production must include all metadata unless that party timely objects to production of the metadata, the parties agree that the metadata should not be produced, or the producing party requests a protective order". *Williams I* was an employment class action involving alleged age discrimination. The plaintiffs had requested "active" electronic versions of Microsoft Excel spreadsheets so that they would be able to determine if the documents "had any actual other columns or types of information available on a spreadsheet". After a protracted discovery battle, the defendant produced electronic versions of the spreadsheets. After reviewing the spreadsheets, the plaintiffs claimed that the defendant "scrubbed" the spreadsheet files to remove metadata, failed to produce a log of the information scrubbed, and "locked cells" and data on the spreadsheets, which prevented the plaintiffs from accessing those cells and electronically searching and sorting the data in them.

The defendant in *Williams I* admitted that it had scrubbed metadata and either redacted or locked certain cells and data, but argued that not only was the metadata irrelevant and certain redacted information privileged, but it also argued that the plaintiffs had never requested production of the metadata. In addition, the defendant claimed that it had acted in good faith, that its modifications were designed to prevent the plaintiffs from discovering information that the Magistrate judge had ruled undiscoverable, and that the modifications served to maintain data integrity. The court ultimately chose not to sanction the defendant, but it ordered the defendant to produce "unlocked" versions of the spreadsheets with the metadata intact.

The metadata discovery battle continued in *Williams v. Sprint/United Management Company*, 2006 WL 3691604 (D.Kan. Dec. 12, 2006) (*Williams II*). The defendant eventually produced the unlocked spreadsheets in native format, but the plaintiffs returned to the court a year later and argued that they could not match the over 11,000 e-mails produced with the respective spreadsheet. They moved to compel the production in native format of all 11,000 e-mails produced that transmitted spreadsheets. The Magistrate judge ultimately held that since the plaintiffs had already received the e-mail production in one format (paper), the amended Federal Rule 34(b)(iii) protected the defendant from having to produce them again in another format (native). [See Endnote 7.]

Further cases to date tend to affirm the notion that absent a showing of a compelling need and/or a timely agreement to the contrary, a court will not order the regular production of metadata. [See Endnote 8.]

As the courts gain further experience with ESI, they are beginning to deal with its varied forms and complexities.

Text Messages. In *Flagg v. City of Detroit*, 2008 WL 787061 (E.D. Mich. Mar. 20, 2008), the court allowed the discovery of certain text messages exchanged between defendant's employees, who the plaintiff accused of delaying the investigation into his mother's murder and concealment of evidence. In its opinion, the court set forth a detailed protocol for preserving, retrieving and reviewing the text messages for discoverability prior to production to the plaintiff. In this more-recent decision, the court ruled on the City's and one other defendant's motion to reconsider that ruling. The moving defendants argued that the federal Stored Communications Act, 18 USC § 2701 et seq., precluded the production of electronic communications stored by a non-party service provider. In rejecting this argument, the court noted that such a reading of the Act would "dramatically alter discovery practice, in a manner clearly not contemplated by the existing rules of law", by permitting a party to defeat the production of ESI that it created and still within its control - information "plainly" discoverable under US FRCP Rule 34 - simply by storing that information with a third party. The court instructed the plaintiff to serve a request for production to the defendants under US FRCP 34 and instructed the defendants to respond in line with the prior order, thereby avoiding the SCA third-party subpoena issue. *Flagg v. City of Detroit*, 2008 WL 3895470 (E.D. Mich. Aug. 22, 2008).

RAM. In *Columbia Pictures, Inc. v. Bunnell*, 245 F.R.D. 443 (C.D. Cal. 2007), the court ruled that Random Access Memory is "stored", no matter how briefly, and therefore ESI under the plain meaning of Rule 34 and ordered the production of information held in RAM on the defendant's servers. The court cited the Advisory Committee's Notes to Rule 34, which call for an expansive reading of ESI, intending it to cover data stored "in any medium from which information can be obtained". The court also rejected the defendant's invocation of international law in this copyright infringement action. In this case, the servers were situated in the Netherlands, where EU and Dutch national law purportedly prohibit US courts from ordering discovery. The court held that Dutch law cited by the defendants, The Netherlands Personal Data Protection Act and the case *BREIN Foundation v. UPC Nederland B. V.*, only prohibit the production of "identifying information", not all information and not the information sought in that case - anonymous Server Log Data, including IP addresses. The District Court further agreed with the Magistrate Judge's finding that "foreign blocking statutes do not deprive an American court of the power to order a party subject to its jurisdiction to produce (let alone preserve) evidence even though the act of production may violate that statute". [See Endnote 9.]

Cache. In *Healthcare Advocates, Inc. v. Harding, Earley, Follmer & Frailey*, 497 F.Supp.2d 627 (E.D. Pa. 2007), the court rejected the plaintiff's claim that the defendant law firm spoliated ESI when it failed to preserve its computer's cache containing the "screen shots" of the plaintiff's archived webpage that the law firm had pulled up using the "Wayback Machine" in its defense of one of its clients. The court found the preservation of information stored in a computer's temporary cache files "impractical" and rejected the request for sanctions. The defendants prevailed in that case and were ultimately awarded US$ 9,000 in costs.

The international practitioner can expect further rulings on these and other matters of first impression as courts continue to confront with these and other novel e-Discovery issues. But not only must courts confront these issues, but companies, their counsel and their service providers must continue to do so as well.

Websites. Finally, in *Arteria Prop. Ltd. v. Universal Funding VTO, Inc.*, 2008 WL 4513696 (D.N.J. Oct. 1, 2008), the court treated the defendant's website as it would any other electronic document. During contract negotiations for a long-term loan to fund real estate development in Australia, the plaintiffs apparently relied on statements on the defendants' website that it was a "leading lender" in the real estate market and that it had "over 50 years experience" in lending. The deal fell through, and Arteria sued. The website apparently still existed and still contained the statements as alleged at the time the plaintiff filed suit. During discovery, the plaintiff sought screenshots of the webpages. The defendants admitted during deposition that the statements on the webpage were untrue and included to induce business, but did not produce screenshots of the webpages. The court focused its analysis on whether the website was under the defendants' control. The court found in the affirmative and went on to state that even if a third-party hosts or maintains the website, the defendants had control over what was posted and deleted from the website, and therefore had the "ultimate authority" over the electronic document. Ultimately, the court ordered that an adverse inference jury instruction be given that the website contained the statements as alleged by the plaintiffs.

6. e-Discovery Vendors: So Who Can We Count on to Help Us Get Through e-Discovery?

As the discovery practices evolve with technology and e-Discovery becomes more prevalent, the effective practice of e-Discovery often requires the services of an e-Discovery vendor. In the past few years, the legal community has seen a rapid proliferation of e-Discovery vendors and service providers that assist counsel and clients in obtaining and managing electronic data prior to and during litigation. The vendor works with the client's counsel and IT staff to ascertain where documents are stored, in what format they are stored and how the data can be retrieved in a way that does not change it. In addition, the vendor generally has access to equipment and personnel that allow legacy data from dormant e-mail, word processing and other systems to be read and retrieved. Vendors convert the data into a format that allows attorneys to review and produce it. Many vendors and service providers often provide additional consulting services and even assist in selecting search terms or perform the first review and filtering of documents. Often an e-Discovery vendor is essential to properly assess and budget, harvest, filter and format ESI for production.

The production of electronic documents and data is now part of the US litigation culture. Cost-effective managing of the harvesting, review and production of such information requires careful selection of e-Discovery vendors. Failure to do so can lead to costly and time-consuming conflicts between lawyer and client.

In the recent past, marquee law firms, vendors and clients have become embroiled in public finger-pointing and even litigation regarding the services rendered. Often the allegations include trading blame for the under- or over-inclusive production of ESI, delays leading to the inability to comply with court deadlines, and allegations of overcharging. Technical glitches in e-Discovery software have cost attorneys, clients and the courts hours of valuable time and thousands in resources. [See Endnote 10.]

In litigation today, e-Discovery vendors are performing services that go beyond mere litigation support. External lawyers and clients ultimately need to keep in mind that they will often be held responsible for mistakes by third-party vendors.

7. Proportionality & Costs: Shifting & Sharing the Benefits & Burdens

The burden of preserving, collecting, preparing, reviewing, and producing electronic documents and data during civil litigation is clearly immense. Traditionally, discovery rules outside of the US foresee that the party seeking the discovery bears the cost of production. In the US, the costs are presumed to fall on the producing party. The e-Discovery amendments to the US Federal Rules do not change that regime, but instead rely on a two-tiered approach to the production of electronic information: Under Rule 26(b)(2)(B) "[a] party need not provide discovery" of ESI "from sources that the party identifies as not reasonably accessible because of undue burden or cost". The burden is on the producing party to show that it falls into this category. Otherwise, case law continues to govern cost-shifting in US e-Discovery.

Increasingly, courts are showing a willingness to pass to the requesting party the burdensome costs of producing e-Discovery.

In Australia, for example, prior to the 1998 Federal Court judgment by Justice Sackville in the case *BT (Australasia) Pty Ltd v. State of New South Wales & Anor* (No. 9) [1998] 363 FCA, the retrieval and analysis of electronic files was accepted as being too costly and challenging a task for Australian litigants to be required to undertake. In his finding that Telstra failed to comply fully with its electronic data discovery obligations, the judge scathingly rejected that view.

Justice Sackville stated that "[he] accept[ed] and appreciate[ed] that the purpose of making and retaining the backup was essentially disaster recovery, rather than archival. Nonetheless, as subsequent events have demonstrated, it is feasible, albeit difficult and expensive, for the tapes to be restored and a review process set in place to identify discoverable material. The fact is that the tapes do contain much material that is relevant to the issues in the proceedings, even though it is technically difficult to retrieve and the task of review is time consuming". The message to Australian lawyers was clear: electronic document discovery may be onerous, costly and time consuming, but there is no excuse for not doing it. Since that time, e-Discovery in Australia has become widely accepted, with the Australian Federal Court Rules now defining document to include any material data or information stored by mechanical or electronic means. [See Endnote 12.] Clearly, Australian litigants are expected to bear and have borne significant costs related to e-Discovery and can, as is the case in traditional discovery, seek a cost order from the court to shift the burden of producing electronically stored information.

In cost-shifting cases in the US, courts routinely relied on the eight factor test articulated in *Rowe Entertainment, Inc. v. The William Morris Agency, Inc.*, 205 FRD 421 (2002), or the seven factor test from *Zubulake v. UBS Warburg LLC*, 217 F.R.D. 309 (S.D.N.Y. 2003) (*Zubulake III*). Courts also sometimes employ the Advisory Committee Notes to the US Federal Rules e-Discovery amendments.

In *Rowe*, the court shifted all e-Discovery production costs to the plaintiff, except the defendants' search of their own materials for privileged e-mails, finding that although the plaintiff could not obtain the information by other means, the plaintiff's discovery requests were very broad and the plaintiff had not been able to prove that the discovery of e-mail would be a "gold mine" of relevant information. In *Rowe*, a group of concert promoters had sued several talent agencies for allegedly freezing them out of the market for promoting certain events. The plaintiffs had moved to compel the production of all documents, including e-mail, concerning any communication between any of the defendants relating to the selection of concert promoters in the course of its business. The William Morris agency alone estimated that it would cost approximately US$ 9,750,000 to fulfil the plaintiffs' discovery request. In reaching its decision, the court employed an eight-factor balancing test. [See Endnote 13.]

The test set forth in *Zubulake III* makes it more difficult to shift costs to the requesting party than under *Rowe*. The court in *Zubulake III* even criticised the approach set forth in *Rowe* for making it too easy to shift costs back to the requesting party, asserting that "there is little doubt that the *Rowe* factors will generally favour cost-shifting" and called the *Rowe* approach "incomplete". *Zubulake III* adopted a three-step analysis, which incorporated some of Rowe's eight factors. Step #1 is to determine whether cost-shifting is even an appropriate consideration. Step #2 requires a factual showing to support shifting the cost of production to the requesting party. Specifically, the responding party must restore and produce a sampling of responsive documents from the inaccessible media. [See Endnote 14.] The final step #3 in the *Zubulake III* analysis takes us to the seven enumerated factors. [See Endnote 15.]

In addition to courts generally applying the *Rowe* and *Zubulake III* factors to determine accessibility and proportionality, another court relied on the Advisory Committee's Notes to Rule 26(b)(2)(B) [see Endnote 16] to conduct the balancing test and find the database in question not "reasonably accessible" under the rules. In *Best Buy Stores L.P. v. Developers Diversified Realty Corp.*, 247 F.R.D. 567 (D. Minn. 2007), a magistrate judge had ordered the plaintiff to restore and provide discovery from a database that the plaintiff had created for a

prior case. The database contained nearly all of the plaintiffs' existing ESI stored outside of its e-mail system and had been "downgraded" at some point during that litigation. In the case at issue, the defendants sought discovery from that database and the magistrate judge agreed, finding estimated restoration costs of US$ 124,000 and monthly maintenance costs of ca. US$ 27,800 - nearly one quarter of the total amount in controversy - "reasonable". The district court, employing the Advisory Committee factors, disagreed and sustained the plaintiff's objection to restoring, maintaining and searching the database in the present litigation. Though the court agreed that the database would likely contain discoverable and relevant information, it nonetheless concluded that absent specific discovery requests or additional facts suggesting that the database was of particular relevance to the litigation, the plaintiff did not have a duty to continue to maintain the database. The plaintiff did not destroy potentially relevant evidence but merely "removed it from a searchable format", and since the defendant was not able to show good cause, the plaintiff need not restore and maintain the database.

Litigants, however, continue to seek access to electronic databases.

8. Direct Access to Corporate Databases

Recently, plaintiffs and their counsel - especially those in product liability cases - ask that courts order corporate defendants to allow the plaintiff (and their expert IT and other litigation consultants) direct access to corporate servers, databases and other electronic information. Some US trial courts - in unpublished decisions - have ordered corporate defendants to give a plaintiff direct, searchable access to certain databases on a case-by-case basis. However, to date, absent agreement from a corporate defendant or a showing of prior discovery violations, US courts have been very wary of giving a claimant such unfettered, unrestricted "live" access to a company's electronic servers.

For example, in *In re Ford Motor Co.*, 345 F.3d 1315 (11th Cir. 2003), a plaintiff alleged that a defectively designed seatbelt buckle caused her injuries. After serving extensive written discovery, the plaintiff filed a motion to compel to obtain direct access to two Ford databases in order to search for related claims; one database contained records of all customer contacts with Ford and the other contained records of contacts by dealers, personnel and other sources. After the trial court granted the motion, Ford sought review by the Court of Appeal. In rejecting the trial court's grant of direct access, the court stated: "Like the other discovery rules, Rule 34(a) allows the responding party to search his records to produce the required, relevant data. Rule 34(a) does not give the requesting party the right to conduct the actual search. While at times - perhaps due to improper conduct on the part of the responding party - the requesting party itself may need to check the data compilation, the district court must 'protect respondent with respect to preservation of his records, confidentiality of nondiscoverable matters, and costs'". [See Endnote 17.]

Ford recently defending another product liability plaintiff's bid to gain access to its litigation database. In *Ford Motor Co. v. Hall-Edwards*, 2008 WL 5070290 (Fla. 3d Dist. Ct. App. Dec. 3, 2008), the trial court granted the plaintiff access to "all of its databases", including an exclusively privileged database, based upon an assumption regarding the ease of production and upon the defendant's violation of a prior court order where the defendant failed to provide sufficient information regarding its search efforts. On remand, the plaintiff was attempting to gather information regarding "other similar instances" of rollover that the plaintiff's expert testified to at trial. The trial court ordered two of Ford's attorneys to be deposed on the completeness of the ordered production and the privileged nature of the information contained in the "litigation management matters system" and, still believing that the defendants were hiding information, the trial court granted access to "all of [the defendant's] databases", including the privileged database. Ford appealed. The appellate court quashed the order, citing the burden of producing the expert reports as ordered and noting that defendant's violations were correctable and non-prejudicial and thus did not justify an invasion of the attorney-client privilege or work product - which would cause "irreparable harm" to the defendant.

9. Sanctions for Failures and Non-Compliance

Under Federal Rule 37(e), a party is exempt from sanctions for the failure to provide electronically stored information lost as a result of the "routine, good-faith operation of an electronic information system" - "[a]bsent exceptional circumstances". It remains to be seen exactly what those circumstances are, but past cases can provide guidance.

Even prior to the amendments to the Federal Rules, a variety of sanctions were and continue to be available for the failure to comply with e-Discovery, both against the non-responsive party and its counsel. Courts have issued sanctions for the failure to have a document retention policy, the failure to issue a litigation hold, the failure to enforce the retention policy or litigation hold, and the failure to produce e-Discovery, including in the form requested or agreed to. As e-Discovery jurisprudence develops, courts are more and more willing to impose increasingly harsh sanctions, including terminating sanctions and monetary sanctions of hundreds of thousands if not millions of US dollars, depending upon the egregiousness of the violation. [See Endnote 18.]

The law on sanctions for e-Discovery abuse continues to develop and warrants close monitoring and consideration of internal policies before and during the conduct of litigation.

10. International Developments in e-Discovery

a. Recent Case Law

Though not as fully developed as in the US, the international jurisprudence on e-Discovery is gaining in mass as well as practical importance. Major case law on e-Disclosures in the UK show that non-US jurisdictions are tacking the same issues as those facing US courts and litigants. The issues surrounding the discovery or disclosure of ESI in civil litigation, including product liability litigation, are becoming more similar throughout the world.

In the seminal UK case *DigiCel v. Cable & Wireless PLC*, [2008] EWHC 2552 (Ch) (23 October 2009), the court applied e-Discovery standards similar to those found in the US to a cross-border discovery dispute involving data located in Europe and the Caribbean. This case involved the alleged breach of a statutory duty in legislation designed to increase competition in the telecommunications market. The defendants refused to restore backup tapes and searched using only limited search terms unilaterally chosen by them. The plaintiffs moved to have back up tapes restored and additional search terms used. After citing the US *Zubulake* decision, the Court rebuked the parties for failing to engage in a meaningful meet and confer session and failing to prepare for the same. The court performed a proportionality test and found that defense counsel misrepresented the scope of a "reasonable search". In fact, defence counsel argued that an additional search would only produce duplicate results. The court disagreed. The court sanctioned the defendant by ordering discovery from backup tapes and required the use of new search terms - at the defendants' expense. The case was an e-Discovery breakthrough in

the United Kingdom, both in its detailed analysis of backup tapes and search terms, and due to its finding that counsel has a legal duty to affirmatively manage e-Discovery in litigation. Courts in England and Wales have already started citing *Digicel* and requiring that parties conduct reasonable due diligence into their client's electronic systems and ESI prior to mandatory meet and confer sessions.

For example, citing the *DigiCel* case, the court in *Abela v. Hammonds Suddards, et al.*, [2008] Claim No. HC07C00250 (Ch), held that the standard under Civil Procedure Rule 31 is "not that no stone must be left unturned" but that a "reasonable search" is conducted. Ultimately, the court decides what is reasonable, "not the disclosing solicitor…". The starting point, however, for defining the scope of a "reasonable search … must be an accurate account of what data or data sets are available, on what media they are stored, in what format or formats they are stored, how the information is organised, and what the overall quantities of data are". In that case, the respondent (Hammond) argued that the recovery of 21 months of backup tapes was unduly burdensome and would possibly cost up to GBP 150,000. Deputy Judge Paul Girolami QC indicated that while he may not agree with the respondent's estimate of the costs and burdens involved, a party giving disclosure is ultimately not required to reduce the other parties' burden in reviewing extensive disclosures by additionally and separately listing documents which supported his own case and documents which supported the other party's case.

Australian courts are also beginning to issue severe sanctions for e-Discovery errors. In a recent case, an Australian court struck out key evidence from the plaintiffs' case because it was obtained in a manner inconsistent with the agreed search protocol - and therefore in violation of Australian law. *Australian Securities and Investments Commission v. Macdonald* (No. 5), [2008] NSWSC 1169 (04 November 2008).

These and other cases in common law jurisdictions show that litigants nee not only take US e-Discovery law into consideration, but that they are also facing new challenges in litigation around the globe.

b. International e-Discovery Considerations

US e-Discovery can potentially reach international corporations when the entity is a direct party to an action, and it can also in theory reach non-US parent and subsidiary corporations and affiliates not directly involved in the litigation as well. Though international choice of law and evidence-gathering treaty restrictions apply, some attorneys are arguing (sometimes successfully) that e-Discovery requests can and do reach beyond US borders.

For example, in the Kingdom of Spain's appeal of a federal magistrate judge's imposition of discovery sanctions due to Spain's failure to meet its obligations under the US Federal Rules to preserve and produce electronic documents and e-mail, the District Court found that the plaintiff had received adequate notice regarding its preservation duties and spoliation issues. The court upheld the award of attorneys' fees as a reasonable sanction for the plaintiff's negligent failure to preserve electronic evidence. See *Reino de Espana v. Am. Bureau of Shipping*, 2006 WL 3208579 (S.D.N.Y. Nov. 3, 2006), *affirmed* 2008 WL 3851957 (S.D.N.Y. Aug. 18, 2008). The *Reino De Espana* decision shows that litigants - even foreign governments - must be prepared to address the preservation and potential discovery of e-mail and other ESI, not just during discovery, but perhaps well before litigation actually commences, regardless of where the discoverable information might be found.

Non-US companies doing business in the US, as well as overseas dependencies of US corporations may well be subject to the new e-Discovery rules and standards should they be hailed in front of US courts. In the past, US courts have actively imposed the burden of global discovery on international litigants coming before them, despite fundamental opposition from both governments outside the US and their constituent companies. On the other hand, for the foreign corporate defendant, ensuring that day-to-day business can continue uninterrupted and without undue burden is necessarily tantamount to their obligations related to discovery in a US product liability case. Unfortunately, international corporations would be ill-advised to simply ignore this new challenge.

Generally, opposition to global discovery is often based on legal and cultural differences that global practitioners and clients faced with the new, even more intrusive US e-Discovery regime must take into consideration. For example, the role of the judge and lawyer are often starkly different in common law versus civil law jurisdictions. In common law jurisdictions, the judge acts as a neutral referee, and the attorneys take a more adversarial and proactive role in developing the case and moving it forward. In civil law countries, by contrast, one or more judges are often active in a case, determining what is discoverable and necessary for the prosecution of that particular case.

In addition, a number of civil law jurisdictions have privacy laws or even specific blocking statutes that prevent the transfer of certain information out of the jurisdiction - and to the US. Regardless of these statutes, many US courts still expect and demand global discovery from internationally-acting parties to US litigation. In the past, US courts often based their analysis on the lack of enforcement of foreign blocking statutes. However, the recent prosecution of a French attorney gathering information for discovery in a US case shows that the tide is slowly turning: In the case In *Re Advocat "Christopher X"*, Court of Cassation (Supreme Court) Criminal Section, Appeal No. 07-83228 (January 16, 2008), a French attorney was criminally prosecuted and fined €10,000 for violation of the French blocking statute.

The practitioner must therefore attempt the often difficult task of ensuring that US obligations are met in a product liability claim while at the same time not violating the laws of the place the discovery is sought. This may require the personal consent of the author of e-mails, for example, or extensive filing and liaising with governmental agencies to ensure the proper and confidential treatment of "personal" data - which is, for example, often liberally construed by non-US courts to include any data identifying the person or his location.

Presently, no concrete, binding methods exist for obtaining e-Discovery outside of the US for use in US litigation. One potential method for obtaining discovery internationally is via the Hague Convention of March 18, 1970 on the Taking of Evidence Abroad in Civil or Commercial Matters, which provides the rules and procedures for obtaining evidence outside of one's home jurisdiction. A threshold questions is, of course, whether the country from which you are seeking discovery is a signatory to the Convention. If so, the requesting party must strictly follow the specific procedures provided in order to request discovery via diplomatic channels. In addition, the requests must also strictly comply with local discovery rules, which may limit the information available, regardless of whether or not the country is a signatory. Further, there are no direct methods of enforcement.

In addition to the Hague Convention on Evidence, the international practitioner must also take into consideration privacy issues. For example, European Directive 95/46/EC prohibits the transfer of personal information outside of the EU unless the country receiving the information provides an "adequate level of protection" for individuals in the processing of personal information. The US is presently not considered to provide adequate privacy protections. These and other regulations may bar making a mirror-image of your non-US client's ESI and taking it to the US for segregation, preservation, review, and production. Often times, offering redaction *may* overcome privacy issues - but, for example, only if the affected

party and your opponent agree.

Though incumbent upon any practitioner, practitioners with a multi-jurisdictional, international practice should take special care to alleviate any such concerns. An international discovery request is likely to meet with greater success if accompanied by a degree of specificity virtually unknown in the US: One should attempt to identify what documents one wants from whom or face rejection at the border and the door of the party. Practitioners should also be aware that web-based e-Discovery platforms may already violate some non-US data privacy and transfer laws. It simply may be illegal to transfer data to the US under current international privacy laws - and random "fishing" for information to support a claim may already violate such international civil and criminal laws and customs.

In addition, the international litigator will often also face language and other cultural barriers, exacerbated by the "new" terminology associated with e-Discovery. Many international corporations find the US pre-trial discovery process intrusive and burdensome. Many are not familiar with or prepared to deal with the adversarial nature of proceedings or the large-scale of discovery. Effective e-Discovery practice on an international scale will necessarily require more time and effort in explaining to non-US clients why they need to accept and support effective e-Discovery - especially with respect to the many foreign employees who counsel will need to assist them in this important process.

For example, in issuing an effective litigation hold, non-US entities must take into consideration not only vastly different legal frameworks and traditions, but also different cultural norms and expectations. Cultural sensitivity and awareness can be of critical importance. And it goes without saying that any litigation hold must follow local laws regarding document retention and destruction. Further, employees may have privacy rights - whether real or perceived - via local law, a specific employment contract or through the works council to information on their employer-issued technical equipment, especially if the employer expects mobile (i.e., which may include after-hours and private) communication from and with its employees. For example in Australia, the Workplace Surveillance Act of 2005 makes it illegal to monitor employee e-mail activity without prior notice to the employee unless the employer has a strong suspicion of criminal activity. Such laws add a new wrinkle to issuing a global litigation hold or even implementing an effective document retention and destruction policy. In addition, the efficient and effective use of e-Discovery technologies will require early consultation with clients and vendors, especially in countries not using the Latin alphabet, and will likely require a vendor with Unicode deduplication and "near duplicate" comparison capabilities.

And finally, in our zeal to represent our clients, it's often the most basic things that we forget - the international practitioner should also take into consideration local customs and holidays. It's not just efficient, best practices for managing a case, it's also simply the right thing to do.

Conclusion

International Electronic Discovery remains an exciting and constantly evolving aspect of product liability litigation worldwide that the international practitioner must take into consideration. Often times, it will be necessary to cooperate with or even engage local counsel to assist in overcoming the hurdles and understanding the nuances incumbent to International Electronic Discovery. Though courts and other entities continue to develop concrete rules, case law and guidance on e-Discovery practice, much of the law in this area remains to be developed. As such, clients and counsel have to actively remain abreast of this ever-changing aspect of the modern, high-tech practice of law.

Endnotes

1 Full legal citations were omitted in this Chapter for the sake of brevity. All law as stated herein is believed by the author to be current as of April 1, 2009.

2 For details regarding the e-Discovery amendments to the US FRCP, please refer to the 2008 "International e-Discovery" chapter in The International Comparative Legal Guide to: Product Liability 2007, published by Global Legal Group Ltd, London.

3 The District of Alaska, Eastern and Western Districts of Arkansas, the District of Arizona, the Northern District of California, the District of Colorado, the District of Connecticut, the District of Delaware, the Middle and Southern Districts of Florida, the Southern District of Georgia, the Central and Northern Districts of Illinois, the Northern and Southern Districts of Indiana, the Northern and Southern Districts of Iowa, the District of Kansas, the District of Maryland, the District of Massachusetts, the Eastern District of Missouri, the District of Nebraska, the District of New Hampshire, the District of New Jersey, the Southern and Eastern Districts of New York, the Western District of North Carolina, the Northern and Southern Districts of Ohio, the Eastern, Middle and Western Districts of Pennsylvania, the Eastern, Middle and Western Districts of Tennessee, the Eastern, Northern and Southern Districts of Texas, the District of Utah, the District of Vermont, the Southern District of West Virginia, and the District of Wyoming all have enacted local rules and/or guidelines dealing with e-Discovery. The Court of Appeals for the Ninth Circuit is also considering e-Discovery local rules.

4 *See, e.g., Mon River Towing, Inc. v. Industry Terminal and Salvage Co.*, 2008 WL 2412946 (W.D.Pa. June 10, 2008) (finding that FRCP Rule 34 does not require the creation of documents for production).

5 In order to address data privacy issues, the US and EU agreed to a self-certification process by which companies handling ESI from the EU agree to abide by certain principles for handling personal information and data, including ESI. Organisations that participate in the safe harbour must comply with the its requirements and publicly declare in writing that they do so. The organisation must state in its published privacy policy statement that it adheres to the safe harbour and its requirements, including its notice, choice, access and enforcement provisions. The US Department of Commerce maintains a list of all organisations that file self-certification letters and makes both the list and the self-certification letters publicly available. Many e-discovery vendors have self-certified under the safe harbour regime.

6 In fact, readily-available on-line products such as Metadata ScrubberTM, Doc ScrubberTM, Metadata AssistantTM, and Evidence EliminatorTM can be purchased and used to "cleanse" electronic documents of metadata. While the scrubbing of metadata is generally permissible outside of the context of a specific litigation, the scrubbing of metadata can constitute spoliation if the metadata is the subject of a litigation hold or otherwise discoverable in litigation. *See, e.g., Arista Records, LLC v. Tschirhart*, 2006 WL 2728927 (W.D. Tex. Aug. 23, 2006). *See also Elec. Funds Solutions v. Murphy*, 134 Cal. App. 4th 1161 (2005) (finding default judgment proper after a showing that defendants ran data scrubbing software during discovery). For a complete analysis of meta data, *see Aguilar v. Immigration & Customs Enforcement Div. of U.S. Dep't of Homeland Sec.*, 2008 WL 5062700 (S.D.N.Y. Nov. 21, 2008) (discussing the rules, guidelines and case law on metadata and recognizing of "a clear pattern" that courts only order production of metadata where the producing party had not yet produced the documents in any form).

7 *Cf. PSEG Power New York, Inc. v. Alberici Constructors, Inc.*, 2007 WL 2687670 (N.D.N.Y. Sep. 7, 2007), *infra* at Endnote 11. In January 2007, the Magistrate judge explained his

reasoning in not awarding sanctions against the defendant in the Williams case. *See Williams v. Sprint/United Mgmt. Co.*, 2007 WL 214320 (D. Kan. Jan. 23, 2007).

8 *See Autotech Techs. Ltd. v. Automationdirect.com, Inc.*, 2008 WL 902957 (N.D. Ill. Apr. 2, 2008) (holding that the plaintiff need not produce a word processing document in its native format with the metadata intact, where the plaintiff had produced the document as a PDF and in hard copy and the face of the document itself included a "Document Modification History" and where the defendant neither specified the form of production nor did it request the production of metadata at the time of its initial requests); *D'Onofrio v. SFX Sports Group, Inc.*, 247 F.R.D. 43, 48 (D.D.C.2008) (holding that metadata need not be produced since the requesting party failed to specifically mention metadata in its original requests); *Kentucky Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc.*, 2006 US Dist. LEXIS 92028, at *21-23 (Dec. 18, 2006) (ruling that Rule 34(b) does not require the production of metadata absent a showing of a particularised need, and the failure to raise the issue prior to production waives the opportunity to object: "[T]he issue of whether metadata is relevant or should be produced is one which ordinarily should be addressed by the parties in a Rule 26(f) conference."). *See also Wyeth v. Impax Lab.*, 2006 WL 3091331, at *2 (D. Del. Oct. 26, 2006) (ruling that production in native format was not required in the absence of foreseeable or necessary requirement for accessing metadata). But see *Superior Prod. P'ship v. Gordon Auto Body Parts Co., Ltd.*, 2008 WL 5111184 (S.D. Ohio Dec. 2, 2008) (ordering production in native format after finding such a preference in US FRCP 26 and a benefit due to the ease at which electronic documents can be stored and manipulated during the litigation process).

9 *Richmark Corp. v. Timber Falling Consultants*, 959 F.2d 1468, 1474 (9th Cir.1992) (citations and internal quotations omitted). *See generally Societe Nationale Industrielle Aerospatiale v. U.S. Dist. Ct for the S. Dist. of Iowa*, 482 U.S. 522(1987).

10 *See, e.g., PSEG Power New York, Inc. v. Alberici Constructors, Inc.*, 2007 WL 2687670 (N.D.N.Y. Sep. 7, 2007) (holding the plaintiff and counsel responsible for a software glitch that led to the "divorce" of e-mails and attachments in a production of ESI and ordering the re-production of the documents with the e-mails and attachments "married" - at an estimated cost of between US$37,500 and US$206,000).

11 *See, e.g., PSEG Power New York, Inc. v. Alberici Constructors, Inc.*, 2007 WL 2687670 (N.D.N.Y. Sep. 7, 2007) (holding the plaintiff and counsel responsible for a software glitch that led to the "divorce" of e-mails and attachments in a production of ESI and ordering the re-production of the documents with the e-mails and attachments "married" - at an estimated cost of between US$37,500 and US$206,000).

12 Australian Federal Court Rules O1, r4.

13 The factors are: (1) the specificity of the discovery requests; (2) the likelihood of discovering critical information; (3) the availability of such information from other sources; (4) the purpose for which the responding party maintains the requested data; (5) the relative benefit to the parties of obtaining the information; (6) the total cost associated with the production; (7) the relative ability of each party to control costs and its incentive to do so; and (8) the resources available to each party. Each factor was weighted, with factors 1-3 carrying more influence than the other factors, even though all factors were deemed important.

14 In formulating this factor, the court followed *McPeek v. Ashcroft*, 202 F.R.D. 31 (D.D.C. 2001), where the court ordered the producing party to restore the electronic data at issue, to "carefully document the time and money spent," in doing so, to search the restored data for responsive documents, and to "file a comprehensive, sworn certification of the time and money spent and the results of the search."

15 The factors are, in order of weight given: (1) the extent to which the request is specifically tailored to discover relevant information; (2) the availability of such information from other sources; (3) the total cost of production, compared to the amount in controversy; (4) the total cost of production, compared to the resources available to each party; (5) the relative ability of each party to control costs and its incentive to do so; (6) the importance of the issues at stake in the litigation; and (7) the relative benefits to the parties of obtaining the information.

16 The Advisory Committee factors are: (1) the specificity of the discovery request; (2) the quantity of information available from other and more easily accessed sources; (3) the failure to produce relevant information that seems likely to have existed but is no longer available on more easily accessed sources; (4) the likelihood of finding relevant responsive information that cannot be obtained from other, more easily accessed sources; (5) predictions as to the importance and usefulness of the further information; (6) the importance of the issues at stake in the litigation; and (7) the parties' resources.

17 Likewise, in *Lytle v. Ford Motor Co.*, 2003 WL 23855089 (Ind. Cir. Ct. Apr. 19, 2003) (unpublished), the court denied a plaintiff's request "to go into Ford's databases and look for any relevant information that might be there," finding the request for production to be overbroad and unduly burdensome. *See also Integrated Serv. Solutions, Inc. v. Rodman*, 2008 WL 4791654 (E.D.Pa. Nov. 3, 2008) (not requiring a non-party to allow the plaintiff, a competitor, to "thumb through an electronic file drawer" to double-check document review for relevance). But *see Bray&Gillespie Mgmt. LLC v. Lexington Ins. Co.*, 2009 WL 546429 (M.D. Fla. Mar. 4, 2009) (allowing access to the plaintiffs' database after numerous e-Discovery violations); *GTFM, Inc. v. Wal-Mart*, 2000 WL 1693615 (S.D.N.Y. Nov. 09, 2000) (the defendant's failure to produce data or provide and accurate description of the computer system led to an order allowing the plaintiff's lawyer and expert to examine the defendant's computer system to look for the requested information at the defendant's expense).

18 *See S. New Eng. Tel. Co. v. Global NAPs, Inc.*, 2008 WL 2568567 (D.Conn. June 23, 2008) (issuing a default judgment in favour of the plaintiffs, resulting in an award of US$ 5,247,781.45, plus costs and fees of ca. US$ 645,760 due to the defendants' "willful disregard for the process of discovery," including the willful violation of a court order to produce general ledgers, the use of wiping software to intentionally destroy evidence, lying to the court about the ability to obtain documents from third parties, providing misleading answers to discovery requests, and given the defendants' long history of violating discovery orders); *Grange Mut. Cas. Co. v. Mack*, 2009 WL 744723 (6th Cir. Mar. 17, 2008) (affirming the trial court's granting of a default judgment in favour of the plaintiffs for damages plus attorney's fees and costs where the defendant purposely delayed discovery, ignored court deadlines and orders, and instructed employees to ignore the same). For prior sanctions cases, please refer to the 2006-2008 "International Electronic Discovery" chapter in The International Comparative Legal Guide to: Product Liability 2006, 2007 & 2008, respectively, published by Global Legal Group Ltd, London.

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Product Liability and Product Recall Insurance in the UK- Practical Issues

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Introduction

The potential liability and cost consequences associated with placing unsafe products on the market has made product liability and product recall insurance a commercial necessity for many manufacturers, distributors and retailers operating in the UK. Before we consider the scope and nature of product liability and recall insurance, it may be instructive to explain the tenor of the underlying UK regulatory and legal position.

Regulatory position

The main product safety statutory instrument in the UK is the General Products Safety Regulations 2005 (SI 2005/1803) ("the Regulations") which entered into force on 1 October 2005. The Regulations implement the EC General Product Safety Directive (2001/95/EC) and complement the existing product specific regulations which continue to apply where there is a gap in the regulatory framework.

The range of products covered by the ambit of the Regulations is fairly wide. "Product" is defined in broad terms and covers items which are sold or provided freely to consumers, as well as those goods which are not intended for consumers but are likely to be used by them. It is irrelevant whether or not the product is new, as used or reconditioned items are also covered under the scope of the Regulations.

The Regulations set down three main obligations on producers and distributers of products:

- to ensure that products are identifiable and traceable;
- to monitor the safety of products; and
- to take appropriate and speedy action (including instigating a recall) in circumstances where an unsafe product is placed on the market.

Plainly, the concept of product safety is integral to the Regulations and there is a general obligation (referred to as the "general safety requirement") which prohibits producers or distributors from placing or supplying (or offering or agreeing to offer) a product on the market, or exposing or possessing a product for placing on the market which is unsafe. Placing a product on the market, making it available or supplying can happen in many ways, for example:

- selling, leasing, hiring it out or lending it;
- entering into a hire purchase or other credit agreement for it;
- exchanging it for any consideration other than money;
- giving it as a prize or otherwise making a gift; and
- providing it in the course of the delivery of a service.

The Regulations provide a list of the factors which should be considered in determining whether or not a product is safe. They include the characteristics of the product (including its composition, packaging, instructions for assembly), maintenance, its effect on other products, presentation of the product (such as labelling, instructions for use or warnings) and any consumers (e.g. children and the elderly) who are particularly at risk when using it. The European Commission has also produced guidance which echoes the factors contained in the Regulations. This includes the severity and probability of the potential health/safety damage and factors relevant to the risk level (e.g. the type of user, adequacy of warnings and the obviousness of the hazard).

Producers and distributors who contravene the general safety requirement can be served with a notice by an enforcement authority. This notice can require them to suspend or halt the offending action, to withdraw or recall the product in question, label the product or otherwise warn consumers who are at risk of the dangers posed by it. Contravention of the regime can also lead to criminal liability in the form of a custodial sentence and/or a fine.

Legal position

A product manufacturer or retailer may also be exposed to other forms of liability under English law, namely, (1) liability for breach of contract, (2) liability in tort, and (3) statutory liability pursuant to the Consumer Protection Act 1987.

Contractual liability may arise in a number of ways. A contract for sale or supply may include express terms as to the nature or character of the product (i.e in the form of a warranty or a guarantee). Terms will also be implied into contracts for the sale of products by the Sale of Goods Act 1979 (as amended) and the Supply of Goods and Services Act 1982 (as amended). These statutes imply terms as to the description, quality and fitness for a particular purpose of products and arise in all contracts of sale/supply. Strict liability is imposed and the buyer does not need to demonstrate fault on the part of the seller, merely that the products were ill-fitting with their description, of unsatisfactory quality or otherwise unfit for their purpose. Contractual liability may also attach to pre-contractual statements which refer to the qualities of the product. Such statements can be incorporated into contracts as terms or, alternatively, form the basis of a separate contract between the buyer and seller or the buyer and a third party. For breach of contract claims the buyer will be able to claim damages. In some cases a buyer will be able to reject the goods and terminate the contract.

The tortious liability upon a manufacturer under English law was established in the landmark decision of *Donogue v. Stevenson*

[1932] AC 562. That case imposed a duty of care on manufacturers of defective products to a class of persons to whom damage (personal injury or property damage) is foreseeable if that product is defective. The standard is tested objectively and the manufacturer will not be at fault if a particular danger could not have been anticipated.

The UK, along with the rest of the EU, also imposes a strict liability regime on certain parties involved in the manufacture and supply chain in respect of consumers who have suffered damage as a result of a defective product. The Consumer Protection Act 1987 (which transposes the Product Liability Directive (85/374/EEC and 1999/34/EC into UK law) imposes strict liability on producers (including persons holding themselves out as producers by selling private label products under their own brand, and importers into the EU) for harm caused by defective products. This allows consumers who are injured or suffer damage as result of defective products to sue for compensation without having to prove that the producer was negligent, provided that it can be demonstrated that the product was defective and the defect in the product caused the damage. A person can sue for death, personal injury or damage to property. The legislation only applies to consumer products and products used at a place of work. There are also a number of available defences including where the state of the scientific and technical knowledge at the time was such that the producer could not have been expected to discover the defect and the defect arose because of the way a component part was used in the final product.

Product Liability Insurance

Policy forms

There is not a standard form of product liability insurance policy wording in the UK, unlike in the US which has the Combined General Liability Policy wording. In spite of the absence of a uniform wording, the form of many product liability policy wordings is similar and is regularly combined with public liability insurance.

Proposal form

When an insured decides to take out a product liability insurance policy for a product which it manufactures or distributes, it will be required to complete a proposal form. This form provides key information to the insurer about the insured's business, the type of products it sells/distributes and the countries where the products are sold/distributed. An insured will also be required to disclose to the insurer any other material facts which are relevant to the products being insured. This may include changes to the product or any other factors which are relevant to the type of risks associated with it. These obligations are imposed by insurers as a matter of course but also form part of the general duty of good faith imposed by law in respect of contracts of insurance (which are based on the principle of utmost good faith). The insured must also refrain from making any untrue statements.

If an insured fails to make full and fair disclosure on the proposal form, it exposes itself to the risk that the insurer will seek to avoid policy coverage on the grounds of non-disclosure if he can show that the non-disclosure induced the making of the contract. Some policies contain innocent non-disclosure clauses which can operate to limit the insurer's right to avoid for non-disclosure.

The scope of cover

The basic indemnity provided by product liability insurance policies is for protection of the insured against legal liability for or in respect of bodily injury, illness or disease or physical damage to property not in the custody or control of the insured which is caused by the product. Damage to the product itself is not, therefore, normally covered.

Generally, the "product" will not normally be defined as a specific item (or items) and the definition will normally include any goods or products after they have ceased to be in the insured's possession or control, including packaging materials and containers.

The use of the words "for" or "in respect of" is of significance and has a limiting effect on the extent of the insurance cover carrying with it the requirement that the liability relate to the loss or damage. It is not sufficient that the liability should simply have had some connection with the loss or damage (*Rodan v. Commercial Union* [1999] Lloyds Rep IR 6499).

Trigger and notification

Product liability insurance policies are often drafted on an occurrence basis (i.e. the damage must occur in the period of cover) but can also be written on a claims made basis, meaning cover will apply to all claims made against the insured by a third party during the policy period.

Insureds will need to pay close attention to the notification provisions in the policy and consider these carefully whenever a product safety situation arises. The notification requirements under a product liability policy written on a claims made basis will invariably include provisions relating to notification of claims and of circumstances which may or are likely to give rise to a claim. The requirement for notification of circumstances will usually also include a 'deeming' provision under which claims which arise after the expiry of the policy period but out of circumstances previously notified to insurers are deemed to attach to the policy under which notification of circumstances was given.

Insureds should take care to ensure that notifications are made strictly in accordance with the notification provisions in the policy and are always carried out in a timely manner. The importance of avoiding unnecessary delay was illustrated in the case of *HLB Kidsons (a firm) v. Lloyd's Underwriters subscribing to Lloyd's Policy Number 621/PK1D00101 and Others* [2008] EWCA Civ 1206 in which the Court of Appeal confirmed that failure to make a timely notification of circumstances could mean that claims arising out of those circumstances after expiry of the policy would not be covered.

External damage

A product liability policy is principally concerned with damage caused to persons and other property by a defective product that is supplied by the insured. In this regard the policy reflects the law of tort by requiring some form of external physical loss or damage.

In English law, "damage" usually refers to a changed physical state to external property and the relevant alteration must be harmful in the commercial context. A defect or deterioration in the commodity or product itself is not "damage". Some product liability policies may, however, contain express provision that damage caused by a defective part to other part or parts of a larger item which is not defective or inadequate will be covered.

The application of the requirement for physical damage can give rise to difficulties where the product supplied by the insured is to be

installed in a larger item for use or onward sale by a third party. In these cases there will be a distinction according to whether or not the product caused damage to the larger item. The test is whether there has been any physical change to the larger item as a result of the incorporation or inclusion of the defective product. If the defective product causes harm to the larger product, such that its value is diminished, physical damage will have occurred. In *Tioxide Europe Ltd v. CGU International Insurance Plc*, a defective whitening pigment used in the manufacture of PVC doors which had caused the PVC to turn pink was found to have caused physical damage to the PVC for the purposes of the insurance cover.

The principle will not, however, apply where a product is installed or fitted alongside the property of a third party where no physical harm is caused and the harmful effects are confined to the product itself. In *Pilkington United Kingdom Ltd and CGU Insurance Plc* [2005] 1ALL ER (COMM), 283 glass panels supplied by Pilkington were installed in the roof and vertical panelling of the Eurostar Terminal at Waterloo in London. A small number of the panels were defective and fractured on installation, although no physical damage was caused to the building. The insurance policy excluded cover for products which were defective at the time when installed and, as the Court held that the only damage was to the glass panels themselves (and not to third party property), the claim failed.

Pure economic loss

As product liability policies are principally directed to damage caused to persons and other property by a defective product supplied by the insured, the English courts tend to construe such contracts in accordance with the law of tort. Accordingly, product liability cover will not normally extend to liability for pure economic financial losses which are not consequential upon the damage.

This is exemplified by *Horbury Building Systems Ltd v. Hampden Insurance NV* [2004] 2 CLC 543 where the insurance claim related to the costs associated with the collapse of a suspended ceiling installed in a cinema auditorium. The cause of the collapse was initially unknown and the whole cinema complex was closed for several weeks although it was accepted by the parties that the damage caused by the collapsed ceiling had not physically prevented the use of the rest of the complex. The court held that the insurer was not liable to indemnify the insured subcontractor in respect of loss of profit arising from the closure of the entire cinema complex; the policy only covered liability for the physical consequences of the damage in the auditorium where the ceiling collapsed and the economic losses caused by that physical damage. The policy did not extend to matters such as the cost of the investigations or precautions taken to avoid physical damage.

Some policies contain financial loss extensions which cover liability for third party financial losses but such coverage tends to be limited. These extensions can be combined with product guarantee insurance which provides protection against an insured's legal liability for claims arising out of the failure of its product to fulfil its intended purpose or function (discussed further below).

Exclusions

There are a number of exclusions generally included in product liability insurance policy wordings which can operate to exclude liability otherwise falling within the scope of the cover. The most common exclusions include:

- The costs of recalling, replacing or repairing the product itself. Plainly, these costs fall outside of the general ambit of a product liability policy which is principally concerned with liability for damage caused to third parties and/or third party property. Insureds can protect themselves against the costs of a product recall by obtaining product recall insurance (discussed below).
- Liabilities which arise from the failure of an insured product to perform its function (so-called "product efficacy" exclusions). Product functionality is only relevant where the failure of product function may give rise to liability. The functionality failure of certain products (such as clothing, electrical goods or toys) will not necessarily cause liability for loss or damage. However, failure of other products to perform effectively (such as medicines or fire extinguishers) will almost certainly give rise to loss and/or damage.
- Contractual obligations assumed by the insured. This exclusion accords with the fact that product liability coverage is designed to cover the insured's liability for injury to persons or damage to physical property. It is not ordinarily intended to cover those types of losses which might be recoverable solely in a claim for breach of contract but not in tort (provided that there is injury or damage it does not matter that the claim is one for breach of contract). It is possible to obtain contractual liability extensions but care must be taken with the way these are drafted to ensure that they do not simply cover contractual liability which is concurrent with that in tort (which is normally covered).
- The insured's deliberate acts or omissions which can reasonably be expected to cause harm, loss or damage which is the subject of the claim. Where an insured fails to carry out adequate due diligence in respect of a product or reacts poorly in the wake of a product liability issue, insurers may seek to deny cover on this basis.

Care should be taken to ensure that the wording of the policy and the exclusions reflect the nature of the insured's business, particularly where there may be technical reasons for a product's failure/defect. If the policy terms are inappropriate or poorly drafted, there may be grounds for dispute. In *John Reilly v. National Insurance & Guarantee Corporation Ltd* [2008] EWHC 722 (Comm), the Court was unable to determine whether a product efficacy exclusion applied as there was a lack of clarity about how the clause applied to insured's products. As a result, it was ultimately unable to determine policy coverage.

Product Recall Insurance

This form of insurance used to be something of a speciality but the insurance industry is now providing a wider array of coverage options in light of a perceived increase in demand. There have been 18 product recalls in the UK in 2009 alone (as at 30 March 2009), and there has been an annual rise on previous year recall levels which is expected to continue. Several factors are attributed with the increased demand for product recall insurance, including the introduction of enhanced regulatory obligations, the increased sophistication and regularity of product testing and continued importance of reputation and brand protection.

The costs of a product recall can be substantial, particularly where the products are distributed internationally and can include costs in the supply chain (such as manufacturing plant cleaning costs and material write offs), the handling costs of the recall (which can include customer returns, call centre costs, trade claims and costs relating to the storage and disposal of the recalled products, advisory fees), and loss of profit (to include damage to reputation and goodwill).

In the current climate many manufacturers and distributors now seek to protect themselves against the consequences of an expensive product recall through insurance cover.

Scope of the cover

Product recall policies (which are often arranged as part of or an extension to products liability insurance) generally cover the following types of risk:

- The insured's legal liability for:
  - the costs of removing, recovering, repairing or replacing a product which is defective or dysfunctional; and/or
  - financial losses incurred by customers or third parties which arise as a result of product impairment (i.e. a product failing to perform the function for which it was manufactured, designed or sold).
- The costs and expenses incurred by the insured which are associated with the cost of recalling its own products (which may also include business interruption losses).

These policies may also extend to providing cover for the costs and expenses of a product recall which are caused by malicious contamination of a product and extortion.

Event triggering the recall cover

The event triggering the product recall insurance cover will normally differ according to the form of indemnity. Indemnities for legal liability tend to be written on a claims made basis requiring notification of a claim (or circumstances which may or are likely to give rise to a claim) during the policy period. By contrast, an insured will normally be covered for the costs and expenses of a recall, provided the decision to recall the product was taken by the insured and notified to insurers during the period of insurance.

Where the cover is for the costs and expenses incurred by the insured in respect of a product recall, the policy will often stipulate that the recall must be necessary in order to prevent or mitigate against the prospects of legal liability arising from the use or consumption of the product.

Some product recall insurance policies will contain more stringent limitations which specify that there must be an actual or imminent threat of danger, injury or harm associated with the product's use. Plainly, as the regulatory regime in the UK encourages pro-active steps (including recall) when an unsafe product may have been placed on the market, insureds may find that they are potentially exposed to uninsured losses where a precautionary recall was carried out in the absence of actual or imminent danger of injury or harm (if such was required by their policy).

Exclusions

Product recall policies will also contain a number of exclusions, the most common of which include the following:

- Where a product recall is necessitated by a product defect which has arisen solely due to exposure to weather or the deterioration or decomposition of a product (e.g. fresh food items).
- Prototypical or experimental products which, by their very nature, are expected to experience problems in the nascent stages of development are also generally excluded.
- Product recalls which are forced upon the insured by the government or a public authority in circumstances where the insured would not have conducted the recall but for the said intervention. The rationale for this is to protect insurers against situations where a government or public authority forces compulsory recalls upon manufacturers or distributors.

Practical considerations

Insureds should establish and shock-test the product recall planning procedures which are in place and ensure that they accord with the requirements of any product insurance held (particularly in terms of notifications to insurers). Such requirements may include:

- Notifying insurers as soon as it becomes apparent that expenditure will need to be incurred in respect of a product recall.
- Maintaining detailed records of any expenses incurred and actions taken in a product recall situation, including steps taken to mitigate or minimise the costs involved.
- Submitting proof that such costs were reasonably and properly incurred.

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Albania

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

Product liability in Albania is mostly regulated by the Albanian Civil Code ("ACC"). Article 628 of the ACC provides that "*producers*" are liable of all damages (to persons or property) resulting from defective products (with the exclusion of agricultural products and products resulting from hunting). However, Article 628 provides for some exemption from liability circumstances, i.e. if the producer did not put the product on the market, the defect that caused the damage did not exist at the time the product was put in the market, or the product that caused the damage was in compliance with the security requirements as defined by the public authorities.

Given the above and taking into account the provisions of Article 629 of the ACC according to which the producers' liability is decreased when a fault of the damaged person has contributed to the damage, we can conclude that product liability in Albania is fault based.

Product liability is non-contractual. As a matter of fact, it is the producer that is liable for damages caused by its products and the contractual relation between the damaged person and the producer is not a condition to the liability.

We do confirm that, as per Law no. 9902, dated April 17, 2008 "*On consumers' protection*" ("Law 9902"), the breach of the statutory obligations provided for by Law no. 9902 shall constitute an administrative contravention or even a criminal offence.

1.2 Does the state operate any schemes of compensation for particular products?

The state does not operate particular schemes of compensation for particular products.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Under Article 631 of the ACC, those considered as a "*producer*" are the manufacturer of a final product, raw material or a part of the final product, as well as any person that presents himself as a producer by putting his name, trademark or other distinctive sign on the product.

Additionally, any person who imports products for reselling, leasing or distributing as a business activity are considered to be a producer. Further, Article 633 of the ACC provides that when the producer cannot be identified, any supplier of the product shall be considered as producer, unless such supplier, within a reasonable term, indicates the producer to the damaged person.

Moreover, under Law no. 9779, dated July 16, 2007 "*For general security, essential requirements and evaluation of conformity of non consumable goods*" ("Law 9779"), the producer is (i) the manufacturer of a final good established in Albania, (ii) the representative of the manufacturer in Albania, in case the manufacturer is established outside the territory of the Albanian Republic, (iii) the importer of the product in Albania, in case the producer is established outside the territory of the Albanian Republic and does not have a representative in Albania, and (iv) any other person involved in the products' distribution chain as long as such person can have an effect on the product's security.

Finally, under Article 22 of Law no. 9863, dated January 28, 2008 "*On food*" ("Law 9863"), all food sector operators intervening in the food production, treatment and distribution phases are considered responsible of any harm caused to the health of individuals from unsafe food consumption.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Under Law no. 9863, the obligation to recall products falls on any food sector operator who considers the food that he has imported, produced, treated or commercialised does not comply with food safety requirements or harms individuals' health. Such decision must be communicated to the National Food Agency and the Ministry of Agriculture, Food and Protection of Consumers. The breach of such obligation shall constitute an administrative contravention punishable with a fine from ALL 500,000 to ALL 1,000,000.

Under Law no. 9779, a product may be recalled by the Technical Inspectorate in case there is evidence that such product may jeopardise life, safety, health, environment and/or other common interests.

1.5 Do criminal sanctions apply to the supply of defective products?

As per Article 288 of the Albanian Criminal Code, producing,

importing, storing or selling foods, drinks and other substances, or medicine which are dangerous or harmful to life or health, as well as introducing chemicals, materials or additive substances into the production and processing of food and drinks, when those acts have led to death or serious harm to the health of an individual, is punishable by up to ten years' imprisonment. When the act has caused death or serious harm to the health of more than one person, it is punishable by no less than five years' imprisonment.

Besides, Article 288/a of the Albanian Criminal Code provides that illegal production of industrial and food items and goods constitutes criminal contravention and is punished by a fine or up to two years' imprisonment. The same offense, if committed in collusion with others, or repeatedly, or if it has caused serious consequences, is punished by three to ten years' imprisonment.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

Pursuant to Article 12 of the Albanian Civil Procedure Code, the party which claims a right has the burden to prove, in conformity with the law, the facts on which it supports its claim.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

According to Article 609 of the ACC, the damage must be an immediate and direct consequence of a person's faulty actions or omissions. If a person who has the legal obligation to avoid a certain event does not taken action to avoid it, he is liable for the damages caused as a consequence of it.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

There are no specific provisions under the Albanian legislation regulating the above scenario. According to Article 6 of Law no. 9902, any producer is responsible for defect/s of goods produced by him. According to Article 633 of the ACC, in the case that several persons are responsible for the damage caused (always concerning responsibility of products), each of them is responsible for the totality of the damage. Hence, according to Article 626 of the ACC: "*When damage is caused by many persons together, they are jointly and severally liable to the damaged person.*"

On the other hand, Article 627 of the ACC provides that the person who has compensated the damage has the right to require from each of the other persons responsible for the damage his share of the damage, proportionally with the measure of the responsibility of each person and of the consequences deriving from it.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Under Law no. 9902, the obligation of the producer to inform the consumers with regard to a product is expressly provided. Information on the use and specifics of the product must be clear.

On the other hand, Article 6 of Law no. 9779 provides that the producer shall give to the consumer all respective data and information in order to provide him with the possibility to evaluate the possible eventual risks that the product may cause. Hereupon, the consumer shall be aware of the danger the product may cause/hold. If the above information/warning is absent, the producer is liable and he might be subject to a fine amounting to ALL 6,000,000.

According to Article 631 of the ACC a producer means any person who imports a product for purposes of sale, lease, or another form of distribution, pursuant to his trade activity. The persons acting in any of the above situations are equally liable as the producer, including with regards to the duty of information. Moreover, according to Article 632 of the ACC, when the producer of a certain product cannot be identified, any supplier of such products will be considered a producer, except in situations when the supplier notifies the damaged person of the producer's identity or the identity of the person who has supplied the product, within a reasonable time limit.

Under the Albanian legislation, the responsibility of the producer is separate from the responsibility of any "learned intermediary" performing commercial actions with regard to the same product. Therefore, the responsibility of a supplier under a duty of information obligation does not discharge the producer from the same obligation and responsibility.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The manufacturer has several defences at his disposal. According to Article 628 of the ACC, the manufacturer is not liable in the following cases: a) the producer has not supplied the product; b) the fault/defect was not present at the time when the product has been supplied; c) the product has not been manufactured for sale or any other form of distribution, with the intent of generating profits for the manufacturer, nor has it been manufactured or supplied in the framework of company or professional activity; d) the defect is a result of compliance with regulations imposed by public authorities; e) the defect was not discoverable given the state of scientific and technical knowledge at the time of supply; or f) it concerns raw materials or components of another product and the defect manifests during the formation of that product, or as a result of the incorrect instructions from the manufacturer of that product.

The liability of the manufacturer can be attenuated or totally removed when the claimant or persons under his responsibility are also liable for the same damages.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

If the fault/defect was not discoverable, given the state of scientific and technical knowledge at the time of supply, than the manufacturer is not liable for damages. In this case, the burden of proof lies with the manufacturer.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

If the fault/defect arises as a direct result of compliance with regulations set up by public authorities, the manufacturer can be excluded from the responsibility.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

We do confirm that claimants can re-litigate issues of fault or defect of a product in separate proceedings in case the claims are brought by different claimants.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

Third party liability for the fault/defect of a product does not effect liability of the manufacturer. However, the manufacturer is entitled from the procedural point of view and in different proceedings seek for partial or total indemnification from any third party/ies.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

We do confirm that the defendants are entitled to allege the above. In case the defendant proves that the damages are due to the defects of the product and the faulty actions of the claimant, the liability of the defendant can be partially or totally annulled (Article 629 of the ACC).

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

Under the Albanian Civil Procedure Code, the court proceedings are conducted by a judge or a college of judges depending on the value of the claim (Article 35 of the Albanian Civil Procedure code).

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

According to Article 224/a of the Albanian Civil Procedure Code, the court is empowered to appoint one or more experts in case their expertise is required for purposes of clarifying scientific, technical or art related facts presented by the parties in the judicial process. However, the role of these experts is solely advisory and is not obligatory to the court.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

According to Law no. 9902, the consumer associations can bring actions against the traders for the protection of their rights. Such claims are not commonly brought in Albania since there is no developed and informed consumer conscience.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

We do confirm that, as per Article 54 dh) of Law no. 9902, the consumer associations are entitled to bring legal actions against the merchants for purposes of protecting the interests of the consumers.

4.5 How long does it normally take to get to trial?

Under the Albanian legislation the normal period to appoint a judge is four days from the day of depositing the claim with the competent court while the first court hearing session is set approximately one month from that date.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The court may decide to suspend the present court proceedings in cases when the present court proceedings cannot be solved before another criminal, civil or administrative issue has been solved. The issues on which the court is entitled to rule can relate to matters of law and fact.

4.7 What appeal options are available?

Under the Albanian Code of Civil Procedure a first instance court decision may be appealed by each party to the Appeal Court. Upon such a party's request, the Appeal Court may consider both the merits of the substantive case and the compliance with procedural law requirements. The statutory limitation period for lodging an appeal is 15 days from the date of the proclamation of the decision as per Article 443 of the Albanian Civil Procedural Code. An appeal against the decision of the first instance court must contain a number of elements in accordance with Article 454 of the Civil

Procedural Code and specifically: *a) the parties involved; b) the decision against which the appeal is being made; c) the reasons for which an appeal is being made; and d) what is being sought in the appeal.*

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The court may appoint experts to assist it in considering technical issues while the parties are also entitled to present expert evidence in case they consider it necessary to support their case (Article 225 of the Albanian civil procedure code).

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

There are no pre-trial factual or expert witness requirements under the Albanian legislation.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

Under Article 204 of the Albanian legislation, the claimant, before presenting the claim, can make a request for an interlocutory injunction to the court in cases when there are reasonable conditions to believe that the execution of the decision at the end of the process will be difficult or impossible. In order to obtain such the interlocutory injunction, the claimant must provide documentary evidence of his title and of the infringement performed by the counterpart. In case the action is found grounded and upon the claimant's request, the competent judiciary authority may decide, at its discretion, to adopt an interlocutory injunction. Hence, the competent judiciary authority would require the accomplishment of two conditions a) provision of due written evidence and b) the claimant should give a guarantee for any possible damages that the defendant might suffer in case of the execution of interlocutory injunction.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Under the Albanian legislation the parties are free to pursue with the alternative methods or extra judiciary dispute resolution such as the mediation (Article 973 and following of the ACC) and arbitration (Article 400 and following of the Albanian Civil Procedure Code).

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Under Article 634 of the ACC, the right to issue court proceedings regarding the product liability against the producer are prescribed within a period of three years from the date in which the person suffering the damage has had or should have had information on the damage, the defects and the identity of the producer.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

The principle as per question 5.1 above does not depend on the nature of the liability or the condition of the claimant. However, in case of claims of juveniles and other persons having no legal capacity to act, the above term is suspended until six months after the appointment of a legal representative to these persons or after they obtain legal capacity to act (Article 129 of the ACC). The Albanian courts do not have discretion to disapply the time limits provided by the statutory provisions.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

There are no provisions regulating the nexus between the subjective actions of the producer (such as acts of concealment and fraud) and the prescription period since the latter is related to the moment in which the injured part has had or should have had information on damage, defects and the identity of the producer.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

In principle, the Albanian courts are entitled to award to claimants, pursuant to a successful judicial process, either monetary compensation and/or injunctive relief.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Under the Albanian legislation the injured party can recover monetary damages constituted by the damage suffered and profit lost. The damage suffered can be represented by the damages to the product itself, damage to health or damage to property (Article 640 and following of the ACC).

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

The above circumstance is not regulated under the Albanian legislation.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

There are no punitive damages awarded under the Albanian legislation.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There are no maximum limits on the damages recoverable from one manufacturer.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

There are no special rules with regard to group/class actions or otherwise. The general principles for the settlement of claims proceedings apply.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

There are no specific provisions under the Albanian legislation regulating the above situation.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Under the Albanian legislation, the successful party is entitled to recover court fees and attorney's fees afforded by the claimant, to the measure the claim is accepted by the court (Article 106 of Albanian Procedure Code).

7.2 Is public funding e.g. legal aid, available?

There are a series of non profit organisations providing legal assistance to parties in economic difficulties, but there is no state budget funding for the provision of legal assistance in product liability related cases. However, under the Law no. 9902 it is provided that the Ministry in charge of the trade affairs supports the consumer associations with funds deriving from the approved state budget, but no specification as to the destination of use of such funds is provided under the law.

7.3 If so, are there any restrictions on the availability of public funding?

Please refer to question 7.2 above.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

There are no specific provisions regulating the above proposed situation.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

There are no provisions under the Albanian legislation prohibiting the third party funding of a product liability related claim.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Albania.

As to the recent developments with regard to product liability law in Albania, we can report that recently, Law no. 9779, dated 16 July 2007 "For the general security, main requirements and evaluation of conformity of non nutritive products" and Law no. 9902, dated 17 April 2008 "On the consumer's protection", have demonstrated a increased interest of the legislator to provide more attention to this issue. However, there are difficulties related especially with the implementation of the relevant statutory acts. In our judgment, the above objective difficulties are related to the necessity of building-up an informed consumer via a series of social, cultural and political instruments and the improvement of the quality of the work of Albanian courts which have been improving very positively in recent years.

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Enkelejda Muçaj, one of the Senior Attorneys of Tonucci & Partners Tirana, has advised clients on contractual arrangements with institutions including negotiations over subject indemnity and publication rights, on product safety, marketing and promotion, etc. Enkelejda has an extended experience in carrying product liability litigation and advised clients especially in mining and telecommunications sector on regulatory and legal issues governing the development, approval, authorisation and marketing of products including the advising on labelling and sales promotion issues thus helping clients to operate within the confines of the appropriate regulatory framework. Enkelejda has acted as part of the legal advisors team of European Bank for Reconstruction and Development in various project financing activities and acted as Legal Adviser to the Minister of Culture Youth and Sports of Albania (position held in 1998-2000).

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Selena Ymeri is one of the attorneys of Tonucci & Partners in Tirana specialised in product liability law and lawsuits. Selena has assisted, advised and represented, during the course of legal proceedings, clients that have suffered injuries and/or property damage resulting from use of faulty or dangerous products. Besides, Selena has advised designers, manufacturers, and distributors of various products to the public about how to comply with consumers' safety legal requirements. Selena is also qualified for legal requirements and procedures of obtainment of different authorisations and permits for the activities of manufacturing and distributing products to consumers (i.e. alimentary permit).

Tonucci & Partners

In alliance with Mayer Brown LLP

Tonucci & Partners is one of the largest independent Italian law firms with over 200 lawyers in centrally managed offices linked by an up-to-date and sophisticated computer network with substantial experience in international law and in the domestic market. The Product Liability Practice includes 2 lawyers as well as lawyers who specialise in insurance recovery, governmental relations, corporate disclosures, and bankruptcy issues within the product liability arena. As such, we have a wealth of experience to draw upon, the ability to staff cases on a national level, and the ability to provide "one-stop shopping" for clients who require legal assistance on the wide variety of issues that are typical of significant product related tort litigation.

Our experience encompasses claims associated with products or facilities. We have been involved in tort product claims and we are successful in presenting science-based defenses on behalf of our clients, including supervising the re-creation and testing of products and failure analyses. We are familiar with the nation's leading experts in the relevant fields, including toxicologists, epidemiologists, pathologists, mechanical, chemical, metallurgical and environmental engineers, and industrial hygienists.

Our law firm has a highly developed practice throughout Central and Eastern Europe and has been involved in several international projects in Albania, Bosnia-Herzegovina, Bulgaria, Czech Republic, Estonia, Hungary, Slovak Republic, Slovenia, Poland, Seychelles and Romania.

The international practice of the firm is significant and growing, and all of the lawyers are selected for their strong and assertive international background.

Legal Business Awards nominated Tonucci & Partners for "European Firm of the Year" in 2000 on the basis of its reputation for excellence, innovation and a strong, client-driven business approach.

Argentina

Leandro M. Castelli

Marval, O'Farrell & Mairal

Alberto D. Q. Molinario

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

Product liability is governed by the general regime for damages of Argentina, which has its legal source in the Civil Code and by the Consumer Protection Law No. 24,240.

- The General regime:

Liability may be: (i) contractual; or (ii) non contractual.

(i) Contractual liability

The liability of the seller is based on the contract entered into with the purchaser. The seller undertakes a safety obligation which consists in a guarantee that the product involved will not harm the purchaser due to defects which could turn it dangerous. This safety obligation is deemed implicit in every purchase agreement, even if it is not expressly referred to in the contract.

As noted, the seller is deemed to undertake an outcome obligation towards the purchaser, because the product involved in the contract is aimed to satisfy a given purpose.

The seller is also liable for hidden defects existing at the time of the purchase.

(ii) Non contractual liability

Product liability may also arise when no contract exists between the plaintiff and the manufacturer because there is an obligation not to harm another person and to indemnify whenever such harm is done. Additionally, such obligations also arise from the defects of the product or from the risk of introducing a defective product into the market. Accordingly, when the damage has been caused by a fault or risk inherent to the product the manufacturer will be strictly liable.

- The Consumer Protection Law ("CPL"):

Product liability was originally exclusively governed by the Civil Code. However, in the nineties, an increasing idea of protection of consumer rights arose. As a result, our Congress passed the CPL which provides further protection when consumers are involved in a consumer contract or relationship.

Consumers are individuals or companies that acquire or use goods or services as end-users, for free or not, and for their own benefit or for the benefit of their family or social group. Any person who is not part of a consumer relationship but acquires or uses products as a consequence of a consumer relationship, will also be considered to be a consumer.

The CPL sets forth the strict, joint and several liability of the producer, manufacturer, distributor, supplier, retailer and/or anyone using its brand or trademark on the product or service, for damages arising from the risk or defect of products or services.

The CPL also includes the right to initiate collective proceedings (class actions) through consumer associations and specific proceedings aimed at solving disputes which affect consumers.

The Commerce and Industry Secretary (an agency of the Ministry of Economy) enforces the CPL by reviewing adhesion contracts, mediating disputes and imposing penalties in the event of violations.

1.2 Does the state operate any schemes of compensation for particular products?

No, the state does not operate any schemes of compensation for particular products.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

If the affected person is a consumer, the CPL establishes that all the members of the marketing line of a risky or defective product are strictly, jointly and severally liable for the damages caused to the consumers. In this marketing line, the CPL expressly names: the producer; the manufacturer; the importer; the distributor; the supplier; the seller; and the one who put its trademark on the product.

The members of the marketing line will only excuse their liability by proving that the harm was caused by a cause alien to them.

If the affected person is not a consumer, the general rules of the Civil Code will apply. There will be contractual liability of the seller, which will be strict, and tort liability of any of the other persons who might have caused the damage, which may also be strict.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

There is not a general obligation to recall products. If suppliers become aware of a defect, they must inform immediately to the administrative authority and to consumers. The notification to consumers must be made through advertising.

1.5 Do criminal sanctions apply to the supply of defective products?

Manufacturers, retailers and distributors may be held criminally liable if the products or services they supply cause injuries or death, if the products in some cases do not meet the requirements of applicable regulations or if the commercialisation involves fraud. Criminal liability requires intentionality or serious negligence.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

In general, the burden of proof lies in the plaintiff. However, in cases of strict liability the defendant must prove *force majeure* or that damages are attributable to the conduct of the plaintiff or of a third part alien to the defendant.

A theory developed in the last decades has changed the traditional rule that plaintiff bears the main burden of proof. According to it, the party required to prove a given fact is the one which is in a better situation to do so. The amendment of the CPL follows this trend.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

We apply the theory of the "adequate cause" in order to determine legal causation. This theory does not provide a scientific test. To the contrary, it is based on the ordinary experience of people, in their common sense. One act or omission will be considered to be the cause of a harm, when according to the regular turn of events (experience of life), such consequence is the typical result of such action.

The cause should never be just a mere condition of the damage. It has to contribute effectively to the harm suffered.

Traditionally, the plaintiff had to prove the link between the tortious conduct and the damage. Today, in cases of strict liability, it is enough to prove the physical contact between the injured party and the risky product or thing.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

The CPL imposes joint and several liability on the members of the same supply chain, but not between different producers of the same product.

There is no legislation on market share liability in product liability cases.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Yes, failure to warn gives rise to liability. Manufacturers must provide appropriate instructions, warnings and recommendations for the use of the product.

The CPL also provides that products and services shall be supplied or rendered providing detailed and true information about their main characteristics, and in such a way that their use under normal conditions does not represent danger for the health of consumers. Those products or services that imply a risk to the consumer's health must be sold according to the applicable rules (or reasonable rules if there are not applicable regulations), mechanisms and instructions to ensure safety, and attaching a user's manual including safety rules.

All the information, advice and warnings provided to the injured party will be taken into account.

In principle, all the members of the supply chain are jointly and severally liable. However, they may prove which one of the members of the supply chain was responsible for the failure to warn.

There is not a principle of "learned intermediary" in the law; consequently, the general principles will apply.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Some of the preliminary motions admitted by the procedural codes are as follows: (i) statute of limitations; (ii) lack of jurisdiction; (iii) lack of legal capacity to take part in an action or of insufficient powers; (iv) lack of standing to sue or to be sued, when this is evident; (v) *lis pendens*; (vi) deficiencies in the way the claim has been presented; and (vii) *res judicata*.

However, as the CPL allows cases to be tried through summary proceedings, some of these defences may not be admitted as preliminary motions.

In strict liability cases the defendant may prove: (i) that there is no causation between the damage and the product; (ii) *force majeure*; (iii) that the plaintiff was responsible for the damage; or (iv) that the damage was caused by a third person and that the defendant has no duty to respond for that person.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

The Civil Code and the CPL do not provide a state of the art/development risk defence. Besides, the liability is strict and as such it does not depend on negligence or intend to harm.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

No, it is not.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

In individual cases the effects of judgments will only apply to those who were a party to the case.

In consumer collective cases, the judgment will have *res judicata* effects on the defendant and on all the consumers who are the same conditions as the representatives.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

When sued by a consumer, defendants may prove the liability of a co-defendant, as long as he or she is a third person and the defendant has no duty to respond for that person. If all co-defendants are deemed joint and severally liable for damages payable to the claimant, they may seek a contribution or indemnity in subsequent proceedings. The statute of limitations for those actions is of two years.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Please see question 3.1 above.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

Argentine law does not provide for lay juries. Cases are decided exclusively by professional judges.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Expert witnesses are appointed by the court at the request of the parties to assist it in considering technical issues.

Parties may be assisted by *ex parte* advisors.

The only evidence to be produced is the one related to contested facts.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

There are different procedure rules to unify cases with the same parties or claims.

a) Joinder of parties

The joinder of parties consists in several individuals acting together as claimants or defendants in the same trial. Voluntary plaintiff joinder arises out of the free will of the plaintiffs, and requires a connection between all actions in their title, subject or both. Mandatory joinder arises when the judgment must be issued in respect of several parties.

b) Collective Actions

The constitutional amendment of 1994 created the possibility of bringing summary legal actions to defend "rights with a collective impact".

Because no general procedure laws have not yet been passed regulating such actions, the applicable rules are being developed by the courts.

The CPL includes some specific procedural rules, but it does not provide a comprehensive treatment. For example, it provides that judges must establish the rules to be followed by the absent members of the class to opt-out before the judgment is rendered.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

The CPL grants standing to the National or local administrative authorities, the Ombudsman, the District Attorney, and associations of consumers in order to defend the interests of consumers when these are threatened or affected duly registered. The standing of individual consumers to bring a collective action is not clear.

4.5 How long does it normally take to get to trial?

As there is no effective discovery and no trial hearing, cases are usually started simply by filing the complaint. In the city of Buenos Aires, there is a mandatory mediation proceeding.

Lawsuits normally take four or more years to be decided by the lower court.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Yes, courts can try preliminary issues. They can relate to matters of law or issues of fact.

4.7 What appeal options are available?

Under the federal system, at least one appeal, and often two, are possible.

a) Appeals to the Courts of Appeals with respect to decisions by first instance judges.

b) Appeals to the Federal Supreme Court with respect to decisions of the Courts of Appeals.

In principle, the Federal Supreme Court may review a decision of a Court of Appeals by means of an "extraordinary appeal" (or certiorari) when it is alleged that the decision conflicts with a provision of the Argentine Constitution or whenever there is a dispute on the interpretation or application of a treaty or a federal law. An "extraordinary appeal" may also be filed with the Federal Supreme Court when the appealed decision is deemed "arbitrary".

The ordinary appeal before the Federal Supreme Court is exceptional.

Most provincial judicial systems also provide at least one appeal.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Please see question 4.2 above.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

No, witnesses must testify in the courtroom, during the proceedings (except for some few exceptions provided by the rules of civil procedure). Witness statements and expert reports are not exchanged prior to trial.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

The procedure for the discovery of documents as it exists in the U.S., does not exist in the Argentine legal system. Parties have the right to produce only the documents upon which they intend to base their case.

The only exception to this principle is the right that a party has to request from its opponent (or a third party) the production of specifically identified documents which are relevant to the dispute. In this case, if the required party does not produce the documents the judge may draw a negative inference against such party at the time of rendering the final decision.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

There is a mandatory mediation proceeding law in the city of Buenos Aires and also in some other provinces.

The Consumer Protection Law provides arbitration proceedings that may be organised by the government only for consumer actions.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Generally, there are no time limits on bringing or issuing court proceedings in private lawsuits. In lawsuits against the Government, short statutory terms may be applicable.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

The statute of limitations for damages resulting from non-contractual obligations (i.e. torts) is 2 years and for damages resulting from contractual obligations is 10 years. In the case of consumer claims, the minimum statute of limitations is 3 years.

The statute of limitation provision is generally computed from the date of the event upon which the plaintiff is suing to the date the complaint is filed.

The age or condition of the claimant, in principle, will not affect the calculation of the term.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Concealment or fraud may affect the running of the statute of limitations because the term may not begin to run until the moment the plaintiff knew or should have reasonably known that he had been damaged, and the nature of the damage. The time limit, in principle, can be extended for 3 months after the impediment or fraud which prevented the plaintiff from suing has ceased.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

Consumers may choose to: a) request specific performance of the obligation provided such performance were possible; b) accept another product or the rendering of equivalent services; or c) rescind the agreement with a right to reimbursement of any monies paid irrespective of the effects already verified and considering the agreement in its entirety. In addition to these remedies, consumers may claim damages.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

The general principle is that awards shall provide full compensation for all damages caused to the injured party that are not remote.

The relief sought may include: (i) compensatory damages, which may include bodily injury, mental damage, aesthetic damage and damage to property; (ii) loss of profit; and (iii) moral damages, which may be recovered when hurt feelings cause physical pain, suffering or spiritual anxiety. Argentine case law has also awarded damages for the "loss of a chance".

Consumer protection regulations also provide for the return of products and the refund of the price.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

In principle, damages must be real, permanent, personal and truly affect a legitimate interest of the claimant. Future damages may only be paid if their occurrence is certain or if they will result from

the aggravation of present damages.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages have been introduced in our legal system when the CPL was amended in April, 2008.

Consumers can request judges to impose punitive damages to the suppliers who breach their legal or contractual obligations. They cannot exceed AR$ 5,000,000 (approximately US$ 1,350,000 at current exchange rates) and they must be paid directly to the consumer.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

No, there is not.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

Yes, once a claim has been filed, the settlement must be approved by the court.

In the case of consumer collective claims, settlements must be approved by courts, after consulting with the public attorney.

If infants are involved, settlements must also be approved by the official in charge of the defence of minors ("*Defensor de Menores*").

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Yes, they could. However, that kind of claim is not customary.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The successful party can recover from the losing party court fees or other incidental expenses as well as their own legal costs.

The general principle that the "loser pays" applies in Argentine litigation. Only in exceptional cases, when the court considers that the controversy was sufficiently complex to justify the decision of the loser to litigate, are counsel's fees borne by each party.

7.2 Is public funding e.g. legal aid, available?

Public funding does not exist. Claimants who are not able to afford litigation costs may request authorisation to litigate *in forma pauperis*. The authorised party is exempt from the payment of the court tax and the winner's attorney's fees, if he/she loses the lawsuit.

7.3 If so, are there any restrictions on the availability of public funding?

Please see question 7.2 above.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Contingency fees are allowed provided they do not exceed 40% of the economic benefit obtained by the party. Such an arrangement does not exclude the right of counsel to collect whatever legal fees must be paid by the losing party.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Third party funding is not regulated. Consequently, it is not illegal but its usage is not customary.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Argentina.

The amendment to the CPL, passed in April, 2008, included some rules applicable to collective cases. Those rules incorporated the possibility of claiming individual patrimonial rights through class actions, despite the fact that the Federal Supreme Court had always been restrictive in recognising collective standing to sue when individual rights were invoked.

However, on February 24, 2009, the Federal Supreme Court ruled in the *amparo* action "*Halabi, Ernesto vs. Federal Executive Branch - Law 25,873 - Decree 1,563/04*" outlining for the first time the characteristics of class actions filed to protect collective rights whose object are individual rights.

The Court's decision classified rights as follows: (i) individual rights; (ii) collective rights whose object are collective interests; and (iii) collective rights whose object are homogeneous individual interests.

It also established the requirements for the admission of these actions: (i) there must be a sole or complex fact which affected a relevant quantity of individual rights; (ii) the action must be focused on the common effects; and (iii) individual interests by themselves must not justify the filing of a lawsuit.

In addition, the Supreme Court decided that the formal admission of any class action requires the fulfillment of certain elemental conditions: (i) the precise identification of the affected group; (ii) the class's attorney-in-fact must be qualified; (ii) plaintiff arguments must be related to facts and rights which are common to the members of the class; (iii) there must be a notification to serve the persons which may be affected by the class action so as allow them to choose whether they want to be left apart or take part in the proceedings; and (iv) there must be proper publicity to avoid multiplication or superposition of class actions on the same matter.

The Federal Supreme Court also granted *erga omnes* effects to rulings passed in class actions proceedings.

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MARVAL, O'FARRELL & MAIRAL

Marval, O'Farrell & Mairal, founded in 1923, is the largest and one of the oldest law firms in Argentina. The firm currently has over 300 professionals. The firm's law practice covers a wide range of legal services to financial institutions, commerce and industry and to diverse sectors of government. Although the firm practices Argentine law, its lawyers are well attuned to business issues and the complexities of multi-jurisdictional transactions. Marval O'Farrell & Mairal is ranked at the top of major legal publications and has been awarded with the Chambers Global "South America Law Firm of the Year 2004" Award, "Who's Who Legal" Law Firm of the Year for Argentina Award (2006/2007/2008), the "International Law Office Client Choice Award 2005" for Argentina, International Tax Review "Tax Firm of the Year - Argentina" Award (2006), IFLR 1000 "Argentina Law Firm of the Year Award 2006", and PLC Which Lawyer?, "Leader Law Firm in Argentina (from 2004 to 2008)" and Managing Intellectual Property "IP Law Firm of the Year for Argentina" Award (2008/2007/2006).

Australia

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

Australia's product liability laws are a mixture of the common law and various federal and state statutes.

A person who claims to have been injured or who has otherwise suffered loss or damage may commence an action for compensation on the following bases:

- the common law tort of negligence which is fault based;
- contract; and
- breach of provisions of the federal *Trade Practices Act* 1974 ("**TPA**"). The TPA imposes statutory obligations including a strict liability regime in Part VA and statutory warranties imposed on manufacturers under Part V Division 2A. Almost identical provisions exist under various state fair trading legislation.

Typically, product liability claims for damage to persons will involve causes of action based on negligence and breaches of various provisions of the TPA.

1.2 Does the state operate any schemes of compensation for particular products?

No formal schemes for particular products exist, except for asbestos related claims. In New South Wales, the Dust Diseases Tribunal has exclusive jurisdiction to determine "dust diseases" claims. Similarly in South Australia the District Court has exclusive jurisdiction to hear such matters.

There are also state-based schemes requiring compulsory insurance in respect of motor vehicle accidents. As a result, personal injury claims arising from motor vehicle accidents have, to date, generally been brought under these statutory schemes, as opposed to being brought against motor vehicle manufacturers.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Liability for fault or defect depends upon the particular facts and cause of action relied upon.

Negligence

It is generally accepted that the manufacturer of goods owes a duty of care to the purchaser and user to safeguard them against the foreseeable risks of injury when using the product as intended.

Retailers, importers and distributors are not expected to test or inspect products which the manufacturer delivers in sealed containers which would not normally be opened until they reach the ultimate consumer. However, in these circumstances, the retailer still has a duty to guard against those dangers known to it or which it has reasonable grounds to expect.

To the extent that any party in the supply chain adds to or modifies a product including packaging and labelling, that party will also owe a common law duty to the purchaser and user in respect of those changes.

Contract

Parties are free to enter into contracts on terms agreed between them, subject to terms implied into the contract by common law or statute.

Part V Division 2 of the TPA and sale of goods legislation in each state and territory require certain implied terms to be incorporated in contracts for the supply of goods to a person - whether that contract be written or oral. These include warranties that the goods are:

- of merchantable quality; and
- fit for the purpose for which they are supplied.

Contractual remedies are only available to parties to the contract. Since, in most circumstances, it is the retailer that will have a contractual relationship with the purchaser, the retailer will bear the liability for any defect or fault in accordance with the express and implied terms of the contract of sale. However this does not prevent a retailer from consequently seeking contractual remedies from other parties.

Trade Practices Act

Under Part V Division 2A of the TPA, manufacturers will be liable directly to consumers for:

- goods which do not correspond with their description;
- goods of unmerchantable quality;
- goods which do not conform to sample;
- goods unfit for a stated purpose; and
- non-compliance with express warranties,

thus, privity of contract is no barrier to relief.

The operation of Division 2A is restricted to claims of consumers who have suffered loss or damage as a result of their use or consumption of *consumer goods*. These are goods that are ordinarily acquired for personal, domestic or household use or consumption.

Under Part VA, manufacturers will be held strictly liable directly to

consumers for injury to persons or property damage suffered as a result of a defective product. Goods are considered to be defective if *their safety is not such as persons generally are entitled to expect.*

The definition of "manufacturer" under Parts V and VA of the TPA is extremely broad and potentially includes anyone in the supply chain.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Under the common law, manufacturers and suppliers of products owe a continuing duty to purchasers and users to prevent a product from causing harm, including after the product is sold. Failure to recall a product which may cause harm may amount to negligence and give rise to the obligation to pay compensation to persons suffering injury, loss and damage as a result.

The issues that will be considered in deciding whether recall action is necessary include the:

- magnitude of the potential harm involved;
- probability of such harm occurring;
- availability and effectiveness of alternative remedial action; and
- degree of knowledge in potential users of the potential harm.

In addition, the product safety provisions of Part V Division 1A of the TPA create a stringent regime for the compulsory recall of goods which:

- do not comply with a prescribed safety standard;
- have been declared to be unsafe goods or permanently banned; or
- will or may cause injury to any person.

1.5 Do criminal sanctions apply to the supply of defective products?

Yes. Certain conduct by corporations and their officers may be subject to criminal sanctions under federal or state legislation.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

In negligence, contract and under some of the provisions of the TPA, the claimant has the burden of proving that the product was defective.

Part V Division 2A and Part VA of the TPA are often referred to as "strict liability" provisions. In the former, a claimant need not prove fault but nonetheless must establish, on balance, that the subject goods are not fit for purpose or are not merchantable in the circumstances. In the latter, a claimant needs to prove that the subject goods are not as safe as persons are generally entitled to expect.

At common law, in contract and in other actions based on the provisions of the TPA, the claimant must establish:

- that loss or damage has been suffered;
- that the relevant conduct is either in breach of a common law duty, in breach of the contract or contravenes one of the provisions of the TPA; and
- that the loss or damage was caused by the defendant's conduct.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The test for causation depends upon the cause of action relied upon.

Prior to the Tort Reform Process in 2002, the position at common law was that causation was a question of fact to be decided according to evidence before the court. Australian courts applied a "common sense" test to determine the question of causation.

Following the Tort Reform Process, while the test varies between jurisdictions, there are basically two requirements:

- first, that the negligence was a necessary condition of the occurrence of the harm (referred to as "factual causation"); and
- second, that it is appropriate for the scope of the negligent person's liability to extend to the harm so caused (referred to as "the scope of liability").

There is, however, an allowance for determining in an "exceptional" case, whether negligence that cannot be established as a necessary condition of the occurrence of harm should nonetheless be accepted as establishing factual causation.

Australian courts have not embraced the view that a plaintiff proves causation or reverses the onus of proof in relation to causation by demonstrating that the exposure they were subjected to simply increased the probability of their injury occurring.

However in a recent case an Australian court held that causation is established under one of the no fault provisions of the TPA where it can be demonstrated that the defendant exposed the claimant to an increased risk of injury.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Under the common law the claimant must establish the identity of the manufacturer that was responsible for the relevant defect. The sole exception to this is where a claimant is able to rely on the maxim *res ipsa loquitur* (when the negligence speaks for itself) when they cannot provide evidence as to why or how the occurrence took place. Under this doctrine a rebuttable inference of negligence may be drawn against the defendant by the mere fact that it would not have happened without negligence.

Conversely the TPA contains deeming provisions that assist claimants in circumstances where it is not clear who actually manufactured the defective product.

Under Part V Division 2A and Part VA the definition of "manufacturer" is very broad and can potentially include anyone in the supply chain, particularly when the actual manufacturer is outside Australia.

Under Part VA, a claimant is entitled to make a written request to the supplier for information about the manufacturer. If, after 30 days, neither the claimant nor the supplier knows the identity of the manufacturer, the supplier is deemed to be the manufacturer.

Whilst no generally established system of market-share liability exists in Australia, as a result of the Tort Reform Process, most jurisdictions have introduced proportionate liability for co-defendants in respect of non-personal injury claims for economic loss or property damage, or claims for misleading or deceptive conduct brought pursuant to state fair trading legislation. In such cases, each co-defendant will only be liable to the extent of its responsibility.

In personal injury claims defendants may still rely on a statutory right

to seek contribution from any or all other parties that would have been held liable for the same damage had they been a party to the proceedings.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

The common law of negligence imposes a duty of care on the manufacturer of a product to take reasonable steps to ensure that ultimate users of that product are given adequate warnings of risks associated with its use to enable users to adjust their use of the product so as to avoid or minimise danger or to make an informed decision about whether or not to use the product.

A failure to warn may also found a claim that a product is defective under Part VA or unfit/unmerchantable under Part V Division 2A of the TPA. In deciding whether the product is defective or unfit/unmerchantable, the court may look at all relevant circumstances including any warnings and the marketing strategy adopted by the manufacturer or supplier to determine whether they placed the user in a position to properly understand the risks associated with the product.

The learned intermediary doctrine has never been considered by an Australian court. However for medical products which may only be accessed through a doctor, the doctrine is consistent with Australian law which acknowledges the importance of the relationship between doctor and patient in the provision of warnings about medical treatment.

Following the Tort Reform Process, in some jurisdictions, evidence from plaintiffs as to what they would have done had there been a warning about a risk of injury is now inadmissible in negligence cases except to the extent that it is evidence against the plaintiffs' interest.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Limitation periods apply to all causes of action pleaded in product liability litigation. Details of limitation defences are set out in question 5.2 below.

Negligence

The following defences may be available to a claim in negligence:

- *volenti non fit injuria* (voluntary assumption of risk);
- contributory negligence; and
- the learned intermediary defence.

Voluntary assumption of risk is a deliberate decision by the plaintiff to assume the risk of injury, loss or damage. To establish the defence of *volenti*, the defendant must show that the plaintiff not only perceived the existence of the danger, but also fully appreciated it and voluntarily accepted the risk. This defence is difficult to establish, but is a complete answer to any claim.

Contributory negligence may be relied on where the plaintiff's conduct fails to meet the standard of care required for his or her own protection and safety and is a contributing cause in bringing about his or her injury. Damages are apportioned by the court in accordance with each party's degree of fault. In certain jurisdictions, contributory negligence can be a complete defence to an action if the court thinks this just and equitable in the circumstances.

There is no express authority in Australia for a learned intermediary defence, although there is no reason why the defence cannot be accommodated within existing common law principles.

The Tort Reform Process has created new statutory defences to an action for negligence, although these differ from jurisdiction to jurisdiction.

For example, the following have been introduced as complete defences in New South Wales:

- where the harm was suffered as a result of the materialisation of an inherent risk, which is defined as the risk of something occurring that cannot be avoided by the exercise of reasonable care and skill;
- where the harm was suffered as a result of the materialisation of an obvious risk associated with a dangerous recreational activity. An obvious risk is a risk that, in the circumstances, would have been obvious to a reasonable person in the position of the plaintiff and includes risks that are patent or a matter of common knowledge;
- where a professional defendant acted in a manner that, at the time the relevant service was provided, was widely accepted in Australia by peer professional opinion as competent professional practice (unless the court considers such opinion to be irrational);
- where the defendant is a good Samaritan or volunteer and has exercised reasonable skill and care under the circumstances; and
- in certain cases where the defendant is a public or other authority.

Part VA Trade Practices Act

There are a number of specific defences to an action brought under Part VA:

- the defect alleged did not exist when the goods were supplied by the manufacturer;
- the goods were defective only because there was compliance with a mandatory standard (see further question 3.3);
- the state of scientific or technical knowledge at the time the goods were supplied was not such as to enable the defect to be discovered (the so-called 'development risk defence') (see further question 3.2); or
- in the case of the manufacturer of a component used in the product, the defect is attributable to the design of the finished product or to any markings, instructions or warnings given by the manufacturer of the finished product, rather than a defect in the component.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

If a product is found to be defective under Part VA of the TPA, the manufacturer or supplier can argue what is commonly referred to as the "state of the art defence" or "development risk defence". The manufacturer or supplier must establish that the state of scientific or technical knowledge at the time when the product was supplied by its

actual manufacturer was not such as to enable the defect to be discovered.

Under Part V Division 2A of the TPA, the issue would be whether the product was fit for the purpose for which it was intended, giving consideration to any description applied to the goods by the corporation, the price received by the corporation for the goods, and all the other circumstances.

In negligence, the claimant must establish that the manufacturer failed to exercise reasonable care. The state of scientific and technical knowledge is often pertinent to this issue and forms the basis of the manufacturer's defence.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Under Part VA of the TPA, it is a defence that the goods had the defect only because there was compliance with a mandatory standard. A mandatory standard is a standard for the goods or anything relating to the goods which, under law, must be complied with when goods are supplied, and which carries a penalty for non-compliance. A standard which simply requires a minimum standard to be achieved is not a mandatory standard.

In an action for negligence and under Part V Division 2A of the TPA, compliance with regulations or standards is a relevant factor in determining whether goods are as fit for the purpose(s) for which goods of that kind are commonly bought as is reasonable to expect.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Claimants may re-litigate these issues. This is not possible in cases where the issue has already been determined in a representative proceeding (class action) in the Federal Court of Australia where the claimant is bound by a ruling made in that class action by virtue of their failure to "opt out" of the proceeding. There are also special rules in dust disease cases litigated in the New South Wales Dust Diseases Tribunal.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

Yes. Defendants are permitted to rely on a statutory right to contribution from other concurrent tortfeasors (whether joint or several). Alternatively defendants may seek to rely on a contractual right of indemnity. These remedies may be pursued either in the same or subsequent proceedings. If subsequent proceedings are required, time limits do apply. These differ between jurisdictions and depend on the cause of action.

Following the Tort Reform Process, all Australian state and territory jurisdictions enacted a statutory regime of proportionate liability for non-personal injury claims for damages. The liability of a defendant who is a concurrent wrongdoer is now limited to an amount reflecting the proportion of the damage the court considers just having regard to the extent of that defendant's responsibility.

Certain state jurisdictions allow parties to expressly contract out of the proportionate liability scheme.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Under the common law and certain legislation, if the defendant can demonstrate the plaintiff contributed to the damage by failing to take reasonable care, damages will be apportioned by reference to the plaintiff's share in the responsibility for that damage. The regime expressly covers personal injury and loss of life.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

Product liability litigation may be brought in either the Federal Court of Australia or the State Supreme Courts. Civil proceedings in Australia are generally heard by a judge sitting without a jury. However, there are provisions in the various court rules for some matters to be heard by jury.

As a matter of practice, juries are usually not available in matters before the Federal Court. However, juries are not uncommon in the State of Victoria.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Courts in several jurisdictions may appoint a "court expert" to inquire and report on a question of fact arising in a matter before the court or an "expert assistant" to assist the court on any issue of fact or opinion identified by the court (other than an issue involving a question of law) in the proceeding, should the need arise.

An expert is generally accepted to be a person who has specialised knowledge about matters relevant to the question based on that person's training, study or experience.

The role of court experts or expert assistants is advisory in nature and does not extend to sitting with the judge and assessing evidence presented by the parties.

In most jurisdictions the parties are joint and severally liable for payment of the expert's fees.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

There is a detailed class action procedure in the Federal Court of Australia and the Supreme Court of Victoria. There are also representative action procedures in other state jurisdictions. An action can only be commenced in the Federal Court where it attracts federal jurisdiction, for example, if it involves a claim under the TPA.

Class actions have involved products including weight loss drugs, heart pacemakers, aircraft fuel, gas, water, tobacco and a variety of food stuffs ranging from oysters to peanut butter. Australia is now the most likely jurisdiction outside North America where a corporation will face a class action.

The Federal and Victorian legislation provides for the commencement

of a class action where seven or more persons have a claim against the same person and the claims are in respect of, or arise out of, the same, similar or related circumstances and give rise to a substantial common issue of law or fact.

If these threshold requirements are met, any of those persons may commence an action on behalf of the group. There is no certification process as occurs in the United States. The representative plaintiff must describe the group but need not identify, name, or specify the number of group members. With limited exceptions, a person's consent to be a group member is not required.

Once proceedings have been commenced, the court will fix a date by which a group member may opt out by written notice to the court, and will give directions regarding the procedure for notifying potential group members of the existence of the proceedings. Unless a person actively opts out of the proceedings, they will continue to be a part of the action and be bound by its outcome.

In order to protect absent group members, the action may not be settled or discontinued without the approval of the court. Similarly, the representative plaintiff may only withdraw from the proceedings or settle his or her individual claim with the leave of the court.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Yes. The TPA expressly provides for the institution of proceedings by the Australian Competition and Consumer Commission ("**ACCC**") on behalf of those who have suffered or are likely to suffer loss as a result of contraventions of the TPA, including certain provisions of Parts V and VA. Under these provisions the ACCC requires the prior written consent of the persons on whose behalf the application is being made.

Recently the Australian government passed a bill that will prevent the ACCC from pursuing a representative action for personal injury or death under the unfair practice provisions of Part V, Division 1 of the TPA (which includes misleading and deceptive conduct).

4.5 How long does it normally take to get to trial?

Time to trial depends on the particular jurisdiction and the nature of the claim. It may take anywhere from six months to several years for a matter to be heard and determined.

Proceedings in the Federal Court are usually heard faster than those in the state and territory supreme courts, due in part to the Federal Court's case management system whereby each proceeding is allocated to a particular judge who manages the case and usually hears and determines it, and the supreme courts' heavier case load.

There are provisions in all jurisdictions for expedited hearings in appropriate circumstances, including the ill health of a litigant.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

In some jurisdictions, the court may try preliminary issues whether of fact or law or mixed fact and law.

Historically, courts have been of the view that trials of preliminary issues should only be granted on special grounds such as whether the preliminary issue will substantially narrow the field of controversy, shorten the trial and/or result in a significant saving in time or money.

Preliminary issues are usually heard and determined by a judge.

4.7 What appeal options are available?

In virtually all jurisdictions there is a right of appeal from the judgment of a trial judge. The procedure varies depending on the jurisdiction in which the original trial was conducted. Leave to appeal is usually necessary when the appeal is from an interlocutory judgment. Even though appeals generally turn on questions of law, it is not uncommon for parts of the evidence used at trial to be reviewed during the course of an appeal.

A party dissatisfied with the decision of a state or territory Court of Appeal or the Full Federal Court may seek leave to appeal to the High Court of Australia, the country's ultimate appellate court. Appeals to the High Court are essentially restricted to questions of law. The High Court will only grant leave to appeal if it is convinced that there is a significant question to be determined.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

See question 4.2. Where the court has appointed an expert in relation to a question arising in the proceedings, the rules provide that the court may limit the number of other experts whose evidence may be adduced on that question, or that a party must obtain leave to adduce such evidence.

Court experts are rarely appointed. However, as a matter of course, parties adduce evidence from appropriate experts.

The nature and extent of expert evidence is subject to the discretion of the court. In a number of jurisdictions, practice notes provide guidance on the number of experts that might be called by any party in a particular area of expertise.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

Depositions of the parties and witnesses are not taken before trial. However, the Australian legal system is more onerous in terms of the obligations imposed on parties to give discovery of documents (see question 4.10).

In some jurisdictions, most notably the Federal Court of Australia, pre-trial directions are made in the ordinary course that witness statements and expert reports be exchanged before hearing and that those statements and reports comprise the evidence in chief of those witnesses.

It is also common for directions to be made requiring the parties to exchange objections to their opponent's statements and reports before trial. Any objections that are not conceded or otherwise addressed are then argued, and ruled upon, before cross-examination of the witnesses at trial.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

A party is obliged to discover - that is to identify and allow the other parties to access - all documents in its possession, custody or power which are relevant to a matter in issue in the proceedings. Discovery occurs at the pre-trial stage so that all documents relevant to the case are disclosed by the parties before the hearing commences.

The obligation to give discovery extends to documents which are no longer in the party's possession, custody or power, but which were

previously. This may occur where a relevant document has been lost, destroyed or provided to someone else. In such a case, a description of the document must be provided to the other parties.

Documents that are relevant to a case include those documents on which the party relies, documents that adversely affect the party's own case, documents that adversely affect another party's case, documents that support another party's case, and documents that the party is required by a relevant practice direction to disclose.

All discovered documents must be listed, and the parties' lists sworn and exchanged. Parties are entitled to inspect each others' documents and if desired, copy them, save for those in relation to which a claim for privilege has been advanced.

Preliminary discovery before the substantive proceedings assists parties in identifying prospective defendants, to determine whether or not they have a claim or to gain information from third parties where any party to a proceeding reasonably believes that a particular party holds a document which relates to any question in the proceeding.

The obligation to discover all relevant documents continues throughout the proceedings. This means that any document created or found after providing initial discovery must also be discovered.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Alternative methods of dispute resolution ("**ADR**") such as mediation, arbitration and conciliation are available in Australia. There is now an emphasis on ADR, particularly mediation, enshrined in various court procedures.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, time limits do exist under common law and statute.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

Contract and tort

There are considerable variations between the limitation periods applicable to common law proceedings in the various Australian states and territories, resulting from a profusion of specialist legislation and court decisions, although the Tort Reform Process has resulted in more uniformity in relation to the limitation period applicable to personal injury actions.

In general terms, limitation periods are routinely defined by reference to the nature of the cause of action, including whether the claimant alleges fault-based or strict liability. In most jurisdictions the limitation period applicable to claims for personal injury is either:

- the earlier of three years from the date the cause of action is discoverable by the plaintiff ("the date of discoverability") or twelve years from the date of the alleged act or omission (the "long-stop period"); or
- three years from the date the cause of action accrued.

Limitation periods including those applicable to personal injury claims are usually suspended while a claimant is suffering from a legal incapacity, which encompasses the period prior to a claimant turning 18, or during which a claimant suffers from a mental or physical disability which impedes them from properly managing their affairs.

Trade Practices Act

Actions brought under Part V Division 2A and Part VA of the TPA must generally be commenced within three years after the time the person becomes aware, or ought reasonably to have become aware, of particular circumstances giving rise to the action. There is also a ten-year period of repose, which requires actions to be commenced within ten years of the supply by the manufacturer of the goods.

Where a claim is brought under these provisions of the TPA for personal injury, the applicable limitation period is the later of the "date of discoverability" or the "long-stop period" as defined above.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Most Australian jurisdictions provide for the postponement of commencement of the limitation period where the plaintiff's right of action or the identity of the person against whom a cause of action lies is fraudulently concealed. The limitation period is deemed to have commenced from the time the fraud was discovered or the time that a plaintiff exercising reasonable diligence would have discovered. Throughout all Australian jurisdictions the courts have various discretionary bases for extending the time period where it is just and reasonable.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

Monetary compensation is available for both pecuniary and non-pecuniary loss. In addition, courts may grant injunctions, including interim injunctions, to restrain breaches or attempted breaches of the restrictive trade practices and consumer protection provisions. The potential breadth of remedies available is illustrated by section 87 of the TPA where a court has power to make such orders as it thinks appropriate against a person who was involved in the contravention of the consumer protection provisions of the TPA.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Common law

The following damages are available for claims of bodily injury:

- general damages, including pain and suffering, loss of amenities and loss of expectation of life; and
- special damages, including loss of wages (both past and future), medical and hospital expenses and the like.

The Tort Reform Process has resulted in caps, thresholds and other limitations being placed on the amount of such damages that can be recovered.

Damages are assessed on a once and for all basis.

Damages are also recoverable for mental damage provided it can be established that the claimant is suffering from a diagnosed psychiatric condition. In addition, common law damages are available for damage to the product itself, or other consequential damage to property. One can recover damages for "pure economic loss" but the nature and extent of such damages is extremely complex.

Part VA of the Trade Practices Act

Under Part VA of the TPA, damages are recoverable for losses suffered

as a result of personal injuries, including medical expenses (subject to similar caps, thresholds and other limitations imposed on common law damages following the Tort Reform Process). A person other than an injured party may also claim compensation where that person suffers loss as a result of the other person's injury or death, for losses relating to personal, domestic or household goods other than the defective goods, and losses relating to private land, buildings and fixtures.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

As a general rule, damages for the costs of medical monitoring in the absence of any established injury or loss are not recoverable.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Exemplary, punitive or aggravated damages can be awarded by the courts, although not in relation to claims brought under the TPA and, in some jurisdictions (as a result of the Tort Reform Process) not in negligence actions seeking damages for personal injury.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

Generally no. However, the Tort Reform Process has resulted in caps, thresholds and other limitations being placed on the amount of damages a personal injury claimant can recover.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

Court approval is required for the settlement of representative proceedings in Australia and is also required for claims brought by infants or people suffering from a legal disability. Under section 33V of the Federal Court Act, a representative proceeding may not be settled or discontinued without the approval of the Court. If the Court gives such an approval, it may make such orders as are just with respect to the distribution of any money paid under a settlement.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Yes, government authorities can reclaim these amounts. A claimant is required to refund that part of the damages awarded or settlements paid, which have previously been awarded to the claimant as part of a social security benefit payment. This is to prevent "double dipping". The damages awarded or settlements paid are withheld from the claimant by the defendant until such time that repayment to the relevant government authority has been resolved.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The unsuccessful party usually pays the costs of the successful party. These costs include, not only court filing fees, copying charges and other out-of-pocket expenses, but also the lawyer's professional fees. In this context, a reference to costs is not a reference to the total or actual costs incurred by the successful party. Recoverable costs are generally calculated by reference to a court scale, which invariably limits the amounts a successful party can claim for disbursements and services performed by their lawyers.

In some jurisdictions the Tort Reform Process has resulted in further limitations being imposed on the legal costs recoverable in small personal injury claims (although there are exceptions including where the lawyer and client have entered into a costs agreement that provides otherwise).

The common law rule has been significantly modified in the case of representative or class actions. Statutory provisions restrict a costs order being made against class members other than those who actually commenced the proceedings. Where the representative action is successful, a costs order may be made in favour of the class members who commenced the representative proceedings in an amount determined by the court.

7.2 Is public funding e.g. legal aid, available?

Yes, public funding is available.

7.3 If so, are there any restrictions on the availability of public funding?

Legal aid services rigorously apply means and merits tests to determine eligibility for aid. As a general rule, very limited funding is available to assist claimants to bring civil actions, including product liability claims. Funding is available at the federal level for, *inter alia*, consumer protection matters, arising under a Federal statute such as the TPA.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Recently, rules prohibiting lawyers from entering into contingency fee arrangements were relaxed and a variety of arrangements are now sanctioned. These new arrangements allow lawyers and clients to enter into an agreement which provides for the normal fee, or a fee calculated by reference to some pre-determined criteria such as the amount of time expended by a lawyer, to be increased by a pre-agreed percentage. The relevant rules generally impose a cap on the percentage by which such fees can be increased. Some jurisdictions allow lawyers to enter into an agreement to be paid an "uplift fee" where an additional fee may be levied, calculable by reference to the initial fees. All jurisdictions continue to prohibit contingency fee arrangements where the lawyer's fee is calculated by reference to a percentage of the client's verdict.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Third party funding of claims is permitted in Australia, subject to the rules set out in question 7.4 above.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Australia.

There is a recent proposal to make wide-ranging changes to Australia's consumer laws and impose new burdens on manufacturers and suppliers. The Federal Government recently released a discussion paper entitled "An Australian Consumer Law: Fair markets - Confident Consumers" by the Standing Committee of Officials of Consumer Affairs. The reform proposals contain three elements.

First, an Australian Consumer Law is to be developed which would be scheduled to the TPA which would be renamed the Competition and Consumer Act and apply at both the state, territory and federal levels.

The proposed legal provisions will be based on the existing consumer protection provisions of the TPA with "changes based on best practice in State and Territory laws". Second, as part of the proposed national consumer law, a new national product safety regulatory and enforcement framework would be introduced. Third, improved enforcement and information sharing between national and state and territory regulatory agencies and new enforcement powers are proposed. If these proposals are implemented it will mean dramatic changes for manufacturers and suppliers of goods in Australia. Further, the possibility is mooted that New Zealand might also adopt aspects of the law "should it decide to do so". The Federal Government is currently seeking comment on the proposals.

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Colin Loveday leads the Clayton Utz product liability group. He is an experienced trial lawyer with particular expertise in the defence of product liability actions involving class actions and multi-plaintiff tort claims and has worked extensively with defence lawyers in other jurisdictions in the coordinated defence of multinational mass tort claims.

Colin has been involved in the development of Australia's product liability laws and in the majority of the major product liability class actions in this area. His defence work includes IUD, pacemakers, diet pills and a variety of prescription products and medical devices.

Colin is internationally recognised for his work in the field of drug and device litigation. He has worked extensively with in-house counsel and lawyers in the US and Europe developing international defence strategies and working with international expert witnesses.

Colin also has a special interest advising manufacturing, pharmaceutical and medical device clients on regulatory requirements, clinical trial, labelling and advertising issues, product recalls and hazard alerts and priorities management issues. He practiced as a barrister in New South Wales between 1985 and 1990, when he became a partner at Clayton Utz.

Colin is a member of the International Association of Defense Counsel, the Australian Product Liability Association, the Defense Research Institute and is Vice-Chair of the Product Law and Advertising Committee of the International Bar Association.

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Stuart Clark is the National Managing Partner of the Clayton Utz Litigation and Dispute Resolution (LDR) department. A highly experienced commercial litigator, his principal area of practice is product liability law and the defence of class actions.

Stuart represents manufacturers and importers who are active in a broad cross section of industries including drugs and medical devices, motor vehicles and consumer products. He has particular expertise and experience in the defence of class actions and claims against drug and medical device manufacturers. He represents a range of clients based in Australia, the United States and Europe.

Over the past decade, Stuart has been intimately involved in the development of Australia's product liability laws and the majority of leading Australian cases in this area. He provides specialist advice in all facets of product liability and his expertise in the defence of class action/mass tort litigation, involving complex scientific and medical issues, is internationally recognised.

Stuart is a member of the International Association of Defense Counsel (IADC), the Defense Research Institute (DRI) and the Australian National Product Liability Association. He regularly speaks and publishes both in Australia and overseas, in relation to class actions and the defence of product liability claims.

Austria

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

According to the Austrian system, product liability may arise out of the general tort law, the contract law and out of various specific liability regimes, such as the Genetic Engineering Act. Depending on the general concept behind the various regimes, product liability can be based on the concept of fault or strict liability.

Product liability based on the Civil Code will only be of relevance if the purchase of a product does not qualify as a consumer transaction; otherwise the Product Liability Act applies (*Produkthaftungsgesetz*, BGBL No. 98/2001, as amended).

In addition, since the introduction of the Product Liability Act (PLA), which provides for strict liability, relying on general tort law will only make sense if the statutes of limitations provided by the PLA have already expired.

The PLA implements the European Directive 85/374/EEC on Liability for Defective Products (the Directive). As required by the Directive, the PLA contains a strict liability system and provides for stricter limits on recoverable damages, and also on the persons liable, as compared to the general tort system.

1.2 Does the state operate any schemes of compensation for particular products?

The Act concerning Compensation for Vaccination Damages (*Impfschadengesetz*, BGBl 371/1973) operates a compensation scheme for damages caused by certain vaccines. Recoverable are damages caused by vaccinations that are, among others:

- recommended by the "mother-child-passport";
- recommended by a regulation issued by the competent minister; or
- ordered by an administrative authority based on §17 of the Pandemic Law (*Epidemiegesetz*, BGBl 186/1950).

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

According to the PLA, the responsibility for a defective product is placed on the manufacturer. The manufacturer could either be the entrepreneur manufacturing the product itself, importing it into the European Economic Area or marketing the product, if the latter fails to disclose the name of the actual manufacturer or importer in due time.

Under the tort concept, every person within the production and distribution chain could potentially be liable. Contrary to the regulations of the PLA, the supplier may even be liable, irrespective of whether the manufacturer can be identified.

Liability could also arise out of the breach of statutory or regulatory duties. In such a case, the person violating the relevant provision could be held liable: for instance, persons covered by the Food Safety and Consumer Protection Act (*Lebensmittelsicherheit- und Verbraucherschutzgesetz*, BGBl 13/2006) or the Product Safety Act (*Produktsicherheitsgesetz* 2004, BGBl 16/2005).

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

The Food Safety and Consumer Protection Act (LMSVG) and the Product Safety Act regulate under which circumstances a product shall be recalled. According to the Product Safety Act, a product must be recalled if (i) the product under normal and reasonably foreseeable conditions of usage presents a risk, or (ii) does not have the minimum risk compatible with the product's use considered to be acceptable and consistent with a high level of protection for the safety and health of persons. In addition, if food products violate the standards laid down in the LMSVG, the relevant authorities may also order a recall of the products. Furthermore, the authorities in charge for medical products and medical devices can order recalls.

1.5 Do criminal sanctions apply to the supply of defective products?

Persons placing for instance food products on the market, which cause damage to health can be held responsible under the Criminal Code (*Strafgesetzbuch*, BGBl 60/1974, as amended). The sanctions can be up to one year imprisonment or a financial fine up to 360 daily rates. The amount of the daily rate depends on the income of the person or turnover of the company. For products placed on the market contributing to the spreading of infectious diseases the fines are increased to two years' imprisonment and, if a person dies, up to three years' imprisonment. In addition, the criminal court may order that the relevant judgment be published in a newspaper. Also legal entities can face criminal sanctions.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The claimant has to prove the damage, the defect, causation and that the product was placed on the market by the manufacturer. The defendant, if relying on the defence that the product was not defective when placed on the market, must prove that the defect that caused the damage did not exist at the time when the product was put into circulation, or that such defect came into being afterwards. In addition, the defendant may also prove that he was not the entrepreneur placing the product on the market and may nominate the actual person placing it on the market.

Under the tort concept, the claimant must prove damages, causation, unlawfulness and, in addition, negligent conduct of defendant.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The test to be applied is the so-called "*conditio sine qua non*" test meaning that the question to be answered is: would the damages have occurred if the product had not been defective? If the answer is affirmative, no liability will exist. In general, it is not sufficient for the claimant to show that the product exposed the claimant to an increased risk. However, if the event follows an established typical course, the Austrian courts consider it sufficient to prove causation by a *prima facie* evidence. This means that the claimant must simply convince the judge that, according to general knowledge and understanding, the event followed a general course and, therefore, it is more likely that the damage was caused by the defendant than by other means. The concept of *prima facie* evidence aims at reducing the burden of proof, but of course, it can be counter evidenced by the defendant.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

The Austrian system does not recognise the concept of market-share liability. However, under certain circumstances joint and several liability could arise, namely if the damages cannot be attributed to one specific person or if two or three persons were intentionally working together to harm the injured person. This concept might perhaps apply to situations where it cannot exactly be established what product caused the harm, but it will definitely not apply when the claimant cannot even allege which product he has actually used.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

A product is defective in the meaning of the PLA if it does not provide the safety that a person is entitled to expect. Therefore, a failure to warn could be considered as a defect. The warnings must generally be of such a nature that the risks associated with the product must be described to the greatest possible extent. Any inconsistencies will be held against the party issuing the warning. In general, the concept applied is whether an average and well-informed consumer would have been reasonably warned about the risks. However, the court decisions in Austria are normally in favour of consumers.

If the product is intended to be used by professionals, the standard could be lower. However, if the manufacturer is aware that the professionally used product is also constantly used by consumers, for avoiding liability, the manufacturer should provide more detailed information.

There is no learned intermediary rule under Austrian law. Consequently, warnings given to physicians normally do not release a pharmaceutical company from providing sufficient warnings to patients. However, it must be specifically taken into account that certain warnings due to the lack of appropriate scientific proofs are not allowed to be included in the package leaflet. Therefore, in product liability cases, the warnings provided in the summary of product characteristics as well as in the package leaflet must be seen as supplementing each other. According to at least one case in Austria, although certain information was not contained in the package leaflet, the manufacturer was not automatically held liable. The Supreme Court stated that the lower court must still establish whether the patient would not have taken the product although recommended by her physician. Therefore, for undermining causation, the learned intermediary defence can be tried.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under the PLA the following defences are available:

- the manufacturer did not place the product on the market;
- the manufacturer can prove that the product did not have the defect that caused the damages at the time the product was placed on the market or the defect came into being afterwards;
- the product was not intended for sale;
- the manufacturer complied with specific mandatory regulations issued by public authorities when manufacturing the product;
- the state of scientific and technical knowledge at the time

when the manufacturer placed the product on the market was not such as to enable the existence of the defect to be discovered; or

- in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instruction given by the manufacturer of the product.

Under tort law, all defences are available that allow the defendant to disprove causation, that the manufacturer was not violating any protective laws, etc.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Austria has implemented the development risk defence as provided for in Article 7 of the Directive. Most legal scholars in Austria assume that this defence will be only available in rare cases, because of the case C-300/95, European Commission vs. the United Kingdom. Advocate General Tesauro stated that the state of scientific knowledge cannot be identified by relying on the views expressed by the majority of learned opinion, but by taking into account the most advanced level of research, which has been carried out at the relevant time. Consequently, publications in a Chinese local journal would still allow a manufacturer to rely on this defence; however, if the article was published in an English journal, the manufacturer could not rely on this defence any longer. Therefore, the requirements to be met are extremely high and it is doubtful whether any company could reasonably meet them.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Compliance with regulatory and/or statutory requirements constitute(s) only a defence when the manufacturer was specifically ordered to comply with these standards. Compliance with "general" authorisations, such as marketing authorisations for medicinal products or with a CE marking in the medical devices fields does normally not constitute a defence under the PLA. However, this is a suitable defence under the general tort concept.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

If a judgment rendered between the same parties becomes valid, the claimant can generally not re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage again (some rare exemptions apply, e.g. the first judgment is based on fraudulent evidences). The principle "*ne bis in idem*" prevents a court from ruling again on an identical claim. The second judge must dismiss the claim if the new claim contains the same requests and is based on the same facts used in the old proceedings. Because a court's decision is binding only between the involved parties, a different claimant can re-litigate any issues of fault, defect or causality. However, if the Supreme Court has, for instance, already decided that under certain circumstances a product was not defective, a lower court will generally follow this ruling. Because fault, defect and causation are questions of law and not of facts, the same claimant can re-litigate these issues provided that he is relying on different facts.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

Manufacturers who only provide raw materials or a part of the finished product will only be held liable if their contribution caused the damage. The plaintiff can freely decide whether the plaintiff relies on the final manufacturer or on the person providing the raw material or parts of the finished product. However, such a claim could fail due to the fact that the final manufacturer is not required to provide the claimant with the name of such an intermediate manufacturer.

Of course there is a possibility to initiate subsequent proceedings if one court rules that the final manufacturer is not liable. Also, it is possible to interplead third parties. However, the ten-year statute of limitations must be met (i.e., an actual action against the third party must be filed in due time). Consequently, if ten years have already elapsed, a claim based on the PLA can no longer be filed. In such a case, the claimant must rely on the general tort concept which is more burdensome for the claimant.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

The PLA allows that the liability of the manufacturer may be reduced if the damage is (partially) caused by the fault of the injured person or any other person for whom the injured person is responsible. The same principle also applies under tort rules.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

In civil court proceedings, the Austrian system does not know a jury system. The proceedings are handled by career judges.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

If the judge does not have the required technical expertise, the judge will invite a technical expert to participate in the court hearings and to ask questions to parties and witnesses. Legally, the facts are assessed only by the judge. In practice, the judge will often rely on expert opinions containing also a summary of facts recorded by the expert.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

Currently, no group or class actions are permissible under the

Austrian legal system. However, the Minster of Justice is considering implementing some sort of group proceedings. A first draft was submitted to Parliament in Summer 2007, but was heavily criticised by the major stakeholders (e.g. for restricting the right to be heard before the court). It is expected that an amended draft will be re-submitted to Parliament in the course of this year. The draft law, as it stands now, would provide for an "opt-in" option.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Contrary to other statutes, consumer associations are not specifically entitled to initiate proceedings. This seems reasonable because the individual medical facts must be taken into account, e.g. predisposition of a plaintiff. However, also here the Ministry of Justice wants to allow such proceedings where the consumer association can classify a pending proceeding as "model case proceedings" because the legal issues involved could be relevant for a huge amount of claims filed against the same defendant.

4.5 How long does it normally take to get to trial?

Austria does not have a pre-trial stage. After the claim is filed, the defendant normally has four weeks to respond. After the court has received the response, it normally takes one to two months for the first hearing to take place.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The Civil Procedure Code (*Zivilprozessordnung*, RGBl. No. 113/1895, as amended) does not provide for the court to try preliminary issues first. Under certain circumstances, the parties may request that, for instance, the judge first issues an interim award with respect to the merits, and only afterwards the amount of the damages to be awarded will be established.

4.7 What appeal options are available?

The first instance judgment can be appealed to the appellate court (there are certain restrictions, however, regarding disputes not exceeding EUR 2,000).

A further appeal to the Supreme Court is admissible if the matter in dispute relates to a matter of substantial or procedural law which is of utmost importance for the consistency or legal certainty of the law, or contributes to a further important development of the legal system. In general, no appeal to the Austrian Supreme Court is admissible if the matter in dispute does not exceed EUR 4,000.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

If a judge does not have the required technical and/or scientific knowledge, the judge can appoint an expert. In general, a judge will allow the parties to comment on the expert selected by the court. The expert is instructed to provide a written opinion on technical and scientific issues, and if so requested, he must also draw a conclusion and provide a thesis.

Parties are allowed to rely on their own experts. However, reports submitted by a party expert are not considered as expert opinions in the meaning of the Civil Procedure Code and are, therefore, of lesser importance. Private expert opinions are normally used to undermine the court expert report because, for instance, the expert report did not discuss all the issues at stake or is not in line with the opinion of the parties. In general, private expert opinions are not submitted before the court appointed expert has rendered his/her opinion.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

There is no pre-trial deposition proceeding in Austria. In general, no expert reports are exchanged before the trial has started.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

In Austria no discovery procedure is available. Consequently, the parties are not required to disclose any documents before the trail has started. However, if a party relies in the proceedings on a specific document, the document must also be given to the other party. In addition, if the document is considered a joint document, for instance, contracts signed by both parties, and it is in the possession of the other party, the possessing party must furnish the other party with this joint document. Only under very limited circumstances could a party legally enforce the provision of such documents. If such document is not provided, the judge will normally hold this against the refusing party.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

In general, alternative methods of dispute resolution are available, but are not relied upon in practice. Sometimes the so-called *Patientenanwaltschaft*, comparable to a patient ombudsman, intervenes on behalf of a patient and tries to achieve a settlement.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

The Civil Code as well as the PLA provide for statutes of limitations.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

With respect to time limits on starting proceedings, it must be distinguished between the relative statute of limitation period and the absolute statute of limitation period. The relative limitation period of three years begins to run from the day on which the claimant should have reasonably become aware of the damage, the defect and the identity of the manufacturer. Under tort rules, the absolute statute of limitation period will be 30 years after the incident of dispute occurred, under the PLA, this time period is

reduced to 10 years. With respect to the latter, the starting point will be the day when the product was placed on the market.

Contractual warranty claims, such as a claims due to the delivery of products not suited for the agreed purpose, must be lodged within two years.

Only if raised by the defendant, the judge must take into consideration the statue of limitation period and dismiss the claim. Under certain circumstances the time period provided for by law can be suspended, for instance, if the parties conducted settlement negotiations. However, such settlement negotiations must be concrete, meaning that there must be at least an exchange of different proposals (rather than one party alleging liability and the other party denying liability).

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Concealment or fraud does generally not affect the running of any time limit. However, because the time limit will only start to run from the actual knowledge of the damage and the person inflicting such damage, concealment will simply result in a later filing of the claim after the facts have surfaced.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

Under the PLA the same remedies are available as in normal civil court proceedings, such as monetary compensation and declaratory relief, e.g. for all future damages. It would also be possible to file a cease and desist claim, but this is never done in PLA proceedings.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

The tort law as well as the PLA cover both monetary and non-monetary losses. Compensation for personal injuries include, among others, the cost for medical treatment, loss of income, etc. Furthermore, damages can be awarded for suffering of pain due to the loss of a close relative. Damages awarded in Austria are much lower than in the United States. For instance, for a man whose arms and legs are paralysed, needs artificial respiration until he dies and he is completely aware of his situation, the Supreme Court awarded an amount of approximately EUR 218,000.

Mental damage as well as so-called disfigurement damages must also be compensated.

Damages to property are generally recoverable under all three regimes, but restricted under the PLA to damages exceeding EUR 500 (i.e., there is a deductible of EUR 500). Under warranty law, damages to the product itself are generally not recoverable, except for damages that have spread to the non-defective portion of a purchased product from a defective part.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Under the PLA such damages cannot be recovered because one of the requirements to be met by the claimant is to prove that damages actually occurred.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

The Austrian legal system does not recognise punitive damages. A foreign judgment granting punitive damages would not be enforceable in Austria (violation of the *ordre public* principle).

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There are no caps on damages under the PLA.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

As mentioned above, Austria does not (yet) have the concept of group or class actions. Claims filed by infants need the approval by a judge and are filed on behalf of the infant by his/her legal representatives.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

The award is only binding between the litigating parties and so payment is only effected between the parties. The government/reimbursement institutions cannot claim any part of the damages awarded to an individual person. In practice, if an unfavourable decision is rendered for a company, sometimes the insurance bodies approach the company requesting to be compensated for the treatment costs.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

According to the Civil Procedure Code, the prevailing party is reimbursed for its necessary legal costs and court fees by the losing party. Recoverable costs will be calculated in accordance with the lawyers' tariff, which is based on the value of the claim.

7.2 Is public funding e.g. legal aid, available?

Legal aid will be granted to physical persons and, in limited circumstances, to corporations. However, the person getting legal aid must still pay the costs of the other party if the other party prevails. Legal aid consists of a waiver of court and expert fees and free representation by an attorney appointed by the bar association.

7.3 If so, are there any restrictions on the availability of public funding?

Legal aid will only be granted if a party does not have sufficient financial means to conduct the proceedings. In addition, the judge approving legal aid must evaluate whether the claim has a sufficient prospect of being successful. Under certain circumstances, e.g. if the financial situation has favourably changed, the legal aid must be paid back.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Austrian attorneys are prohibited from working on a contingency fee or on a "no win - no fee" basis. It is admissible to agree on a bonus for successful work. This prohibition was recently confirmed by the Austrian Constitutional Court.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Third party funding of claims is permitted under Austrian law. In general, a request is sent to a private company asking for financial assistance, which will normally only be granted if the amount in dispute exceeds a certain threshold. Based on the expected outcome, the compensation for the private financer is between 20% to 50% of the awarded amount.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Austria.

Although discussed for years, Austria still has not implemented any form of group-actions. The new Minister for Justice intends to implement such a system. In addition, the tort law is due to be modernised. This could perhaps have an impact on the product liability regime.

It was recently decided by the Supreme Court, which was for a long time under discussion, whether a non-functioning product, namely a wood preservative, which did not protect the wood against the weather, is defective under the meaning of the PLA. Most of the scholars assumed that a non-functioning product would only give rise to claims under the warranty provisions.

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Belgium

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Thelius

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

In Belgium, the question of product liability may be analysed under four aspects:

- strict (objective) liability;
- contractual liability;
- tort liability; and
- criminal liability.

Several specific legislations reinforce consumers' protection, such as for instance:

- Royal decrees of 6 June 1960 and 14 December 2006 on pharmaceutical products;
- Act of 24 January 1977 on consumer health protection and Act of 9 February 1994 on products and services safety;
- Act of 14 July 1991 on commercial practices and the information and protection of consumers; and
- Act of 5 July 1994 on blood and blood by-products.

A) The strict (objective) liability:

The main text is the Act dated February 25, 1991 on Liability for defective products (hereafter "Product Liability Act") which implements the EU Directive 85/374 on liability for defective products. This Act came into force on April 1, 1991. It was slightly modified by the law dated December 12, 2000 implementing the Directive 1999/34 EC of the European Parliament and of the Council European Parliament of Mai 10, 1999.

Under this Act, the producer shall be automatically liable for damage caused by a defect in his product. This liability without fault exists towards any injured person (the buyer or other party).

The plaintiff must prove the defect in the product, the reality and importance of the damage suffered, as well as the causal link between the defect and the damage.

B) Contractual liability:

a) Pursuant to article 1641 to 1649 of the Belgian Civil Code, the seller guarantees the buyer for the hidden defects in the product sold. These articles are still in force and apply to any sales.

An act dated September 1, 2004 introduced new articles in the Civil Code (articles 1649 bis to 1649, 8) but limited to consumers' sales. They impose on the professional seller a conformity warranty of the goods delivered.

b) In application of the latent defect warranty regime, the seller is not liable for apparent defects which the buyer could notice himself (article 1642 of the Belgian Civil Code).

The warranty concerns exclusively latent defects of the good sold, if these defects make the product unsuitable for the use for which it is intended or is material enough to render the product unfit for use or to reduce its value.

The Belgian case law imposes on the seller, and more particularly on the professional seller, three duties:

- competence;
- advice; and
- warranty.

The competence duty has been established by the Supreme Court. This one has decided that the manufacturer or the seller must ensure that the product manufactured or the product sold to a buyer is not affected by hidden defects. The seller, the manufacturer or the specialist have the obligation to take the necessary steps to detect all possible defects and to ensure to the buyer a proper use of the product.

The information duty results clearly from article 1645 of the Belgian Civil Code. According to this article, if the seller was aware of the defect of the product and did not inform the buyer, he is obliged to full compensation.

The warranty duty exists even if the seller legitimately ignores the latent defect in the product sold. Even if no reproach may be addressed to the seller, the buyer may rescind the sale and recover the purchase price or request a price reduction and keep the product (article 1644 of the Belgian Civil Code).

c) Within the framework of the conformity warranty in sales to consumers, a product answers to this conformity obligation, according to article 1649 ter of the Belgian Civil Code if:

- it corresponds to the description given by the seller and presents the quality of the good presented by the seller as a sample or model to the consumer;
- it may be affected to the specific use that the consumer intends to give to this product and of which he has informed the seller at the time of the conclusion of the agreement, and that the seller has accepted;
- it is fit for the uses to which goods of the same type are usually affected; or
- it presents the quality of a good of the same type, quality to which the consumer may reasonably expect, taking into account the nature of the good and eventually the public declaration made by the seller or the manufacturer, for instance through publicity or labelling.

C) Tort liability:

Pursuant to articles 1382 and 1383 of the Belgian Civil Code, any

act which causes damage to another obliges him by whose fault it occurred to make reparation and each one is liable for the damage which he causes not only by his own act but also by his negligence or imprudence. The injured party must therefore prove the fault, the damage and the causal link between the fault and the damage.

As from the date the Product Liability Act came into force, the recourse (still authorised) to articles 1382 and 1383 of the Belgian Civil Code does not make much sense. Why should the plaintiff accept to bear the burden of proof of a fault of the seller or of the manufacturer while he may obtain the indemnification of the damage by proving only the defect in the product as well as the damage and the causal link?

D) Criminal liability:

The Belgian Criminal Code organises severe sanctions towards sellers that act fraudulently.

Article 498 of the Belgian Criminal Code provides sanctions for the seller misleading the buyer on the identification, nature or origin of the good sold.

The Supreme Court considers that there is a fault in the meaning of article 498 of the Criminal Code when the good may not be affected to the use for which it was bought and if it is certain that had the buyer been aware of this circumstance, the contract would not have been signed.

Article 499 of the Belgian Criminal Code is more severe toward the seller which by fraudulent acts has misled the buyer on the characteristics of the good sold.

Article 500 of the Belgian Criminal Code organises sanctions towards the persons who have falsified or modified foods or who have sold or exported goods whilst knowing that they were adulterated.

There are also more general provisions on involuntary homicide or infliction of involuntary bodily injury. These provisions may be applied to the manufacturer or the seller who, by negligence, has allowed the sale of a dangerous product likely to provoke bodily injuries.

As regards to the liability for defective products, criminal complaints are rare and seldom succeed.

1.2 Does the state operate any schemes of compensation for particular products?

Federal Authorities have not created compensation schemes for particular products, except for asbestos. A law dated December 27, 2006 creates a Fund for victims of asbestos (chapter VI of title IV of the law programme dated December 27, 2006 creating a Fund for indemnification for the asbestos victims and Royal Decree dated May 11, 2007).

The Walloon government has created a compensation scheme for waste damages sustained in the Walloon region (Walloon Decree dated June 27, 1996 and Walloon government order dated November 5, 1998).

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

A) Objective (strict) liability:

According to article 1 of the Product Liability Act, the producer is responsible for the damage caused by the defect in the product. Articles 3 and 4 of the Act define the notion of "producer", by distinguishing the real producer, the apparent producer and the presumed producer.

The real producer is the one who actually manufactures the product. Article 3 of the Act defines the "producer" as: "*the manufacturer of a finished product, the manufacturer of a component part of a finished product, or the producer of any raw material*".

This definition is large. For example, in the case of a plane crash due to the defect of the metal used in the manufacturing of screw bolts used for the engine, one must consider as the manufacturer responsible, the steel producer, the screw bolts producer, the engine producer and the plane producer.

The apparent producer is "*any person presenting himself as a manufacturer or producer by affecting on the product his name, trademark or other distinguishing feature*" (article 3). The seller who affects his name on a product for marketing reasons does not present himself as a "producer". However, supermarkets selling products which they have asked smaller companies to manufacture and which are commercialised under their own brands, must be considered as "producers" in the meaning of article 3 of the law.

Some persons are deemed to be "producers" in order to allow the user of the product to contact a producer (article 4, § 2) established within the European Union (article 4, § 1).

According to article 4, § 2, the supplier is deemed to be a producer when the producer of the product cannot be identified unless he informs the injured person, within a reasonable time, of the identity of the producer or of the person who has supplied him with the product.

According to article 4, § 1, any person who imports a product into the Community shall be responsible as a producer. This article protects the consumer who will not be obliged to bring a case against a producer established outside of the Community.

B) Contractual liability:

Under contractual liability, the seller is responsible for the defects in the product. The seller is liable towards the buyer or the consumer for the latent defect or lack of conformity of the product.

C) Tort liability and criminal liability:

The responsibility will be borne only by the person who has committed a fault.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

The Act dated February 9, 1994 on products and services safety, establishes a general safety rule: "the producers are obliged to market only safe products and to offer exclusively safe services". This leads to a duty to inform and warn consumers, suppliers and public authorities in the event of a defective product being produced and eventually to recall that product.

In application of article 4 § 2 of this Act, the Secretary in charge of consumer protection may order the withdrawal from the market of a product when it has been noticed that one of several elements of this product do not answer to the general principle of safety.

The Secretary in charge of consumer protection will contact the producer of the product and inform him at the latest 15 days after withdrawal must have been made. The producer may bring recourse against the Secretary's decision before the Administrative Jurisdiction (*Conseil d'Etat*). This recourse is not suspensive.

Not to comply with an obligation organised by this Act amounts to a fault and allows the injured party to bring a claim based on article 1382 or 1383 of the Belgian Civil Code.

1.5 Do criminal sanctions apply to the supply of defective products?

As explained earlier (see question 1.1 D), the seller of defective products is punishable of criminal sanctions.

The Criminal Code organises sanctions towards the seller who has deceived the buyer in respect of the quality, quantity or origin of the products.

The Criminal Code (articles 418 to 420) also organises sanctions towards the person liable for involuntary homicide or the infliction of involuntary bodily injuries.

Finally, the law dated February 9, 1994 on products and services safety also provides criminal sanctions towards the persons who market products for which they know or should have known on the basis of European or Belgian regulations that they did not present the safety imposed by the regulation.

In addition to fines, the judge may order the confiscation of the illicit benefits carried out with the favour of the infringement, and order, to the expense of the contravener, the advertisement or publication (during a determined delay) of the judgment of its summary, in the press or by any other media.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

Each party has the burden of proof as regards the facts alleged (article 870 of the Judicial Code).

Article 7 of the Product Liability Act confirms: "*the burden of proof of the defect, the damage and the causal link between the defect and the damage belongs to the injured person*".

There is no exception to this principle neither in tort liability nor in criminal liability.

As regards contractual liability, the buyer availing himself of a latent defect in the product must prove not only the latent defect, but also establish that this defect existed when he bought the product.

However, the case law gives some support to the person who buys a product to a professional seller. In this case, the Supreme Court has decided that the professional seller is obliged to the full compensation of the buyer's damage if the existence of the defect is established unless the seller demonstrates that the defect could not be detected. This case law is strict: the circumstance that the defect could not be detected or could only be detected by a destructive investigation after the manufacturing of the product or of one its elements, does not exclude that the manufacturer is presumed to be aware of the existence of the defect.

As regards sales to a consumer, the Belgian Civil Code presumes that the lack of conformity - appearing within a six-month delay calculated as from the delivery - existed at the moment of delivery unless proof to the contrary (article 1649 quarter, § 4).

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The Belgian case law is attached to the "*theory of the equivalence of conditions*". The causal link is established when the damage, as it occurs, would not have occurred if the fault had not been committed. The criterion of the causal link is simple: it is the test of the *sine qua non* condition. One need only ask the question to know whether the damage would have occurred, as it occurred, had there been no fault. If the answer is affirmative, the causal link does not exist. If the answer is negative, the causal link is established.

The causal link must not be direct. It may be indirect as soon as it appears necessary, meaning that it is certain that the damage is an unavoidable consequence, however immediate, of the fault.

It does not matter that the damage is not a usual consequence of the fault, if, without the fault, the damage would not have occurred. In such a case the causal link is established.

However, the causal link must be certain. If there is doubt, the injured party who has the burden of proof will see her claim dismissed.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Under tort liability, if there are several producers of one defective product which led to just one damage, the producers will be held jointly and severally liable for this damage, without prejudice of the recourse between the producers to obtain full or partial reimbursement of the damage paid.

If it is impossible to determine the identity of the producer, the injured party is allowed to act according to article 4 § 2 of the Product Liability Act, against the supplier. If the injured party cannot identify the producer or the supplier, she has no right of action.

The Belgian law does not recognise market share liability.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

The Belgian case law gives a large application to the principle of good faith execution of the agreements.

The good faith forces the one who knows or should know to transfer to the contracting party all the information that one may need for useful and safe use of the product bought.

This duty to inform is stated, implicitly but certainly, by article 1645 of the Civil Code. The law dated February 25, 1991 adds that in the appreciation of the defect of the product, one must take into account, among others, its presentation. A product is defective when it does not offer the safety to which one could legitimately expect taking into account all the circumstances. The reference, among the circumstances to be taken into account, to the "product presentation" demonstrates that the insufficient information of the consumers is included in the notion of "defect". For instance, if the producer of a toxic paint informs, in an appropriate manner, the users of the product's characteristics and invites these users not to

use the paint, among others for children's toys, the public may not legitimately expect that this paint does not present any toxic effect.

The information that must be given is all the details which could be useful for the users. When the user is already informed either by a third party or by himself (professional user), the information is not useful.

The main criterion is the reception of the information by the user, whether received directly or indirectly by the producer.

When a medicine is not available over the counter, but may only be bought with a prescription, the doctor must verify if the medicine is appropriate to the patient and must draw his attention on the possible harmful effects. This does not exempt the producer to establish, in application of the law, a notice describing the conditions of use of the medicine, the contra-indications and the possible side effects.

3 Defences and Estoppel

3.1 What defences, if any, are available?

A) Strict (objective) Liability:

Article 8 of Product Liability Act enumerates six causes of defences for defective product liability. The producer must prove that he meets the following conditions:

1 The producer did not put the product into circulation (i.e. the product has been stolen).

2 Having regards to the circumstances, the defect which caused the damage did not exist at the time when the product was put into circulation by the producer or this defect came into being afterwards.

It should be underlined that, under the cover of granting to the producer a defence, article 8, b, of the Product Liability Act reverses the burden of proof. Indeed the liability of the seller towards the buyer and third parties only covers the risk existing at the moment of delivery. It is in principle to the injured party to establish the existence, at the moment of delivery, of the latent defect alleged. The Act derogates to this principle by obliging the producer to prove that the defect came into being after he was put into circulation.

3 The product was neither manufactured for sale or for any form of distribution for the economic purpose of the producer, nor manufactured or distributed by the producer in the course of his business. This provision exempts, for example, a person who donates blood as this one has not been manufactured for sale or for any kind of distribution with an economic purpose.

4 The defect is due to compliance of the product with mandatory regulations issued by the public authorities. Indeed, there is no fault in complying with an act ordered by the law or a public authority. The exemption nevertheless does not apply if the public authority intervention is limited to mere recommendations or authorisations.

5 The state of scientific and technical knowledge at the time when the producer put the product into circulation was not such as to enable the existence of the defect to be discovered (so-called development risk).

6 For the producer of a component or for the producer of a raw material, when the defect is attributable to the design of the product in which the component or the raw material has been built-in or to the instructions given by the producer of this product. This case is in fact a repetition of the principle stated at article 8, b.

Article 10 § 2 of the law adds that the liability of the producer may be reduced or disallowed when the damage is caused by a defect in the product and by the fault of the injured person of a person for whom the injured person is responsible (contributory negligence).

In addition the liability of the producer may not, in relation to the injured person, be altered by a contractual provision reducing or exempting the producer from his liability.

B) Other liability systems:

In the other liability systems, the producer or the seller may avoid or limit his liability while putting forward a case of absolute necessity ("*force majeure*") or a fault of the injured party. Clauses that disclaim or limit liability are in principle valid, but have been held unenforceable towards consumers and each time the manufacturer or the seller was dishonest (for instance the seller who was aware or should have been aware of the latent defect and did not reveal it).

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

The development risk is a defence for the producer under the Product Liability Act. According to Article 8, e, the producer must prove that the state of scientific or technical knowledge at the time when the product was put into circulation was not such as to enable him to discover the defect.

As regards contractual liability, the Supreme Court has often decided that the existence of a latent defect leads for the professional seller to a breach of his knowledge duty, "*unless he proves that - whatever his diligence - he could not be aware of it*". The professional seller will prove an exemption cause only if the defect "*was of such nature that it was impossible for him to notice it at the time of the sale*".

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

A manufacturer may not be exonerated for his liability when it complies with regulatory and/or statutory requirements. The manufacturer will be exonerated from his liability if he proves that the defect is due to compliance of the product with mandatory regulations imposed by public authorities and not just to compliance with minimum safety standards.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

The principle of *res judicata* precludes the same claimant to bring a new trial which would lead to re-litigate issues already judged. The *res judicata* principle only applies between the same parties as regards the same object and cause of action.

Any person who did not take part in the initial trial has therefore the right to bring against the producer a trial similar to the one which has led to a judicial decision.

The judge who will decide in the new proceeding is not bound by the previous decision (no estoppel as regards defect or causal link).

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

The liability of a producer towards an injured person is not reduced or dismissed towards the injured party when the damage is caused both by a defect in the product and by the intervention of a third party (article 10 § 2 of the Product Liability Act).

However, the producer has a subrogated action against the third party which must be brought within five years to be calculated as from the date the victim had knowledge of her damage or within 20 years to be calculated as from the fact at the origin of the damage.

When a partial liability can be reproached to a third party, the producer should file a third party intervention (within the initial proceeding brought by the victim) against this party to obtain his guarantee.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

When the damage is caused both by a defect in the product and by the fault of the injured party of any person for whom the injured person is responsible, the liability of the producer may be reduced or disallowed.

The judge has full discretion to determine the liability share to be brought by the producer and the injured person.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

In Belgium, there is no jury for civil matters; the case is submitted to a judge.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The Belgian Judicial Code (article 962) allows the judge to appoint experts "*in order to make findings of facts or to give a technical advice*".

The expert appointed by the judge may not have other missions. He is not allowed to give his advice on the merits of the claim; he is not allowed to research evidences.

The parties have to give to the expert "*the necessary elements*" to allow him to make useful findings or give technical advice (article 972 of the Judicial Code).

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

The Act of 14 July 1991 on commercial practices and the information and protection of consumers allows the Ministry for Economic Affairs and any consumers rights association with legal personality and represented at the Consumption Council or recognised by the Ministry of Economic Affairs, to ask the President of the Commercial Court to order cessation of a practice infringing the provisions of the Act of 14 July 1991 (for instance: misleading advertisement).

The sale of harmful products could be considered as an act contrary to the fair trading practices. The case law, however, does not give any example of such claim.

Except for this injunctive relief action described here above, the class action procedure for the matter under review does not exist in Belgium.

There is no opt-out system in which eligible plaintiffs are automatically part of a class unless they decline to be included. There is no opt-in procedure.

However, when damage is suffered by a large number of consumers, each of them must file individually a claim for damages. Plaintiffs with similar but separate claims can institute proceedings before the same court and ask the court to handle their claim at the same hearing without joining them.

If a consumers association would bring a claim for damages, its claim would not be admitted because it has no quality to claim damages for a damage suffered by others (the consumers).

In practice, when several consumers have suffered similar damages with the same origin, they can contact one law firm which shall file one claim for damage in the name of all the injured persons.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

See the answer given under question 4.3.

4.5 How long does it normally take to get to trial?

The length of a proceeding depends on various factors (overloaded courts, lawyers' diligence, number of parties, need for an expertise and its progress, incidents during the proceeding, among others).

Taking into account these elements, the proceeding may last between six months and six years.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The Court may render a preliminary judgment on the question of competence, proceeding or ordering investigation measures (for instance an expertise). Such judgment does not prejudge the final decision.

4.7 What appeal options are available?

The decisions of the Court of first instance and of the Commercial Court on a demand which does not exceed EUR 1,860.00 may not be appealed (Judicial Code, article 617).

In all other cases, an appeal may be brought as soon as the judgment is rendered, even if this one is a preliminary decision or if it is a judgment by default (Judicial Code, article 1050).

The appeal has to be brought within one month of the notification of the judgment (article 1051).

The defendant may form an incidental appeal any time against all the parties before the appeal judge (article 1054).

The appeal brings to the appeal judge the case in all its facts and law aspects (article 1068).

The parties may bring recourse against the appeal decision before the Supreme Court. This one only knows about the matters of law and not of fact. The Supreme Court must check, within the limits of the grounds indicated in the request for cassation, if the judge has correctly applied rules of law. The Supreme Court does not take into consideration the case, but the criticised decision.

If the Supreme Court finds that the law has not been properly applied or that the decision criticised is not sufficiently legally grounded, it remands the case to another court of the same degree and type as the court which rendered the criticised decision.

The court of remand is not obliged to follow the decision of the Supreme Court.

When, after a cassation, the second decision is criticised for the same grounds as the ones in the first recourse, the case is brought before the Supreme Court in full session (Judicial Code, article 1119).

If the second decision is annulled for the same grounds as the first cassation, the remand judge to which the case is sent must obey the decision of the Supreme Court on the legal points judged by this one (article 1120).

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Upon one party request, on its own initiative, the judge may appoint a judicial expert for a technical advice.

Each party may have its own technical adviser who shall file a report that the judge may or may not take into consideration.

The judge does not have to follow the judicial expert's advice and moreover is not bound by the report of the technical adviser of one party.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

There is no pre-trial deposition or formal prior disclosure procedure.

During the proceeding the parties must exchange all supporting documents (witness statements, expert reports and any other evidence before the hearing) with their written submissions.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

The parties must exchange the supporting documents on which they intend to rely before they are produced during the proceeding (article 736 of the Judicial Code).

There is no pre-trial discovery procedure, but when there are serious concurring and precise presumptions that one party or a third party holds a document proving a relevant fact, the judge may order the disclosure of this document which shall be filed with the proceeding (article 877 of the Judicial Code).

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

The parties may decide to refer the case to mediation or arbitration but only on a voluntarily basis.

As regards arbitration, the parties must agree to be bound by the arbitrator's decision which shall be enforceable as a judgment of the Court.

As regards mediation, this is expressly organised by the Judicial Code since 2005 and tends to develop also in liability cases. It must be underlined that if conciliation fails, the plaintiff will have to file a lawsuit to pursue his claim.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

There are time limits on bringing proceedings (see question 5.2).

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

A) Strict (objective) liability:

The Product Liability Act provides that proceedings for the recovery of damages are barred at the end of a period of three years as from the date on which the plaintiff became aware or should have become aware of the damage, the defect and the identity of the producer (article 12 § 2). This delay may be interrupted or suspended.

In addition, the manufacturer's liability is extinguished ten years after the product was put into circulation (article 12 § 1).

B) Contractual liability:

a) Latent defect:

In application of article 1648 of the Civil Code, the claim of the buyer against the seller based on latent defects of the good must be brought "*within a short delay*".

The appreciation of the short delay in which the case must be brought is left to the discretion of the judge who takes into account all the factual circumstances and for instance the nature of the good sold, of the defect, the customs of the relevant trade and industry, the quality of the parties and the judicial and non judicial acts (negotiation) accomplished by them.

The Court normally considers that the "short delay" starts when the buyer discovered or should have discovered the latent defects. A delay of six months up to one year is often considered as a "short delay".

b) Lack of conformity:

The claim brought by the consumer is barred at the end of a period of one year as from the date on which he notices the lack of conformity. This delay may not terminate before the end of a two-year delay which is the delay for the conformity warranty.

C) Tort liability and criminal liability:

As regards tort liability and criminal liability, article 2262 bis § 1 of the Civil Code provides a double delay:

- Five years as from the date on which the plaintiff was aware of the damage or of its worsening and of the identity of the person liable.
- 20 years as from the date on which occurred the fact which led to the damage.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

The statute of limitations for the different claims (see question 5.2) starts generally as from the date the injured party is aware of her damage and of the defect in the product. The issue of concealment or fraud necessarily affects the running of the time limit. The fault consisting to conceal the defect in the product would delay the starting point of the statute of limitations.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

In most of the cases, monetary compensation is granted as a remedy in civil product liability cases. The injunctive relief is organised under the Act of 14 July 1991 on commercial practices and the information and protection of consumers (see the answer to question 4.3).

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

A) Strict (objective) liability:

According to article 11 of the Product Liability Act, damages for bodily injuries and moral damages are recoverable.

The damages to goods are recoverable only if the goods are normally intended for a private purpose and have been used as such by the victim, with the application of a EUR 500.00 threshold.

The damages to the defective product itself are not recoverable.

B) Contractual liability:

a) Latent defects:

If the seller was aware of the latent defects of the good or does not demonstrate its invincible ignorance of the defect, he must provide full compensation of the damages resulting from the latent defects in the product.

If the seller legitimately ignored the latent defects of the good and demonstrates that the defect could not be detected, he will have to reimburse the price paid and the expenses resulting from the sale (article 1646 of the civil Code).

b) Lack of conformity:

In case of lack of conformity of a good sold to a consumer, this one may choose between the repair of the product, the reimbursement or the rescission of the contract.

In a first stage, the consumer has the right to repair or replacement of the good except if it is not possible or disproportionate. There is disproportion when the repair or the replacement obliges the seller to costs which are unreasonable taking into account the value of the good without the conformity defect, the importance of the defect and the fact that another way of indemnification can be chosen without major inconvenient for the consumer.

The consumer may obtain a price reduction or the contract rescission if he has no right to the repairs or the replacement of the good or if the seller has not repaired or replaced the good within a reasonable delay.

C) Tort liability and criminal liability:

When the producer or the seller is held liable, this one must provide full compensation for the damages. He must place the injured person in the position he/she would have been in if no fault had been committed.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Following decisions of the Supreme Court, when the seller knows that the products put on the market are affected by a latent defect, he must, even after delivery, inform the buyer of the existence of this defect

6.4 Are punitive damages recoverable? If so, are there any restrictions?

There are no punitive damages under Belgian law.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no maximum limit on the damages recoverable provided by law even for a series of claims.

The liability insurance policies subscribed by companies provide a maximum for the indemnification in case of a series of claim.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

There are no specific rules as regards settlement of claims/proceedings in the matter of product liability.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Belgian Government authorities concerned with health and social security matters may not claim a portion of damages awarded or settlements paid to the plaintiff as the result of a product liability lawsuit. However, these authorities could claim from the producer the reimbursement of treatment costs, unemployment benefits or other costs paid by them to the plaintiff, not under the Product Liability Act but under Tort liability (articles 1382 and 1383 of the Belgian Civil Code).

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Any final decision orders the payment of the judicial costs by the losing party (article 1017 of the judicial code).

The costs can be compensated by decision of the judge if each party

loses on one or another claim. The proceedings costs include judicial costs as such, investigation measures (judicial expert costs) and the "proceedings indemnity".

In application of article 1022 of the judicial Code (as modified by the law dated April, 21, 2007), the proceedings indemnity is a fixed intervention in the fees and costs of the lawyer of the successful party. The proceedings indemnities are determined by Royal decree, mainly according to the value of the claim. Upon request of one party and by a justified decision, the judge may reduce or increase the proceedings indemnity within the minimum and maximum fixed by the Royal decree.

7.2 Is public funding e.g. legal aid, available?

Legal aid is available to persons of insufficient income.

7.3 If so, are there any restrictions on the availability of public funding?

The legal aid is total or partial depending on the person's resources and is granted to Belgians or foreigners legally residing in Belgium.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

The lawyer's fees may not be based only on contingency or conditional fees (article 459 of the Judicial Code), even if success fees are allowed for part of the lawyers' costs.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Third party funding of claims is not prohibited but is not organised by the law (except for the legal aid). The plaintiff's lawyer may not fund the claim.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Belgium.

The main recent developments in Product liability occurred at the European Community level.

In Belgium, the Product Liability Act is often considered to be lacking in innovation since it is more or less the formalisation of an existing case law on the subject and, as explained, there are several other liability systems on which the injured party may rely to claim compensation for damages resulting from a defective product.

Out-of-court settlements as well as an increase in the level of product safety also explains why there is only an average of 15 decisions published based on the Product Liability Act since it came into force.

Three recent decisions are worth mentioning:

a) By a decision dated **February 10, 2005** the **Civil Court of Brussels** considers that if the producer has been informed of serious side effects such as irreversible hearing disorders while the notice only mentions reversible hearing disorders, this medicine should be considered as defective in the meaning of the Product Liability Act. The fact that the notice has been submitted to and duly approved by the Health Ministry does not exonerate the producer from his liability since it is impossible to believe that the Health Ministry would have prevented the producer from mentioning in the notice that the hearing side effects could be irreversible. The fact that irreversible hearing disorders were mentioned in specific literature prevented the producer relying on a risk development defence.

The Civil court considers that the causal link between the damage and the defect in the product requests a high degree of certainty but not an absolute certainty (Bruxelles civ., 10 February 2005, JLMB 2006, p.1193).

b) The interpretation of the risk development (see question 3.1) given by the European Court of Justice has been followed by the **Belgian Supreme Court** in a decision dated **April 6, 2006.** The Belgian Supreme Court brings an end to the controversy on the burden of proof: the victim does not have to demonstrate that the scientific knowledge at the time the producer put the product into circulation was such as to enable the existence of the defect to be discovered. On the contrary, the producer must demonstrate that it was impossible to discover the defect taking into account the state of scientific and technical knowledge at that time.

The defence based on the impossibility to detect the defect may not be based on the "*concrete and subjective knowledge*" of the producer but must be based on an objective situation of scientific and technical knowledge the producer was supposed to be aware of when he put the product into circulation (Cass., 6 April 2006, RGDC 2007, p.188).

This decision is also interesting because the Belgian Supreme Court considers that the company managing an electricity network may be considered as a producer (in the meaning of article 3 of the Product Liability Act) even if the product delivered - due to a defect of the delivery system - may not be considered as a finished product.

In application of article 10 of the Product Liability Act, this producer is not authorised to limit his contractual liability towards the injured person.

c) By a decision dated **May 4, 2007,** the **Belgian Supreme Court** confirmed that in order to demonstrate that he is not liable, the producer must not establish as a certainty that the defect did not exist when the product was put into circulation or that this defect came into being afterwards, but must demonstrate that it may be considered that the defect did not exist at the time when the product was put into circulation or that it came into being afterwards. However, the producer who claims that the cause of the damage is uncertain does not bring the necessary proof (Cass., 4 May 2007, R.W. 2007-2008, 1283).

The main subject of interest in the coming years will probably be the application of the risk development defence, amongst other in the biotechnology field (GMO), the application of the Product Liability Act to energy distribution and the insurance aspects.

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

In the Private Law sphere, the Brazilian Consumer Protection Code ("CDC") provides for strict and objective liability (strict liability in tort) for manufacturing defects and services defects. The CDC also sets forth the joint liability of all suppliers in the supply chain for damages caused to consumers. In the criminal sphere, our legislation does not provide for any objective product liability. Contractual limitation of liability is allowable only on a B2B type of relationship.

1.2 Does the state operate any schemes of compensation for particular products?

No it does not.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

In Brazil, when individuals are harmed by an unsafe, defective or dangerous product, they may have a cause of action against the persons/entities who designed, manufactured, imported, distributed or furnished that product, that is, against any company that stands in that chain, that are jointly liable *vis-à-vis* consumers pursuant to the CDC. Then, depending on the contractual terms, the supplier that was considered liable may have a right of recovery against the party of the supply chain that actually caused or was responsible for the damage.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Under Brazilian legislation, recall is a request to return to the manufacturer a batch or an entire product production, usually due to the disclosure of safety matters. The recall is an effort to limit liability for corporate negligence (which can cause costly legal penalties) and to improve or avoid publicity damage.

The general provisions set forth in the Brazilian Consumer Protection Code concerning recall are complemented by more specific provisions defined in the Decree n. 2,181/1997, which creates the National System of Consumers' Protection under the competence of the Brazilian Ministry of Justice.

In this context, the Ordinance n. 789, enacted by the Brazilian Ministry of Justice on August 24th 2001, regulates the recall procedure in Brazil and, in general words, states the following steps:

- Firstly, the producer or dealer must notify the Department of Consumers' Protection and Defense (part of the Brazilian Ministry of Justice) of the disclosure of safety risks or defects in products which were introduced in the market as well as of their intention for recall. In this notification, all defects and risks must be described in details.
- Then, consumer hotlines or other communication channels must be established, since the producers and dealers shall promptly inform the consumers about the disclosure of safety risks or defects in products. In this phase the recalled products must be specified by their serial numbers or batch numbers.
- Recall announcements are disclosed by the Brazilian Ministry of Justice Website after the notification previously described. Said notices must also be published in the metropolitan daily newspapers and, in certain circumstances, television news reports advising the recall must also be carried out by producers and dealers.
- Finally, producers and dealers must send to the Department of Consumers' Protection and Defense a full report about the products recalled by them.

It is relevant to point out that in Brazil the recall does not prevent the consumers' right to be indemnified against any kind of damage caused by unsafe, defective or dangerous products.

1.5 Do criminal sanctions apply to the supply of defective products?

In the Criminal sphere, our legislation does not provide for any objective product liability. It means that, in order for the criminal liability to arise, a personal and subjective negligence must take place.

The Brazilian Consumer Protection Code lists crimes against consumer relations. The legally protected right is, therefore, consumer relations, with respect to interests and expectations of consumers, the most vulnerable party to the legal relationship.

The criminal acts described provide that the active and passive subjects are respectively the supplier (the corporation operating in the consumer market) and the consumer.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The Brazilian Consumer Protection Code, Law No. 8078/90, provides for the possibility of shifting the burden of proof to benefit the consumer when, at the discretion of the court, the consumer's claim is reasonable or when he is disadvantaged.

A reasonable claim is one likely to be true, whether or not supported by evidence. In addition, it is possible to shift the burden of proof if the consumer is disadvantaged, which happens in case of both economic and technical disparity between the litigants, which makes the consumer vulnerable.

The causes for exemption from civil liability are expressly and categorically provided by the Brazilian Consumer Protection Code. See question 3.1.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The consumer protection system in Brazil provides for the concept of product and service liability. The quality of products and services is insufficient when fitness defects and safety defects arise.

In the case of safety defects in the product or service, there is a distinction between inherent danger and acquired danger. Inherent danger is latent, normal, and foreseeable in the product, while acquired danger is the result of an unexpected defect in the product.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

All economic agents involved in the production and sales of a certain product are responsible for ensuring its safety and quality. All of them are, therefore, jointly and severally liable to fully compensate the consumer for defects in the product or service and, of course, have a right of recourse against who actually caused the defect.

The Consumer Protection Code and the Civil Code do not provide for the impossibility of determining what product damaged the consumer and do not define any method for sharing of liability based on the suppliers' share in the relevant market. In addition, there is no case law in this respect.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

The information and warnings required to be placed on products are sparsely determined in various regulations issued according to the product class.

Anyway, the Brazilian Consumer Protection Code establishes certain information that is required on products or services: characteristics; qualities; quantity; composition; price; warranty; expiration period; origin; and risks. Therefore, failure to warn is a violation of law.

In case of an anonymous, misidentified, or perishable product requiring special storage, the merchant can also be held liable because it becomes the apparent supplier and if there are intermediaries in the supply chain, they are jointly liable as mentioned above.

In either case, there is a right of recourse against who actually caused the damage, if it can be proven.

Finally, there is no "learned intermediary" principle under Brazilian laws.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The causes for exemption from civil liability are expressly and categorically provided by the Brazilian Consumer Protection Code, without prejudice to exemption from liability in case of an act of God as defined in the Brazilian Civil Code. They are: failure to offer the product in the market; lack of defect in the product or service; and exclusive fault of the victim or third party.

The Brazilian Penal Code, in turn, provides for events of criminal law exclusion and exemption from guilt. In addition, in the criminal field, liability will always depend on the subject's criminal intent and it is unreasonable to speak of objective liability.

Likewise, liability of independent professionals depends on negligence.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defense, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Generally speaking, note that the Brazilian Consumer Protection Code and the Civil Code did not include, among the causes for

exemption from liability, development risks, that is, risks and defects that could not be foreseen due to the current state of technique and science when the products would have been offered in the market.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

The Brazilian Consumer Protection Code and the Civil Code did not include, among the causes for exemption from liability, proper compliance with rules and requirements for the product because liability for a product or service defect is objective.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

It is possible that different consumers may exercise their right of action for a product or service defect, except in the case of class actions.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

All economic agents involved in the production and sales of a certain product are objectively responsible for ensuring its safety and quality. All of them are, therefore, jointly and severally liable to fully compensate the consumer for defects in the product or service. It is possible, however, to exercise the right of recourse against who actually caused the defect through a subsequent lawsuit.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Exclusive fault of the victim is an event of exemption from civil and criminal liability. In case of contributory fault of the victim or third party, there may be a reduction in the compensation payable.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

Under the Brazilian legal system, civil actions are not subject to Jury Trial. Brazilian law limits Jury Trial to very few and specific types of crime, limited to cases involving intentional crimes against life, such as homicide, infanticide or kidnapping with death.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Yes, a court can appoint an expert in the cases where evidence of the disputed fact requires technical expertise. This professional cannot only examine the evidence presented by the parties but can also produce expert evidence in the procedure. Note that the number of experts involved in the investigation can be increased according to the fields of knowledge involved in the matter. Thus, a court can, for example, appoint a medical expert and a mechanical engineer to examine injuries caused by a defect in a home appliance.

In addition, it is worth remembering that the parties may appoint a technical assistant to be present in the expert examinations and assess and challenge the final report submitted by the expert appointed.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

Protection of collective rights in consumer relations is obtained through civil class actions, regulated by Law 7347 of July 24, 1985. In these actions, like the entire Brazilian collective law, *res judicata* only operates *secundum eventum litis*, that is, the effect of a judgment granting a collective claim is necessarily extended to the entire community. Instead, if the claim is denied, *res judicata* will prevent a new class action from being filed, but will not stop individual actions on the same matter. Thus, there is no practical need for, for example, the right to opt out because *res judicata* on a class action only operates to the benefit of the community, not to its detriment. In other words, unfavourable *res judicata* cannot even affect or prevent filing of an individual action seeking the same rights.

With regard to class actions, in accordance with Article 82 of the Consumer Protection Code, the following also have standing to sue: (i) the Public Prosecution Service; (ii) the Federal Government, States, Municipalities and the Federal District; (iii) centralised and decentralised governmental agencies; and (iv) associations duly organised for at least one year with a mission that includes the defense of collective interests and rights.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Yes, as set forth in question 4.3, associations, including those for consumer protection, have standing to sue on behalf of a group of consumers.

4.5 How long does it normally take to get to trial?

Not applicable. There is no pretrial stage in the Brazilian legal system.

4.6 Can the court try preliminary issues, the result of which determines whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Yes, motions for dismissal of the case can be decided preliminarily. Thus, before trying the claim brought to the court, matters like standing of the parties, legal right to sue, and legally cognizable relief are heard before consideration of the merits.

4.7 What appeal options are available?

All types of appeal provided by the Brazilian Code of Civil Procedure are applicable against decisions issued in civil actions on consumer law. Thus, considering that the Brazilian appellate system provides for various remedies against decisions issued by court and that the consideration of each appeal would go beyond the scope of this work, we will address only the appeals normally applied to civil actions, which are: (a) *Appeal*, which can be lodged against any and all decisions, whether or not on the merits. In an appeal, the matter considered in the first instance will be entirely sent to the Court of Justice of Federal Regional Court (Brazilian second instances), which may reverse the judgment in whole or in part (ruling - collective decision); (b) *Interlocutory Appeals*, a type of challenge applicable against all interlocutory decisions (act whereby the court resolves an incidental matter in the course of the case) of the first instance, e.g. denial of production of a certain type of evidence; (c) *Motion for en banc rehearing*, which is applicable against Appellate Court decisions when a non-unanimous ruling (e.g. 2 votes against 1) has reversed in the appellate stage a judgment on the merits; (d) *Motion for Clarification*, which is lodged when an ordinary order, an interlocutory decision, a judgment or ruling (collective decision) contains some ambiguity, contradiction, or omission. Its purpose is to amend the defective decision by clarifying its omissions or clearing its ambiguities or contradictions; and (e) *Special and Extraordinary Appeals*, which are extreme remedies that, unlike an appeal, do not seek reconsideration of the matter. The Special Appeal is only admissible for cases decided, in a single or ultimate instance, by the Federal Regional Courts or by the Appellate Courts of the States, Federal District and Territories, when the appealed decision violates a treaty or federal law or denies their effectiveness, or also gives a federal law an interpretation contrary to that given by another Appellate Court (among other events). The Extraordinary Appeal may be lodged against cases decided in a single or ultimate instance and generally applies in the event that the appealed decision violates a constitutional provision. The Special Appeal will be heard by the Superior Court of Justice and the Extraordinary Appeal by the Federal Supreme Court.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

As answered in question 4.2, in the Brazilian system, a court can appoint experts in the cases where evidence of the disputed fact requires special expertise, without formal restriction on the nature and extent of evidence.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

Not applicable. There is no pretrial stage in the Brazilian legal system.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

In the Brazilian legal system, all types of evidence are produced in court and production is directly presided over by the judge of the case. Thus, it is up to the judge to consider the utility of the type of evidence requested by the parties by approving those deemed appropriate for the resolution of the case or otherwise denying.

Note that, only through very exceptional remedies, evidence can be collected in the evidentiary stage (e.g. incidental preliminary injunction) or even before the filing of the claim (e.g. preparatory preliminary injunction), and even in these cases, evidence must be produced before the judge of the case. In addition, in these cases, the party must demonstrate in court that it has a fair likelihood to succeed in its claim and also prove that there is likelihood of harm to its interests in the ordinary course of litigation.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

After the enactment of the Brazilian Arbitration Law, Law 9307/1996, the alternative methods of dispute resolution has gained prominence in Brazil. According to such law, it was possible to overcome former obstacles such as the absence of a legal regime to ensure enforcement of the arbitration agreement and the need for double exequatur of the arbitration award.

Specifically in consumer relations, it is worth making a remark on the arbitration clause in adhesion agreements. It so happens, in compliance with the very concept of Arbitration, based on the freedom of the parties, the choice of arbitral jurisdiction must be specifically expressed by all parties, especially the consumer, which is specially protected by the Brazilian legal system.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

The Consumer Protection Code provides for laches of claims for defective products and services and a limitation period for claims for damages arising from consumer injuries.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to not apply time limits?

In case of a defective product, the consumer's right to claim expires within thirty (30) days for the supply of non-durable products and services and within ninety (90) days for durable products and services. With respect to the time count, it commences when the product is actually delivered or the services are completed. Laches is also prevented by: 1) claim proven to be asserted by the consumer against the supplier of products and services pending its negative response, which must be unequivocally transmitted; 2) commencement of civil inquiry; and 3) in case of hidden defect, laches commences when the defect is evidenced.

We emphasise that such periods for claims for defective products and services prescribed by the Consumer Protection Code are more beneficial to the consumer than those specified in the Brazilian Civil Code in the doctrine of hidden defects and are preferred by the Brazilian case law in cases of consumer lawsuits.

There is no change in the limitation periods based on the consumer's age or physical condition.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

The statutes of limitation set forth by the law are not affected by issues of concealment or fraud.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

If proved that the injuries (or even deaths) were caused by the regular use of a given product, as well as that these injuries were not proportional to the acceptable and inherent risks of such product, the Brazilian Court would determine the amount of the applicable indemnity. Such indemnity is usually applied through a monetary compensation, although there are no restrictions to injunctive or declaratory relief.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

The aggrieved consumer may claim compensation for any type of damage caused by a defective product or service.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

The basic premise for compensation for defective products or services to be granted in the case of injuries is the damage. If there is a concern that a product may cause injury in the future, either the consumer must bear the costs of monitoring or they must contact a district attorney's office or the police, which will determine whether there is a probable cause to initiate an investigation.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are not recoverable, only moral damages.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

The extent of the indemnity will depend on the type of injury and the age of the person, although the Civil Code and the Consumer Protection Code do not provide any threshold or limit for the indemnity. The judge in charge of the case shall balance the peculiarities of the concrete situation. It is relevant to point out that the plaintiff would need to demonstrate to the court the existence of a direct connection between the damage and the product (causation theory). Also, the amount of the indemnification will have approximately the same size of the amount of the damage. It differs from the criteria used by US courts.

The doctrine has combined the risk theory with the notion of reasonableness (products that are reasonably dangerous) and of proportionality in order to determine the agent's liability limits.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

Groups of plaintiffs have filed consolidated lawsuits (class actions) against the manufacturers of certain products in Brazil. The lawsuits have been handled in State Courts and have been decided according to case-by-case rationality.

The collective protection shall be allowed in the case of:

I. diffuse interests or rights, meaning the transindividual, indivisible interests or rights held by indeterminate persons linked by factual circumstances;

II. collective interests or rights, meaning the transindividual, indivisible interests or rights held by a group, category or class of persons linked to each other or to the opposing party by a common legal relationship; or

III. homogeneous individual interests or rights, meaning those stemming from a common origin.

For purposes of bringing a class action, the following entities have collective standing:

I. the office of the Attorney General;

II. the Federal, State or Municipal Governments and the Federal District;

III. entities and agencies of the direct and indirect public administration, including those without legal identity, specifically designed for the protection of the interests and rights protected by Brazilian Consumers Protection Code; and

IV. associations legally incorporated for at least one year, whose institutional purposes include the protection of the interests and rights protected by this Code. An authorisation to bring suit from the association members is not required.

The requirement for prior incorporation may be waived by the court in class actions for the protection of homogeneous individual rights, in the case of manifest social interest, evidenced by the extent or characteristics of the damage, or by the relevance of the juridical object to be protected.

For class actions, the decision shall be *res judicata*:

I. *erga omnes* in class actions for the protection of diffuse rights, unless the claim is deemed groundless due to insufficient evidence, in which event any entity with collective standing may file the same action, making use of new evidence;

II. *ultra partes* in class actions for the protection of collective rights, but limited to the group, category or class, except in the event of dismissal for insufficient evidence, in which event any entity with collective standing may file the same action, making use of new evidence; and

III. *erga omnes* in class actions for the protection of homogeneous individual rights, only if the claim is granted for the benefit of all the members.

The effects of *res judicata* on class actions in protection of diffuse and collective rights shall not adversely affect the individual rights of the members of the class, who can bring individual or class action for damages. However, if the claim is granted the class judgment will benefit the members, who may then file an action for calculation of damages and enforcement.

The effects of *res judicata* on condemnatory criminal judgments shall not adversely affect the individual rights of the members of the class, who can bring individual or class action for damages. However, if the defendant is convicted, the criminal judgment will benefit the members, who may then file an action for calculation of damages and enforcement.

Finally, class actions do not entail *lis pendens* for corresponding individual actions. However, the effects of *erga omnes* or *ultra partes* of the class decree shall not benefit the plaintiffs that fail to apply for suspension of their individual actions within thirty days of gaining knowledge, in the case record of the individual action, of the existence of a corresponding class action.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Not applicable under Brazilian laws, Government authorities are not entitled to part of the damages awarded to the claimant. Note, though, that the authorities may have a separate cause of action against the manufacturer if they can prove the damages caused by the product and the causation link.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The successful party may recover court fees or other incidental expenses.

The losing party will also be ordered to pay attorney's fees, but they are to be paid directly to the attorneys for the successful party and they are usually limited to a percentage of the amount attributed to the lawsuit (for purposes of calculating court costs) and not to actual attorney's fees disbursed by the prevailing party.

7.2 Is public funding e.g. legal aid, available?

Yes. In Brazil, there is a Public Defender's Office for legal aid to economically disadvantaged people. In addition, some institutes or foundations provide legal aid on specific matters and some Law firms offer *pro bono* service.

7.3 If so, are there any restrictions on the availability of public funding?

The public defender's office limits its free legal aid to economically disadvantaged people.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

No, it is not.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

No, it is not.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Brazil.

There have been no notable developments in Product Liability Law in Brazil.

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

In general, Bulgarian law recognises three legal grounds for product liability in the sphere of civil law and one in criminal law: general tort liability (*delict*); strict product liability; contractual liability; and criminal liability.

Strict product liability, defined in Art. 133 of the Consumer Protection Act (the "**CPA**"), is a specific liability which compared to tort liability is non-fault and is based on objective reasons. In order to successfully engage the strict liability under the CPA, consumers have to prove three main interrelated facts: a defect, existing at the time of putting the product on the market; material damage; and causal link between the defect of the product and the relevant damages. Unlike general tort liability, this specific liability does not provide the liable person with opportunity to exculpate on subjective grounds by proving he was not acting intentionally or he was not negligent. There are, however, objective grounds to exempt liability of the producer which are expressly enumerated in the law and are to be proved by the producer who refers to any of them. Another characteristic feature is that the compensation may cover only material damages.

General tort, defined by Art. 45 *et seq.* of the Obligations and Contracts Act (the "**OCA**"), is applicable, *inter alia*, to matters regarding product liability. Tort under the OCA is fault based either on intent or negligence on the side of the wrongdoer who in cases of product liability could potentially be the manufacturer, the importer or the retailer. Fault under the OCA, i.e. negligence, in the form of non-compliance with the objective test of *due care*, is presumed, thus shifting the burden of proof for a *corpus delicti* fact from the injured party and resulting in the procedural burden for the wrongdoer to prove that he indeed applied the *due care* and that his behaviour was not in breach of law. The consumer shall prove that the wrongdoer acted or omitted to act; the act or omission to act caused was in breach of law; the damage suffered by the consumer, and a direct causal link between the unlawful behaviour of the wrongdoer and the damage. Since Art. 131 of the CPA explicitly limits strict product liability of the manufacturer or the supplier only to obligation for compensation for material damages, should a party injured by a defective product seek indemnification of non-material damages, the only existing legal solution would be to follow the general procedure by claiming damages in tort. In the latter procedure as set forth in Art. 52 of the OCA the court based on equity resolves on the non-material damages resulting from tortious behaviour.

Contractual ground is another legal option for seeking relief for damages suffered from a defective product. Unlike the strict and tort liabilities, contractual liability may include obligation for compensation for damages arising only from the defective product itself and not from the death, personal injury or damage to other property of the consumer, caused by the defective product. Contractual liability can be brought only against a party to the contract, and can be based only on contractual non-conformity. Besides claiming damages, the consumer may also claim: (i) reimbursement of the money paid; (ii) replacement of the defective product with another (in case of generic goods); (iii) price discount; and (iv) free repair of the defective product.

The aforementioned legal grounds work on a concurrent basis i.e. the different forms of liability (strict, tort and contractual) do not exclude but supplement each other as to provide the consumer with sufficient and efficient integral indemnification.

The CPA provides that consumers and consumer associations are entitled to submit alerts, complaints and petitions to the control authorities performing consumer protection functions in any case of breach of statutory obligations of producers and retailers. Control bodies can impose administrative sanctions including fines on the wrongdoers.

In serious cases when acts or omissions to act are of a nature to adversely and substantially affect the interests of consumers and society criminal liability is applicable as provided by the **Penal Code**.

1.2 Does the state operate any schemes of compensation for particular products?

Currently, under the EU rules and the national legislation on the implementation of the common organisation of markets of agriculture products and processed agriculture products, Bulgaria implements EU schemes for export refunds for export of agriculture and processed agriculture products and compensations in case of withdrawal of fresh fruits and vegetables from the market.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Under the strict liability regime the liability for the defect, respectively for the damages incurred, is borne by the manufacturer. 'Manufacturer', according to the CPA, is any person who

manufactures finished products, raw materials or component parts included in the manufacturing of other products and any person who, by putting his name, trade mark or other distinguishing sign on the product presents himself as its manufacturer. Without prejudice to the liability of the manufacturer, any person who imports into the European Community products for sale, hire, leasing or any form of distribution in the course of his business shall be deemed to be a manufacturer within the meaning of the CPA and shall be responsible as a manufacturer.

If neither the manufacturer nor the person who has imported the products into the European Community can be identified then the supplier should be hold liable. According to the CPA, 'supplier' (distributor or trader) is "any person other than the manufacturer who puts the product into circulation." The supplier shall not be held liable if he informs the injured person, within a term of 14 days, of the identity of the manufacturer, importer or the person who supplied him with the product. The supplier, however, may not direct the injured person to any person outside the territory of the Republic of Bulgaria.

Provided that several persons qualify as liable manufacturers, importers or suppliers they bear joint liability and may eventually seek within their internal relations distribution of the liability engaged. Where damage has been caused by a defective product which is a component part of another product, the manufacturer of the said component part and the person who installed it shall be liable jointly.

In case of tort, only the person in fault (manufacturer, importer or supplier) could be held liable. If an injury was caused by the act/omission to act of several wrongdoers they would bear joint liability.

In cases of contractual breach, joint liability exists only if explicitly stipulated in the contract, otherwise defaulting contractors may bear only several liability.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

In case it is established that certain products placed on the market represent a threat to the life and/or health of consumers, recall of such product from consumers shall take place as a last resort if other measures undertaken by manufacturers, distributors and suppliers are not sufficient to prevent the risk to consumers. If a producer, a distributor or a provider of services knows or ought to know, on the basis of the information in his/its possession, that his/its products or services placed on the market pose a risk to the health and safety of consumers, the said producer, distributor or service provider shall immediately (within 24 hours after he/it came to know of the danger) inform the control authorities of this and shall give the said authorities details of the action taken to prevent and terminate risks to the health and safety of consumers. Any such information must contain, as a minimum, the particulars specified in the law. Government Regulation specifies the terms and procedure for submission of such information.

For failure to provide information on dangerous (risky) goods the producers/distributors/service providers may be sanctioned with a monetary sanction between BGN 3,000 and BGN 10,000.

In such case, the control authorities may impose mandatory measures including to order, coordinate or organise, together with the manufacturers and the distributors, the recall from consumers of dangerous products already supplied to them and to order their destruction. These measures shall be without prejudice to assessment of the criminal liability of the party concerned.

Another Government Regulation stipulates the procedure for product recall, collection from consumers and destruction of dangerous goods. For failure to recall dangerous products the persons responsible for the recall shall bear administrative liability with a monetary sanction between BGN 500 and BGN 5000. Any damages caused as a result of failure to recall dangerous products can as well be claimed by the injured persons.

1.5 Do criminal sanctions apply to the supply of defective products?

Art. 228 and Art. 231 of the Penal Code provide criminal liability for persons who as managers of enterprises or as control bodies order or allow the production of low-quality, sub-standard or incomplete sets of industrial goods or articles which do not meet the requirements established for them with respect to quality, type or features. Criminal liability is as well provided for persons who release for sale such industrial goods in considerable qualities or of considerable value, without express declaration of their defects.

It should be noted that for engaging the criminal liability of the perpetrators it must be proven that they have acted with intent to commit the respective crime.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

In case of **strict product liability**, the burden of proof of the consumer includes only the obligation to prove the defect, the damage and the causal link between them. No burden to prove the fault for the defect and/or damages is required.

In case of **tort**, the injured person must prove the damage, the act or omission to act of the wrongdoer and the casual link between the act or omission to act and the damage incurred. The law lays down a refutable presumption about the existence of fault (negligence) and the burden of proof lays with the manufacturer/supplier who may seek means of proving that he was not negligent and has applied the required professional effort thus satisfying the requirement of the abstract, objective and relative *professional due care*.

In relation to potential **contractual liability**, the party claiming damages as a result of non-performance has to prove the non-conformity of the product with the specifications as set out in the consumer agreement.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

In order to identify the relevant damages two tests are usually applied, corresponding to two different causation theories. The first test is related to the *condition sine qua non* theory of causation, proving that there is *factual* causation between the defect, existing at the time of the passing of risk to the consumer, and the damages suffered. The defect is viewed as one of several preconditions which lead to the damage of the consumer. Would the damage still occur, if the defect of the product is imaginarily taken out? A negative answer leads to establishing a factual causal relationship. However, it has to be pointed out that not all factual damages are recoverable under the Bulgarian law. The *legally relevant, direct* damages are the limit of the civil liability. That is why in order to

identify the direct damages we put the factual damages to a second test using the *adequate causation* theory. This test would isolate only damages which are: a typical, normally occurring and necessary result; a consequence from contractor's default; or unlawful behaviour, which are characteristic and repeat under the same related conditions".

In view of the aforesaid it is not sufficient to prove exposure to increased risk that *might have led to* or *is usually associated with* the damages of the bodily constitution or property of the injured person provided that the consumer cannot prove that the specific injury would not have arisen without such particular exposure.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

If several manufacturers have taken part in the manufacturing of the defective product and it cannot be established which of them exactly manufactured the defective part of the product, then they would bear joint liability.

There is no market-share liability system in Bulgaria.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

The CPA explicitly grants to the consumer the right to information before acquiring a product and the obligation for providing certain information lies with the retailer. The information provided has to be presented in the Bulgarian language and have to cover a minimal scope of characteristics of the product - contents, packaging, directions for use, price and quantity, impact on other goods, the risks associated to the use or maintenance, terms and conditions of the warranty and expiry date. The CPA specifically provides that the retailer could not exonerate his failure to perform the above obligations, arguing that he was not provided with the necessary information by the manufacturer or the supplier.

Any products the use of which requires technical knowledge, any products containing dangerous substances or any products where the use presupposes possession of special skills or compliance with special safety requirements, must be accompanied by instructions for use prepared by the manufacturer. The instructions for use shall contain information needed by consumers for the correct and safe use and installation, coupling, maintenance or storage of the products.

The Bulgarian law does not apply the principle of "the learned intermediary". It places the main burden for providing information to the consumer with the direct retailer rather than the manufacturer or importer. Hence, manufacturers or importers, excluding retailers, are under an obligation to provide information to the consumer allowing them to assess only the health- and life-threatening risks, related to the normal or foreseeable circumstances of use. That is why despite the fact that the manufacturer or importer might have provided some information to distributors as intermediary in the chain of supply to the consumer, the direct retailer is still under an obligation to provide the consumer with particular information regarding the safety of the product.

3 Defences and Estoppel

3.1 What defences, if any, are available?

In case of the strict product liability there are 6 grounds under the CPA for exclusion of the manufacturer's liability: (i) he did not put the product into circulation; (ii) having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards; (iii) the product was neither manufactured by him for sale or any form of distribution for economic purpose nor manufactured or distributed by him in the course of his business; (iv) the defect is due to compliance of the product with mandatory regulations issued by the public authorities; (v) the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered; or (vi) in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instructions for the product given by its manufacturer.

In case of contract there are 4 grounds for exclusion of manufacturer's liability: (a) there is no breach of contractual obligation; (b) that the breach of contract or non-conformity is not attributable to the manufacturer and could not have been foreseen, i.e. it is due to *force majeure*; (c) there is no causal link between the particular damage and the breach of contract; or (d) the defect/damage is not covered by the terms and/or conditions of the applicable contractual warranty (e.g. it is time-barred).

In case of tort it has to be proved that there is no fault (negligence) on the part of the manufacturer/supplier, i.e. the burden of proof rests on the manufacturer to demonstrate that he did not breach his general *duty of care*.

In all hypotheses the liability of the manufacturer may be fully excluded or reduced proportionally where the consumer has solely caused or has contributed by his own act or omission to act for the occurrence of the damages.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

The state of the art/development risk defence is given in Art. 137, Par. 1 item 5 of the CPA as "*state of scientific and technical knowledge*". The manufacturer/supplier have to prove that the defect was not discoverable at the time of the release of the product in question in circulation on the market. This is an objective test.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Under Art. 137, Par. 1 item 4 of the CPA the manufacturer must prove

that "the defect is due to compliance of the product with compulsory requirements issued by state authorities". However, the observance of the applicable minimum statutory standards and/or quality and safety requirements will not be sufficient *per se* to exclude the liability of the manufacturer unless he can prove that compulsory instructions of a state authority had been issued and complied with.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

A different claimant (who is a third party to a solved court case) can lodge an identical claim against the same manufacturer, and thus, "re-litigate" issues of fault, defect or causation already adjudicated on the solved case.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

Yes, the defendants may seek the liability of a third party, either in the same proceedings or in subsequent proceedings. If the defendant decides to implead the third party in the pending proceedings this motion must be made with the written response to the statement of claim at the latest and simultaneously a recourse action against the third party-defendant must be brought in the same proceedings. The impleader shall not be granted if the third party does not have a permanent address in the Republic of Bulgaria or is resident abroad.

If the defendant decides to bring action against the third party in subsequent proceedings there is no time limit on commencing such proceedings except for the general five-year time limit for filing of a claim - see question 5.2 below.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Yes, the liability of the defendant may be reduced proportionally if he proves that the damage is caused both by the defective product and by the fault of the claimant or of any person for whom the claimant is responsible. Respectively the defendant's liability may be excluded in case the damage was caused by the claimant exclusively.

In addition it may be noted that under the CPA "the liability of the producer shall not be reduced when the damage is caused both by a defective product and by the act or omission of a third party".

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

The trial is by a judge.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Experts are to be appointed by the court if the judge possesses no specific scientific or technical knowledge. Experts are appointed either *ex officio* or upon request of a party. When appointed experts may with the permission of the court ask questions to witnesses if that would be necessary for the clarification of facts. Experts do not sit with the court and do not take part in the decision-making process. They are required by the law to be non-biased and their opinions are to be true and impartial. Expert opinions are non-binding upon the court. The court has the sole discretion whether to rely on the findings in the expert's opinion, assessing it in the light of all other relevant evidence on the case.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

The new Civil Procedure Code (effective as of March 1, 2008) introduced the first procedural law provisions regulating class action procedure in Bulgaria.

A class action lawsuit may be initiated on behalf of persons who are harmed by the same infringement where the circle of affected persons cannot be defined precisely but is identifiable. Any person who claims that he/she has been harmed by such infringement, or any organisations responsible for the protection of injured persons, may file a complaint on behalf of all injured persons against the alleged wrong-doer petitioning the court to proclaim the harmful act and to issue a decision for cessation of the infringement, for rectification of the consequences of the infringement and/or for compensation for the damages inflicted on the plaintiffs.

The statement of claim shall contain the circumstances upon which the class action is founded, shall specify the circumstances which identify the circle of injured persons and state the form in which the publication of the opening of the procedure should be publicly announced. The court shall accept the participation in the case of any other injured persons and/or organisations responsible for the protection of the injured persons that have declared, within a time limit set, a motion for participation in the procedure. The court shall exclude the injured persons who have declared, within the time limit set, that they will pursue a remedy in separate proceedings. Hence, the Bulgarian class action procedure is a typical "opt -in" procedure.

The judgment of the court shall have effect in respect of the defendant, the person or persons who have brought the action, as well as in respect of those persons who claim that they are harmed by the established infringement and who have not declared that they wish to pursue a remedy independently in a separate procedure. The excluded persons may avail themselves of the judgment whereby the class action has been granted.

As of the date of this article we are aware of only one class action statement of claim filed and presently the proceedings are pending.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Yes, registered consumer associations may bring claims for termination of violation of the CPA or other applicable laws directly or indirectly protecting consumer rights and for compensation of the damages caused to the collective consumer interest as a result of such violation.

4.5 How long does it normally take to get to trial?

There is no pre-trial procedure in Bulgaria. A case is considered

opened at the moment when the claim is lodged with the competent first instance court conditional on its acceptance as admissible by the latter. Depending on the workload of the competent court, a first court hearing is normally scheduled within 1 to 3 months from the filing of the claim.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

After verification of the admissibility of the action brought and the conformity of the statement of action, the court shall verify *ex officio* the capacity of the person or persons who have brought the class action to protect the harmed interest seriously and in good faith and to incur the charges related to the conduct of the case, including the costs. The court shall not admit the case to examination if none of the persons who have brought the action satisfies the said conditions or if all such persons together do not satisfy these conditions.

There is no trial by jury proceedings.

4.7 What appeal options are available?

The decision on the merits of the calls action rendered by the court of first instance may be appealed to the appellate court. The appeal may be grounded both on issues of law and fact.

The decision of the appellate court may be challenged before the Supreme Court of Cassation if grounds for cassation appeal can be found. The Supreme Court of Cassation has discretion to decide whether to accept the appeal and will decide only on questions of law.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

See the answer to question 4.2. Courts usually appoint experts included in the lists of experts on different fields of science, profession or practice. Such lists however are not exclusive and parties may propose other experts. Experts' opinions are prepared for and submitted with the court.

Parties may present written expert opinions prepared by experts of their own but such opinions are not considered evidence gathered under the requirements of the law.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

No. There is no pre-trial procedure in Bulgaria.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

The claimant is under the obligation to attach to his claim all supporting documentary evidence at his possession. The same obligation falls on the defendant when filing the response to the statement of claim. Only in specific hypothesis where there is danger of destruction or loss of evidence or that its collection would be hindered or prevented, may a party request from the court to order certain preventive measures in order to collect such evidence prior to the filing of the statement of claim.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Alternative dispute resolution methods are also available but have not yet become common in product liability cases. The CPA provides for conciliation commissions assisting in the resolution of disputes related to warranty liability, right of claims for goods and services and unfair contractual terms.

Pursuant to the Mediation Act, product liability disputes may be referred to mediation by the parties. In such case the dispute may be settled amicably with the help of mediators, by entry into a binding settlement agreement. Monetary claims regarding product liability disputes may also be referred to arbitration if the parties agree so.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes time limits do exist.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

As a general remark: the lapse of the time limit specified in the law only precludes the right to file a claim and does not extinguish the substantive right to compensation for the damages suffered - any payment made by the manufacturer to the injured person after the lapse of the time limit shall not be subject to reimbursement.

In case of strict liability, the claim for compensation has to be filed with the court within 3 years from the date on which the injured person became or should have become aware about the damage, the defect and the identity of the manufacturer but in all cases not later than 10 years from the date on which the defective product was put on the market.

In case of tort, within 5 years starting from the date when the wrongdoer is discovered, e.g. the manufacturer of the defective product has become known to the injured person.

In case of contract. the time limit for filing of a claim for compensation for damages caused by a non-performance of contract is set at 3 years from the date on which the receivable has become due and payable.

In principle, age or condition of the claimant does not affect the calculation of the time limits. However, the OCA stipulates that the running of the time limit shall be suspended in respect of minors or judicially disabled individuals for the period during which they do not have a duly appointed statutory representative or guardian and for 6 months after the appointment of such or, respectively, after the end of the judicial incapacity.

The court has no discretion to disapply time limits and at the same time, time limits are not applied by the court *ex officio* - it is the defendant who has the right to raise that question as part of his defence.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Concealment and fraud are not among the exhaustively listed grounds for suspension or discontinuance of the running of time limits under the OCA.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

An individual consumer as an injured party may bring an action against the allegedly liable person seeking monetary compensation for the damages suffered. In case a class action is brought the persons who claim that have been harmed by the alleged infringement, or any organisations responsible for the protection of injured persons may file a statement of claim petitioning the court: (i) to proclaim the harmful act or omission to act, the wrongfulness of the said act or omission and the fault of the defendant; (ii) to issue a decision for cessation of the infringement, (iii) for rectification of the consequences of the infringement; and/or (iv) for compensation for the damages inflicted on the plaintiffs.

The court may sentence the defendant to perform a specific act, to refrain from performing a specific act, or to pay a specific amount. Acting on a petition by the plaintiff, the court may rule on adequate interim measures for protection of the harmed interest.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Under the strict product liability system only *material* damages are recoverable, both actual damages and lost profits, resulting in personal injury, death or damage to objects, other than the defective product itself, in the property of the injured person. The consumer would have a legal interest to claim compensation under the special strict liability regime provided the defective product has damaged other goods with a value not lower than BGN 1,000 (EUR 500). In cases of personal injury no such limitation is set.

The *moral* damages (pain and suffering), resulting from caused death, disability, health deterioration etc., may be compensated on the grounds of tort liability as set in Art. 52 and Art. 45 of OCA.

The damage to the product itself is recoverable based on the contractual relationship between the seller (in most cases retailer) and the consumer.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

So far the Bulgarian jurisprudence has been very consistent that in order for a compensation to be awarded there has to be actual damage incurred. The case of medical monitoring relates to potential damages, normally associated to certain risk factors. Given the present legal standards in Bulgaria, only medical expenses following and in direct relation to the damage could be recovered.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

The civil liability in Bulgaria, including the strict product liability, has only compensatory, no punitive function. Contractual liability may include punitive damages if so agreed by the parties but is not common in consumer contracts.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

No maximum limit set in the form of a fixed amount exists with respect to the strict product liability under the CPA or the general tort liability under the OCA.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

In case of class action a settlement agreement may take effect only after being approved by the court. The court shall approve the settlement if it does not conflict with the law and good morals and if the harmed interest can be protected to a sufficient degree through the measures envisaged in the settlement agreement. In case of claims brought by infants the consent of their legal representatives is required prior to the court approval of the settlement.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Bulgarian law does not provide for reimbursement of health and social security payments made to claimants in connection with their damages allegedly caused by the product.

In addition, it may be noted that the Commission on Consumer Protection may bring actions for cessation or for prohibition of acts or commercial practices infringing the collective interests of consumers.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

In principle, the losing party must bear the legal costs, including court fees, fees paid for legal assistance and representation in front of the court, commensurate to the portion of the action granted.

7.2 Is public funding e.g. legal aid, available?

Yes. Legal aid, financed by the state budget, is available to individuals in difficult material situation. Legal aid is granted by request. Legal aid refers to free of charge legal assistance for bringing and handling of a court action. In addition on request of a party the court may waive his or her obligation to pay court fees and costs for proceedings.

7.3 If so, are there any restrictions on the availability of public funding?

The law does not provide for any requirements or restrictions on the availability of legal aid. The judges have discretion to apply the court fees and costs for proceedings waiver on a case-by-case basis.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Government funding of legal aid does not operate on the basis of conditional or contingency fees. However, contingency fee arrangements between plaintiffs and their lawyers are allowed by Bulgarian law.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Bulgarian law does not provide for third party funding of claims. There is no prohibition for such funding either.

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8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Bulgaria.

Following the entry into force of the new Civil Procedure Code which introduced for the first time in Bulgaria the class action procedure, in March 2008, the first class action based on alleged violation of the consumer protection rules was filed. It must be noted that the practical issues arising in connection with this case show that the current class action rules are insufficient and not very clear as a lot of questions of significant importance for the development of class action litigation are not regulated at all. Currently, this case is still at the stage of assessment of admissibility.

China

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

Product liability claims in China can be based on three different legal theories or "causes of action": (a) strict product liability; (b) fault-based tort liability; and (c) contractual liability. Each cause of action may independently or concurrently support a product liability claim.

Strict Product Liability

Strict product liability is set out in the People's Republic of China ("**PRC**") Product Quality Law ("**PQL**") and is strict in the sense that liability is determined without consideration of fault. Article 41 of the PQL provides that "if a product defect causes physical injury or damage to property other than the product itself, the manufacturer is liable for damages". Thus, liability lies where a claimant can prove: (1) a defect in the product; (2) injury to a person, or damage to property; and (3) causation between the defect and injury or damage.

The PQL provides two standards for product defect. PQL Article 46(1) defines a "defect" as an "unreasonable danger existing in the product that threatens the safety of a person or property". In addition, Article 46(2) provides that a product is considered defective if it is subject to state or industry quality standards governing health, personal safety, or safety of property, and fails to meet these standards.

Where a product does meet applicable state or industry quality standards, however, it is extremely difficult to argue a defect effectively, and while there is no express statement in statute, satisfying state or industry quality standards is essentially a presumption that the product is not defective.

Fault-based Tort Liability

According to PRC Civil Law General Principles ("**Civil Law**") Article 106, a fault-based product liability claim can be brought against a seller if the product is defective due to the seller's fault and the defect contributes to physical injury or damage to property other than the product itself. The Civil Law does not define fault, but the term generally includes intent and negligence. Breach of statutory obligations and failure to act in accordance with accepted industry practices may also be deemed negligence.

Contractual Liability

The PRC Contract Law permits a claimant to claim against the seller for product liability based on breach of contract if the product's quality fails to meet contractual standards. Contractual obligations may include express contractual obligations (e.g. arising from product specifications) as well as implied contractual obligations (e.g. arising from statutory requirements). Only a claimant who is party to a purchase or supply contract may sue on a contract theory.

There are also specific statutory provisions under Chinese law that support a breach of contract/warranty claim. PRC Protections of Consumers' Rights and Interests Law ("**PCRIL**") Article 22(1) provides that a seller should ensure that the products it provides have the "quality, functions, uses, and date of expiry that they should have during the normal use" of the products, "except where a purchaser is already aware of the existence of flaws before it purchases" the products. If the products do not meet the requirements, the claimants who purchased the products can sue the seller of the products based on a breach of contract theory of liability.

1.2 Does the state operate any schemes of compensation for particular products?

The state does not operate any such schemes generally. In some large scale cases, however, such as the recent melamine-contaminated milk situation, the state will promote an administrative scheme of compensation over judicial remedies.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Under the strict liability scheme, responsibility for defective products rests on the producers in accordance with Article 41 of the PQL. Sellers may also be subject to strict liability under Article 122 of the Civil Law, or under Article 42 of the PQL where the identity of the producer of the defective product cannot be identified. Producers include those who appear to be a producer by connecting their names, titles, trademarks or other distinguishable marks to the defective products.

With respect to claims brought in tort, responsibility for defective products can rest on anyone whose fault contributed to the injury or damage.

If a claim is brought based on the law of contract, the direct responsibility for the defective product will rest on the party that has a contract with the injured party. However, after paying

damages to the injured party, the paying party may, depending on a case-by-case basis, make a request to its supplier for indemnity.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

In China, there is not a general system for recalls. Rather, the government issues industry-specific recall regulations. To date, all the recall regulations apply only to products in the Chinese domestic market.

The newly-enacted PRC Food Safety Law Article 53 provides that food recalls are now required for food that does not meet Food Safety Standards. Article 20 defines Food Safety Standards as regulations which will specify: a) limits on pathogenic microorganisms, pesticide residue, veterinary drug residue in food and food-related products, heavy metals, contaminants and any other substance hazardous to human health; b) types, scope of use and dosages of food additives; c) requirements on nutrient content of staple and supplementary food exclusively for infants and other specific groups of people; d) requirements on labels, marks and instructions regarding food safety and nutrition; e) hygienic requirements on food production and operation process; f) quality requirements regarding food safety; g) methods and procedures for food inspection; and h) other contents which are necessary to be formulated as food safety standards. The PRC Provisions on the Administration of Recall of Defective Auto Products ("**Automobile Recall Provisions**") are applicable to the "activities of production, import, sale, leasing and repair of auto products within the territory of the People's Republic of China" (Article 2 of Automobile Recall Provisions). Automobile manufacturers (including importers) must recall any automobile in which a defect is found. Defect is a design or manufacturing fault commonly found in a particular automobile model which causes unreasonable danger to a person or property or a condition commonly found in a particular automobile model that falls under the national safety standard. Anyone may report a defect to the General Administration of Quality Supervision, Inspection and Quarantine ("**GAQSIQ**", also known as AQSIQ) or a local authority. When the manufacturer or importer confirms that such defect exists, it may initiate the recall on its own volition. If the manufacturer (importer) does not recall on its own volition, and if GAQSIQ through its own investigation confirms that a defect exists (or when the manufacturer fails to prove that there is no such defect), GAQSIQ can order the recall.

There are similar regulations for toy recalls (applicable to toys produced and distributed within the borders of PRC) under the Administrative Provisions on the Recall of Children's Toys, and drug recalls (applicable to drugs distributed within the borders of PRC) under the Measures on the Administration of Drug Recalls. Notably, the drug recall regulations apply to overseas drug manufacturers of imported drugs.

Under Articles 31 and 35 of the Measures on Administration of Drug Recalls, a producer that fails or refuses to recall may be subject to fines, disciplinary warnings, and revocation of its drug-producing license. Failure to recall a defective product may also give the injured party a claim in tort for losses and damages caused.

Additionally, while there are no specific laws on the recall of defective medical devices, there are measures and regulations that effectively create a system of recall, granting the government broad power to seize defective medical devices, confiscate illegally sold or used medical devices, and stop the production or importation of defective medical devices.

1.5 Do criminal sanctions apply to the supply of defective products?

Yes. Articles 140-150 of the PRC Criminal Law set out criminal sanctions for: (1) producing or selling products mixed with fake ingredients, adulterated products, counterfeit products, seconds as best quality products, unqualified products as qualified goods; (2) producing or selling counterfeit drugs or drugs with inferior quality; (3) producing or selling food not in compliance with hygiene standards; (4) producing, selling, or knowingly selling poisonous and harmful food or food products mixed with poisonous, harmful, inedible ingredients; (5) producing, selling, or knowingly selling medical instruments and medical materials not in compliance with State or industry standards; (6) producing, selling, or knowingly selling products not in compliance with State or industry safety standards; (7) producing, selling, or knowingly selling pesticides, veterinary drugs, fertilizer and seeds which are counterfeit or of inferior quality; and (8) producing, selling, or knowingly selling cosmetic products not in compliance with State or industry standards.

If a product falls within the above categories and causes "severe consequence" or serious harm to human health, the producer, seller, and the person knowingly selling the products may be subject to criminal sanctions. A judicial interpretation issued by the PRC Supreme Court and the PRC Supreme Procuratorate on 9 April 2001, gives guidance as to what constitutes severe consequence in different circumstances. In general, an injury to a person or sales revenue exceeding RMB 50,000 (USD 7,352) constitutes severe consequence and criminal sanctions may ensue.

The criminal sanctions include a fine, confiscation of personal property, detention, fixed-term imprisonment, life imprisonment, and death penalty. The severity of the sanctions depends on the nature of the criminal act, the nature of the defective product, and the severity of the consequence. Life imprisonment and death penalties normally require that the defective products be counterfeit or harmful and cause serious damage such as death, disability, incurable diseases or injuries to many persons.

When a company is held criminally liable for supplying defective products, the person in charge of the company (e.g. Chairman of the Board or General Manager) or relevant responsible person is subject to the criminal sanctions mentioned in the preceding paragraph. The company itself is subject to a fine.

Under Articles 74 and 75 of the PRC Medicine Control Law, the producer or seller of fake medicine or substandard medicine may also be subject to criminal sanctions.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The general rule is that the claimant bears the burden of proving its claim, unless the law specifically imposes a reverse burden of proof.

For a product liability claim based on strict product liability, the claimant does not need to prove the defendant's fault. However, he or she does need to prove: (1) the product is defective; (2) damage has occurred; and (3) causation between the defect and the damage. The defendant has the burden of proving any statutory defence available to it (please see the answer to question 3.1).

For a product liability claim based in tort, the claimant bears the burden of proving: (1) the tortfeasor's tortious act; (2) damage; and (3) causation between the tortious act and the damage.

For a product liability claim based on breach of contractual obligations, the claimant bears the burden of proving: (1) the contract with the defendant; and (2) the quality of the product was sufficiently defective to constitute a breach of contract.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The law does not provide specific tests for proof of causation. From a few decided cases relating to personal injury claims, it appears the courts require the claimant to show the defendant's conduct was both the proximate cause and the cause in fact of the claimant's injuries. It is not clear whether the courts applied a "but-for" test in these cases to determine cause in fact. With respect to proximate cause, it appears the courts applied a foreseeability test (i.e. conduct is not a proximate cause of an injury or damage unless the injury or damage was foreseeable at the time). Thus, courts may not hold the defendant liable for exposing the claimant to increased risk if they consider the injury was not foreseeable at the time of exposure.

China is not a common law country and binding value is not given to prior judicial decisions. The courts have discretion to determine what test should be applied for proof of causation. They are not required to follow another court's test unless they wish to do so.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

The legal position in China is that the producers should be jointly and severally liable to the injured party unless they are able to prove the injury is not attributable to them. (Article 4 of the Interpretation of Several Issues Relating to the Application of Law in Trials of Personal Injury Claim Cases.) This means that the claimant may claim full compensation from any one of the producers.

"Market share" liability is not recognised under Chinese law. The courts have discretion, however, to determine how to allocate liability between the producers.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Article 27 of the PQL provides that products whose improper use is likely to cause the products themselves to be damaged or which endanger personal safety and/or the safety of property should carry warning marks or warnings in Chinese. It is a statutory obligation for the producer to warn against improper use. Failure to warn may result in fines and/or the halt of production (Article 54 of the PQL), and may give the injured party a claim in tort.

The content of the warning depends on how the product is expected to be used. If both end user and intermediary have a chance to use the product, the producer has the obligation to warn both the end users and the intermediary.

There is no principle of the "learned intermediary" defence in Chinese law.

3 Defences and Estoppel

3.1 What defences, if any, are available?

For a product liability claim based on strict product liability, the defences available to a defendant are set out in Article 41 of the PQL. These include: (1) the product has not been put into circulation; (2) the defect did not exist when the product was put into circulation; and (3) the development level of the science and technology is such that it did not enable the defect to be identified when the product was put into circulation.

When a product liability claim is made in tort, the defendant will be able to avoid liability if: (1) there was no fault or wrongful act by the defendant; and/or (2) the claimant's injury or damage was not caused by the defendant's fault or wrongful act. In the case of a seller, the defendant may seek indemnity if it can identify the manufacturer or supplier of the defective products.

When a product liability claim is based on the law of contract, the defendant will be able to avoid liability if: (1) there was no contract between it and the claimant; (2) there was no breach of contractual obligation; or (3) the consumer was already aware of the existence of the defects before purchasing the products.

In any case, the defendant may avoid liability if the claim was made after the expiration of the limitation period. Additionally, the defendant may argue for a reduction in the award of damages if: (1) the claimant contributed to his or her own injury or damage; or (2) a third party contributed to the claimant's injury or damage.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Yes, there is a state of the art/development risk defence (please refer to the answer to question 3.1). The defendant bears the burden of proving that the defect was not discoverable when the product was put into circulation.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Compliance with applicable *manufacturing* standards may be a defence to a claim based on strict liability. Regulatory compliance with manufacturing and other standards may also be a defence when the claim is based in tort or on the law of contract, because it may amount to a defence of no fault or no breach of contractual obligations.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Yes, a different claimant can re-litigate the same issues. "Issue estoppel" only applies between parties to a proceeding, not in respect of any third party.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

If the fault/defect was due to the actions of a third party, the defendants may: (1) apply to the court to join the third party as a co-defendant so that the court is able to determine the liability of the defendant and of the third party; or (2) seek an indemnity from the third party by filing subsequent proceedings.

If the defendant decides to file subsequent proceedings, the limitation period for filing the subsequent proceedings is two years. (Please refer to the answer to question 5.2 for more information about the statute of limitation.)

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Yes. (Please refer to the answer to question 3.1.)

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

There is no jury system in China. Pursuant to Article 40 of the PRC Civil Procedure Law ("**Civil Procedure Law**"), trial is conducted by a single judge or a judicial panel consisting of an odd number of judges and/or assessors. Assessors have the same rights and obligations as judges.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Only the judge has the discretion to assess the evidence presented by the parties. However, the parties may retain experts to give explanations of certain technical issues. The experts may be questioned by the court and by the opposing party at trial. In certain cases involving complex technologies, courts have asked for an expert to assist the courts directly.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

The Civil Procedure Law does provide for a "joint action procedure" for claims brought by more than two claimants.

A joint action is available when: (1) there are more than two claimants; (2) the claims are the same or of the same category; (3) the claimants agree to their claims being tried in one action; and (4) the court considers the claims can be tried in one action (i.e. the court has jurisdiction over all claims and the same civil procedure is applicable to all claims).

If the number of claimants exceeds ten, the claimants may proceed either by themselves or they may elect two to five representatives to act on their behalf to proceed with the action. The representatives' acts are binding upon the claimants they represent and the court delivers one judgment which determines what damages should be awarded in respect of which claims.

The procedure is "opt-in". According to the Civil Procedure Law, if the number of claimants cannot be determined upon filing of the action, the court may issue a public notice stating the particulars of the case and the claims, and requesting affected parties to register with the court within a certain time period. If the registered claimants fail to agree on representatives, the court may designate representatives among the claimants. The judgment delivered by the court is effective and valid for all registered claimants and also for those unregistered claimants who file proceedings before expiry of the limitation period.

Very few joint actions have been brought in China and the rules and practice are still under development. Most joint actions that have been brought relate to securities fraud.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

No, claims cannot be brought by a representative body on behalf of a number of claimants where the representative body is not directly harmed.

4.5 How long does it normally take to get to trial?

For a domestic case at the first instance, the court should deliver its judgment within six months of the date the case was accepted by the court unless the Chief Judge of the court extends it by another six months. There is no time limit for the court to deliver a judgment if there are any foreign elements to the claim (i.e., one or more parties are foreigners or foreign enterprises; or the subject of the claim is located outside of China).

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

No, under the Civil Procedure Law, there is no provision to allow the court to try preliminary issues. However, if certain facts of the case are evident, the court may issue a judgment on those facts at an earlier stage of trial.

4.7 What appeal options are available?

If one party is not satisfied with a decision made by a first-instance court, it is entitled to appeal to the next highest court as a matter of course, with the lower court judgment stayed in the interim. The decision rendered by a second-instance court is deemed final. Where the court of first instance is the PRC Supreme People's Court, the decision rendered by the Supreme People's Court is final.

A party may still apply for "review" of a final judgment by a higher court or by the issuing court, at the court's discretion. The Supreme

People's Court, for instance, will often review cases. Unlike an appeal, the underlying decision is not stayed pending review.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The court may designate an appraisal institution to assess technical issues and provide a written appraisal report. Under Chinese law, the parties may also apply to the court for an assessment of technical issues. Where the parties are unable to reach agreement on selecting an appraisal institute, the court may make the selection.

The parties may also apply to the court for one or two experts with specific knowledge to explain specific issues in the case. These experts may examine the appraisal institution issuing the written appraisal report, and may themselves be questioned by the court and the opposing party.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

Pre-trial depositions do not exist in China.

Courts may provide that parties exchange evidence prior to trial. In such case, the date for exchange is the deadline for presenting evidence. The parties should make their witness statements or expert reports ready for exchange on that date; otherwise they will be admitted only with leave from the court.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

China has no discovery procedure whereby relevant documents must be disclosed automatically to the opposing party.

Obligations to disclose documentary evidence arise when the court issues an evidence preservation order at the request of the opposing party. Such an order is issued when there is a risk that it will be impossible or very difficult to obtain such evidence in the future.

However, as a practical matter, there are few sanctions for failure to comply with an evidence preservation order. There is only one published case (which has no precedential value) wherein a court drew an adverse inference against a defendant based upon a failure to comply with an evidence preservation order.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Under the Chinese Civil Procedure Law, the court may proceed with judicial mediation based upon the parties' voluntary participation. The court conducts the mediation, and in the event of a successful mediation, issues a legally enforceable mediation statement (with the effect of a judgment) that identifies the claims, key issues in the case, and the result of the mediation.

Private mediation is also allowed. However, any agreement reached is not binding, and either party may elect to file a case with a court.

Domestic arbitration is also available. Contractual disputes and other disputes over the rights and interests of property between citizens, legal persons, and other organisations may be filed with a domestic arbitration institution except in narrowly exempted policy and administrative disputes.

International arbitration is available where one party is not a Chinese entity.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, time limits do exist.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

The limitation period varies depending on the legal ground of the claim.

The limitation period for claims for defective products under the PQL is two years from the date the claimant knew or should have known his rights were infringed. Claims also become time-barred after ten years from the day the defective product was delivered to the first consumer, unless the product clearly indicates that the period of safe use has not yet expired.

For claims based in tort or on the law of contract, the limitation period is two years from the date the claimant knew or should have known his rights were infringed. However, if the claim is for compensation for bodily injury or for the sale of substandard goods without notice, the limitation period is one year. Nevertheless, claims become time-barred after 20 years from the date the claimant's rights were infringed.

The limitation period is discontinued when the claimant issues a demand letter, initiates its claim, or the defendant agrees to fulfil its obligations. A new limitation period starts from the time of the discontinuance.

The limitation period is suspended during the last six months if the claimant cannot exercise its rights because of *force majeure* or other obstacles. The limitation period resumes on the day when the grounds for the suspension are eliminated. The court has discretion as to what constitutes legitimate obstacles to bringing suit. It may consider the age or condition of the claimant as the obstacle and suspend the limitation period.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

In cases of concealment or fraud, the limitation period starts from the date when the claimant becomes aware of the concealment or fraud.

However, claims are still time-barred if the claimant fails to bring them before the expiration of the 10-year and 20-year bars discussed in the answer to question 5.2.

6 Damages

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

Courts can issue monetary compensation and declaratory relief, such as repairing, reproducing, replacing, or returning products, or reducing the price of products. Courts cannot issue injunctive relief in product liability cases; certain regulatory agencies, however, may have the ability to do so.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Under the law of tort, a tortfeasor is liable to the injured party for bodily injury, mental damage, and damage to property. In the case of death, the tortfeasor is also liable for the annuity of those persons to whom the injured party owed a duty of maintenance.

Under the strict liability regime, the damages recoverable are the same as under the law of tort.

Under the law of contract, damage to the product itself and damage to property are recoverable, but bodily injury and mental damages are not. The injured party's lost profits may also be recoverable.

Under the Consumer Protection Law, damage to the product itself, bodily injury, and damage to property are all recoverable.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Not under the strict liability regime or the law of tort because actual damages are required.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are generally not available except in narrow circumstances. One such circumstance is where a business operator practises fraud in providing a commodity or service to a consumer. The newly-enacted Food Safety Law also provides for punitive damages in certain circumstances, although the punitive damages consist of only ten times the value of the food product.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

No, there is no maximum limit on the damages recoverable.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

No special rules apply.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

No. Government authorities responsible for the provision of social benefits cannot claim from any damages awarded or settlement sums paid to claimants. In the case of private insurance, the insurance company may not recover from the claimant. The law is silent as to whether the insurance company may separately seek recovery directly from the defendants.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The judgment issued by the court will order the losing party to pay for court fees. The successful party will be able to recover reasonable expenses and legal costs from the losing party. The court has discretion as to how much expenses or cost is reasonable.

7.2 Is public funding e.g. legal aid, available?

Public funding in the form of free legal service is available in narrow circumstances; for instance, when seeking compensation from the state or when seeking annuity from a tortfeasor in a death resulting from product liability. Judicial aid is also available to claimants who cannot afford court fees to claim damages for personal injuries, whereby the claimant may file an application to the court requesting it to waive or reduce the court fees. (Article 107 of the Civil Procedure Law.)

7.3 If so, are there any restrictions on the availability of public funding?

Not applicable.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Yes, contingency fees are allowed in China as long as the parties agree to it. The Measure for the Administration of Lawyers' Fees, issued by the Ministry of Justice, requires that as of 1 December 2006, contingency fees should not exceed 30 per cent of the value of the claim, and prohibits contingency fees for collective actions.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Third party funding is not a concept recognised in China, nor is it expressly prohibited by law.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in China.

In the face of several international food safety crises, China's Standing Committee of the National People's Congress promulgated a new Food Safety Law on 28 February 2009, scheduled to come into effect on 1 June 2009.

The new Food Safety Law is notable for several key provisions. First, the new law specifies that the Ministry of Health ("**MOH**") will take primary responsibility for regulation of food safety. The Ministry of Agriculture ("**MOA**"), State Food and Drug Administration ("**SFDA**"), GAQSIQ, and other administrative agencies that previously had concurrent (and often conflicting) jurisdiction will generally have a subordinate role to MOH.

Under the new law, consumers will also be able to claim punitive damages for food product liability. The Food Safety Law Article 96

provides that consumers can claim up to ten times the price of the product from manufacturers or sellers who knowingly distribute food that does not meet the Food Safety Standards. As noted above, punitive damages are extremely rare under Chinese law.

The Food Safety Law also places priority on damages for civil damages to consumers, where a manufacturer or seller is also subject to administrative or criminal fines for violations, but has insufficient assets to satisfy all such penalties.

In part as a reaction to China's recent melamine-contamination scandal, the new Food Safety Law bans the use of all chemicals and additives in food production other than those specifically authorised. The new law provides for a state-level food safety commission, and imposes new record-keeping requirements on food manufacturers and sellers.

Although the new Food Safety Law makes key advancements, legal scholars and commentators have already questioned the ability to effectively implement the law, particularly with respect to reconciling the currently conflicting food standards and lines of governance.

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Cyprus

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

The legal framework in respect of product liability is robust and primarily consists of:

a) Law 105(I)/95 - The Defective Products (Civil Liability) Laws of 1995 to 2002 ("Defective Products Law") which implement European Directive 1999/34/EC into Cyprus law;

b) Law 41(I)/2004 - The General Safety of Products Law of 2004 ("Safety Law") which implements European Directive 2001/95/EC;

c) Contract Law Cap 149; and

d) Civil Wrongs Law Cap 148.

A consumer has a *prima facie* claim under the Defective Products Law if he can prove that the product was defective and that it caused damage. The full definitions of 'damage' and of a 'defective product' are provided in the Defective Products Law. The law does not permit the producer to limit his liability via a contract or another form of agreement with the purchaser. The Safety Law imposes the legal requirements for product safety on all goods other than those for which specific legislation has been enacted. Specific legislation exists in respect of toys and electrical goods.

Cap 149 allows an injured purchaser to claim for breach of contract against the immediate supplier of a defective product only. Liability depends on both the express and the implied terms of the contract between them. The Sale of Goods Law 10(I)/94 as amended implies several terms to contracts for the sale of goods to the consumer including fitness for purpose.

Cap 148 allows an injured person to bring a claim for negligence provided that he can prove that a duty of care was owed to him, that the defendant breached that duty of care and that damage was suffered as a result of that breach.

1.2 Does the state operate any schemes of compensation for particular products?

There are no such compensation schemes in place at this time.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Under the Defective Products Law and the Safety Law, the injured party is able to claim against:

a) the manufacturer of the defective product;

b) any person who has manufactured any component part thereof (including the production of raw materials);

c) any person who, by putting his name on a product or using a trade mark or other distinguishing mark in relation to a product, has held himself out to be the producer;

d) the importer of the product; and

e) a supplier who fails to disclose details of the producer within a reasonable timeframe when asked in writing to do so provided that such a request is made within reasonable time from the cause of damage.

Where under the law more than one person is held liable for the damage suffered the liability is joint and several.

Cap 149 allows an injured purchaser to claim for breach of contract against the immediate supplier of a defective product only.

Under Cap 148, claims are usually made against the product manufacturer but they can be brought against other parties in the supply chain if fault can be established.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

The provisions in the Safety Law mirror those of Directive 2001/95/EC article 3. Product recall is viewed as an action to be taken as a last resort. A recall will be issued by a producer:

a) where other measures would not suffice to prevent the risks involved - for example where the defect in the product cannot be made safe;

b) if the producer considers it necessary, for example if there is evidence to suggest that the product is dangerous despite it complying with criteria designed to ensure general safety; or

c) where the producer is obliged to do so further to a measure taken by the competent authority. In Cyprus this is the Competition and Consumer Protection Service ("the Service") which is a division of the Ministry for Commerce, Industry and Tourism. Failure to recall in such circumstances is a criminal offence. Proceedings against the offender will be initiated by the Service.

1.5 Do criminal sanctions apply to the supply of defective products?

The Safety Law obliges producers to only place products on the market which under normal conditions of use do not contain any danger for the health and safety of consumers. Breach of this obligation is a criminal offence.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The onus under the Defective Products Law is on the claimant to prove that the product was unsafe, namely that its use, consumption or storage by any person exposes:

a) that person or any other person to a risk of personal injury of any kind, including any risk to health, which persons generally should not reasonably be expected to incur thereby; or

b) any property (including immovable property) to a risk of loss or damage which property generally should not reasonably be expected to incur thereby.

The claimant must also establish that the damage complained about was caused, either entirely or partly, by the unsafe product.

The burden of proof in claims under Cap 148 and 149 is also on the claimant.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

As stated in question 2.1, the claimant must prove that the injury was caused either entirely or partly by the defective product.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

The position of the claimant is unaffected as the Defective Products Law will treat the supplier of the product as the producer unless the supplier identifies the producer to the claimant within a reasonable timescale. In a situation where one or more parties may be responsible for the damage, the Defective Products Law allows for liability to be joint and several. The liability of a supplier cannot be diminished if the damage is caused both by the defective product and by the act or omission of a third person. However, liability under the Defective Products Law does not affect the supplier's right to claim indemnity or contribution from the third person.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

A failure on the part of a producer to give adequate product warnings may give rise to criminal liability under the Safety Law. The Law specifically provides that within the limits of their respective activities, producers must provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks. The presence of warnings does not exempt the producer from the general safety of goods requirement laid down in the law.

There is no principle of a "learned intermediary" in Cyprus product liability law.

3 Defences and Estoppel

3.1 What defences, if any, are available?

A number of defences are available to the producer under the Product Defect Law. These are that:

a) he neither manufactured or imported, the product for sale or supply in the course of his business;

b) he did not put the product into circulation;

c) the product was used as a component in another product and that the defect was wholly attributable either to the design of the other product or to compliance on his part with instructions given by the producer of the other product;

d) the defect was wholly attributable to compliance on his part with requirements imposed on him by any provision of law;

e) the defect did not exist in the product at the time when it was under his control or that it came into existence at some later time;

f) not being the producer or importer of the product, he has made known the identity of the producer or of the person who supplied the product to him; or

g) when he put the product into circulation, the standard of the scientific and technical knowledge could not permit the determination of the existence of the defect.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

There is no state of the art or development risk defence available.

As stated in question 3.1, there is a defence available if the product defect was not discoverable at the time of supply because of the standard of scientific and technical knowledge prevailing then. The onus is on the defendant to prove that this was indeed the case.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

As stated in question 3.1, compliance with regulatory and/or statutory requirements is a specific defence available to the manufacturer.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

There is no issue estoppel to prevent such proceedings. A final judgment in previous proceedings is only conclusive between the parties to those proceedings.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

The liability of a producer (or those treated as producers) under the Defective Product Law cannot be diminished if the damage is caused both by the defective product and by the act or omission of a third person. This is without prejudice to the rights of the producer against the third person. Thus a defendant may either join the third party in the main proceedings within a month from the date of filing of the defence, or alternatively bring separate proceedings against the third party, in which case the time limit is governed by the normal limitations law (see question 5.1).

The Law is silent on how any liability is apportioned between these parties and each case will be judged on its own merits but it may generally be assumed that all such persons will be jointly and severally liable towards a consumer for any damages which may have been caused by a defective product.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

It is possible to make such an allegation.

Under the Defective Products Law (s7) and Cap 149, liability may be reduced or disallowed when the damage is caused both by a defective product and by the fault of the person damaged or of any person acting under his responsibility.

Cap 148 also acknowledges the possibility of contributory negligence on the part of the claimant.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

Both criminal trials and civil trials are conducted by a judge.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The court does not have the power to appoint technical specialists. However, it is common practice for the parties to make use of such specialists as expert witnesses.

An expert witness testifying on behalf of one of the parties may be challenged by expert testimony introduced by the adversary. The court will form its own opinion as to the weight that should be attached to such testimony.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

Cyprus Civil Procedure Rules do allow for class and representative body actions although in practice such actions are not common.

Where many persons share the same interest, a class action may be filed after one or more of such persons are authorised by the court to sue or defend in this class action on behalf of, or for the benefit of, all persons interested. Before the court grants the relevant authorisation, a power of attorney signed by the persons to be represented and certified by the Registrar or certifying officer and empowering the person or persons who are to sue or be sued on their behalf to represent them in the cause or matter specified must be lodged alongside the main action. An exception to this arises in the case of any unincorporated religious, charitable, philanthropic, educational, social or athletic institution or association not established or conducted for profit. Where a class action is allowed the persons represented are bound by the judgment of the court in the action, and such judgment may be enforced against them in all respects as if they were parties to the action.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Claims can be brought by a representative body as stated in question 4.3. As with a class action the approval of the court must be obtained prior to filing the action.

4.5 How long does it normally take to get to trial?

The time taken to get to trial may normally be expected to exceed the Supreme Court's target average of a maximum three years. The actual period taken will be influenced by a number of factors including the complexity of the claim and the tactics employed by the relevant legal advisors. Attempts to reach an out of court settlement may also delay proceedings as might a request for interim orders in respect of matters such as document disclosure.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

It is both possible and common for the courts in Cyprus to try such preliminary issues, but only on points of law. The Court will not consider issues of fact at a preliminary stage, but only at the hearing of the substance of the case.

4.7 What appeal options are available?

Decisions issued by both the civil and the criminal lower courts are subject to appeal before the Supreme Court of Cyprus. An appeal against an interlocutory decision must be filed within 14 days of that decision. Case precedent allows that only interlocutory judgments that have an imminent effect on the rights of the parties may be appealed.

Notice of an appeal against a final judgment must be filed no later than six weeks after the date of the judgment. The appellant may appeal against either the whole or a part of the final judgment.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

As stated in question 4.2, the court does not have the right to appoint expert witnesses but the parties to the hearing may present expert evidence. Such evidence is restricted only in the sense that:

a) it must be relevant to the case being heard; and

b) it must be admissible, that is, it must comply with Cyprus law of evidence.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

There is no requirement for factual or expert witnesses to present themselves for pre trial deposition. The judge may on application order the discovery of witness statements or expert reports at the pre trial stage. See question 4.10 for more detail. Without the granting of such an application, pre-trial exchange of such documents is not a legal requirement.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

In general there is no obligation to disclose such evidence. A disclosure obligation will only arise if, following an application by either party to the action, the court orders the discovery of documents relevant to the action which are under the control of the other party.

Such an order will only be granted if the evidence in question is deemed material to the case in as much as:

a) its disclosure is necessary for disposing fairly of the action; or

b) its disclosure will result in significant cost savings.

The Courts will not encourage so-called "fishing" expeditions and actual discovery only takes place after the completion of the pleadings and the particulars.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

In most disputes the option of resolving a dispute via arbitration or mediation does exist although there is no single scheme in place which is specifically designed to deal with consumer product liability issues.

The Service and the two major consumer associations that exist in Cyprus will often mediate between consumers and suppliers with a view to obtaining an out of court settlement. This does not preclude legal action on the part of the consumer if no settlement is reached.

Domestic arbitration proceedings are governed by the Arbitration Law, Cap 4 of the codified laws of Cyprus, whilst international arbitration proceedings are governed by Law 101 of 1987 which adopts, with some minimal amendments, the UNCITRAL Model Law. Domestic arbitration law allows for extensive intervention by the courts in all stages and it should be noted that if an arbitration agreement covers disputes which involve a question of whether one of the parties has been guilty of fraud, then the court will step in so far as necessary to enable that that question is determined by the court. In these circumstances the court has the power to order that the arbitration agreement shall cease to have effect and has the power to revoke any agreement made thereunder. Law 101 of 1987 minimises the court's intervention in proceedings.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Time limits do exist and they are detailed in question 5.2.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

The Defective Product (Civil Liability) Law requires proceedings for compensation of damage to be commenced within three years from when the claimant became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer of the defective product that caused the damage.

No claim may be made under the Law after the expiry of ten years from the time at which the actual defective product, by reason of whose defect the damage was suffered, was put into circulation, unless either:

a) the producer or, as the case may be, the importer of the product has given an express warranty that the product can be used for a longer period; or

b) the injury was caused within the ten-year period but could not be reasonably discovered until sometime thereafter.

Time limits for contractual claims are set out in the Limitation of Actions Law, Cap 15. It should, however, be noted that this law is currently suspended until 31 March 2010.

With respect to torts, section 68 of Cap 148 states that generally, no action can be brought in respect of any civil wrong unless such action commences:

a) within three years after the act, neglect or default of which the complaint is made;

b) where the civil wrong causes fresh damage continuing from day to day, within three years after the ceasing of such damage;

c) where the cause of action does not arise from the doing of any act or failure to do any act but from damage resulting from such act or failure, within three years after the claimant suffered such damage; or

d) if the civil wrong has been fraudulently concealed by the defendant, within three years of its discovery by the claimant, or of the time when the claimant would have discovered such civil wrong if he had exercised reasonable care and diligence.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

As stated in question 5.2, Cap 148 allows an action to be brought within three years of:

a) the discovery of the concealment or fraud; or

b) the time when the claimant would have discovered such wrong if he had exercised reasonable care and diligence.

An action to enforce a charge against or to set aside a property transaction will not be entertained by the courts if it is brought against a *bona fide* purchaser.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

In all cases the claimant has a right of action for damages. Additionally the claimant may, under Cap 149, obtain equitable remedies such as a right of action for a quantum meruit, a right to sue for specific performance or an injunction, a right to request rescission of the contract, or a refusal of further performance of the contract by the aggrieved party.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Under the Defective Product Law, compensation for damage caused by a defective product is assessed in the same way as a claim for negligence. In accordance with common law principles the aim is to put the injured party into the position he would have been in if the negligent act had not occurred. Damages in contract claims will also aim to put the injured party into the position he would have been in if the breach had not occurred.

Damages can be recovered for death or personal injury including mental injuries) and damage to property (subject to a *de minimis* lower limit of €427). There is no upper limit, and the right to claim compensation is without prejudice to the claimant's contractual rights or his rights under any other law. No recovery may be made in respect of damage to the product itself.

Liability may be reduced or disallowed when the damage is caused both by a defective product and by the fault of the person so damaged or of any person acting under his responsibility.

Cyprus law does not generally limit the amount of damages awarded in tort claims. The courts have been reluctant to permit contract exclusion clauses which have been imposed on a weaker party by a stronger party. Furthermore, the court may find exclusion clauses abusive and consequently ineffective under the Abusive Clauses in Contracts Law 93(I)/1996. The Defective Products Law expressly provides that any contractual term or any notice or other provision that purports to limit or exclude liability under it is ineffective.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

No. Damages are only available when actual harm occurs.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

As stated in question 6.2, the intention in awarding damages is to put the injured person in the position that he would have been in had the injury not occurred rather than to punish the defendant. Consequently it is rare for punitive damages to be awarded.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

No such limit exists.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

In such instances the parties to the dispute declare before the court that they have reached a settlement of the claim. The court will then issue a consent order incorporating the settlement.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Such a claim is not permissible. The relevant authorities will need to either sue the defendant or join the claimant as a party to any existing litigation in order to attempt to obtain such reimbursement.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The court will exercise its discretion when awarding costs. Generally both types of costs will be awarded against the unsuccessful party to the action. Occasionally costs may be allocated between the parties or may be referred by the court to the Registrar of the Court for assessment.

7.2 Is public funding e.g. legal aid, available?

The Law on Legal Aid 165(I)/2002 does not provide for legal aid to be made available in product liability claims.

7.3 If so, are there any restrictions on the availability of public funding?

See question 7.2.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

The use of contingency fee arrangements is not permitted in

Cyprus. Outside of this restriction advocates are free to negotiate their payment terms with a client subject to compliance with local Bar rules.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Third party funding of claims is permitted. There are no regulations governing the basis of funding.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Cyprus.

There have been no significant cases brought in the past year. There have also been no major changes in trends or the law. A "Law on the Out of Court Settlement of Consumer Disputes by Arbitration" which would provide for an Alternative Dispute Resolution scheme in keeping with EU Commission recommendation 98/257/EC remains under discussion but there is no agreed timetable for its introduction.

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Denmark

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

Directive 85/374 on liability for defective products was implemented into Danish law by Act no. 371 of 7 June 1989 concerning product liability and amended by Act no. 1041 of 28 November 2000 implementing Directive 1999/34. The Act was amended again in 2006 after the European Court of Justice overturned section 10 of the Act in case no. C-402/03 and again in 2007 in order (to a limited extent) to accommodate the new Time Limit Act that took retroactive effect on 1 January 2008.

The Product Liability Act applies to personal injury and damage to consumer goods.

The producer's liability for defective products was based on the principles of the Law of Tort until the Product Liability Directive was implemented into Danish law. In Denmark the Law of Tort is not set out in any Act, but has been developed over the years by the courts. The Act is a supplement to existing Danish law on product liability and not a replacement. Product liability has generally been defined as a producer's liability for damage caused by a defect in his product. According to the ordinary rules of Danish law on product liability, it is a condition for liability that the defect in the product is due to negligence on the part of the producer. The burden of proving negligence is not onerous.

The Danish Sale of Goods Act of 1906 (*købeloven*) with later amendments governs the obligations between purchaser and vendor in sales of goods. The Act does not govern the right to compensation for damage caused by the product. The Sale of Goods Act governs damage to the actual product sold, including any damage or problems with its ingredients, as these types of damage are not considered to be product damage.

It should be noted that Denmark has implemented the Convention on Contracts for the International Sale of Goods (CISG).

The main difference between contract law and tort in relation to product liability is the limitation period for bringing claims. According to the Sale of Goods Act the limitation period is two years from delivery of the goods.

Although product liability is not governed by the Sale of Goods Act of 1906, the existence of a contract between the parties can be of relevance. If the contract is entered into between professionals it may regulate, limit or eliminate product liability. The contract may state certain obligations of the professional purchaser to check the product. Danish courts will not accept limitation of liability for product damage in case of personal injury and, as a main rule, limitation of liability will not be accepted if the seller has shown gross negligence. Danish courts tend to be critical in their interpretation of limitation on liability using the in dubio contra stipulatorem rule of interpretation.

Under the Product Liability Act it is not possible to limit or eliminate product liability.

1.2 Does the state operate any schemes of compensation for particular products?

Patients who suffer damage from drugs may claim damages from the Government according to the Act on Damage from Use of Drugs. The Act gives the Government the right of recourse against the producer according to product liability rules, *cf.* section 16, subsection 1.

Existing acts on liability for nuclear plants, vaccine damage and damage occurring during military service, deal with product liability in these specific areas.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

According to ordinary Danish rules on product liability the producer bears responsibility for the fault/defect.

According to the Product Liability Act, the producer, as defined in the directive art. 3, bears responsibility for the defect.

Since the 1930s it has been held that the supplier is immediately liable for defects in the product delivered by the producer even though the supplier has not acted negligently himself (the supplier then has a right of recourse against the producer). This found its way into the original section 10 of the Danish Product Liability Act according to which the supplier was immediately liable to the claimant and any other suppliers in the chain of distribution for any product liability incurred by the producer, also in case of personal injury or damage to non-commercial goods regardless of whether the supplier had acted negligently.

However, on 10 January 2006 the European Court of Justice ruled that Section 10 of the Danish Product Liability Act could not be upheld, *cf.* the European Court of Justice case C-402/03.

The judgment was in line with the conclusion of the French case C-52/00. A national rule according to which the supplier is answerable without restriction for the producer's no-fault-based liability is therefore no longer possible.

As a consequence of the European Court of Justice case C-402/03, section 10 of the Product Liability Act was changed in 2006. According to the new section 10 of the Act, the supplier is liable without restriction only for the producer's fault-based liability.

The change entails that the supplier is only immediately liable if the claimant can prove that the producer acted negligently, but where the assessment of evidence of whether the producer acted negligently is in fact non-existing, it will most likely not be accepted by the European Court of Justice. This is due to the fact that such a national rule will be identical to section 10 that was held by the European Court of Justice not to have been in accordance with the Directive.

Against this background, the Danish courts will in the future have to evaluate the question of liability more carefully than they have previously done in order to avoid conflict with the European Court of Justice.

The assessment of evidence is likely to be more lenient and the claimant must probably invest more time in gathering evidence showing what steps other producers took to ensure that the product was safe, what regulations those producers observed, how much time was invested in ensuring that the product was safe in an attempt to convince the courts that the damage in question could have been avoided had the producer in question acted in the same way.

The Danish courts will test the producer's margin of error in the future, and only time will show to what extent the Danish courts are willing to be more lenient.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Obligations to recall products are governed by the Act on Product Safety, which implements the Product Safety Directives 92/59 and 2001/95. A failure to recall under the obligations of the Product Safety Act may lead to product liability or even criminal sanctions.

Even if a recall cannot be required according to the Product Safety Act a producer may be under an obligation to warn relevant parties about possible dangers of the product. A failure to warn may lead to liability according to ordinary rules on product liability.

1.5 Do criminal sanctions apply to the supply of defective products?

According to the Act on Product Safety criminal sanctions (fines) apply if the product does not meet the specified requirements set out in public regulations.

Moreover, The Danish Penal Code could also apply in case of gross negligence.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

Under Tort Law it is up to the claimant to prove that the product is defective, that the producer has shown negligence, that a loss has been suffered and that there is causation between the defective product and the loss suffered.

No particular rules exist as to what standard of proof must be met by a claimant or defendant in order to sustain his burden of proof. The court is free to evaluate the evidence in the particular case and on the basis of this concrete evaluation the court will determine whether the burden of proof has been sustained or not.

Under the Directive it follows from Article 4 that the injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The basic rule of Danish law is that the claimant must prove a causal relationship between his/her particular injury and the defect. There are no rules under Danish law stipulating the standard of proof. The principle of the courts' freedom to assess evidence applies. The standard of proof is set by the courts in each particular case from an overall assessment of the claimant's possibilities of providing evidence, the defendant's situation, the nature of the defect and the situation in general. Danish law does not provide specific rules on how the court is to assess the evidence, the court will on the basis of what has been presented to the court during the trial and the production of evidence, decide on which facts of the case to base its decision.

The courts' freedom to assess evidence applies to all evidence, both direct evidence, e.g. witnesses or technical equipment (cameras, measuring devices, etc.) having observed a particular event, and indirect evidence where the court from the circumstances of the case decides on what fact to base its decision. It is not impossible that a court of law on the basis of strong statistical evidence could find that it is enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product. Even if it cannot be proved by the claimant that the injury would not have arisen without such exposure it is, however, a prerequisite that the statistical evidence to a very high degree of certainty must exclude that the particular injury could have other causes.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

If it cannot be established which of several possible producers have manufactured the defective product, the claimant has not lifted his burden of proving who the producer/responsible party is. It is for the courts to decide how onerous the burden of proof is in the particular situation. No form of market-share liability applies.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

A failure to warn can give rise to liability. The producer has an

obligation to warn anyone who the producer knows or should have known is in possession or will be in possession of the particular product.

3 Defences and Estoppel

3.1 What defences, if any, are available?

See the answer to question 3.2.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Under tort law and under the Product Liability Act (which implements the Product Liability Directive), the producer is not liable if he can prove state of the art defence or prove that the damage suffered is a so-called system damage i.e. a case of damage from a product with known but unavoidable defects (e.g. tobacco).

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

It is not necessarily a defence for the producer that he has complied with regulatory or statutory requirements, but it will be a strong argument when assessing whether the product is defective.

The producer is not liable if he proves that the defect is caused by the product having to conform to mandatory statutory requirements, *cf.* the Product Liability Act, section 7. This also applies to product liability according to Tort Law.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

A claimant can litigate issues of fault, defect or the capability of the product to cause damage even though another claimant has litigated regarding the same issues. However, the first trial may have a substantial effect on the second trial.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

The defendants can and will usually summon the third party to the same proceedings and make a recourse claim towards the third party if the third party has caused the defect and has acted negligently.

It is possible to involve a third party in subsequent proceedings provided that the case between the claimant and the defendant has not dealt with the issue of the third party's negligence.

As a main rule the same time limit applicable between the claimant's claim against the defendant, will be applicable to the defendant's recourse claim against a third party, but in some instances additional time limits of one year will apply, *cf.* question 5.1 below.

In case the claimant interrupts the time bar by commencing litigation against the defendant or the defendant fulfils the claim or gives an extension of time, the defendant's recourse claim will according to section 12 of the Time Limit Act be subject to a time limit of no less than 1 year calculated from the interruption/fulfilment/extension.

However, in regards to a supplier's recourse claim against the producer within the scope of the Product Liability Act, the absolute time limit of 10 years calculated from the date when the producer placed the product into commerce cannot be extended in this way.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Yes. If the claimant has not acted in accordance with, for example, instructions for use or has otherwise acted inexpediently, the defendant can claim that the claimant has shown contributory negligence.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

The trial is by a judge, never a jury.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The parties can ask for a court-appointed expert to answer questions formulated by the parties and accepted by the court with regard to factual or scientific issues. The expert is appointed by the court and the rules on judges' impartiality apply to these experts as well. The expert will give written answers to the questions raised, and can be heard as a witness.

Under certain circumstances the court may decide that the case must be heard by one judge with a legal background and two judges with a lay background, i.e. experts within a particular field.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

A group action system took effect on 1 January 2008.

The provisions regarding group actions are laid out in chapter 23a of the Administration of Justice Act.

There is an 'opt-in' as well as an 'opt-out' procedure available.

The 'opt-out' procedure will normally only be available in case the individual claims are so small (up to approx. DKK 2,000) that filing individual claims would be disproportionate. A group action procedure based on the 'opt-out' procedure can only be brought by public authorities that have been granted statutory power to do so. As of yet only the Danish Consumer Ombudsman has been granted such a power.

Group action based on the 'opt-in' procedure can be brought by either an individual member of the group, private organisations/ associations or public authorities with statutory power to do so (The Danish Consumer Ombudsman).

The first group action claim procedure before a Danish court was initiated in February 2008 and it is therefore too early to tell whether group action claims will commonly be brought in Denmark.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

See the answer to question 4.3 above.

A representative body can intervene in an existing trial or can litigate on behalf of a claimant.

4.5 How long does it normally take to get to trial?

Court cases generally progress slowly and, depending on its complexity, a product liability case will invariably last 1-3 years in the first instance. In the second instance it will usually take less time to pursue the claim.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The court can try preliminary issues, the result of which determines whether the remainder of the trial should proceed.

Thus questions of jurisdiction, capacity to sue and time limits may be dealt with on a preliminary basis. If there is an advantage to it, the court may decide that the question of liability should be dealt with before the question of damages is handled.

4.7 What appeal options are available?

The ordinary courts in Denmark are organised in a three-tier system: City Courts; High Courts; and a Supreme Court.

Denmark is at the moment divided into 24 City Court districts with one judge dealing with civil and criminal matters.

The second tier consists of two courts of appeal, Eastern High Court seated in Copenhagen and Western High Court seated in Viborg. At present there are about 100 judges at The Eastern and Western High Courts. Three judges will participate in a case.

With the status as a High Court, The Maritime and Commercial Court is seated in Copenhagen. This court will sit with one judge with a legal background and two or four lay judges with a commercial background.

The Supreme Court is situated in Copenhagen and consists of 19 judges, one of whom is the president. All cases start at the city court level except for cases that involve matters of principle. These cases will be transferred to the High Court and can be appealed to the Supreme Court. At least five judges will participate in a case.

The judicial system is based on the principle that a case may be tried at two instances, and that further appeal requires permission.

A court of appeal may try questions of fact as well as questions of law. New evidence may be submitted by the parties, but new claims and allegations may only be introduced with the consent of the other party or the court.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

As will be seen from the answer to question 4.2 above, experts may be appointed by the court to answer questions of fact or science. An expert opinion unilaterally obtained by a party before legal proceedings have been instituted usually cannot be admitted as evidence.

The parties can present expert evidence to a very limited extent.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

There are no pre-trial depositions under Danish procedural rules.

The expert's written answers are exchanged prior to trial and may give rise to supplementary questions.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

Documentary evidence must be disclosed before written proceedings have been finalised and in advance of trial. Only in very special circumstances will the court admit new evidence during trial.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

There are provisions in the Administration of Justice Act that enable mediation through the courts - these provisions are not applicable to the Supreme Court.

Mediation is also available through Danish Attorney Mediators, an association within the Danish Bar and Law Society.

Arbitration is available and commonly used in business to business relations. Both ad-hoc tribunals as well as permanent arbitration tribunals are available. An organisation called Danish Arbitration handles disputes within a wide array of fields, while there is a specialised arbitration institution that handles disputes relating to the building and construction sector. Both these institutions also offer mediation.

Arbitration is rarely used in disputes where consumers are involved, as arbitration clauses in consumer contracts cannot be enforced if the consumer regrets such choice of forum once a dispute arises. A consumer must in fact reconfirm that arbitration is the agreed method for solving the dispute, or else an arbitration clause will be deemed void.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

According to the new Time Limit Act that came into retroactive effect on 1 January 2008, the general time bar in all product liability cases is three years calculated from the date the injured party knew or ought to have knowledge of the damage, defect and the relevant producer or supplier. The requirement is that the injured party must be able to identify his claim and the producer or supplier. The time

bar is interrupted by acknowledgment or commencement of litigation.

There is an absolute limitation period in addition to the general three year time limit, mentioned above. The length of that period will depend both on the nature of the claim and on whether the claim is against a producer or supplier.

Claims against a producer within the scope of the Product Liability Act (personal injury and damage to consumer goods) will be subject to an absolute 10-year limitation period - in accordance with the Product Liability Directive - calculated from the date when the producer placed the product into commerce.

Claims against a producer relating to damage to commercial goods will in most cases also be subject to an absolute 10-year limitation period, but if the claim relates to pollution (air, water, soil etc.) or disturbances (noise, tremors etc.) the absolute limitation period will be 30 years.

Claims against a supplier will be subject to an absolute 10-year limitation period, but if the claim relates to pollution (air, water, soil etc.) or disturbances (noise, tremors etc.) or personal injury the absolute limitation period will be 30 years.

Furthermore the new Time Limit Act introduces detailed provisions regarding additional one-year minimum time limits under certain circumstances, including in relation to recourse and criminal behaviour.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

See answer to question 5.1.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Criminal sanctions imposed on a producer or supplier will in some instances 'awaken' civil claims that have already been time-barred, thus enabling a claimant to pursue such claims within a new time limit of one year.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

Monetary compensation as well as declaratory relief is available.

The Danish Safety Technology Authority can subject to conditions laid out in the Act on Product Safety issue interim notices, including prohibition and recall notices regarding products that are deemed to be unsafe.

If the supplier or producer objects to such a notice, the Danish Safety Technology Authority will have to obtain an injunction awarded by a court to replace the interim notice.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

In case of total loss of or damage to property, the replacement cost, less a deduction for depreciation due to age, wear and tear and reduced applicability, determines the amount of damages payable.

In case of partial loss or damage to property, damages payable equal the cost of repair. If repair does not fully restore the utilisation value or commercial value of the damage to property, compensation may also be claimed for the remaining loss.

In addition to the above the claimant can recover consequential damages.

In case of personal injury the Danish Act on Liabilities and Damages applies. In general, compensation for personal injury in Denmark is low, when compared to other Western European countries and the US. For damage that occurs after 1 July 2002 the level of compensation has been increased to a certain extent.

The following types of damages are recognised: medical expenses; temporary loss of earnings; pain and suffering; permanent injury; permanent loss of earning capacity; and compensation for loss of support.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

If at a later stage the product malfunctions or causes injury then previously incurred costs of investigations or tests may be recoverable if the court finds that the costs incurred have been relevant.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

No, punitive damages are not recoverable.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

No such limit exists in Denmark.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

Settlement of class action claims will have to be approved by the court. Settlement of claims by infants will have to be approved by the guardian as well as the appropriate State County. Settlement sums to infants will in most instances have to be managed by certain branches of banks approved by the Danish Ministry of Justice until such a time when the infant in question comes of age.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Government authorities will not be able to claim reimbursement of treatment costs.

If the claimant receives benefits under the Danish sickness benefits

regime, Government authorities will be able to claim reimbursement of sums paid from a liable producer or supplier.

The claimant will only be able to recover temporary loss of earnings for a certain period of time, i.e. to the extent that a) the claimant continues to suffer such a loss and b) that damages for such a temporary loss has not been replaced by damages for permanent loss of earning capacity (a lump sum that basically is a capitalisation of temporary loss of earnings until such a time when the claimant would have retired).

The authorities' reimbursement claim will 'live and die' with the claimant's own claim, thus once the claimant ceases to be able to recover temporary loss of earnings, the Government authority will no longer be able to claim reimbursement of sickness benefits paid, even if the claimant continues to be eligible for benefits under the sickness benefits regime.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

A successful party can recover legal costs, including court fees, from the unsuccessful party. The amount recoverable, however, is determined by the court and the amount seldom covers all costs. The court may approve legal costs if for example a party wins some, but not all, points in issue in the case.

7.2 Is public funding e.g. legal aid, available?

Denmark has a system of legal aid, which is governed by the Administration of Justice Act. The County Authority can grant legal aid. If legal aid is refused the applicant can appeal to the Ministry of Justice. It is a requirement that the applicant is of moderate financial means, however, a substantial number of Danish families will meet the conditions.

As of 2008 the annual income for a single person must not exceed DKK 256,000, for a married person the household income must not exceed DKK 325,000 with DKK 44,000 added per child.

In general it is an additional condition that the chances of winning the case in court are reasonably good.

Many families have some access to legal aid through their private insurance, usually limited to a moderate sum.

7.3 If so, are there any restrictions on the availability of public funding?

See answer to question 7.2.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

There is no tradition for contingency fee arrangements in Denmark.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Yes, third party funding is permitted and is usually provided through product liability insurance policies. Taking out an insurance policy covering criminal sanctions (fines) is however not permitted.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Denmark.

All recent developments have been mentioned in the questions above, most notably the new Time Limit Act and the new group action procedures for multiple claims.

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Jens Rostock-Jensen was recently appointed member of the Administration of Justice Council under the Ministry of Justice, which advises the Ministry on procedural matters.
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England & Wales

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

Product liability claims may be made under the Consumer Protection Act 1987 ("CPA"), in negligence or in respect of breach of contract. Although claims can be made in respect of the breach of some statutory obligations, such as certain duties imposed by product safety and health and safety legislation, consumer fraud legislation does not give rise to private law rights to claim compensation.

The CPA, which implements the Product Liability Directive, 85/374/EEC, in the UK, imposes liability on the producer of defective products for damage caused by the defect. A product is defective if it is not as "safe as persons generally are entitled to expect" taking account of a number of factors including any instructions or warnings provided with the product and the manner in which it has been marketed. Liability is strict: it is not necessary to prove that the manufacturer was at fault in causing the defect. The Claimant need only prove a defect and a causal relationship between the defect and the injury.

Claims may only be brought under the CPA in respect of products put into circulation (i.e. entering the distribution chain) after 1 March 1988. Claims relating to products supplied before this date must be brought in negligence or for breach of contract.

In order to establish negligence, it is necessary to prove that the Defendant owed a duty of care to the Claimant, that he breached that duty by failing to take reasonable care, and that the breach caused the damage complained of. Such claims are commonly brought against the manufacturer of a defective product, although they may also be brought against other parties in the supply chain, if fault can be established.

Claims for breach of contract may only be brought against the immediate supplier of the defective product to the person injured. Liability is strict where the contract has been breached and will depend upon the terms of the contract agreed between the parties or implied into the contract. Under the Sale of Goods Act 1979 (as amended) and the Supply of Goods and Services Act 1982 standard terms are implied into all contracts for the sale of goods, unless the parties agree to exclude them. Products sold in the course of business must be:

- of satisfactory quality; and
- comply with the description applied to them or a sample supplied.

The seller will not be liable for faults drawn to the buyer's attention prior to the contract, or which should have been revealed by the buyer's examination of the goods.

Additional obligations apply to contracts between a business and a consumer ("consumer contracts"). There is a presumption that goods that malfunction during the first six months after delivery were in breach of contract at the time of supply. Public statements made by manufacturers, importers, distributors and retailers of the product, for example in labelling and advertising, must also be factually correct and form part of the retailer's contract with the consumer.

There are also restrictions on the extent to which manufacturers, retailers and others in the supply chain can exclude or limit their liability. Under the Unfair Contract Terms Act 1977 the implied term of satisfactory quality cannot be excluded in consumer contracts (and it may only be excluded in business contracts if the exclusion is reasonable). Liability under the CPA and for death or personal injury resulting from negligence can never be excluded. Other liability for negligence may only be excluded if the restriction is reasonable. Additional rights apply in respect of standard terms not individually negotiated with consumers.

In practice, claims for breach of contract are rarely brought in respect of the supply of defective medicines. Where medicines are supplied on prescription by the National Health Service there is no contract between the patient and the prescribing doctor or the pharmacist dispensing the drugs. In general, contractual claims will therefore only arise where medicines are supplied privately.

Claims for breach of statutory duty can be brought where the courts are satisfied that a statute was intended to create a private law right, actionable by an individual harmed by the breach. It is well established that claims can be made in respect of damage caused by the breach of many product safety and health and safety regulations. However, no such rights have been found to arise from breach of consumer statutes such as the Trade Descriptions Act 1968, the Consumer Protection from Unfair Trading Regulations 2008 and the Business Protection from Misleading Marketing Regulations 2008, which regulate unfair commercial practices and the provision of trade descriptions and advertisements to consumers. To date there has been no UK litigation similar to the consumer fraud litigation pursued in some US states.

1.2 Does the state operate any schemes of compensation for particular products?

Yes. Under the Vaccines Damage Payments Act 1979 fixed

compensation is paid to persons suffering severe disablement as a result of certain vaccinations. Compensation schemes are also sometimes set up to resolve specific claims e.g. the schemes relating to HIV and Hepatitis C contamination of blood products.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Under section 2 of the CPA, liability principally rests on the 'producer' (the manufacturer), or the importer of the product into the EU, or an own brander (i.e. any person who, by labelling or the use of trademarks, holds himself out as being the producer of the product). The supplier (whether the retailer, distributor or a wholesaler) may be liable in place of the manufacturer if, in response to a request by the Claimant, he fails to identify the producer or at least the person who supplied the product to him. In the context of a recent reference to the European Court of Justice from the English Court (Case C-127/04, *O'Byrne v Sanofi Pasteur MDS Limited and Sanofi Pasteur SA*) Advocate-General Geelhoed stated in his opinion that "if the supplier is erroneously sued as the producer, he should immediately inform the suing party as to the identity of the producer… If he were to fail to do so, by analogy with Article 3(3) of the Directive he should be treated as the producer". This issue was not considered in the ECJ's judgment, but the opinion suggests that a supplier should take the initiative to identify the producer rather than await a request, despite the requirement for a request in the CPA.

In negligence, fault rests on the party found to be negligent; this can be any person or organisation in the supply chain.

Contractual liability may be passed down the supply chain through a series of contractual agreements between the manufacturer, distributor, retail supplier, customer and others, depending on proof of breach of the contractual terms in each case and subject to any exclusion clauses.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Claims for a failure to recall may be brought under the CPA, in negligence and in contract. A duty to withdraw unsafe products underpins the CPA as this imposes strict liability for defective products. Manufacturers/retailers may owe a duty of care in negligence to institute a recall or product withdrawal in appropriate cases. They owe a duty to keep the products they produce/supply under review and to warn of risks that come to light after the product has been supplied. If warnings are not adequate to manage the risk, the product may need to be modified or withdrawn.

Under the General Product Safety Regulations 2005, producers must ensure that they only place safe products on the market, and must take measures to manage any risks that are identified including, in appropriate cases, issuing warnings or withdrawing or recalling the product from the market. The GPS Regulations impose an obligation on producers and distributors to inform the authorities if a product is unsafe. Although the regulations impose criminal penalties, breach of the requirements may be of evidential value in supporting a civil claim.

1.5 Do criminal sanctions apply to the supply of defective products?

Yes. Criminal sanctions are imposed for breach of the General Product Safety Regulations 2005. It is an offence for a producer to offer or agree to supply or otherwise place an unsafe product on the market, punishable on conviction with a maximum fine of £20,000 and/or a 12 month term of imprisonment (if the case is tried on indictment in the Crown Court). A range of penalties apply to other breaches of the GPS Regulations. The enforcement authorities also have the power to issue notices compelling the producer to take certain actions e.g. compelling the withdrawal or recall of products or requiring the provision of warnings.

The GPS Regulations apply to all products to the extent that these are not subject to other specific safety requirements imposed by EU law. Separate regulations apply to specific types of products, such as medicines, medical devices, foods, toys, cosmetics, machinery and electrical equipment, and this legislation imposes its own criminal sanctions.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The Claimant has the burden of proving his/her case on the 'balance of probabilities':

- Under the CPA, the Claimant must prove that the product is defective, and that the defect caused damage to the Claimant. However, where the producer relies on defences under the CPA, including the development risks defence, the producer has the burden of proving that defence: see the answers to questions 3.1 and 3.2 below.
- In negligence, the Claimant must prove that the Defendant breached the duty of care he owed to the Claimant, and that this negligence caused damage to the Claimant.
- In contract, the Claimant must establish that the Defendant breached his contract with the Claimant by supplying product(s) that did not meet the terms and conditions of the contract, and that such breach damaged the Claimant. The burden of proving breach of contract is reversed in the case of consumer contracts if the product malfunctions in the first six months after delivery; the product is presumed not to conform to the contract at the time of supply.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The Claimant has the burden of proving on the balance of probabilities that the Defendant's product caused the Claimant's injuries. The traditional test of causation is the 'but-for test': the Claimant must prove that, but for the Defendant's negligence, or (as the case may be) supply of a defective product, the Claimant would not have sustained the injury. However, this rule was relaxed by the House of Lords in *Fairchild v Glenhaven Funeral Services Ltd and Others* [2002] 3 All ER 305 in the context of workplace injuries involving negligent exposure to asbestos in successive employments. The court held that where there are a number of potential causes of the Claimant's injury and the causative agents operated in the same way, but the state of scientific knowledge means it is impossible to prove on the balance of probabilities by whose negligent act the injury was caused, it is sufficient for the Claimant to show that the Defendant's wrongdoing materially increased the risk of injury. In *Barker v Corus (UK) Plc* [2006] 2 WLR 1027 the House of Lords confirmed that the *Fairchild*

principle applied where one of the potential causes of the injury was not tortious provided the potential causative agents acted in the same way. In *Bailey v Ministry of Defence* [2008] EWCA Civ 883 the Court of Appeal suggested that the material contribution test should be applied in all cases involving cumulative causes of injury. However, the test has not yet been applied to a product liability case under the CPA and it is unclear whether the Courts will extend the approach to such claims. In *Bailey*, a case involving allegations of clinical negligence, it was found that where there are several causes of injury which have a cumulative effect and medical science cannot establish causation applying the 'but for' test but it can be shown that the contribution of a negligent cause was more than negligible, the 'but for' test is modified and causation is established. However, if the injury would have occurred in any event as a result of a non-tortious cause, liability is not established. The principle does not apply to a case where there are multiple risk factors or causative agents and the Defendant's negligent act adds a new risk factor (an agent acting in a different way).

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

At present the position remains that, where it cannot be established which of several possible producers manufactured the defective product, the Claimant's evidential burden cannot be met and the claim will be dismissed. The English courts have not adopted so-called "market-share" liability. In *Fairchild* (see the answer to question 2.2 above) Lord Hoffman considered this issue and stated obiter that market share liability did not fall within the scope of the present law on causation as the existence of several manufacturers supplying the same defective product did not materially increase the risk of injury. However, he indicated that the issue should be left for further consideration. In *Barker v Corus* he drew a comparison between the *Fairchild* principle and market share liability, but again declined to decide the point. It remains to be seen whether the English courts will extend the *Fairchild* decision to impose market share liability where the manufacturer of the defective product cannot be identified.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

A failure to warn may give rise to liability under both the CPA and in negligence.

The CPA provides that the "get up" of the product and any instructions or warnings relating to its use form part of the circumstances to be taken into account in assessing if the product is defective. Whilst it seems clear that warnings provided directly to consumers with the product must be taken into account in assessing liability under the CPA, the relevance of warnings provided to intermediaries, such as doctors, is uncertain and has not yet been decided by the English courts. In the so-called "Hepatitis C" case (*A and Others v The National Blood Authority and Others* [2001] 3 All ER 298) the court ruled that that the medical profession's knowledge of the possible risk of infection with the Hepatitis C virus arising from the use of blood products was irrelevant in assessing whether those products were defective. The defect was assessed by reference to the legitimate expectations of the public at large. The fact that physicians were aware of the risks of infection was irrelevant as they did not generally inform patients of those risks and the risks were therefore not known and accepted by patients. It remains uncertain how the English courts would approach this issue if there was evidence that the intermediary generally provided warnings to consumers.

In negligence, manufacturers and suppliers owe a duty to take reasonable care to provide adequate warnings and instructions with their products. There is no duty to warn of dangers that are obvious or a matter of common knowledge (see for example, *B (A Child) v McDonalds Restaurants Ltd* [2002] All ER (D) 436 where the court found McDonalds were not negligent in supplying cups of hot tea and coffee without a warning as consumers generally knew that there was a risk of scalding if hot drinks were spilled). Manufacturers owe a duty to warn of dangers identified after the product was first supplied.

In some circumstances warnings provided to learned or responsible intermediaries may be sufficient to discharge the manufacturer's duty of care in negligence. Whether such a warning is sufficient will depend on factors including the likelihood and gravity of the risk and the practicality of providing a personal warning to the ultimate consumer. The learned intermediary doctrine has become less important in cases involving medicinal products as manufacturers of medicines are now required to provide patient information leaflets with their medicines unless the warnings and information can be provided on the container or outer packaging of the product.

It may be argued that a failure to warn in breach of duty may be sufficient to establish liability even if it cannot be established that the inadequate warning caused the damage suffered by the Claimant. In *Chester v Afshar* [2005] 1 AC 134 the House of Lords found that a neurosurgeon was liable for his negligent failure to warn of a rare but serious complication of spinal surgery even though the risk was unavoidable and the Claimant would probably have had the surgery, in any event, even if later. The court considered that a remedy should be available where there was a failure to obtain informed consent. It is unclear whether the same principles would be extended beyond the facts peculiar to that particular case or whether they would be adopted in a product liability context in relation to a company's obligation to warn in product information.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under the CPA the following defences are available:

- the defect is due to compliance with legal obligations imposed by UK or EU law;
- the defective product was not supplied by the Defendant;
- the product was not supplied for profit and in the course of business;
- the defect did not exist at the time the product was supplied;
- the so-called "development risks defence" applies: the state of scientific and technical knowledge at the relevant time

was not such that a producer of products of the same description as the allegedly defective product might be expected to have discovered the defect if it had existed in his products while they were under his control; and

- if the product was a component used in another product, the producer of the component will not be liable if he can show that the defect was due to the design of the final product, or to defective specifications provided to the component producer by the producer of the final product.

The Defendant has the burden of proving each of these defences. Such defences have rarely been successful. However, in *Terence Piper v JRI (Manufacturing) Limited* [2006] 92 BMLR 141, the Court of Appeal found that the manufacturer of a defective hip prosthesis was not liable when the prosthesis fractured after implantation as the prosthesis was not defective at the time it was supplied to the hospital. The court was satisfied, based on evidence of the manufacturer's inspection and quality control systems, that a defect in the surface of the prothesis would have been detected prior to delivery, even though there was no evidence of inspection of the specific prosthesis. It was not necessary for the manufacturer to prove the actual cause of the defect and when it arose.

Liability under the CPA and in negligence may also be limited by the principles of contributory negligence (see the answer to question 3.6 below).

In negligence it is a defence if the Claimant freely and voluntarily agreed to run the risk of injury in full knowledge of the nature and extent of the risk (*volenti*). Otherwise, the Defendant will defeat the claim if the Claimant cannot establish each of the elements of negligence. Thus if the Defendant can show that no duty was owed, or his conduct was reasonable, or the negligent act or omission was not causally related to the damage, he will escape liability. Proof that the fault in the product was not discoverable based on the state of scientific knowledge at the time of supply is often described as the 'state of the art' defence (see the answer to question 3.2 below).

In contract no specific defences arise, but the claim will fail if the Claimant cannot establish the breach of contract and damage due to that breach.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Yes, there is a development risks defence. The UK Government opted to include it in the CPA: see the answer to question 3.1 above. Under the CPA it is for the producer to prove that the defect was not discoverable.

The defence was considered by the English courts in the "*Hepatitis C*" case, which found that its scope is limited. Based on current authority the defence applies if the defect was not discoverable in the light of the scientific and technical knowledge at the time the product was supplied. The Defendant's conduct is irrelevant. The court found that the defence was not available if the existence of the defect in the product was, or should have been, known. It was irrelevant whether or not the defect could be avoided because measures to identify and rectify the defect were impractical or impossible.

In negligence, whether the Defendant exercised reasonable care in relation to the design/development, manufacture, supply, marketing and, in appropriate cases, licensing of the product, will be assessed in the light of the state of scientific and technical knowledge at the time these activities were carried out. Manufacturers also owe a continuing duty to warn of any faults identified after the product has been supplied and, where a warning is not sufficient, to modify or withdraw the product. If the Defendant manufacturer is able to show that he acted in the way that a reasonable manufacturer would have done, this is often described as the "state of the art" defence. It is significantly wider than the development risks defence outlined above, because the court must assess the Defendant's conduct; not just whether the defect was discoverable. Factors such as whether the defect could be avoided, and compliance with statutory obligations are relevant.

These issues are not relevant to claims for breach of contract.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

It is a defence to proceedings under the CPA if the manufacturer can show that the defect is due to compliance with UK or EU laws. Otherwise there is no general defence under the CPA, in negligence, or in contract, in circumstances where the manufacturer is able to demonstrate compliance with regulatory and statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product.

Such compliance is, however, of evidential value, and may help in the defence of negligence claims by demonstrating that the manufacturer exercised reasonable care. It may also be a relevant circumstance for the purpose of determining what persons are generally entitled to expect in relation to the safety of a product for the purpose of proceedings under the CPA. Although the Defendant's conduct is generally irrelevant for the purpose of CPA claims, evidence that it had in place appropriate systems to detect any defects in the product and for post marketing surveillance may also be relevant to the question of whether a defect was "discoverable" for the purpose of establishing whether the development risks defence is applicable. Such systems are commonly mandated by statute, for example, in the field of medicines and medical devices.

However, failure to comply with a regulatory standard, compliance with which is not required by law, may not be decisive in determining liability. In *Tesco v Pollard* [2006] EWCA Civ 393 Tesco were not liable for supplying a bottle of dishwasher powder in a screw top bottle, where the child resistant cap fitted did not meet the British Standard, as there was no statutory requirement for such a cap to be fitted and all that the public could legitimately expect was that the bottle would be more difficult to open, which it was.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

In general, a final judgment or order is conclusive as between the parties to the proceedings and their successors (save where the judgment can be set aside, for example because of fraud, or because the decision was not based on the merits). An estoppel arises that prevents the parties from re-litigating in subsequent proceedings the decision or any issues that were an essential part of the legal basis of the judgment.

In principle, an estoppel cannot arise in proceedings involving non-parties. However, in certain circumstances it may be possible to

defeat a challenge to a prior decision by a party to that decision on grounds of abuse of process. For example, it may be an abuse of process in group litigation to seek to re-litigate in the individual proceedings generic issues decided in the lead actions. Even if the doctrines of estoppel and abuse of process do not apply, the prior findings of another court based on similar facts are likely to be persuasive.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

Yes. Claims for contribution or indemnity can be made against a third party where the third party is liable to the Claimant for the same damage as the Defendant. Such claims can be brought either in the same proceedings (by means of a "Part 20" claim) or in subsequent proceedings. In the case of subsequent proceedings the claim must be brought within two years from the date of judgment in or settlement of the Claimant's claim.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Yes. Liability under both the CPA and in negligence can be limited if the Defendant can prove that the Claimant's negligence caused or contributed to the damage.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

Trials are by a judge.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Yes, but this power has never been used in the product liability field. In practice, assessors are most commonly appointed where technical issues arise. In product liability claims they haven't been appointed to assist the court in deciding issues of liability; on the whole in such cases the court prefers to leave technical issues to the experts called by the parties themselves and to evaluate the experts' evidence having heard it tested in cross-examination.

The court can appoint one or more assessors to assist the judge to enable him to reach a properly informed decision on matters in which the assessor has skill and expertise. The assessor provides assistance as directed by the court. This can include sitting with the judge during all or part of the trial and preparing a report for the court on any matter at issue in the proceedings. The assessor does not have judicial status and does not play a part in deciding the case: his role is to educate and assist the judge.

Under the Civil Procedure Rules (CPR), which lay down procedural rules for the conduct of proceedings in England and Wales, the parties to any proceedings must be notified of the appointment of the proposed assessor and can raise objections.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

Yes. Where claims give rise to common or related issues of fact or law the court has the power to make a group litigation order (GLO) enabling it to manage the claims covered by the Order in a co-ordinated way. Many group claims have been brought over the last 30 years in relation to defective products and medicines, cases of industrial disease and sudden accidents or disasters.

The procedure is 'opt-in'. Claims managed under a GLO remain individual actions in their own right. However, the court will usually order that one or more actions that are representative of the rest of the claims cohort are tried as lead actions. The outcome of the lead actions does not, in theory, determine liability in the remaining cohort of claims, but those actions will establish findings of law and fact that may, in practice, allow the parties to compromise or simplify resolution of the remainder of the litigation by focusing further proceedings on clarifying any remaining points of principle.

Proceedings can be brought by any party that has a claim, whether an individual, a company or another legal entity. There is currently no mechanism by which claims can be brought by a representative body on behalf of a number of claimants (see the answer to question 4.4 below).

Once a GLO has been made a group register will be established on which details of the individual claims to be managed under the GLO are entered. A managing judge will also be appointed with overall responsibility for case management of the litigation. He may be assisted by a Master or District Judge appointed to deal with procedural matters.

Co-ordinating judges have an extremely wide discretion to manage the litigation as they see fit. The court will usually make directions, including directing the transfer of claims to the court that will manage the litigation, giving directions to publicise the GLO so that Claimants may join the group register, and imposing a cut-off date during which claims proceeding under the GLO must be issued. The court often also appoints lead solicitors to act on behalf of the Claimants and Defendants.

Claims can also be pursued in a representative action where one representative claimant or defendant acts on behalf of a group of individuals. The procedure is rarely used as it is only available where the group of litigants have the same interest in one cause of action; it is not available if they have different defences or remedies. The court also has power to consolidate a number of individual proceedings into one action, or order that two or more claims should be tried together.

Although there is currently no 'opt out' class action procedure in England and Wales, the Civil Justice Council (CJC), in its December 2008 report "Improving Access to Justice Through Collective Actions" has recommended that a generic collective action should be introduced which would apply to all civil claims affecting multiple claimants. Under the proposed new rules a generic collective action can only be commenced with the Court's permission, and the court will determine whether the case should proceed on an 'opt-in' basis (similar to the current GLO procedure) or an 'opt-out' basis. The introduction of a new 'opt-out' procedure would be a significant change to the current law and would require legislation.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

No - not in the product liability field. Proceedings must be brought

by the person/body that has suffered the damage/injury. However, representative actions may be brought on behalf of consumers seeking damages for infringement of competition law.

The CJC has recommended that collective claims should be brought by a wider range of representative parties, including individual representative claimants or defendants, designated bodies (such as Which?) and *ad hoc* bodies. If this proposal is progressed, product liability could, in future, be brought by a representative body as part of a collective action.

4.5 How long does it normally take to get to trial?

This depends on the complexity of the case and the value of the claim. According to the 2007 Judicial and Court Statistics published by the Ministry of Justice, unitary actions proceeding in the County Court (excluding certain small claims which are fast-tracked), on average, took 49 weeks from the issue of proceedings until trial. Equivalent statistics are not available for High Court actions, but these cases are generally more complicated and therefore take longer to come to trial (in 2004 the average was 20-32 months). Complex group actions may take many years to come to trial. For example, in the third generation oral contraceptives litigation it took approximately 6½ years from the issue of the first proceedings until judgment. In all cases, delay is largely a result of the conduct of the parties and is not inherent in the court system. Delays may also occur in publicly funded group litigation as regular reviews of the case carried out by the Legal Services Commission can lead to funding being revoked and the case being delayed while this decision is submitted to an appeal process (which can then result in funding being restored, and the action once again proceeding) - see further answer to question 7.3 below.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Yes. In accordance with general case management powers the judge can order the trial of preliminary issues of law and fact in separate proceedings prior to the main trial, and can decide the order in which issues are to be tried in the main trial.

4.7 What appeal options are available?

An appeal may only be made with the permission of the court (either the appeal court or the lower court that made the decision subject to appeal) and such permission will only be granted if the appeal appears to have a real prospect of success or there are other compelling reasons why it should be heard.

The appeal will usually be limited to a review of the lower court's decision, but the court retains the power to order a re-hearing in the interests of justice. An appeal will be allowed where the decision of the lower court was wrong (because the court made an error of law, or of fact, or in the exercise of its discretion) or was unjust because of a serious procedural or other irregularity of the lower court. However, in practice, the courts will rarely disturb findings of fact made by the trial judge who had the benefit of hearing first hand the witness and expert evidence.

The appeal court may affirm, vary or set aside any order or judgment made by the lower court, order a new trial or hearing or make any other appropriate order.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Experts are generally appointed by the parties to litigation rather than by the courts. No expert may give evidence, whether written or oral, without the court's permission and the court may, in appropriate cases, dispense with expert evidence or require that evidence on a particular issue be given by a single joint expert. (The court will select a joint expert from a list prepared by the parties if they cannot agree who should be instructed.)

The extent of the expert evidence that is permitted will depend on the type and value of the claim, with more extensive evidence permitted in complex cases. In all personal injury cases, the Claimant must serve a medical report with his or her Statement of Case substantiating the injuries alleged in the claim.

Expert evidence should be independent and comprehensive. An expert owes an overriding duty to assist the court on matters falling within his expertise; and this duty overrides any obligation to the party instructing the expert. Experts can only give evidence on matters of opinion falling within their expertise.

Evidence must be provided in the form of a report disclosed to the other parties. The Court Rules give the parties a right to put written questions to an expert about his or her report in order to clarify the report. Where several experts are instructed it is usual for experts in particular disciplines to meet on a "without prejudice" basis, after the exchange of reports and before giving oral evidence, in order to explore areas of agreement and narrow the matters in dispute.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

The factual and expert evidence that the parties intend to rely upon at trial must be provided in the form of witness statements and expert reports that are disclosed by the parties prior to the trial. Evidence is usually exchanged, but the court may, in appropriate circumstances, direct that it is served sequentially. Factual and expert witnesses are required to give oral evidence at the trial unless the court orders otherwise. However, the witness can only amplify the evidence given in his/her written statement or report with the court's permission.

Witnesses are not generally required to present themselves for pre-trial deposition. However, the court may order evidence to be given by deposition if the witness is unable to attend the trial. The increased use of video conferencing facilities has reduced the use of depositions in proceedings in England and Wales. Evidence can be taken by video if the witness is abroad or too ill to attend court.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

A party to an action is required to disclose the documents in his control on which he relies and which adversely affect his own case or support another party's case. A document is in a party's control if he has, or had, physical possession of it, a right to possession of it, or a right to inspect and take copies of it. The obligation may therefore extend to documents in the hands of a party's professional advisers or an associated company provided control can be established.

'Document' means anything on which information of any

description is recorded and includes paper records, drawings, microfilms, information held on tape, video, CD or DVD, and electronic documents such as emails and metadata (including electronic documents that have been 'deleted' which are held on servers and back up systems).

The parties are required to conduct a reasonable and proportionate search for disclosable documents. The obligation to give disclosure continues until the action is at an end and applies to documents created while the proceedings are underway. Additional obligations apply in the case of the disclosure of documents held in electronic form and the Court Rules require the parties to exchange information about the electronic documents that they hold and to seek to agree the scope of searches for electronic documents.

The duty to disclose the existence of documents is a strict one and is enforced by the court. A party may not rely upon any documents that it does not disclose. Moreover, if a party withholds documentation that should have been disclosed, the court may impose cost penalties or draw an adverse inference.

Disclosable documents are identified in a List of Documents served on the opposing party. All disclosed documents can be inspected save for those which are privileged from inspection. Two of the most important types of privilege are "legal advice privilege", which applies to confidential communications between a lawyer and his client made for the sole or dominant purpose of seeking or giving legal advice and assistance, and "litigation privilege", which applies to documents between the potential party, his lawyer and any third party, created after litigation is contemplated or pending, for the sole or dominant purpose of seeking or giving advice in relation to the claim, or collecting evidence for use in the litigation. Legal advice privilege only applies to lawyer-client communications with company employees who are regarded as the "client" (generally senior managers or the in-house lawyer), not all employees. Litigation privilege will only apply if there is a real likelihood of litigation, rather than a mere possibility.

Disclosure usually takes place after pleadings setting out the parties' cases have been served. In addition, a party may also seek an order for disclosure of specific documents or classes of documents. However, the court also has power to order pre-action disclosure in appropriate cases in order to fairly dispose of the proceedings. Such disclosure may only be ordered in respect of specific documents or classes of documents that would have to be disclosed in any event once the proceedings are underway. Any documents disclosed in accordance with these rules may only be used in connection with the proceedings in which they are disclosed until such time as they are referred to at a hearing held in public, or the parties agree, or the court otherwise gives permission.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Yes. There are a variety of different methods including mediation, arbitration and neutral evaluation. The courts encourage the use of alternative dispute resolution (ADR) to resolve disputes and the pre-action protocols to the court rules provide that the parties should consider whether some form of ADR is more suitable than litigation before commencing proceedings. While the courts cannot compel the parties to use ADR procedures (*Halsey v Milton Keynes General NHS Trust* [2004] EWCA Civ 576), failure to follow the protocols may result in a cost sanction. Indeed, courts have refused to award costs to a successful party where they unreasonably refused to mediate (*Dunnett v Railtrack plc* [2002] EWCA Civ 303).

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, see our answer to question 5.2 below.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

Under the Limitation Act 1980, the basic limitation period for tortious actions (including negligence claims) and for breach of contract is six years from the date on which the cause of action accrued. Additional requirements apply in the case of latent damage caused by negligence.

Special time limits apply to personal injury claims for damages in respect of negligence, nuisance or breach of duty. In such cases, the claim must be brought within three years from the date on which the cause of action accrued (i.e. the date of injury or death) or the date of knowledge by the Claimant of certain facts. The date of knowledge is when the Claimant is aware of the identity of the Defendant, that the injury was significant, and that it was attributable in whole or part to the alleged negligence, nuisance or breach of duty. The court has a discretionary power to disapply this time limit where it would be equitable to do so.

Where proceedings are brought under the CPA there is also a general long-stop provision. A right of action under the CPA is extinguished ten years after the defective product was put into circulation and this applies irrespective of the other provisions of the Limitation Act (including the requirements relating to the date of knowledge set out above). A reference to the ECJ from the English Court in the O'Byrne case (see the answer to question 1.3 above) sought a ruling on the meaning of "put into circulation" and the ECJ's judgment was that "a product is put into circulation when it is taken out of the manufacturing process operated by the producer and enters a marketing process in the form in which it is offered to the public in order to be used or consumed". The *O'Byrne* case also addressed whether the Courts can substitute a correct defendant for an incorrect one after the long-stop period has expired. The ECJ's ruling on this issue was found to be unclear by the House of Lords (*O B v Aventis Pasteur SA* [2008] UKHL 34), which has referred the matter back to the ECJ for further clarification.

Special rules apply to persons under a disability, during such period as they are a minor or of unsound mind. In general time only begins to run for limitation purposes when the Claimant dies or ceases to be under a disability. However, the 10-year long-stop for CPA claims still applies.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Where an action is based on the Defendant's fraud, or the Defendant has deliberately concealed any fact relevant to the Claimant's right of action, the relevant limitation period does not begin to run until the Claimant has, or could with reasonable diligence have discovered the fraud or concealment.

6 Damages

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

It is possible to seek a range of remedies including monetary compensation (damages) and injunctive or declaratory relief. However, most claimants in product liability cases seek to recover damages.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Under the CPA, damage includes death or personal injury (including mental injury) or loss of, or damage to, property for private use and consumption (provided the damages recoverable in respect of property loss exceed the minimum threshold of £275). Damages are not recoverable in respect of damage to the defective product itself.

In negligence, damages are awarded to put the injured party into the position he would have been in if the negligent act had not occurred. Damages can be recovered for death or personal injury (including mental injuries), damage to property and damage to the product itself. Pure economic losses which are not consequent on physical damage are not generally recoverable in negligence.

In contract, damages are intended to put the injured party into the position he would have been in if the contract was performed. Damages are usually awarded for monetary loss (for example, in respect of damage to property and to the defective product itself), but they can include non-pecuniary losses, such as damages for death or personal injury (including mental injury) where this was within the parties' contemplation as not unlikely to arise from the breach of contract. Economic losses, such as loss of profits, are recoverable if these are a foreseeable consequence of the breach.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Medical monitoring claims of the type pursued in the USA in recent years have not been litigated before the English courts. English law does not generally permit recovery of the cost of tests or investigations unless the product has actually malfunctioned and caused physical or psychiatric injury or damage. Such medical monitoring costs are usually treated as medical expenses consequential on the main injury.

The courts have ruled that minor physical signs, such as pleural plaques on the lungs, which are neither ordinarily visible nor symptomatic and do not impair bodily functions, do not amount to 'damage' on which a claim for compensation can be based. Furthermore the combination of minor signs, the risk of future injury and anxiety that such injury may occur cannot be aggregated to make an actionable tort. In *Johnston v NEI International Combustion Limited and Others* [2007] UKHL 39 the House of Lords made it clear that claims could only be brought in tort where the Claimant had sustained a symptomatic injury. However, if a contractual relationship exists it may be possible to recover damages in contract for the risk of developing such an injury/disease.

The extent to which the courts will permit a Claimant to recover damages for a recognised psychiatric injury sustained as a result of the Claimant becoming aware that he is at risk of sustaining a serious disease or injury depends on whether, in the circumstances of the case, such damage was a foreseeable consequence of the Defendant's fault/defect and therefore, whether the Defendant owed a duty of care to the Claimant. In the Johnston case (see above) the House of Lords declined to extend the law to allow the recovery of damages in such circumstances. A Claimant was diagnosed with depression as a result of anxiety caused by his knowledge that he was at risk of sustaining an asbestos-related disease. The Court found that there was insufficient evidence to allow it to conclude that an ordinary person would have sustained a psychiatric injury in these circumstances and concluded that the injury was not reasonably foreseeable and therefore dismissed the claim.

This case can be contrasted with the Creutzfeldt-Jacob Disease Litigation, (*Group B Plaintiffs v Medical Research Council and Another* 41 BMLR 157), where the court found that children who were at risk of contracting CJD (but who had not yet contracted the disease and might never do so) could recover damages for psychiatric injuries sustained as a result of knowledge of that risk. Liability was established because the Claimants' psychiatric injuries were a foreseeable consequence of the Defendants' negligent actions, due to the close relationship between the children and the Defendants who supplied the human growth hormone to them, the fact that they were minors and did not choose the treatment, there were only a limited number of claimants, and the seriousness of the potential illness. The *CJD* case was considered by the House of Lords in *Johnston* who commented that there were special factors which applied to the case that allowed the court to find that a duty of care was owed. In the absence of such special circumstances, it therefore appears that the English courts will not generally allow a Claimant to recover damages where he/she sustains a recognised psychiatric illness as a result of becoming aware that he/she is at risk of sustaining a disease/illness, or to recover the costs of future medical monitoring to determine if that disease/injury has arisen. If such liability can be established, medical expenses consequent on the psychiatric injury, such as tests to determine if the disease has been sustained, are recoverable. However, the English courts only permit recovery for recognised psychiatric injuries. Mere anxiety or distress are not actionable and are not, on their own, sufficient to ground a claim for damages (see *AB and Others v Tameside & Glossop Health Authority and Others* [1997] 8 Med LR 91).

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Punitive or exemplary damages are rarely, if ever, awarded. They are not generally available in respect of claims for breach of contract. Although they are available in tort claims (see *Kuddus (AP) v Chief Constable of Leicester Constabulary* [2001] 2 WLR 1789), exemplary damages will only be awarded in certain limited circumstances, including where the Defendant's conduct was calculated to make a profit that exceeds the compensation recoverable by the Claimant or where there has been oppressive, arbitrary and unconstitutional conduct by Government servants (see *Rowlands v Chief Constable of Merseyside* [2006] All ER (D) 298 (Dec)). Exemplary damages are not generally recoverable in circumstances where a Defendant has already been fined in respect of his conduct (see *Devenish Nutrition Limited v Sanofi-Aventis SA and Others* [2007] EWHC 2394 (Ch)).

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no such limit.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

The Court's permission is required to discontinue proceedings after a Defence has been served. Court approval is also usually sought where there is a settlement or compromise of a claim made by, or on behalf of, or against, a child (aged under 18) or an adult who is incapable of managing their own property and affairs as such a compromise is not enforceable without the approval of the court. There is no requirement to seek court approval in other circumstances, for example, on the settlement of the claims comprising a group action.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Yes. Under the Social Security (Recovery of Benefits) Act 1997, where compensation is paid in respect of an accident, injury or disease, the compensator is liable to repay to the Government state benefits paid to the Claimant in respect of that accident, injury or disease. The scheme is administered by the Compensation Recovery Unit (CRU) which issues certificates setting out the recoverable benefits (CRU payment). The compensator can offset the CRU payment against certain types of compensation paid to the Claimant (in respect of loss of earnings, costs of care and loss of mobility). No deductions can be made from the damages paid in respect of the injury/disease itself.

A similar scheme applies to the recoupment of National Health Service (NHS) charges in accordance with the Health and Social Care (Community Health and Standards) Act 2003. Where the Claimant has received NHS treatment or been provided with NHS ambulance services as a result of the injury which is being compensated, the costs of that treatment must be paid by the compensator in accordance with a statutory tariff.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The assessment of costs is a matter for the court's discretion. The general rule is that the unsuccessful party pays the costs of the successful party (costs "follow the event"), including both court fees and legal costs (including incidental expenses). However, the court can make such orders as it considers appropriate reflecting matters such as the parties' success or failure on particular issues in the proceedings (issue based cost orders) and the parties' conduct. Where a party makes a payment into Court and this is not accepted by the other party in satisfaction of their claim, unless that other party achieves a better result at trial, he may become liable for all costs incurred after the payment in was refused.

Of particular importance in product liability actions are the rules relating to the recovery of costs from publicly funded Claimants. (Most group litigation in the product liability field is funded by legal aid.) Costs will only be enforced against a publicly funded Claimant in exceptional circumstances, as the Claimant may only be ordered to pay such amount as is reasonable taking account of all the circumstances, including the parties' resources. Although costs are generally awarded against a legally-aided party they cannot be enforced without the court's permission and, in practice, this will not be granted unless the Claimant's financial position improves significantly. In effect this means that Defendants are unlikely to recover their costs of defending unsuccessful proceedings brought by legally aided Claimants.

Although Defendants may seek costs against the Legal Services Commission ("LSC"), who are responsible for administering legal aid services, costs will only rarely be awarded at first instance, as it is necessary to prove the Defendant will suffer hardship unless the award is made. Costs awards are normally made if the LSC funds an appeal and this fails.

If the amount of costs cannot be agreed between the parties they will be assessed by the court to determine if the sums claimed are reasonable; costs are commonly discounted (sometimes by up to one third) on assessment. The court also has power to manage the costs incurred during the course of the litigation. For example, it can impose a cap on the costs to be incurred by the parties where there is a substantial risk that without such an order the costs incurred will be disproportionate to the amounts in issue (see *AB and Others v Leeds Teaching Hospitals NHS Trust and in the matter of the Nationwide Organ Group Litigation* [2003] Lloyds Law Reports 355.) It can also order the parties to provide an estimate of the costs that they would seek to recover if they were successful in the case.

7.2 Is public funding e.g. legal aid, available?

Public funding is available in England and Wales.

7.3 If so, are there any restrictions on the availability of public funding?

Civil legal aid is only available to fund advice on specific types of issues including family, immigration and social welfare matters, claims for clinical negligence and cases involving a 'wider significant public interest'. It is not generally available to fund contractual or tortious claims, and personal injury claims arising from negligence or breach of a statutory or contractual duty equivalent to negligence Legal aid will also be refused if alternative funding is available, for example, if the Claimant's case can be pursued under a Conditional Fee Agreement (CFA). The combination of these rules means that the majority of product liability claims involving personal injury are unlikely to benefit from public funding, unless they satisfy the 'wider significant public interest'. If the type of work is eligible, full funding will only be granted if the following requirements are met:

- means test - the applicant meets certain financial eligibility criteria; and
- cost-benefit test - the likely benefit of the proceedings to the applicant and others justifies the likely costs, having regard to the prospects of success.

Additional criteria apply to the funding of 'high cost' cases and group litigation. Funding may be refused in the light of the resources available; a high cost case will have to compete against other cases which also meet the basic funding criteria and which are seeking funding. The LSC sets funding priorities which may change from time to time and have regard to the overall resources available in the Central Budget. An annual affordability review is carried out which takes account of factors including the prospects

of success, the likely costs, the importance of the case to the Claimants and the public interest. Guidance issued by the LSC makes clear that legal aid will not generally be granted to conduct scientific research and that actions against manufacturers of products that are subject to a sophisticated regulatory regime (such as medicines) will generally be considered a lower funding priority.

These factors will be reassessed throughout the course of the litigation as new information becomes available. The Defendant may submit written representations to the LSC opposing funding or seeking discharge of the Claimant's legal aid certificate.

The effect of these rules is that public funding is only available to pursue product liability claims in strictly defined circumstances. Suggestions that this inhibits proper access to justice prompted the CJC to recommend in its March 2009 report "Improved Access to Justice - Funding Options and Proportionate Costs" that a range of additional funding options should be considered to fund group actions and other high value claims, including the introduction of regulated contingency fees and setting up a supplementary or contingency legal aid fund that could, for example, be funded by a levy paid from costs/damages awarded in successful legally aided cases. It is unclear whether this proposal will be pursued.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Yes, through CFAs. There are broadly 2 types of CFA: "no win no fee" agreements; and "less (or nothing) if you lose" agreements. The precise terms of the CFA are strictly regulated and agreements that fall outside the legal requirements are unenforceable.

In general under a CFA the costs recoverable against the unsuccessful party are increased in return for accepting no, or a reduced fee if the claim/defence is unsuccessful. In order to protect the Claimant/Defendant from the potential costs exposure of bringing or defending proceedings it is usual to combine a CFA with either insurance or membership of an organisation, such as a trade union, that will bring proceedings on behalf of its members and pay the costs of an unsuccessful action. A range of "after the event" insurance products are available and in some cases insurers may agree to defer the payment of premiums in return for an increased premium. The success fee and any premium paid to obtain legal expenses insurance will be recoverable in addition to legal costs, where a party with the benefit of a CFA successfully pursues or defends an action. A further source of funding is the provision of legal expenses insurance commonly attached to household insurance policies. However, the sum insured is often insufficient to enable anything more than the bringing of a relatively uncomplicated claim.

Contingency fees are not permitted. However, the CJC proposed in its March 2009 report "Improved Access to Justice - Funding Options and Proportionate Costs" that court regulated contingency fees should be permitted to fund multi-party cases where no other form of funding is available. It is uncertain whether this proposal will be adopted.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Yes, in certain circumstances. In *Arkin v Borchard Lines* [2005] 1 WLR 2055 the Court of Appeal made clear that, in principle, third party funding may be an acceptable means of funding litigation. However, certain third party funding arrangements may be unenforceable. In *R (Factortame) Ltd v Transport Secretary* (No.8) [2002] EWCA Civ 932 the court held that in deciding whether a funding agreement is objectionable (champertous) the courts will take into account whether the funder controls the proceedings, whether the agreed recovery rate is fair and whether the agreement facilitates access to justice. The key test is control: if the funder controls the proceedings the agreement will usually be champertous and unenforceable. In addition, as he will generally be treated as if he was a party to the proceedings, he will be exposed to costs liability.

Arkin concerned the award of costs against a third party funder. The Court of Appeal held that in the case of an objectionable agreement the funder will be liable to pay his opponent's costs without limit if the claim fails; in the case of acceptable agreements the funder's cost liability is limited to the amount of the funding he provided.

The CJC has proposed that third party funders should be regulated and it appears that some form of supervision may in future be introduced, possibly through a code of practice.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in England & Wales.

Save as outlined above there have been no new developments or trends of note.

Acknowledgment

This chapter was prepared jointly by Alison Brown and Ian Dodds Smith of Arnold & Porter (UK) LLP and Michael Spencer QC of Crown Office Chambers. Alison Brown's profile can be found in Chapter 1 "*Recent Developments in European Product Liability*".

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Arnold & Porter is an international law firm with over 600 attorneys in eight offices in the U.S. and London and Brussels. With more than 80 attorneys engaged in product liability matters, Arnold & Porter is one of the most experienced firms internationally, providing clients with an integrated product liability service on a transatlantic basis.

The European product liability group is a recognised leader in the UK and Europe, with comprehensive experience in handling the defence of claims. Its lawyers have been at the forefront of "group action" litigation, with experience derived from the successful defence of many major multi-claimant cases that have been brought in the UK and elsewhere in the EU over the last 30 years. In the US, the firm has acted both as national counsel for companies and as trial counsel in cases involving personal injury and property damage claims.

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

There are two main systems of product liability: strict liability under the Product Liability Act (694/1990); and fault based liability under the Torts Act (412/1974), the Sale of Goods Act (355/1987), and the Consumer Act (38/1978). Liability under the Sale of Goods Act and the Consumer Act is limited to damage to property. Liability can be imposed for breach of the Consumer Act's provisions on unfair marketing practices. Product liability can also be based on the breach of an express or implied contractual term concerning the quality or safety of a product.

1.2 Does the state operate any schemes of compensation for particular products?

The state operates compulsory insurance schemes under the Patient Injury Act (585/1986) for injuries caused by medical treatments and clinical trials, the Traffic Insurance Act (279/1959) for certain traffic-related injuries, the Accident Insurance Act (608/1948) and the Farmers' Accident Insurance Act (1026/1981) for work-related injuries and occupational diseases. In addition, a private Pharmaceutical Insurance Scheme covers product liability for pharmaceutical products. These Acts and schemes apply as parallel sources of remedies, along with product liability under the Product Liability Act.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Liability under the Product Liability Act is imposed on the manufacturer, the importer, and the marketer (i.e. the party under whose trademark or other commercial identifier the product has been marketed). If the product's manufacturer is not indicated on the product, any other supplier is liable as a manufacturer unless they, upon request, identify the manufacturer or the person from whom they have acquired the product. The same rule applies if the importer is not indicated on the product.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

General Finnish product liability rules impose an obligation on the manufacturer to recall products upon becoming aware of their defective qualities, if such defects cannot be eliminated in other ways. In addition, under the Act on the Safety of Consumer Products and Services (75/2004) the Finnish Consumer Agency may order a recall of a product intended for general consumption if the Agency deems that product to be defective or dangerous, subject to criminal penalties. Breach of the duty to recall products does not in itself establish grounds for a civil claim under Finnish law, but is rather treated as negligent conduct.

1.5 Do criminal sanctions apply to the supply of defective products?

Under the Penal Code (39/1889), if a person deliberately or through gross negligence supplies a defective product in violation of the Act on the Safety of Consumer Products and Services and certain other product safety legislation, such that the act is conducive to endangering the life or health of another person, that person may be convicted of a health offence and sentenced to a fine or to imprisonment for up to six months.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

Under the Product Liability Act, the injured person has the burden of proving the harm, the defect, and the causal relationship between the defect and the harm. Under general tort law rules, the injured person is further required to prove negligence. Under the Patient Injury Act and the Pharmaceutical Insurance Scheme, the claimant need only show that a causal connection between the product and the harm is probable.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

Case law indicates that courts will find causation to have been sufficiently proven if the claimant can show that the injury is

typically associated with the product, unless the defendant is able to establish that causation is not medically possible or that another factor can be a probable cause of the injury.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Market-share liability is not recognised in Finland. It is unclear what position a Finnish court would take if a claimant could not prove the identity of the defective product's manufacturer. As the Product Liability Act places the burden of proving a case on the plaintiff, it is unlikely that a court would e.g. assist the plaintiff by reversing the burden of proof so that each defendant would be required to disprove that it did not manufacture the defective product.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Failure to warn may incur liability if the insufficient safety of the product is attributable to the marketing of the product and/or instructions (or lack thereof) for its use. The Product Liability Act does not rule out that information provided by another source than the manufacturer can be taken into account. Therefore, information provided to the consumer by an intermediary, such as a doctor, could be considered relevant to an assessment of the product's safety. There is, however, no recognised "learned intermediary" principle under which the manufacturer's duty to inform would be completely discharged by supplying information to an intermediary rather than to the consumer. It should be noted, however, that there is no responsibility to warn of harmful properties or risks related to the product which are generally known.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under the Product Liability Act the defendant will not be held liable if it proves that it did not manufacture or put the product into circulation, or that the defect is due to the product having to comply with regulatory requirements. Liability may also be avoided if the defendant demonstrates that the defect did not exist at the time the defendant put the product into circulation. The producer of a component part may avoid liability if it proves that the defect was attributable to the instructions given by the manufacturer of the product.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

There is no state of the art defence under the Product Liability Act. Since development risk in fault based liability requires negligence on the part of the manufacturer (by non-compliance with the state of the art scientific and technical knowledge), the claimant has the burden of proving that the defect was discoverable.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Mere compliance with regulatory requirements or the fact that the product has been appropriately tested or licensed is not as such a sufficient defence, unless it can be shown that the defect was caused by or inevitably resulted from compliance with mandatory requirements.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

A final judgment on issues of fault, defect or the capability of a product to cause a certain type of damage is an absolute bar to the same issues being raised in subsequent proceedings between the same parties, including their successors, if those issues were necessary to the first judgment. While different claimants cannot in subsequent proceedings re-litigate a judgment establishing the defendant's liability with regard to the first claimant, the court is not bound by the assessment of facts in the former case.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

If a claim is made to such effect, it follows from the Tort Liability Act that a claim for compensation of damages shall be divided among several liable parties according to what the court finds reasonable, based on the degree of each party's responsibility for the injury or loss and other relevant circumstances. If the payment of damages has been divided among several parties, but one party has in fact paid damages in an amount that exceeds its part, that party is entitled to be indemnified by the other liable parties. Claims for indemnity would often be decided in separate subsequent proceedings. The statute of limitations for bringing such proceedings is three years from the date of payment.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

If defendants can demonstrate that the claimant has contributed to his or her own injury or loss, the damages may be adjusted.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

The trial is by judge. In civil litigation the District Courts, which are the courts of first instance, generally comprise one judge as chairman (in criminal cases and in civil cases regarding family law issues, guardianship or tenancy, an additional panel of three lay people are also members of the court; in complex criminal cases, the panel may consist of three judges). Major civil cases or cases involving complex issues of law are often adjudicated by a three-judge panel.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The court does not have the power to appoint expert members to sit with the judge in the assessment of evidence in a product liability case. As to the appointment of experts to assist in technical issues, see question 4.8.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

The Act on Class Actions entered into force on 1 October 2007. The Act applies to disputes between consumers and businesses falling within the Consumer Ombudsman's authority. The right of initiating actions and representing the class is assigned to the Consumer Ombudsman. Individual members have no right of action, but may file complaints with the Ombudsman. To become members of a class, individuals must "opt-in". The members have no responsibility for the costs of the proceedings, which costs are carried by the state. To qualify as a class action, a case must concern a group whose claims against the same respondent are based on similar circumstances. Furthermore, it must be expedient to bring the action as a class action.

Finnish procedural rules on actions involving multiple claimants permit common claims only where the claims concern essentially the same legal relationship. Thus, multi-party product liability actions can be brought if the damages stem from the same act.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

No. Product Liability legislation does not give a representative body a right of action under Finnish procedural rules.

4.5 How long does it normally take to get to trial?

Civil litigation in the District Court begins with a preparatory stage, followed by the main proceedings. In the preparatory stage, the parties exchange written pleadings (application for summons, response, and possibly subsequent written submissions). The preparatory stage usually takes 4-6 months but may last over a year in complex cases.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The court is required to try defence pleas concerning procedural requirements made in connection with the defendant's first response. During proceedings, the court may under certain preconditions also separately try an independent claim in a matter involving several claims, and, at the request of a party, the court may try an issue that determines how a claim will be decided. Such issues may relate to issues of both law and fact.

4.7 What appeal options are available?

District Court judgments may be appealed to the Court of Appeal without restriction. Appeal to the Supreme Court requires leave to appeal.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

While the court may, if necessary, appoint an expert to give a statement on a particular technical issue or other issue requiring specialist knowledge, this rarely occurs in practice. If the parties agree on an expert, the court is required to appoint said expert if he or she is suitable to act as an expert. In this case, the court may appoint an additional expert. A court-appointed expert is required to give a detailed report of his or her findings, and, based on such findings, a reasoned statement in response to a question presented by the court. The statement shall be in writing unless the court decides it necessary to have the statement delivered orally. The usual way of providing expert testimony is that the parties appoint their own experts, who are then heard as witnesses. Expert testimony may also be given in the form of written statements. There are no specific restrictions on the nature or extent of expert evidence, other than it must be relevant to the case at hand and that the adverse party shall be given an opportunity to cross-examine.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

There is no requirement for deposition of witnesses or exchange of statements or reports during the preparatory stage of proceedings. During the preparatory phase, the court will determine which witnesses will be heard at the main hearing.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

There is no obligation to disclose documentary evidence before proceedings commence or as part of pre-trial procedures. At an oral hearing conducted before the main hearing, the parties are required to identify the evidence they intend to present. A party may ask the court to order the other party to produce a specified document in its possession that can be assumed to have evidentiary significance, at the main hearing or outside the main hearing if presentation of the document in the main hearing would cause undue inconvenience.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

As parties to product liability disputes may settle the dispute, they may also agree to alternative methods of dispute resolution, e.g. mediation or arbitration. A consumer is not bound, however, by an arbitral agreement entered into before the dispute has arisen. A form of public service ADR is offered by the Consumer Disputes Board, which gives recommendations for settlements in disputes between consumers and businesses, e.g. in consumer products cases. Its recommendations are not binding but are followed in some 80 percent of the cases. Pendency of a complaint or a decision by the board is not an obstacle to initiating court proceedings. The Consumer Ombudsman may also institute a group complaint in the Consumer Disputes Board. Under the Act on Mediation of Disputes in General Courts (663/2005), which entered into force on 1 January 2006, parties to a dispute may request courts to assist them in solving their disputes amicably. Court mediation is conducted by judges only. The use of non-judges as mediators is prohibited. The initiation of court-annexed mediation proceedings does not require the dispute to be pending before the court. The initiation of proceedings requires that both parties wish to mediate and that the court finds that the dispute is suited for mediation and that mediation otherwise is expedient with regard to the parties' claim(s).

Parties in dispute may also resort to mediation under the Finnish Bar Association's mediation rules. The mediator cannot render a binding award, but assists the parties in finding an amicable solution to their dispute. The mediator does not give legal advice to the parties. Mediation is voluntary and confidential, and may be terminated at any time by the parties without adverse consequences.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, time limits do exist.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

Proceedings for strict liability under the Product Liability Act shall be instituted within three years from the date on which the claimant became aware of the damage, the defect, and of the identity of the party liable for the damage. However, proceedings may not be instituted later than 10 years from the date the defective product was put into circulation by the party liable for the damage as a manufacturer, importer or supplier. The statute of limitations for contractual and fault based liability is similarly three years from the date on which the claimant became aware of the damage and the identity of the responsible party, but no more than 10 years from the event or act that caused the damage. The latter time limit does not, however, apply in cases of personal injury. The claimant's personal circumstances may affect the court's determination of when the claimant should reasonably have become aware of the damage and the identity of the responsible party, i.e. the date on which the limitation period began to run, but the court does not have discretion to disregard time limits.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Concealment or fraud do not in general affect the running of time limits as such, but may affect the determination of when the claimant should have become aware of the damage and the responsible party. If damage has been caused by a criminal act, however, a claim will not be statute-barred for as long as the right to institute criminal proceedings has not become statute-barred or the criminal case is pending.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

In situations of liability for injury or damage to property resulting from the supply of products found to be defective or faulty, the available remedy is monetary compensation.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

The Product Liability Act provides for compensation for direct personal injury and damage to personal property worth at least Euro 400. Damage to the product itself and pure economic loss cannot be claimed under the Product Liability Act, but may be recoverable under contract or fault liability. In the case of fault based liability, the Torts Act provides for compensation for personal injury and property damage, including consequential loss where the injury or loss was caused by intentional or negligent conduct. Damages for personal injuries include compensation for medical expenses and other direct costs, loss of income or support, pain and suffering, impediment or other permanent disability or disfigurement, and reasonable funeral expenses. Mental harm as a result of bodily injury may also be compensated.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Finnish law permits recovery of the costs of precautionary measures, if such measures are taken to prevent or mitigate injury or loss and are prompted by the existence of a specific fault or defect. Although to our knowledge there is no specific reported case law on this point, it is plausible that costs of medical monitoring undertaken to mitigate harm that is subsequently caused by a known defect in a product would be recoverable, provided that a sufficiently direct link between the defect and the precautionary measures can be established.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Damages are exclusively compensatory under Finnish law. Punitive or aggravated damages are not recoverable.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no maximum limit on damages either for fault based or strict liability.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

In order to become binding on the members of a class in a class action, the settlement must be affirmed by the court. The court cannot affirm the settlement if it is contrary to the law or evidently unreasonable, or if it violates the rights of a third party.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Under the Act on Compensation for Crime Damage (1204/2005), the state has a right of recourse against a person who has caused injury or loss by a criminal act if the victim has been compensated by the state. By contrast, the state should not be able to claim reimbursement of, e.g., treatment costs from damages awarded or settlements paid to the Claimant without admission of liability by the alleged wrongdoer.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Usually the losing party must pay court costs and the reasonable legal costs of the successful party. Where the court deems the case to have involved such complex legal questions that the losing party had reasonable grounds for pursuing the case, each party may be ordered to bear its own costs in full or in part.

7.2 Is public funding e.g. legal aid, available?

Legal aid is available to a party who cannot, without difficulty, afford the cost of proceedings, including attorney's fees.

7.3 If so, are there any restrictions on the availability of public funding?

Legal aid is available to persons whose available means do not exceed an amount determined by a Government Decree (currently Euro 1,500 per month for a single person or Euro 1,300 each for spouses). Unless special reasons exist, legal aid is not granted to applicants with legal expenses insurance. The merits of the case have no bearing on the grant of legal aid.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

According to the Finnish Bar Association's fee guidelines, conditional or contingency fees are allowed if there are special grounds for using them, but there would seem to be no authoritative guidance as to what such special grounds may be. Conditional or contingency fees are, in any event, rarely used.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

An injured party who has been compensated by insurance has the right to claim additional damages only to the extent that the loss or injury suffered exceeds the insurance compensation. The insurer has a right of recourse against the party liable for the damages in certain cases, e.g. where said party has caused the injury or loss intentionally or by gross negligence, or where the liable party is under a legal obligation to compensate the injury or loss regardless of negligence. Under Finnish law, there are no specific rules restricting or governing the use of external financing of a claim. To our knowledge, however, third party funding of claims has not been marketed to the public as a financial service.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Finland.

A new trend in Product Liability Law is the Act on Class Actions, the first of its kind in Finland, which entered into force on 1 October 2007 (for an outline of the procedure, see question 4.3 above). While the Act has a rather narrow scope and has not come to play a significant role in Finnish legal practice, it could be seen to offer a platform for the further development of Class Actions.

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France

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

In addition to the two general systems of contract and tort liability, which are mutually exclusive, a French statute dated 19 May 1998 which transposed into French law the 1985 EC Directive 85/374 on liability for defective products, introduced a specific system of strict product liability. Pursuant to Article 13 of this Directive, this strict liability system should not affect any rights an injured person might have under "*the rules of the law of contractual or non-contractual liability*" or "*a special liability system*". Accordingly, Article 1386-18 of the French Civil Code provides that the strict product liability system shall exist alongside the contractual or tort liability systems.

■ **Strict product liability (Articles 1386-1 to 1386-18 of the French Civil Code)**

The statute dated 19 May 1998 (Act No. 98-389 on liability for defective products), implementing the Directive, introduced a new title, "*liability for defective products*", into the French Civil Code. This set of articles has been amended by two successive statutes, a "Simplification of the Law" statute dated 9 December 2004, and a statute of 5 April 2006 (see question 1.3).

This specific system of product liability is based on strict liability. It enables an injured party to bring an action without having to prove any breach of contract, fault or negligence on the part of the producer, the cornerstone of this system being the notion of "defect". The defective product is defined by Article 1386-4 of the French Civil Code as "*a product which does not provide the safety which a person is entitled to expect*", taking all circumstances into account.

The producer owes the same duty towards any injured party, whether a contracting party or a third party. For strict product liability to apply, the claimant must prove that the product was defective, the existence of a damage (bodily injury or damage caused to property, under certain restrictions, see question 6.2 below) and the causal link between the defect and such damage.

■ **Contractual liability**

Where the injured party is in privity of contract with the supplier, he or she has no option, apart from using the strict liability system, but to bring a suit based under contract law. Moreover, there are cases where, despite the absence of privity of contract with the liable person, an injured party must however sometimes sue this person under contract law. This is the case when there are several successive sale contracts, forming a "chain" of French contracts, which all transfer the property of the same product, and a dispute arises between different parties to the successive contracts. Indeed, in such case, the potential claim is considered to be transferred with the product itself.

Pursuant to the general principles of French contract law developed by case law on the basis of Articles 1134 and 1147 of the French Civil Code, if there is privity of contract between the supplier and the injured party, the latter may recover damages if he or she can prove the following:

1. the supplier failed to comply with an express or implied obligation (an implied obligation is one provided by law or case law, irrespective of the terms of said contract);
2. there is a causal link between such a failure and the injury suffered; and
3. the damage suffered by the injured party was foreseeable at the time of the formation of the contract (Article 1150 of the French Civil Code). Yet, a supplier will be liable for those unforeseen and unforeseeable injuries which resulted from his fraudulent or grossly negligent behaviour.

The injured party may also rely on the **warranty against hidden defects** (Articles 1641 et seq. of the French Civil Code). Under these provisions, the seller may be held liable where a defect, which is not apparent, renders the product sold unfit for the use for which it is intended, or diminishes the usefulness of the product to such a point that the plaintiff would not have acquired it or would not have paid the agreed-upon purchase price, had he or she known of the defect. The fact that the seller was unaware of the existence of such a defect is not a valid defence. Indeed, where the supplier is a professional (not a consumer), he is presumed to be aware of the hidden defects in the products he sells.

■ **Tort liability**

Tort liability constitutes an appropriate remedy (except in the particular case of chains of contracts mentioned above) when a party is seeking damages for an injury which does not result from the breach of a contractual obligation by a co-contracting party.

Liability for fault based upon Article 1382 of the French Civil Code

Article 1382 of the French Civil Code provides that in order for a claim in tort to be successful, the claimant must prove:

1. that the defendant has been negligent, i.e., failed to behave like a "reasonable man", or breached an obligation imposed by a statute or regulation;
2. that he or she has suffered a loss; and
3. that there is a causal link between the two.

Although there is a strict separation under French law between liability in contract and in tort, it is possible for a person who suffered damage from a breach of contract he or she was not privy

to, to rely on such a breach in order to satisfy the first condition of Article 1382 (a negligent act or omission).

Article 1382 of the French Civil Code applies irrespectively of the intentional breach or omission to act as a reasonable man. Moreover, an action based upon Article 1382 may be brought where there has been a breach of a statutory obligation, when such a breach causes an injury, regardless of the existence of other specific sanctions punishing such a breach in particular.

Strict tort liability based upon Article 1384 of the French Civil Code

Article 1384 provides that "*one shall be liable [...] for the things that one has under one's custody*". Under this system of liability, no fault is required. The claimant only has to prove that his or her injury was caused by a "thing", of which the defendant had the powers of use, control and management.

As regards accidents caused by products, French case law has adapted this principle in order to hold a manufacturer or a distributor strictly liable, by considering that they have retained "custody" of the products, despite their apparent transfer to the users. This has been applied by case law when the product, by its nature, contained a latent potential for harm (e.g., explosion of products such as televisions, gas cylinders, fire extinguishers and bottles of sparkling water or sodas).

1.2 Does the state operate any schemes of compensation for particular products?

The French legislator has sometimes tried to ensure that where there are multiple victims of the same harmful product, these victims should be properly compensated. The State has budgeted for various funds created by the legislator (e.g., statute of 23 December 2000 creating the fund for the victims of asbestos ("FIVA")). The aim of such public compensation systems is to give victims full and fast compensation, instead of having to go through long and expensive court proceedings. Similarly, an establishment created in 2002 ("ONIAM") compensates victims, on behalf of the State for some damages caused by medicines, such as serious side effects of mandatory vaccinations or therapeutic hazards. ONIAM also compensates patients contaminated by HIV or HCV via transfusions of blood and injections of blood-derived medications.

Such establishments and funds usually rely on both direct aid from the State and private insurance schemes. Moreover, they may bring subrogation actions before courts against the parties liable for the harmful effects of the products, under certain conditions.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Under strict product liability, since the Simplification of the Law statute of 2004, a seller, lessor or professional distributor may only be held liable if the producer (defined by Article 1386-6 of the French Civil Code as the manufacturer of a finished product, producer of raw material, or the manufacturer of a component) is unknown (Article 1386-7 of the French Civil Code). He may escape liability by designating, within three months from the time he is notified of the victim's claim, his own supplier or the manufacturer.

Supposing he has not done so, the seller, lessor or professional distributor can still sue the producer, under the same rules as if he had been the victim and if he commences this action within one year of being sued under the strict product liability regime.

Under contractual liability, because there are implied warranties and obligations which bind the seller and/or the distributor, these parties may often be held liable for the defect of a product (e.g., on the grounds of the warranty against hidden defects, see question 1.1 above).

Under Article 1382 of the French Civil Code, any party in the distribution chain may be held liable if he or she has committed a fault.

Under Article 1384 of the French Civil Code, any party who may be regarded as having kept the powers of use, control and management over the product may be held liable. For example, the lessor of a device, having teams of technicians at his disposal, may be held liable, on the grounds that he had the power of control of the product (French Supreme Court, 3 October 1979).

When a product liability claim has been brought against a seller, lessor or professional distributor, they may then choose to bring a claim against another party further up the supply chain, either by a third-party action during the same proceedings (it is known as "*appel en garantie*" (Article 1640 of the French Civil Code)) or a claim for redress after they have been held liable (it is known as "*action récursoire*" (Article 1214 of the French Civil Code)).

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Directive 2001/95/EC of 3 December 2001 on General Product Safety (hereinafter "GPSD"), which is aimed at protecting consumers from products that would not meet safety standards, was implemented into French law notably by an Ordinance dated 9 July 2004 completed by a recent Ordinance dated 22 August 2008. In order to ensure such protection, national authorities have been granted additional powers and further obligations have been imposed on the manufacturers and distributors.

■ ***Follow-up and recall obligations***

Under the general principle of consumer safety set out in Article L.221-1 of the French Consumer Code, all products sold in France must, when used under normal conditions or under abnormal conditions which are reasonably foreseeable by a professional, present the level of safety which one may legitimately expect and not endanger the health of persons. This is a "performance obligation", which means that the sole failure to achieve this result will be regarded as a breach of this obligation.

The notion of professional covers producers and distributors. Since the Ordinance of August 2008, Article L.221-1 of the French Consumer Code clearly defines the notions of producer and distributor.

The producer has a duty to take the necessary measures to be kept informed of any risk that his or her product may create and, where necessary, to withdraw and recall any product that may endanger the consumers (Article L.221-1-2 of the French Consumer Code).

The distributor shall not provide a product if he is aware of the fact that safety requirements are not fulfilled (Article L.221-1-4 of the French Consumer Code).

Given that producers and distributors are under an obligation to act diligently and may not supply products which they as professionals knew (or should have known) did not meet the required standards, a failure to recall a defective product constitutes a fault, which may give rise to an action for compensation, should the other conditions of liability be fulfilled.

■ ***Notification obligation***

Producers and distributors are obliged to immediately notify the authorities (DGCCRF, DGAL or DSCR) if they discover that their product is dangerous (Article L.221-1-3 of the French Consumer

Code). The method by which the professional must inform the authorities, including the required information and the appropriate authorities for different categories of products, is prescribed by a Notice to the operators dated 10 July 2004 and a Ministerial order dated 9 September 2004. The failure to notify the French authorities will not give rise *per se* to a sanction, but it will be taken into account in any civil or criminal proceedings concerning the product.

Due to the existence of the EU Rapid Information System ("RAPEX"), the notification of one Member State of a defect or danger automatically leads to the notification of all Member States.

■ ***Powers of the administration***

Independently from the affirmative actions of the suppliers, investigations and checks are performed on a regular basis by civil servants, e.g., the agents of the DGCCRF who act on behalf of the Ministry of Economy Industry and Employment. They monitor the products found on the market, and their conclusions are sent to the competent Ministry, which may order appropriate measures.

Temporary measures may be taken by the Ministry in charge of Consumer Affairs in conjunction with other concerned authorities, if the danger presented by the goods is serious or immediate. The production, importation, exportation, sale, distribution or availability of the goods may be suspended for a period not exceeding one year. The authorities may also order that the product be withdrawn from the market wherever it may be found, destroyed if such destruction is the only means available to prevent the danger, or that the supplier issues warnings and supplemental instructions, or carry out recalls, exchanges, modifications or reimbursements. Where such temporary measures have been taken, the product in question may however be reintroduced on the market before the end of the temporary suspension period, if it has been certified that it complies with all applicable regulations (Article L.221-5, paragraph 3 of the French Consumer Code).

Whenever a product violates the general principle of consumer safety, the administration may also order ***permanent measures*** after consulting the Commission for Consumer Safety (which is composed of experts, members of administrative and civil courts and representatives of consumer associations). These permanent measures may consist of ordering that such products be withdrawn from the market, recalled in order to be modified, repossessed by the seller in consideration for either the reimbursement of all or part of the purchase price or their exchange against conforming goods, or destroyed. Given that such measures would be permanent and therefore particularly severe, they can only be ordered by way of a "*Décret en Conseil d'Etat*", which is a specific order taken by the Government after having requested the position of the Supreme Administrative Court acting as a regulatory body.

Violations of orders given by the Ministry in charge of Consumer Affairs or by any other appropriate government authority are criminal (and punishable by a fine of up to 1,500 Euros for individuals and 7,500 Euros for legal entities). The supplier may also receive additional sanctions, such as the publication at his own expense of the decision which convicted him of the violation, the withdrawal or destruction of the products which violate the applicable safety standards, and/or the confiscation of all or part of the proceeds of the sale of goods which violate applicable safety norms.

1.5 Do criminal sanctions apply to the supply of defective products?

The harmful effects of a product may constitute grounds for criminal sanctions. Brought by the public prosecutor on his or her own initiative or following from a complaint filed by a victim, prosecutions in matters of product liability may be based upon the alleged criminal conduct of the manufacturer, distributor and/or seller. In addition to the criminal conviction of the guilty party, the victim may obtain civil damages from such party before the criminal court.

The main offences provided for by the French Criminal Code which may apply in respect of product liability are presented below.

Endangering the lives of others. Article 223-1 of the French Criminal Code prohibits "*the direct exposure of another person to an immediate risk of death or injury likely to cause mutilation or permanent disability by the manifestly deliberate violation of a particular obligation of safety or caution imposed by law or regulation*". The mere fact that there was a danger is enough to convict without it being necessary to prove that the victim suffered personal injury.

Infliction of bodily injury. Whenever a product causes bodily injury, the supplier may potentially be subject to criminal sanctions. If the bodily injury results in the death of the victim, the supplier may be found guilty of manslaughter ("*homicide involontaire*", Article 221-6). If the bodily injury suffered by the victim does not result in death, the sanctions imposed on the supplier vary, depending on whether the victim was unable to work for more or less than three months (unintentional bodily harm, Articles 222-19 and 222-20).

Last year the Saverne Criminal Court found a car manufacturer liable on the grounds of manslaughter and unintentional bodily harm following a car accident in which a failure of the braking system would have played a role. The Court of Appeal of Colmar confirmed the judgment in a judgment dated 18 December 2008.

Offences involving fraud. A supplier of a product may be held criminally liable where he or she deceived the person to whom the product was sold by furnishing inexact or partial information (*deceit*, Article L.213-1 of the French Consumer Code) or where he or she sold a product for human or animal consumption which was falsified and thus did not conform to the various regulations prescribing the raw materials and methods used to make the product (*falsification*, Article L.213-3 of the French Consumer Code).

It should be noted that under the new French Criminal Code which came into force on 1 March 1994, legal entities may be found criminally liable for offences committed after this date by one of their management bodies or representatives acting on their behalf. All existing offences are applicable to the conduct of legal entities after 31 December 2005, whereas only the offences which specifically provided so were applicable to legal entities before that date.

If a legal entity is found criminally liable, this does not prevent its legal representative from being held liable as well. However, following a statute dated 10 July 2000, the regime applicable to company legal representatives is not as strict as the one applicable to companies. Moreover, in some cases, French law specifically provides that persons other than the legal representative of the company may be held criminally liable (e.g., pursuant to Article L.5124-2 of the French Public Health Code, "*responsible pharmacists*" are personally responsible for complying with provisions relating to the safety of the medication manufactured and sold by the company).

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The burden of the proof generally falls on the claimant according to the rule "*actori incumbit probatio*" (Article 9 of the French Code of Civil Procedure, Article 1315 of the French Civil Code, in respect

of contracts or obligations). Pursuant to this principle, an injured party must prove that the supplier of a product is at fault, that he or she has suffered a legally recognised injury and that there is a causal link between the fault of the supplier and the damage suffered.

However, in certain fields, the defendant may have to rebut the presumption that he or she is at fault. For example, a supplier of a product may be presumed to be at fault if he or she failed to respect his obligation to warn the injured party of the inherent dangers of the product. In other cases, such as under strict tort liability based upon Article 1384 of the French Civil Code, the third party injured by a product does not even have to prove the fault of the supplier of such product, as long as the supplier is deemed to have retained control over the product (see question 1.1).

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The same principle relating to the existence of a causal link applies in the different liability systems. As a general rule, the damage must be the immediate and direct result of the supplier's breach. Whether there is a direct causal relationship will be determined on a case-by-case basis by the trial courts based on two principal theories of causation. The first, called the theory of "equivalent conditions" provides that an act or omission will be deemed to be the proximate cause of the damage, if such damage would not have occurred in its absence. The second theory, known as the theory of adequate causality, provides that an act or omission will be deemed to be the proximate cause of the damage if, "*given the normal course of events*", this act or omission made it probable that the damage would occur.

It is difficult to predict how these theories will be applied. For example, the French Supreme Court adopted the theory of equivalent conditions in cases involving a victim of a car accident who was infected by a virus, as a result of a blood transfusion following surgery rendered necessary by the accident (French Supreme Court, 17 February 1993 (AIDS), 12 July 2007 (hepatitis C)). In these cases, the judges reasoned that the proximate cause of the injury was the car accident. Consequently, the party responsible for this accident was held liable for the damage suffered by the victim of the contaminated transfusion. In comparison, when a patient was infected with the AIDS virus, due to a blood transfusion which was necessary after several surgical operations following from the fault of the surgeon, the court adopted the theory of adequate causality and held the surgeon liable for the damage suffered by the patient.

With six judgments handed down on 22 May 2008, the French Supreme Court has modified its position on the causal link in the pharmaceutical field. The French Supreme Court now requires the judges to support their decisions with sufficient factual arguments in addition to epidemiology showing a causal link or not. In this respect, the judges can rule on the basis of serious, precise and concordant presumptions. On the contrary, they can no longer rely only on the lack of scientific certainty to dismiss the claims.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

In principle, there is no market-share liability in France. This absence is somehow palliated, under contractual law and tort law, by the system of joint and several liability (Article 1200 of the French Civil Code). For the injured party, the advantage is that he or she may obtain the entire reparation for his or her injury from any of the people held responsible for the several acts or omissions having each contributed to the damage. However, such joint and several liability may not be presumed (Article 1202 of the French Civil Code), i.e., it must have been contractually stipulated by the parties or be applicable as a direct effect of the law.

Under the strict product liability system, a supplier may only be held liable if the producer cannot be identified, and provided that the supplier does not inform the victim of the identity of the producer within three months of being notified of the claim of the injured person (Article 1386-7 of the French Civil Code).

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Failure to warn may give rise to liability on different grounds. The intensity of the obligation of information and the burden of the proof regarding the delivery of the information will vary depending on the knowledge and quality of the parties in presence. Lack of information may give rise to liability based on either tort, should the information have to be given before the conclusion of the contract (i.e., information which may influence the other party's decision to conclude the contract, such obligation sometimes being provided for by the law, e.g., Articles L.111-1 to L.111-3 of the French Consumer Code), or on the ground of contractual liability, if the information should have been given during its performance (e.g., information of the user as to the manner in which the product is to be employed and which is necessary to use the product properly and accomplish the task for which it was designed).

The obligation to warn comes into play whenever the supplier or the seller has a particular technical or professional expertise relating to the product to be sold or when the party with whom he deals is so inexperienced or incompetent that he would be unable to obtain such information himself. The fact that a particular product may not appear harmful to the supplier does not discharge the latter's obligation to warn the purchaser or the user. According to case law, a smoker is supposed to be aware of the harmful effects associated with the consumption of tobacco, as such information is common and widespread social knowledge. Therefore, smokers cannot expect the manufacturer to assume responsibility for the damages caused to their health by tobacco (French Supreme Court, 8 November 2007, considering that the smoker could not have remained unaware of the dangers of smoking).

Under the strict product liability system, according to Article 1386-4 of the French Civil Code, the safety that one is entitled to expect must be assessed taking into account the "*presentation of the product*". As a result, any absence of sufficient warning of the potential dangerous effects of a product, in the notice of information, may be regarded as a defect (e.g., French Supreme Court, 7 November 2006, when the notice of use of concrete did not

draw enough attention to the harmful effects of the product when it comes into contact with the skin; French Supreme Court, 22 November 2007, when a product intended to reduce wrinkles did not contain warnings drawing the attention of the patient to the risks of inflammation). The fact that the consumer received the product from a "learned intermediary" (e.g., a doctor prescribing to the patient the use of the product) does not exonerate the manufacturer from being held liable, as the fact that the intermediary did not inform the consumer as to the potential harmful effects of the product does not prevent the product itself from being classified as defective under Article 1386-4 of the French Civil Code.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Where all the conditions for civil liability are fulfilled, the supplier may however be totally or partially exonerated from his liability.

Force majeure, the effect of which is to totally exonerate the supplier from his liability, is traditionally defined as an event which is unavoidable, unforeseeable and outside the control of the defendant. Two important decisions from the French Supreme Court dated 14 April 2006 reasserted this definition. *Force majeure* can result from the fault of the victim or the act of a third party, as long as they present the above-mentioned characteristics. The supplier may invoke *force majeure* regardless of the type of claim brought against him. As regards contractual liability, parties may in their contract exclude some events from being considered as *force majeure* (e.g., strikes). Under the strict product liability regime, *force majeure* only applies when it results from the fault of the victim or the act of a third party (Article 1386-13 of the French Civil Code).

Strict product liability. In addition to the fault of the victim or the act of a third party being considered as *force majeure*, the supplier may also be completely exonerated from his liability pursuant to one of the five defences set out by Article 1386-11 of the French Civil Code. In particular, the producer may prove (i) that he did not place the product on the market, (ii) that the product was not intended to be sold or distributed by any means or (iii) that the defect did not exist when the product was placed on the market. Two other applicable defences provided for by this Article are referred to in questions 3.2 and 3.3 below.

Contractual liability. In addition to *force majeure*, a supplier of a product may limit or eliminate the risk of a product liability claim being made against him based on contractual law by including a clause to that effect in the contract. However, such a clause will be ineffective if the injury caused to the user resulted from an intentional act or omission or the gross misconduct of the supplier or the "breach of essential duties". Moreover, clauses limiting the warranty against hidden defects only have effects where co-contractors are professionals of the "same specialty" (which is narrowly interpreted by case law). They are ineffective in contracts entered into between a professional and a consumer.

In chains of contracts, in which the buyer is entitled to bring an action against the supplier of its seller on the basis of a contractual claim, limitation of liability clauses in the contract between the manufacturer and the distributor are effective against the buyer, even though the buyer is not a party to that contract. Such a clause would be enforceable against a subsequent buyer even if the latter were a consumer, provided it is valid in the original contract. Indeed, case law considers that it would be unfair to deprive the manufacturer of the right to invoke the clauses it concluded with his contracting party. Conversely, the manufacturer who did not provide for any limitation of liability in his contract with the distributor, is not entitled to rely on an exclusion of liability clause in the contract entered into between the distributor and the subsequent buyer.

Finally, in certain cases, the liability of a supplier may also be limited by the insertion of a liquidated damages clause ("*clause pénale*") in the contract pursuant to which the product was sold. Such a clause, which fixes the amount of damages which the supplier may be required to pay, will be enforceable unless the court determines that the amount of damages prescribed by this clause is patently excessive or insufficient; in such a case, the judge may award such damages as he deems necessary or appropriate to compensate the injured party (Article 1152 of the French Civil Code).

Tort liability. In addition to *force majeure*, the supplier may also be partially exonerated from his liability by proving that the damage is partially due to the fault of the victim or an act of a third party (see question 3.6 below).

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Article 1386-11 paragraph 4 of the French Civil Code does provide for a development risk defence. The producer (such as defined at Article 1386-6 of the French Civil Code, see question 1.3) will be exonerated from his liability under the statute on liability for defective products of 1998, if he proves that the "state of scientific and technical knowledge" at the time when the product was placed on the market, was not such as to permit the discovery of the defect. However, the French Supreme Court ruled on 15 May 2007 that this cause of exoneration, being optional for the Member States as regards the 1985 EC Directive, may not be invoked for products put into circulation before the statute of 1998, implementing such a Directive, entered into force.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Under tort law, the general obligation of caution and of due care applies even if an act has been done while respecting the applicable statutes (French Supreme Court, 14 June 1972). Under the strict product liability regime, the principle is the same as the producer may be held liable even though he complied with professional rules or applicable standards, or if the product he manufactured is covered by a marketing authorisation (Article 1386-10 of the French Civil Code).

However, Article 1386-11, paragraph 5, of the French Civil Code does provide for a defence resulting from the compliance with specific regulatory or statutory requirements. In order to avoid liability, the producer will have to demonstrate that the defect of the product results from his compliance with requirements imposed by imperative statutes or regulations.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

The principal effect of a judgment rendered by French Courts is to

bar the suit from being brought again by the same parties on the same event when it has already been the subject of a previous legal cause of action that has already been finally decided between the parties. The *res judicata* of a final judgment is aimed at avoiding the multiple judgments being handed down between the same parties. In civil law systems, the *res judicata* does not preclude the possibility of other plaintiffs of bringing an action on similar factual issues and legal causes of action, against the same defendant. This is known as "*autorité relative de chose jugée*". However, the holding of a judgment only applies to the parties of the dispute but the judgment, as a whole, constitutes for any other third party a fact which may be used to support any type of argument (e.g., to prove that there is a consistent case law regarding a particular matter).

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

The act of a third party does not exonerate the liable party from his or her liability towards the victim, but only allows him or her to recover from this third party the amount of damages which corresponds to this third party's direct contribution to the damage. A third party may therefore be forced to intervene in the same proceedings. The liable party sentenced for the whole damage may also later, by way of a subrogation action, obtain payment from the third party. In such a case (see question 5.2 below), the supplier who brings a claim against the producer after he has been declared liable has to do so no later than twelve months after the beginning of the main legal proceedings on the merits.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

The fault of the victim which is not a case of *force majeure* could however constitute contributory negligence, when it has directly caused the injury, even partially. Such a fault may partially exonerate the defendant and thus lead to a shared liability between the defendant and the claimant. The percentage of the damage for which the defendant will be liable will depend to what extent the victim was himself or herself at fault for causing the damage.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

Except in the *Cour d'assise* (which is the French criminal court having jurisdiction over felonies, i.e., according to Article 131-1 of the French Criminal Code, crimes punished by law with a prison sentence of at least ten years), there is no trial by jury in France. The Civil Courts are exclusively composed of professional judges. However, some first instance courts, such as commercial or labour courts, are composed of non-professional elected judges (judges who sit in the commercial courts are businessmen elected by businessmen and those who sit in the labour courts are employers and employees representatives). All the Courts of Appeal, regardless of the nature of the dispute, as well as the French Supreme Court, are composed of professional judges.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Under French law, there are no expert assessors who assist the judges and sit with them in court. However, judges may personally check the facts in question and can be assisted by technicians.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

There is no group or class action procedure under French law. However, since 2005 its possible introduction in France has been discussed. Four years later, this project is still not yet definitive.

According to the latest project, class actions in France would most likely have the following features:

- designated consumer associations could bring actions against companies before the civil courts in cases where consumers had suffered damage because of a breach of a contractual obligation by the company;
- the amount of compensation awarded to each consumer would be limited;
- if the company were found liable, any consumer who had suffered a loss would be able to request compensation from it within a specific period of time under the "opt-in" system;
- if the company were to refuse to compensate the plaintiffs, or did not respond to the judgment, the consumer would be able to claim compensation. The court could order the company to pay this by means of a penalty for failure to comply; and
- if any action by an association was found to be vexatious or an abuse of process, the plaintiffs would be obliged to compensate the defendant for any damage that it had suffered.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

In consumer related matters, environmental matters and financial market matters, two types of actions may be brought by a representative body. The first action is the collective interest action ("*action d'intérêt collectif*"), whereby an accredited association can defend a collective interest acknowledged by the law. The association acts to obtain compensation for the loss suffered by the group, but only the association benefits from any possible damages granted. A collective interest action is therefore very different from a class action since it is the collective interest which is defended and the collective loss which is compensated.

The second action is the joint representation action ("*action en représentation conjointe*"), which is a specific method of representation before the courts. It can be brought by an accredited association when "*several identified individuals have suffered individual losses which were caused by a fact caused by the same entity and which have a common origin*" and when such an accredited association has received at least two instructions for representation. The association acts to obtain compensation for the personal loss suffered by the victims who instructed it. The beneficiaries of the judgment are only the victims that instructed the association.

4.5 How long does it normally take to get to trial?

As in all legal systems, in France there are summary proceedings and proceedings on the merits. In summary proceedings, an order

may be obtained in a few hours or days if the circumstances require such urgency. In general, an order in summary proceedings can be obtained within two to three months. As to proceedings on the merits, different factors may influence its length, especially if expert proceedings need to be carried out before. Otherwise, the average length of proceedings is a year and a half for a first instance decision and two more years in case of an appeal.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

In civil matters, preliminary issues are adjudicated by a specific judge, who is in charge of all the questions that may arise as regards the pre-trial phase of the procedure. This judge ("*Juge de la mise en état*") has jurisdiction to decide on any procedural plea (such as lack of jurisdiction, *lis pendens*, connexity and pleas of voidance) and any motion which aims to put an end to the proceedings pending before the court (such as time limitation in a suit). Such decisions may be appealed. However, there are no such judges before the Commercial Courts, which in general render a unique and global decision on the merits of the case once all submissions have been exchanged between the parties.

4.7 What appeal options are available?

Judgments of first instance may in principle be appealed before the Courts of Appeal within one month from the date of the service or notification of the decision (plus two months for the appellants domiciled abroad), unless the amount of the claim brought before the first judge(s) did not exceed 4,000 Euros, in which case the appeal may only be lodged with the French Supreme Court. The Court of Appeal rules once again on the facts and on the law. The Courts of Appeal are not bound by the decision of lower judges, whether on a question of law or of fact.

Decisions of Courts of Appeal can be appealed before the French Supreme Court ("*Cour de cassation*"), in principle, in civil matters, within two months as from the date of service of the decision. The *Cour de cassation* either rejects the appeal or quashes the order and, generally, refers the case to a different Court of Appeal to be reviewed again.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

In general, when the dispute regards a technical issue, the plaintiff would ask for the appointment of an expert in summary proceedings ("*en référé*"), i.e., before he or she launches any proceedings on the merits (see Article 145 of the French Code of Civil Procedure, in question 4.10 below). When proceedings on the merits have already been brought, the plaintiffs have to file any such request in proceedings on the merits. In such a case, an expert may be appointed at any time during the proceedings, subject to the discretionary power of the judge. At the end of the expert proceedings, the expert files his or her report before the Court. Such proceedings are frequent in France and almost systematic in product liability litigation. Moreover, parties are free to appoint their own private expert should they so wish. It is frequent that the parties appoint their own experts in order to be assisted by specialists at the expert meetings and to prepare accurate technical statements ("*dires*"), which are exchanged during the expert proceedings. Such a private expert may be chosen by a party from the official list, which generally gives such statements more authority.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

In civil or commercial matters, experts are not required to present themselves for pre-trial deposition. Under the adversary principle, reports and statements must be filed in court and exchanged between all the parties prior to the trial hearing. Any document not properly exchanged would be disregarded by the Court.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

There are no proceedings for discovery or disclosure of documents under French civil procedure. Indeed, as a general principle, the parties freely decide what factual evidence they want to file in support of their claims. However, Article 145 of the French Code of Civil Procedure allows a party to request from a judge, in specific circumstances and at the discretion of the judge, that he enjoins another party or a third party to file or disclose a specific element of proof which is in its possession. Before proceedings are commenced, a party may also request *ex parte* from a judge to be authorised to empower a bailiff to seek elements of proof on which the solution of the dispute may depend (e.g., seizure of the hard disk of a computer).

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Arbitration is an available alternative method of dispute resolution provided that the dispute at stake is of an "arbitrable" nature. Parties may choose to resort to arbitration either in their initial contracts (in an arbitration clause) or after a dispute has arisen (in a compromise).

Arbitration is governed by rules set out in the French Code of Civil Procedure. Among those rules, the following apply to arbitration agreements:

- Both the arbitration clause and the compromise must, in order to be valid, designate the arbitrator or arbitrators, or provide for the terms and conditions for their appointment.
- The arbitration clause must also be in writing and included either in the main contract or in a document to which the main contract refers.
- The compromise must determine the subject-matter of the dispute.
- The compromise will become void where an arbitrator that it designates declines the assignment entrusted upon him.

Mediation is also possible (as long as no "unavailable" right is involved) and is available before and throughout the course of the judicial proceedings.

Mediation proceedings which take place in the course of judicial proceedings and imply the intervention of the judge is called judiciary mediation. It does not suspend the proceedings.

Extra-judicial resolution of disputes through mediation is authorised and even encouraged.

Finally, mediation proceedings can be "conventional" in the absence of any formal requirement and "institutional" when they are governed by specific rules.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

All civil and criminal actions related to product liability are subject to time limits. There are however notable differences between the various regimes.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

Time limits are set out by law and apply irrespective of the law applicable on the merits. They are compulsory for the judge, as the latter has no discretionary power as to whether to apply them.

Under the strict product liability regime, the producer may be found liable for ten years after the product was put on the market (Article 1386-16 of the French Civil Code). Within such a period of time, the victim's claim must be filed no later than three years after it has or should have reasonably known about the defect, the identity of the producer and the existence of the injury (Article 1386-17 of the French Civil Code). If the plaintiff is a supplier who has not manufactured the product but is sued by the injured party, he may bring an action against the manufacturer under the same rules applicable to the injured party, no later than one year after the suit against him is filed (Article 1386-7 of the French Civil Code). After ten years from the date on which the product was put on the market, a claim can still be filed on classic grounds of contract or tort liability provided the time limitation for such actions has not expired.

A statute dated 17 June 2008 has completely modified the rules governing prescription of claims under French law. Actions brought under contractual liability (by which the party does not seek to obtain the nullity of the agreement but to obtain compensation) and under tort liability are barred after five years (Article 2224 of the French Civil Code and Article L.110-4 of the French Commercial Code), running from the date when the claimant is or should be aware of the facts accounting for the action, unless more restrictive provisions apply having regard to the category of contract. In particular, actions arising from bodily injury are barred after ten years, which runs from the moment when the act or omission results in injury, or when it is aggravated (Article 2226 of the French Civil Code).

This new statute came into force on 19 June 2008. Naturally, as for actions brought before this date, claims are dealt with and judged according to the previous law. However, the new provisions extending the duration of a limitation period apply to cases where the limitation period was still running on 19 June 2008: the time that has already lapsed is then taken into account. When the new provisions prescribe a limitation period which is shorter, this period applies and runs as of 19 June 2008 (unless the new limitation period ends after the one provided for under the old regime, in which case the previous limitation period applies).

Under the warranty against hidden defects regime, pursuant to which the seller is liable for hidden defects of the object sold as soon as these defects render it unfit for its intended purpose, the injured party must bring the action alleging a breach of the seller's warranty within two years of the discovery of the defect (Articles 1641 and 1648 of the French Civil Code). This fixed time-bar replaces the previous "short delay" requirement which was interpreted by case law as being no more than one year. Contracts entered into before the 1999/44 Directive was implemented into French law (i.e. before 17 February 2005) are still subject to the "short delay" requirement.

The differences that exist between the systems of liability, regarding the applicable time limits, are often explained by the capacity of the party which is supposed to bring the action and the degree of protection that the legislator has intended to grant to it. The age or condition of a party, where provided by law, may in addition suspend the application of the statutes of limitations. In particular, Article 2235 of the French Civil Code provides, regarding persons aged under 18 ("*mineurs*") and persons over 18 placed under the highest degree of Court protection that exists in France ("*tutelle*"), that time only starts running against them once they become able, or start being able again, to bring legal actions on their own behalf. Indeed, the time that elapsed before they reached the legal age to bring an action in court or during the effects of the protective measure is not taken into account regarding the time limit.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Except where the law provides for an interruption or a suspension of the limitation period, there is in principle no relief for a claimant who is time-barred.

However, case law considers that when the running of a time limit results from the behaviour of the defendant (i.e., the time limit being exceeded due to the defendant's behaviour), the latter may not invoke the limitation period (French Supreme Court, 28 October 1991).

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

Monetary compensation as well as injunctions to do, injunctions to cease to do and injunctions to pay are available remedies. As an action is admissible only if the claimant has a legitimate and present interest to it (Article 31 of the French Code of Civil Procedure), declaratory relief is not available in principle. There are however some rare exceptions especially in the field of private international law and in matters of nationality.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

French law recognises two types of damage: physical damage ("*dommage matériel*"); and non-physical damage ("*dommage moral*"). Physical damage is that which is caused to the person (e.g., bodily injury) or property of the injured person.

Non-physical damage includes the pain and suffering of the injured party, the loss of enjoyment, the aesthetic injuries, the damage caused to the honour or emotions of the injured party (e.g., slander or the mental suffering resulting from the death of a spouse). By nine decisions dated 12 September 2008, the Paris Court of Appeal ruled that the damage resulting from the fear to bear a potentially defective cardiac catheter could be recovered. The potential defect was signalled by the manufacturer to the doctors so that they could follow up the catheter holders. By a decision dated 4 February 2009, the Versailles Court of Appeal ruled that the neighbours of a base station sustained a "legitimate fear" and should be compensated even if no scientific research has been able to prove the impact of exposure to electromagnetic fields on one's health.

The loss of an opportunity to obtain a future benefit may also give rise to an award for damages if the court finds that the injured party had a good chance of obtaining such a benefit.

Under the strict product liability system, pursuant to Article 1386-2 of the French Civil Code, the recoverable damages are the damages caused by the defective product to the victim itself (i.e., death or personal injury) and to goods (other than the defective product itself) irrespective of whether the said goods are used for private or professional purposes. By a decision dated 24 June 2008, the French Supreme Court referred a preliminary question to the European Court of Justice to determine whether the French legislation which extends the strict product liability regime to goods used for professional purposes is contrary to the 1985 EC Directive. In line with the 1985 EC Directive, as regards damages to goods, France has set a 500 Euros threshold for the applicability of this regime.

Whereas, under the 1985 EC Directive, the Member States could set a ceiling on the producer's liability for bodily damage, France has chosen not to do so.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Only the loss directly caused by the product and which the injured party has actually suffered in the past or which the victim is certain to suffer in the future may give rise to an award of damages. Therefore, the possible future damage may not be compensated (French Supreme Court, 19 December 2006). However the fear and the anxiety provoked by the threat of the defect of a product and its associated risks for the health constitute a recoverable moral injury (same decision).

As for medical monitoring expenses incurred in order to control the evolution of the risks of illness or injury associated with the defective product (e.g., a defective cardiac implant), or as regards the costs of a surgical operation preventing the risk created by the defective product, they are not recoverable. In some cases, statutes provide for the indemnification of the medical monitoring (e.g., decrees issued in respect of the "*post-professional*" medical monitoring for workers exposed to asbestos).

6.4 Are punitive damages recoverable? If so, are there any restrictions?

In the French system of civil liability, the damages granted to the injured party are supposed to compensate the injury, not to punish the liable party. Their amount must correspond to the exact extent of injury. Therefore, there are no punitive damages under French civil law.

In a contract, the parties may stipulate a liquidated damages clause ("*clause pénale*") which may provide for an amount of damages which exceeds or limits the amount of damages resulting from the sole breach of a contractual duty. The judge has a discretionary power to reduce or increase the amount fixed by such clauses, if this amount is patently excessive or insufficient (Article 1152 of the French Civil Code, see question 3.1, *Contractual liability*).

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There are no maximum limits for the total amount that a liable party may be required to pay to injured parties. The only limit to the amount that may be due in respect of claims brought on the grounds of a same accident or incident results from the principle that the damages must correspond to the actual extent of the injury.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

Court approval is not required for the settlement to be applied by the parties. Nevertheless, a party may request the President of the Civil Court to enforce the settlement should the other party refuse to abide by it (Article 1441-4 of the French Code of Civil Procedure).

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

A person claiming compensation before a court for damages allegedly resulting from an injury caused by a product has the obligation to summon the relevant social security fund when he or she launches his or her action against the manufacturer/seller. If the claimant fails to comply with this obligation, the social security fund can request the decision to be declared void within two years following the date on which the decision was rendered. Therefore, the social security fund usually is party to the proceedings. In this way, it is able to request the manufacturer/seller to repay the expenses generated by the injury (including unemployment benefits and treatment costs). These sums are deducted from the damages to be paid to the claimant, but the deduction is made on the specific damages awarded for each head of damage identified. There can be no deduction from the damages awarded to compensate personal harm suffered by the claimant, such as emotional distress, unless the social security fund can prove that some amounts paid to the claimant related to such type of damage. As a result of this calculation, the manufacturer/seller who is found liable will pay part of the damages to the claimant and the other part to the social security fund.

There is no obligation to inform the authorities in the context of a settlement but the social security fund does retain the right to bring a claim against the manufacturer/seller for the reimbursement of its expenses.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

One must here distinguish between the court fees, the other incidental expenses, i.e. the procedural costs which are strictly necessary pursuing the suit ("*dépens*"), and the other expenses incurred by a party in respect to the dispute.

(a) Pursuant to Article 696 of the French Code of Civil Procedure, the successful party may be able to recover all the procedural costs ("*dépens*") listed at Article 695 of the French Code of Civil Procedure (e.g., the necessary translation costs, the court appointed experts' fees, the witnesses' expenses and the counsels' fees (when their intervention is required by law, such as the "*Avoués*" who

represent the parties before the Court of Appeal, and only up to the amount fixed by Decree)).

(b) Any other legal costs incurred by a party, such as the legal fees when they are freely determined between the lawyer and his or her client, fall under the scope of Article 700 of the French Code of Civil Procedure, which states that "*the judge shall order the party bearing the procedural costs, or failing that, the losing party, to pay to the other the sum of money that the judge shall determine and which corresponds to the costs incurred which are not included in the procedural costs. The judge shall take into account equity or the economic position of the sentenced party. He can, even automatically, giving reasons based on similar considerations, decide that no such order is needed*". In this respect, the recoverable amounts will be determined on a case-by-case basis. However, the amounts that are generally granted rarely exceed 10,000 to 20,000 Euros.

7.2 Is public funding e.g. legal aid, available?

Legal aid is available in France and consists in a financial aid (total or partial) in proceedings before State courts (direct payment by the State to the appointed counsel or bailiff, exoneration of certain taxes, etc.).

7.3 If so, are there any restrictions on the availability of public funding?

Jurisdictional aid is only available for proceedings before French national courts. It is generally granted to individuals who can prove that their income is too low to afford access to justice. It is not required to be a French citizen, as legal aid may be granted to any national of a Member State of the EU, or whose country has entered a Convention with France or whose permanent residence is in France. However, this condition of residence does not apply to people under the age of 18, or if criminal charges have been brought against them. In 2009, full legal aid may be available for the persons whose incomes are below 911 Euros per month, and partial legal aid for those with incomes between 912 and 1,367 Euros.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Contingency fee arrangements ("*pacte de quota litis*") are forbidden in France. However, since 1991, it is possible to enter into, in writing, a fee agreement with the client stipulating an increase of fees in the event of a particularly positive result and the calculation of which is set out in advance.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Third party funding is not customary at all in France. Lawyers should actually refuse to be paid by a third party when: (i) the third party is not aware of the circumstances of the payment; or when (ii) the third party is breaching the law by paying the fees. For instance, the use of company funds to pay the legal fees of an employee for his/her defence in a private case should not be accepted as it constitutes fraudulent use of corporate property.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in France.

Notable decisions handed down in product liability cases during the last year include:

In the pharmaceutical field, since several judgments handed down by the French Supreme Court on 22 May 2008, judges shall analyse the facts such as chronology of events or other risk factors to decide whether a causal link exists, even when scientific causation between the use of the product and the alleged adverse effect is not established. This case law has mainly been developed with respect to the hepatitis B vaccine. Some claim that the latter may trigger neurological disorders but there is no scientific evidence of such a link. However, so far the French Supreme Court has never upheld a decision granting damages to a claimant in such a case.

By nine decisions dated 12 September 2008, the Paris Court of Appeal ruled that the damage resulting from the fear to bear a potentially defective cardiac catheter could be recovered. The French Supreme Court has not yet given its position on this issue.

Potential health risk induced by base stations gives rise to several decisions on the legal basis of private nuisance. A network operator has been ordered by the Versailles Court of Appeal on 4 February 2009 to dismantle its base station situated in a residential area near Lyon and to pay damages to the neighbours in consideration of the "legitimate fear" they sustained. The same decision was taken towards another operator by the Carpentras Civil Court on 16 February 2009 regarding its base station located near Avignon. Again, the French Supreme Court has not yet given its position on this issue.

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Thomas is a partner in the Lovells' Paris office where he is in charge of the dispute resolution practice. He specialises in litigation, with an emphasis on product liability litigation and product safety.
Thomas regularly handles cross-border and multi-party disputes and has gained broad experience with respect to emergency proceedings (*ex parte* applications and summary proceedings).
He is regularly involved in product safety matters including advising on the effect of regulations, assisting with product recalls, responding to the demands of regulatory authorities and representing clients in civil, commercial and criminal proceedings.
Thomas has broad experience in industrial product liability matters on behalf of, for example, manufacturers of household appliances, as well as industrial risk litigation (industrial accidents or environmental claims). He regularly appears on behalf of clients in product liability matters concerning the automotive industry, pharmaceutical products, telecommunications and the food and drink industry. He also has significant experience working on the side of the defence in aviation matters and tobacco-related litigation.
Thomas is a member of the class actions working group of the *Mouvement des Entreprises de France* ("MEDEF"). He is also an active member of the International Association of Defense Counsel ("IADC") of which he is the International Vice-Chair of the Product Liability Committee. He contributes regularly to the Lovells European Product Liability Review and speaks frequently at product liability and product safety seminars.
Thomas was admitted to the Paris Bar in 1992. He read law at the Universities of Paris II (Assas) and Paris I (Panthéon-Sorbonne), and is a graduate of the Paris Institut d'Etudes Politiques (Sciences-Po). He became a litigation partner with Siméon & Associés in 1998, before joining Lovells in 2001.

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

The law of product liability in Germany is based on three grounds: the law of contract; the traditional (fault based) law of torts; and strict liability law. These regimes form concurrent legal bases. Article 13 of the European Directive 85/374/EEC on liability for defective products ('the Directive') preserves this coexistence.

Most product liability claims in tort are based on *negligence* (section 823 (1) of the Civil Code). This requires the breach of a duty of care (*Verkehrspflicht*). The Federal Supreme Court characterises putting a defective product on the market as indicative of a breach of duty (see also question 2.1). In this context, the Supreme Court has identified three types of defects: design defects; manufacturing defects; and instruction defects (i.e. failure to warn/provide proper instructions). The producer is also obliged to monitor the product and to take appropriate measures once the product is in circulation.

German tort law further includes liability for *breach of a statutory or regulatory provision* (section 823 (2) of the Civil Code). Important examples of such provisions can be found in the Product Safety Act, the Food Act, the Drug Act, the Medical Devices Act and the Criminal Code.

Strict liability for products in Germany includes the Product Liability Act 1989 ('PLA'), the Drug Act 1976 (the 'Drug Act') and the Genetic Engineering Act 1990 (the 'Genetic Engineering Act').

The PLA implements the Directive to introduce liability for *defective* products. While the PLA was rarely applied during the first years of its existence, more and more claims are now brought on the basis of this regime. One of the reasons for this development, besides a general increase in product liability claims in Germany, lies in a reform of the law in 2002 that made it possible to recover compensation for pain and suffering under strict liability regimes.

The Drug Act is an important strict liability regime for pharmaceutical products, which takes priority over the PLA. The Drug Act includes liability for development risks (see question 3.2) and renders insurance compulsory. The Genetic Engineering Act provides for liability for damage caused by genetically manipulated organisms (GMO). This also includes liability for development risks.

Contract law is only relevant where the injured person and the defendant have a contractual relationship. The law of contract provides for compensation for damage caused by a product, in particular, where the product is not in conformity with the contract, although this will in most cases, additionally, require fault on behalf of the defendant. However, according to statutory contract law, fault may be presumed if the defendant delivered a defective product.

1.2 Does the state operate any schemes of compensation for particular products?

Thalidomide victims have a right to benefits provided by a public foundation established in 1971. Another public foundation has been set up to help patients who were infected with HIV through contaminated blood products before 1 January 1988. In both cases, the endowments are shared by the state and the relevant pharmaceutical companies. There is also financial aid available for a specific group of people who have been infected with the Hepatitis C Virus through particular batches of vaccine.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Under the PLA the responsibility for a defective product is on the 'producer'. The term producer includes the manufacturer of the product or a component, the producer of raw material, the own-brander and the person importing into the EU (EEA). The supplier of the product is only liable if the producer cannot be identified. The supplier can also exonerate himself by informing the injured person, within one month, of the identity of the producer or any other person higher up in the chain of supply, provided this person is located within the EU/EEA. The same applies if the importer cannot be identified even if the identity of the producer is known.

The Drug Act assigns responsibility to anyone who, in his own name, puts the drug into circulation in Germany. This also includes any marketing authorisation holder who is not the manufacturer of the product. A similar rule applies under the Genetic Engineering Act for liability for products incorporating GMOs.

A duty of care in tort can rest on all persons who are involved in the production and marketing of a product, although the characteristics of the duty may vary, depending on the role the individual person has in this process. In contrast to the situation under the PLA, the supplier may be liable in tort, regardless of whether the producer can be identified. A duty of care can also rest on managers and other qualified persons of a company. Liability for breach of

statutory or regulatory duty falls on the person to whom the relevant provision assigns the duty (e.g. on producers and suppliers under sections 4 and 5 of the Product Safety Act).

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Where a producer becomes aware of risks emanating from a product that is already on the market, he is under a duty of care to take appropriate measures to avoid or minimise the risks. Often, it will be sufficient to issue warnings, but the producer can be under a duty to recall the product where other measures are inadequate.

An obligation to recall products can also follow from an order by the relevant authority. Under the Product Safety Act, as amended in 2004, authorities can issue a recall order if they have reason to assume that a product is not in conformity with the safety requirements under the Act, provided a recall is the most appropriate form of action.

The failure to issue warnings or to recall the product gives the injured person a claim in negligence or for breach of statutory/regulatory duty. Furthermore, some courts also accept a claim for mandatory injunction for warnings and even recalls.

1.5 Do criminal sanctions apply to the supply of defective products?

There are criminal sanctions for the supply of defective products. Relevant provisions exist, for example, in the Criminal Code in the Food Act and in the Drug Act.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

Section 1 (4) PLA puts the burden of proving *defect* on the injured person, who has to show that the product did not provide the safety a person is entitled to expect (section 3 PLA). As to the proof of manufacturing defects, this means the higher the expectations of safety to which the typical consumer is entitled, the lower the extent to which the claimant has to investigate the exact nature of events leading to the product's failure - and vice versa. As far as design defects and warning defects are concerned, proof of defect effectively comes close to establishing corporate negligence.

Under section 84 of the Drug Act, the claimant must prove (i) that the risks of the product in question outweigh its benefits, or (ii) that the information in the product labelling (e.g. on potential adverse events) did not accurately reflect the state of scientific knowledge at the time when the product was put into circulation. As a result, in practice, the standard under the PLA and under the Drug Act will be very similar.

While in tort the burden to prove *fault* is usually on the claimant, this rule is modified in product liability cases. Where a breach of a duty of care is in question, it suffices that the consumer proves that the product was defective. The producer must then show that he did everything necessary and reasonable to discover and avoid the defect. Finally, it is for the claimant to prove *damage*, i.e. his injury and any consequential damages resulting from the injury.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

In order to prove causation, the claimant has to show that the damage would not have occurred but for the defect, or the breach of duty, respectively (*condition sine qua non test*). The claimant does, as a rule, not satisfy this test by demonstrating that the product created an increased risk.

According to the rules of *prima facie* evidence, the claimant can prove causation by establishing a typical course of events. This does not mean, however, that the claimant only needs to demonstrate an increased risk or a certain probability of causation. It means that the court can infer causation from the circumstances of the case if it is an established fact that those circumstances typically indicate a causal link.

Following a reform of the Drug Act in 2002, the claimant no longer needs to prove that the drug he used did in fact cause his injury. He only needs to prove that, considering all the circumstances of the individual case, the drug was "capable" of causing the damage. Causation will then be presumed, and it is for the defendant to prove the absence of a causal link. However, this rule does not apply where other factors were (also) capable of causing the damage, which is often the case in practice. For example, the courts have confirmed that this rule does not apply where the claimant's injury could also have been caused by individual risk factors.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

The theory of market share liability does not apply in Germany. Instead, according to section 830 (1) of the Civil Code, joint and several liability applies "if it cannot be ascertained which of several participants caused the damage through his conduct". This provision may apply where the claimant can prove that several manufacturers breached their duty of care towards the consumer and that each breach of duty could have caused the damage, as long as other causes can be ruled out.

It has been argued that this provision also applies in cases where the claimant cannot prove which of several defective products he used caused the damage, provided he can demonstrate that each defective product could have caused the injury. Whether this theory has a basis in the statute is the subject of some controversy. What is clear is that this provision does not apply where the claimant cannot prove: (i) exactly which products he used; (ii) that all products he used were defective; (iii) that each of these defective products could have caused the damage; and (iv) that no other factors could have caused the damage.

As mentioned above, under the Drug Act, the claimant only needs to prove that the relevant product was capable of causing the damage. It is then for the defendant to demonstrate that other factors were also capable of causing the damage. Significantly, the defendant cannot point to the application of other drugs as an alternative factor unless liability for the other drugs would be excluded for other reasons than the lack of a causal link (section 84 (2) 4). This will be the case, in particular, where the other drugs are not defective, for example because the alleged event is labelled in the product information.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Failure to warn constitutes a warning defect if, in the absence of warnings, the product does not provide the safety a person is entitled to expect (section 3 (1) (a) PLA). The relevant test here is that of a "reasonably well informed and reasonably observant and circumspect consumer". Where a product is normally only used by professionals, the standard needs to be adjusted accordingly. Therefore, the information accompanying a medical device used by surgeons needs to contain instructions and warnings required by surgeons (not the public generally).

There is no direct application of the 'learned intermediary rule' in cases of prescription drugs. Articles 11 and 59 of Directive 2001/83/EC (and the Drug Act) set out detailed labelling requirements for the summary product characteristics (SPC) and the package insert leaflet (PIL). Accordingly, information on indications, contraindications, precautions for use, and possible undesirable effects has to be provided to doctors and patients, respectively.

However, in line with the relevant European regulations, the SPC provided to the prescribing physicians often contains more detailed information than the PIL provided to patients. This does not constitute a failure to warn. Also, even where patients might have been entitled to expect the same detail of information as was provided to the prescribing physician, it will be difficult for the claimant to prove a causal link between any purported informational deficit and the damage. The claimant would need to show that - against the instructions of his doctor - he would not have taken the product had the package leaflet contained more information.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The defendant will not be liable in tort if he can show that he did not breach a duty of care (see question 1.3).

There are also several defences under the PLA. According to section 1 (2) - (4), the defendant is not liable only if he proves:

- that he did not put the product into circulation;
- that it is to be assumed that the product did not have the defect which caused the damage at the time when the producer put it into circulation;
- that he manufactured the product neither for sale nor for any other form of distribution for economic purposes;
- that the defect is due to compliance of the product with mandatory regulations issued by public authorities;
- that the state of scientific knowledge at the time when the product was put into circulation was not such as to enable the defect to be discovered; or
- in the case of the manufacturer of a component, that the defect is due to the design of the finished product or that the component was made according to the instructions of the producer of the final product.

The defendant avoids liability under the Drug Act if he can prove that the harmful characteristics of the drug are not attributable to its design or manufacturing, but came into existence further down in the chain of supply (section 84 (3)).

Finally, contributory negligence is a defence under all regimes.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

A defence for development risks is incorporated in the PLA (see question 3.1). According to the case law of the European Court of Justice as well as the German courts, to succeed with this defence, the producer of a defective product must prove that the defect could - objectively - not be discovered, taking into account "the most advanced knowledge" at the time the product was put into circulation. However, such knowledge must be accessible.

Moreover, the development risks defence does not apply where the problem with a certain product is known, since the issue then is one of *avoidablility* rather than *discoverability*. The German courts therefore deny the defendant the possibility to rely on the development risks defence in most cases of manufacturing defects since they say that the possibility of a manufacturing defect arising is generally known even if it cannot be avoided.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Compliance with regulatory (and/or statutory) requirements is an automatic defence only where compliance with the relevant provisions has necessarily led to the damage (see question 3.1). Compliance with regulatory requirements is no automatic defence where they simply impose minimum standards. However, the courts consider compliance with the relevant regulatory requirements as strong - and in some cases conclusive - evidence that the product is not defective. This is the case, in particular, with products from highly regulated industries such as pharmaceutical products.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

The effect of a judgment in the German law of civil procedure is that a claimant cannot bring the same claim again based on the same set of facts (*res judicata*). 'Claim' here refers to the relief sought by the claimant, regardless of the legal basis. Judgments will normally be determinative only of the rights of the parties to the proceedings. A different claimant can therefore litigate issues of fault, defect or causation against a producer who has already successfully defended a claim, on the same issues, brought by someone else.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

Where the damage was caused by the fault of the defendant and a third party, the defendant and the third party are jointly and severally liable, irrespective of their individual contribution to the damage.

Under the PLA, every producer is liable for a defect in the product irrespective of the actions of a third party. The producer is not liable, however, "if it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards" (Article 7 (a) PLD). This is the case, for example, if a third person (or the claimant) tampers with the product post-circulation. Moreover, the producer is not liable "in the case of a manufacturer of a component, if he proves that the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product" (Article 7 (f) PLD).

Where the defendant and the third party are jointly and severally liable, the defendant may be able to seek recourse from the third party. It is in this procedure that the court will apportion the respective share of liability. The defendant can seek recourse against the third party only in subsequent proceedings, and there are time limits for such proceedings. However, the defendant can issue a third party notice in the original proceedings in order to suspend the limitation period.

3.6 Can defendants claim that the claimant's actions caused or contributed towards the damage?

The defendant can claim that the claimant's actions caused or contributed towards the damage. In the first case, the defendant will in general not be liable; and in the second case, damage awards will be reduced depending on the proportion of the claimant's contribution to the damage.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

The trial is by a judge or a chamber of judges.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

No, it is only for the judge to assess the evidence (see also questions 4.1 and 4.8).

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

Class actions, or similar forms of collective redress, are not available for product liability claims in Germany. There are procedures to consolidate multi-claimant proceedings in securities litigation, and the government is considering whether similar mechanisms could and should be introduced for other areas of law, including personal injury litigation. Although the EU debate on collective redress has had some impact on the legislative activities in Germany, the government has not yet expressed a clear desire for reform in this area. What we have been observing in multi-claimant litigation, however, is that judges gradually develop their own mechanisms of case management to deal with the increasing number of cases.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Representative actions are not available in the area of product liability.

4.5 How long does it normally take to get to trial?

There is no formal pre-trial stage in Germany. The period of time between the filing of a claim and the first court hearing is usually between two and six months. Although a case can be decided as early as in the first hearing, the period of time between the first hearing and a first instance judgment is generally between five weeks and two years.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

There is no trial about preliminary issues of law or fact. That is, the court cannot formally split a trial and decide on certain preliminary issues with binding effect for subsequent proceedings. The only practical exception to this rule is that a court can render a decision on the merits, whilst reserving until later the assessment of damages (quantum).

What a court can do, however, is to consider certain issues (of law and fact) first and, if necessary, take evidence on those issues. For example, in pharmaceutical cases, courts often limit the proceedings to issues regarding causation. Therefore, if the claimant cannot prove causation, the court will dismiss the case without having to consider other relevant issues such as the existence of a product defect.

4.7 What appeal options are available?

Appeal from the decisions of the court of first instance (Berufung) may be taken as of right where the amount of complaint exceeds €600. Otherwise, the party requires leave to appeal. The Federal Supreme Court revises the decision of the court of appeal on questions of law only (*Revision*) if either it or the court of appeal allows revision.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The court can, and must, appoint an expert where it lacks the required technical or scientific knowledge itself. The court-appointed expert will prepare a written report on the technical and scientific issues as identified by the court and the parties.

However, the court can dismiss a case without appointing an expert, even in pharmaceutical cases, if it finds that the claimant's submissions are unsubstantiated (e.g. because of a failure to make precise statements on the medical history) or do otherwise not allow a finding of causation or a product defect and/or fault (e.g. because the scientific studies presented are evidently not supportive of the claimant's case).

The parties can also obtain their own private expert opinions, although such an opinion will have minor probative value unless the parties agree that it will be treated as a formal expert opinion. The main purpose of private expert opinions is to educate the court-appointed expert and the court on certain scientific and medical issues and/or challenge the findings of a court-appointed expert.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

There is no formal pre-trial deposition in Germany. The parties are free to exchange private expert opinions and similar documents before the trial, if they wish.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

There is no general pre-trial discovery procedure and no general claim for disclosure that would help the claimant establish liability. However, recent reforms of the CCP and the Drug Act have introduced new rules for the disclosure of documents.

Under section 84a of the Drug Act, the injured person may now request that a pharmaceutical company (and/or the relevant regulatory authority) provide information on the known effects, side effects and interactions of a drug. This claim is usually brought prior to the damage action.

Procedural law also grants the court the power to order the disclosure of specified documents in the possession of a party, or a third person, if a party refers to those documents. Although this provision is increasingly being used in litigation, it does not allow for extensive document disclosure procedures.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Alternative methods of dispute resolution, e.g. mediation and arbitration, are available in Germany, although these methods are hardly ever used to resolve product liability cases.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, time limits do exist.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

The time limit for bringing compensation claims under tort law and under the strict liability regimes is generally three years. Recent law reforms have introduced a 'year-end-limitation'. That is, the three-year limitation period now begins at the end of the year in which the claimant became, or ought to have become, aware of the facts on which his claim is based. For example, if the claimant knew, or ought to have known, of the relevant facts giving rise to his claim on 1 August 2008, the limitation period will start on 31 December 2008 (24:00 h).

Time limits expire regardless of this knowledge 30 years after the incident in question occurred; claims for property damage, however, will be limited to only ten years from the time when the damage manifests itself (subject to the 30-year limitation from the harmful event). Rights under the PLA will be extinguished after ten years from the day on which the producer put the product into circulation, unless the claimant has in the meantime instituted proceedings.

The court does not have discretion to disapply time limits. However, the defendant has to invoke the statute of limitations defence.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

As the time limit begins at the end of the year in which the claimant became aware of the facts giving rise to a claim, concealment of these facts, or fraud, would delay the start of the time limit.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

Claimants can file a claim for compensation and/or declaratory judgment on the question of liability.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

As of 1 August 2002, all product liability regimes cover, in principle, both pecuniary and non-pecuniary loss.

Pecuniary loss resulting from *personal injury* includes, for example, the costs of medical treatment and, usually in the form of an annuity, any loss of profit, income or maintenance.

Non-pecuniary loss includes *pain and suffering* as well as *loss of amenity*. The highest amount so far awarded by a German court for pain, suffering and loss of amenity added up to the equivalent of €600,000. *Mental damage* in the form of a recognised psychological disorder must be compensated, whether it manifests itself as pecuniary or non-pecuniary loss.

Damage to property is recoverable under all regimes, except for the Drug Act and the Genetic Engineering Act, but is subject to a number of restrictions. The PLA limits property damage to products other than the defective product. It further excludes damage to items that are usually, or that were largely, used for business purposes. Finally, €500 will be deducted from the damage.

Damage to the product itself is covered by the law of contract. Tort law allows the recovery of damage to the *product itself* only in exceptional circumstances, for example, where a separable part of the product causes damage to the rest of the product.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

A claim for the expenses of medical monitoring would have no basis in negligence or under the PLA as these regimes require an actual injury to body or health. It is hardly conceivable that the courts in Germany would follow the example of some state courts in the U.S. and give up this requirement. If at all, such claims would be brought for *breach of statutory/regulatory duty*. However, it is unlikely that a court would hold that the relevant statutes and regulations serve the purpose of covering medical monitoring where the claimant is entirely asymptomatic.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are not recoverable. Moreover, awards of punitive damages in foreign jurisdictions are regarded as being contrary to the German *ordre public* and are thus not enforceable in Germany.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

The PLA limits the liability of the producer to a total of €85 million. The Drug Act sets a ceiling of €120 million and €7.2 million p.a. (for annuities) and cuts individual claims at a maximum of €600,000 (€36,000 p.a. for an annuity). The Genetic Engineering Act has a total limit of €85 million. There are no specified limits in tort or contract.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

There are no special rules for the settlement of product liability claims or multi-claimant litigation in general. The parties can settle in court or out of court. Both types of settlements have pros and cons, and decisions will be taken on a case by case basis, if a settlement is the objective.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

There have been cases of public health insurers and other public entities claiming from product manufacturers the reimbursement of social benefits (i.e. costs of medical treatment or employment benefits) paid out to the injured person. Under social security laws, any rights of the injured person in relation to damage awards resulting from personal injury are, by law, transferred to the public entity responsible for providing the relevant social benefits.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The successful party can recover all necessary costs, including court fees and legal costs. The 'necessary' costs for a lawyer are reimbursed according to a statutorily fixed amount, which depends on the value of the claim.

7.2 Is public funding e.g. legal aid, available?

The claimant can apply to the court for legal aid. In addition, legal insurance is common in Germany.

7.3 If so, are there any restrictions on the availability of public funding?

Legal aid will be awarded if the applicant does not have the financial resources to fund the claim and if the claim has sufficient prospect of being successful.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

As of 1 July 2008, conditional fee arrangements - including contingency fees - are, in certain circumstances, permitted under German law. The recent changes in legislation follow a decision by the Federal Constitutional Court, holding that the long-standing prohibition of such arrangements was not in line with the German Constitution.

According to the new legislation, fee arrangements can be made conditional upon the success of a claim if the specific circumstances of the case justify such an arrangement. The legislation specifically provides that such a situation may arise where the client, due to his financial situation, would otherwise be prevented from pursuing his claim.

The new legislation permits both conditional fee arrangements - in the sense of pure 'no win/no fee' and 'no win/less fee' arrangements' - as well as contingency fee arrangements where the fees are calculated as a percentage share of the eventual recovery awarded to the claimant in the case of success. However, the new legislation does not allow legal practitioners to carry the other side's costs and/or court fees in the event of their client losing.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Third party funding has been available in Germany for several years. There are several institutions offering third party funding. However, in our experience, third party funding has not played a significant role in product liability litigation so far as the relevant institutions have not shown a great interest in funding these types of claims.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Germany.

This year the German Federal High Court of Justice [*Bundesgerichtshof* - BGH] published a widely expected judgment on the question of whether manufacturers have to provide a free of charge replacement in the event of safety risks arising from products they have put on the market. The BGH pointed out that there is no general obligation under German tort law to repair or replace products because of safety risks. This means that, in many cases, the manufacturer could comply with its obligation of hazard prevention by issuing warnings, by requesting that the use of the products be stopped, or by informing the competent authorities. According to the Court, these principles apply in cases where users can easily be identified and in cases where it can legitimately be assumed that the warnings will be observed.

As to the general tendencies, over the last few years there has been a significant increase in the number of product liability claims in Germany. While this development affects nearly all industries, the most noticeable increase in claims has been in the area of pharmaceuticals. This trend has begun in the last few years and is still ongoing. The reasons for the increasing number of claims include an increased media interest, heightened consumer awareness, easier access to information and a more active claimant bar. Moreover, by European standards, obtaining funding for claimants to pursue product liability claims is relatively easy in Germany. In addition to the availability of legal aid, legal cost insurance is widespread and alternative methods of funding are developing. The recent changes in the law permitting the use of conditional fee arrangements as well as contingency fees may contribute to a further increase in claims.

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Ina is chair of the German Steering Committee of DRI Europe and a member of the International Association of Defence Counsel ("IADC"). She is also an author of numerous publications on product liability law issues and assisted on the conduct of a major study on the practical operation of product liability laws throughout the EU and the feasibility of greater harmonisation of those laws in the instruction of the European Commission.

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

Law 2251/1994 on the "Consumers' Protection" (the "Consumers' Law") which implemented EU Directive 85/374/EEC "on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products" (as amended by EU Directive 99/34/EC) sets the main product liability rules in Greece. Moreover, Ministerial Decision Z3/2810/14.12.2004 (the "MD") implemented EU Directive 2001/95/EC on "General Product Safety". The Consumers' Law was for the last time amended by virtue of Law 3587/2007 (in force since 10 July 2007).

The Greek legal system establishes a strict liability regime, thus not a fault based one. Article 6 para. 1 of the Consumers' Law provides that "the producer shall be liable for damage caused by a defect in his product". It derives that, in order for a producer to be held liable, the pre-requisites are: a) a product placed on the market by the producer is defective; b) damage occurred; and c) a causal link between the defect and the damage exists.

1.2 Does the state operate any schemes of compensation for particular products?

No it does not.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Article 6 paras. 2-4 of the Consumers' Law provides that the "producer", who bears responsibility for the defect, is the manufacturer of a finished product or of any raw material or of any component, and any other person who presents himself as a producer by putting his name, trade mark or other distinguishing feature on the product. Moreover, any person who imports (within the EU) a product for sale, leasing or hire or any form of distribution, shall be responsible as a producer. Where the producer of the product may not be identified, each supplier of the product shall be treated as its producer unless he provides the injured person with information on the identity of the producer or of the person who supplied him with the product. The same applies to the supplier of imported products when the importer's identity is unknown, even if the producer's identity is known.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

According to article 7 of Consumers' Law and article 3 of the MD, producers are obliged to only place safe products on the market. Accordingly, producers must provide consumers with the relevant information to enable them to assess the product's risks throughout the normal or reasonably foreseeable period of the product's use. Within these limits producers must take any action needed in order to avoid these risks as well as take any appropriate preventive and corrective action (such as a recall of the product) depending on the specific circumstances. Based on the above, a claim for failure to recall may be brought on the grounds of the producer's negligence to act accordingly.

1.5 Do criminal sanctions apply to the supply of defective products?

According to article 13a of the Consumers' Law, a series of administrative sanctions may be imposed on a producer supplying defective products, without prejudice to other relevant provisions, including the provisions of the Greek Penal and Market Codes (article 7 of the MD).

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The plaintiff - consumer - has to prove the defect, the damage and their causal link whereas proof of fault is not needed (see above under question 1.1). Where a plaintiff sues in tort, as a rule he must prove the defendant's fault. However, case-law and theory hold that the burden of proof may be reversed if the plaintiff would otherwise be unable to prove the defendant's culpable conduct. This is held when the fact to be proven lies in the exclusive sphere of the defendant's influence, and the plaintiff is unable to gain access in order to meet his burden of proof obligations; in such a case the defendant is required to prove that he was not responsible for the occurrence of the injurious fact. The reversal is applied under the case law primarily for consumers' claims.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

Per the (existing) case law, it is not enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of injury. Thus, direct connection between the injury and the specific defect has to be established by the claimant.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

It is primarily a matter of proof. Market-share liability may be possible but only where the status of a "producer", as defined by law, can be established, the various "producers" being liable jointly and severally.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

The producer has to provide the adequate warnings for the risk evaluation of the specific product and failure of this may result in his liability. The learned intermediary doctrine is one of the important defences available to manufacturers of medicines and medical devices mostly, as it provides that manufacturers of prescription drugs and medical devices discharge from their duty of care to patients by providing warnings to the prescribing physicians. However, in case where the use of the product, even according to the producer's guidance, bears danger for the consumer, this fact needs to be clearly brought to the consumer's attention by the producer. Failure to warn is seen to have caused the damage only when it is fully proven that the use of the product according to the producer's guidelines would have prevented the damage.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The producer may be relieved from liability if he proves that: a) he did not place the product on the market; b) when he manufactured the product, he had no intention whatsoever of putting it into circulation; c) at the time that the product was placed on the market the defect did not exist; d) the defect was caused by the fact that the product was manufactured in a way from which a derogation was not permitted (subjection to mandatory regulation); or e) when the product was placed on the market, the applicable scientific and technological rules at that time prevented the defect from being discovered (the state of the art defence).

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

There is a state of the art defence, as noted above under question 3.1 (item e), and it is for the manufacturer to prove that the fault/defect was not discoverable.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Yes, as noted above under question 3.1 (item d). In particular, two opinions were expressed on this, namely: a) the manufacture of a product according to the applicable scientific and regulatory safety requirements is one of the factors determining its expected safety level. The producer's observance with the set safety requirements does not necessarily mean that the product is not defective but it simply indicates a lack of defect, which must be proven by the producer (this is followed by the current jurisprudence); and b) the producer's conformity with the applicable safety specifications leads to the assumption that the product lacks defectiveness and the damaged consumer must argue against it.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Greek Courts' final decisions which may not be challenged through appellate proceedings: a) are irrevocable; and b) have a *res judicata* effect, but only among the litigants, only for the right that was tried and provided that the same historical and legal cause apply. In that respect, re-litigation by other claimants is possible.

The above rule does not apply in case of a court's decision issued following a collective lawsuit. Per the Consumers' Law (article 10), in such cases, the decision issued has an *erga omnes* effect and further a *res judicata* effect in favour of any consumer damaged, even if they did not participate in the relevant trial, especially when a decision recognises the damage suffered by the consumers due to an unlawful behaviour. As a result, any damaged consumer may notify his claim to the producer. In case where the producer does not compensate the consumer at issue within thirty (30) days, then the latter may file a petition before the competent court asking for a judicial order to be issued against the producer. On the contrary, a consumer is not affected by the rejection of a collective lawsuit and may at all times commence proceedings individually.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

The producer's liability cannot be limited due to the fact that a third party is also liable.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Producer's liability can be limited or abolished in cases where the damaged consumer's contributory negligence may be proven.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

Private law disputes, including product liability claims, are tried exclusively by civil courts and only by a judge, depending on the amount of the dispute. Justices of the peace are competent to examine claims up to €12,000, one-member first instance courts claims between €12,000 and €80,000 and three-member first instance courts for claims exceeding €80,000.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Yes, if the court finds that the issues to be proven require special scientific qualifications, it may appoint one or more experts.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

Class action procedures for multiple claims brought by a number of plaintiffs do not exist in Greece, but there are provisions regarding collective actions as analysed herein (e.g. see under question 4.4).

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

A number of claimants may bring claims by means of a collective lawsuit. The collective lawsuit is distinguished from a common one, where more claimants connected to each other with a specific object of the trial are represented before the court by one or more of their co-claimants. The collective lawsuit may only be filed by consumers' associations, under the pre-requisites specified in the Consumers' Law.

4.5 How long does it normally take to get to trial?

As an average, an action is heard approximately ten to twelve (10-12) months following its filing and the decision is issued six to eight (6-8) months after the hearing, provided that the hearing fixed initially is not adjourned (rather a practice).

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Not applicable.

4.7 What appeal options are available?

Every definite judgment issued by a first instance court may be contested before the Appellate Court. An appeal can be filed not only by the defeated party but also by the successful party whose allegations were partially accepted by the court. Further, a cassation before the Supreme Court may be filed against Appellate Court's decisions.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

As stated above under question 4.2, the court may appoint experts to assist it in considering technical issues. The expert(s) may take knowledge of the information in the case file and/or request clarifications from the parties or third parties. The parties are also entitled to appoint one technical advisor each, who reads the expert report, submits his opinion and raises relevant questions to the court expert. Additionally, the parties may submit to the court an unlimited number of expert/technical reports supporting their allegations.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

No, they are not.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

No disclosure obligation exists.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Parties may choose mediation or arbitration as the means for resolving their disputes, even for actions pending before the court. Also, before initiating actions they may address to the competent Judge of the Peace, asking for the latter's intervention in order for the dispute to be settled in an early stage. Furthermore, the parties may address to the following bodies/authorities for resolving their disputes having their origins to product liability, namely to: a) Consumer's Advocate, an authority aiming out-of-court and amicable resolution of disputes between manufacturers and consumers; b) Committees for Friendly/Amicable Settlement, which are composed by the local Prefectures and are overseen by the Consumer's Advocate; c) the European Centre of Consumer, which is the European network for resolving disputes resulting from transactions where the manufacturer and the consumer are based in different EU Member States, operating under the General Secretariat for Consumers; d) the SOLVIT network which deals with problems that result from defective application of rules of the

Internal Market on behalf of the public administrations at the cross-border level and operates as the department of the Ministry of Finance; and e) Citizen's Advocate, an authority dealing with the resolution of differences between citizens with government owned institutions and services.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes (see article 6 para. 13 of the Consumers' Law).

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

For strict liability and according to article 6 para. 13 of the Consumers' Law, a three (3)-year limitation period applies to proceedings for the recovery of damages, while the right to initiate proceedings against the producer is extinguished upon the expiry of a ten (10)-year period from the date that the producer put the product into circulation. The age or condition of the claimant does not affect the time limits calculation while the Court may not disapply time limits.

For a claim in tort, a five (5)-year prescription period applies (article 937 of the Greek Civil Code)

In case of a collective lawsuit, it must be brought within six (6) months from the last unlawful behaviour challenged, unless the mere recognition that an unlawful act had taken place is sought, where a five (5)-year prescription period applies.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

The Consumers' Law (article 6, para. 13) sets as the starting point from which the limitation runs "the day on which the plaintiff became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer". Regarding the knowledge of the damage, it is not required for the plaintiff to be informed of the individual damage, but the knowledge of the possibility of a forthcoming loss-making result is enough. The knowledge of the defect includes the circumstances from which it results that the use of the product does not meet the consumer's safety expectations. Furthermore the consumer needs to be in a position to know that the damage is the result of the specific defect of the product.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

Monetary compensation and injunctive measure are available for the victim. Especially by means of a collective lawsuit, consumers' unions may ask a) that a producer abstains from any unlawful behaviour even before it occurs, b) for the recall, seizure (as injunctive measures), or even destruction of the defective products, c) for moral damages, and d) that the court recognises that the producer's unlawful behaviour led to the consumers' damage.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

According to article 6 paras. 6 and 7 of the Consumers' Law the types of damage that are recoverable are: a) damages caused by death or by personal injury to anyone; and b) damage or destruction caused due to the defective product to any consumer's asset other than the defective product itself, including the right to use environmental goods and provided that i) the damage exceeds the amount of €500 and ii) the product was ordinarily intended for and actually used by the injured person for his own private use or consumption. Furthermore, compensation for mental distress or moral harm may also be claimed.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

A causal link is always required between the defect and the damage in order for the producer to be held liable. So in cases where the product has not yet malfunctioned and caused injury, there is an absence of this condition. If the product malfunctions in the future, medical monitoring costs may be recovered as positive damage suffered by the consumer.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

No. But, in collective lawsuits, the fact that the amount awarded for moral harm is invested (by law) for purposes of serving the consumer's education, briefing and protection in general, brings it closely to a pecuniary sentence, a so-called "civil sanction" imposed on the producer.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

No, there is not.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

No special rules apply to the settlement of claims, unless the parties choose to settle by means of a judicial settlement by a Judge of the Peace or, for lawsuits pending before the three-member first instance courts, by settling through an obligatory court settlement attempt which must take place no less than thirty five (35) days prior to the hearing. Out of court settlement is characterised as a typical civil contract where the parties need a) to conform to *bonos mores* or public policy/order in general, b) to be capable of entering into contracts and c) to be legitimately represented (in cases of companies by their legal representatives and in case of minors by their parents or the person who has the power to represent them). Special permission needs to be granted by the court in cases where a minor waives any claims by settling them.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Yes, they can initiate proceedings against the claimant for recovery but only in case the claimant received the amount of damages awarded or settlement by committing fraud against the State.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The loser-pays rule applies. Court expenses are "only the court and out-of-court expenses that were necessary for the trial" and in particular are a) stamp duties, b) judicial revenue stamp, c) counsels' minimum fees set by the Greek Lawyer's Code, d) witnesses' and experts' expenses and e) the successful party's travelling expenses in order for him to attend the hearing. However, the expenses that the successful party recovers are, as per the general practice, substantially lower than his actual expenses.

7.2 Is public funding e.g. legal aid, available?

Yes. Law 3226/2004 on the "Provision of Legal Aid to low income citizens" sets the relevant requirements.

7.3 If so, are there any restrictions on the availability of public funding?

Beneficiaries of legal aid are low income citizens of the European Union, as well as of a third state, provided that they reside legally within the European Union. Citizens of low income are those with annual familial income that does not exceed the two thirds (2/3) of the minimum annual income provided by the National General Collective Labour Agreement. Furthermore, legal aid may be granted under the condition that the case, subject to the discretion of the court, is not characterised as apparently unjust.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Legal aid in civil and commercial matters purports to an exemption from the payment of part or the total of the court's expenses and following the submission of a relevant petition by the beneficiary and the nomination of a lawyer, notary and judicial bailiff, in order to represent him before the court. The exemption includes stamp duties payment and judicial revenue stamp. Furthermore, the beneficiary is exempted from paying the remuneration of witnesses and experts and the lawyer's, notary's and judicial bailiff's fees.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

No it is not.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Greece.

As already mentioned, Law 2251/1994 on the "Consumers' Protection" was rather recently amended (by Law 3587/2007, in force since 10 July 2007). That latest amended was a significant one both generally to the various other topics the Consumers' Law regulates and especially to its product liability rules. Accordingly, it remains to be seen what the case law will be on newly introduced topics such as: a) the expansion of the defectiveness concept to not only include the standard *safety* consideration but now take into account the product's "expected performance per its specifications"; b) the subjection of the moral harm compensation to the ambit of the strict product liability rules (formerly covered under the general tort legislation); or c) the new rules on collective actions to the extent they will concern product liability infringements. The case law conclusions on the above "hot" topics are expected with great interest.

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BAHAS, GRAMATIDIS & PARTNERS

Bahas, Gramatidis & Partners traces its origins to the Law Office Marios Bahas in 1970. In 1988, the original firm merged with Law Office Yanos Gramatidis to form Bahas, Gramatidis & Associates with the participation of Dimitris Emvalomenos in 1990. Finally, in 2002, Bahas, Gramatidis & Associates merged with Law Office Athanassios Felonis & Associates and with Law Office Spyros Alexandris & Associates, to form Bahas, Gramatidis & Partners. At the core of the Firm's practice is the representation of corporations, financial institutions, investment banks, non-profit entities and individuals in complex financial and corporate transactions and litigation. Headquartered in the city of Athens the Firm has associated offices in 35 countries. Bahas, Gramatidis & Partners' corporate team advises companies and businesses on a daily basis on all aspects of carrying business in Greece from commercial regulatory matters to regulatory compliance. The Firm developed a unique expertise in product liability - safety recognised worldwide, including medical negligence and related issues. The Firm is a part of an established network of contacts promoting, among other topics, product liability and related issues such as the British Institute of International and Comparative Law / Tort Law Centre, European Justice Forum, the University of Oxford and DRI Europe. The Firm represents a good number of multinational companies being leaders in their own business areas in complex advisory work and litigation.

Hong Kong

Lovells

Allan Leung

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

For historical reasons, Hong Kong's legal system is based upon English law, with its laws (including those relating to product liability) based on the common law, rules of equity and local legislation (known as "Ordinances"). Similar to the position under English law, product liability can arise in contract, tort and/or breach of statutory duty. There is no strict liability regime in Hong Kong similar to that in the PRC.

Contractual Liability

A contractual relationship is formed between the buyer and immediate supplier upon the sale and purchase of a product. Liability is strict if the consumer can prove that the terms of the contract have been breached. The extent of the liability will depend upon the contractual terms, which can be express or implied.

Express terms may be written, or made orally, as is the case with most consumer sales, or they can be inferred from the conduct of the parties. Terms may be implied either by legislation, mainly the Sale of Goods Ordinance ("SOGO"), or if it is necessary to do so to give "business efficacy" to the contract or according to trade custom. Pursuant to the SOGO, there are implied contractual terms that goods sold in the course of business should have good title, be of merchantable quality, correspond to any description or sample, and be reasonably fit for their purpose.

Fault-based Tort Liability

A buyer may bring a tortious claim against the manufacturer or supplier for negligence where the conduct of the manufacturer or supplier falls below the standard of care expected at law. Liability is fault-based and is extended not only to the buyer but to those other end-users who come into contact with the purchased product. The manufacturer must take reasonable steps to ensure that the product is not defective. This includes taking reasonable steps to monitor safety issues at all stages of the production process, from the research and design to the manufacturing and the safety instructions on the labelling. The supplier (such as the distributor or the retailer) must take reasonable steps to ensure that the product is safe to be sold and that adequate instructions and warnings are given where necessary.

Statutory Duty

A manufacturer, retailer or supplier can be found criminally liable by committing offences relating to product safety and standards under various Ordinances. Many of these offences impose strict liability although defences may be available.

A claimant may have a cause of action under one or more of these heads.

1.2 Does the state operate any schemes of compensation for particular products?

No, the state does not operate any such schemes.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

The retailer, being the immediate supplier of the defective product, will in nearly all cases be the party liable to the buyer in contract. The retailer can also be liable in negligence if fault is established.

The manufacturer, importer and distributor will usually only be found liable to the buyer in negligence as it is unlikely that there will be a direct contractual relationship between the buyer and these parties.

Liability may be excluded or limited by an appropriately worded exclusion clause in the contract or by giving notice to persons to whom a duty of care is owed. However, the Control of Exemption Clauses Ordinance requires that any attempt by the manufacturer or supplier to limit their liability must be reasonable in order to be effective and there is an outright prohibition on any attempt to limit liability for negligence in so far as it causes death or personal injury. Furthermore, where the purchaser is a consumer, any contractual term attempting to restrict or exclude the implied terms under the SOGO as to title, fitness for purpose, conformity with sample or merchantability will be void.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Under the Consumer Goods Safety Ordinance and the Toys and Children's Products Safety Ordinance, the Commissioner of Customs and Excise may exercise his power to serve a recall notice requiring the immediate withdrawal of any consumer goods, toys or children's products which he believes to be unsafe and may cause serious injury. Certain goods such as pesticides, electrical products, food and water and tobacco products are specifically excluded from the definition of consumer goods under the Consumer Goods Safety Ordinance.

Recalls of electrical products and food are governed by the Electricity Ordinance and the Public Health and Municipal Services Ordinance respectively. The respective governmental departments may recall electrical products that do not meet prescribed safety requirements under the Electrical Products (Safety) Regulation and food that is considered to be unfit for human consumption.

Aside from mandatory recalls, the Government has issued guidelines for manufacturers who wish to carry out a voluntary recall of toys and children's products, consumer goods, electrical products, and food.

1.5 Do criminal sanctions apply to the supply of defective products?

Yes. Criminal sanctions range from fines to the imprisonment of company directors and managers.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The burden of proving fault/defect and damage lies with the claimant.

In a civil claim based on breach of contract, the claimant must prove on a "balance of probabilities" that the defendant breached the terms and conditions of the contract and that the claimant suffered damages as a result of those breaches.

Similarly, in a civil claim for negligence, the claimant must prove on "a balance of probabilities" that the defendant owed the claimant a duty of care and that the defendant breached that duty resulting in damages being sustained by the claimant. There may be cases where the claimant is unable to produce sufficient evidence of the negligence, for example, where the defective product has been consumed or has disintegrated or where the evidence no longer exists. In these situations, the claimant may rely on the doctrine of *res ipsa loquitur* (which means in Latin, the thing speaks for itself) to show that the defect or damage could only have been caused by negligence on the part of the defendant.

Criminal proceedings may only be instigated by public enforcement authorities and they have the burden of proving "beyond reasonable doubt" that the party being prosecuted is guilty of a criminal offence.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

First, the claimant must prove that "but for" the defendant's negligence, the claimant would not have sustained the loss or injury. Causation is a question of fact for the judge to determine. Second, the claimant must show that the loss or injury incurred is not, in law, too remote a consequence of the defendant's breach of duty.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Failure on the part of the claimant to prove which of several possible producers actually manufactured the defective product will result in the claim being dismissed. Although this may cause injustice to the claimant because often much of the evidence required is within the knowledge of the defendant, at present there is no recognised concept of "market-share" liability in Hong Kong.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

For manufacturers and suppliers, a failure to warn may give rise to liability in negligence as they owe a duty to take reasonable care to provide adequate warnings and instructions. It will depend on the circumstances of each case whether the warning given was adequate to discharge the duty imposed. Some of the more important factors that will be taken into account are the likelihood and gravity of the potential danger to the consumer; the extent of the information made available to any intermediaries and the consumer and the practicality of providing the information to the consumer. The principle of "learned intermediary" does exist under Hong Kong law.

A failure to warn may also give rise to criminal liability under statute. For instance, under the Consumer Goods Safety Ordinance, the relevant statutory body can require the publication of warnings about goods where the Commissioner reasonably believes that those goods are unsafe. These warnings must also be given in both English and Chinese. Failure to comply amounts to an offence. The Smoking (Public Health) Ordinance provides that all tobacco products sold to the general public must contain a health warning in the prescribed manner otherwise an offence is committed.

3 Defences and Estoppel

3.1 What defences, if any, are available?

In addition to the defences that are available under the usual principles of contract and tort law, the manufacturer or supplier may also be able to avoid liability if they can show that: (1) the claimant had knowledge of the defect, fully appreciated its risk and voluntarily assumed such risk (the *volenti non fit injuria* defence); or (2) the injury was attributed to the rare allergy or abnormal sensitivity of the claimant which the manufacturer could not reasonably have foreseen.

The defendant may also be able to reduce its liability if it can show that the acts of the claimant contributed to the damage, for example, if the claimant ignored the warnings or did not follow the instructions when using the product.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Yes. In a negligence claim, the issue of whether the defendant exercised reasonable care in relation to the manufacturing, distribution or supply of the product will be determined in the light of the state of scientific and technical knowledge at that point in time. It is for the manufacturer to show that it took all the precautions that a reasonable manufacturer would have taken at the time of supply.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

No, it is not a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

"Issue estoppel" should not prevent a different claimant from bringing a claim in separate proceedings based on the same defective product. However, the prior findings of a claim based on similar facts are likely to be of some persuasive value and may well lead to settlement without the need for court proceedings.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

Yes. Under section 3 of the Civil Liability (Contribution) Ordinance, the defendant can seek a contribution from another party in respect of any damages he is held liable to pay to the claimant. That party can be joined as a Third Party to the same proceedings to save time and costs or the defendant can elect to sue the party in separate proceedings. A claim for a contribution from a third party must be brought within two years from the date on which that right accrued.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Yes. Such an allegation does not amount to a defence but, if successful, will result in the damages awarded to the claimant being reduced.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

The trial is by a judge.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The court rules provide that the court may obtain the assistance of any person specially qualified to advise if the court thinks it expedient to do so. However, in practice, the court does not nominally invoke this power.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

There is no equivalent to the US class action procedure. All claims remain individual actions in their own right, although the parties may apply to have similar actions consolidated or heard together.

To avoid duplication of effort and costs, one consumer may bring a representative action on behalf of a group of consumers where those parties have the same interest in the proceedings. However, this provision has its limitations and is only helpful in the context of a relatively small number of parties. It is inadequate as a framework for dealing with large-scale multi-party situations.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

No, claims cannot be brought by a representative body on behalf of a number of claimants.

4.5 How long does it normally take to get to trial?

It normally takes two to three years for a matter to get to trial.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Yes, both in relation to matters of law and issues of fact, although the former are more common.

4.7 What appeal options are available?

An appeal against the decision of the trial judge is available as of right to the Court of Appeal. An appeal against a decision of the Court of Appeal is made with leave to the Court of Final Appeal, Hong Kong's highest appellate court.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Expert evidence is normally adduced by the parties themselves. Experts can only give evidence on matters of opinion falling within their expertise and they owe an overriding duty to the court regardless of who is paying them. In all personal injury cases, the claimant must serve a medical report with his Statement of Claim substantiating the injuries alleged in the claim. The court will usually limit the number of experts that each party is allowed to call at the trial.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

Pre-trial depositions do not exist in Hong Kong.

Witness statements and expert reports are exchanged prior to trial. The factual witnesses and experts will then give their oral evidence and be cross-examined during the trial.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

In personal injury cases, it is possible to apply for the discovery of documents from a likely party before proceedings are commenced or from a non-party before trial to encourage settlement negotiations between the parties concerned as soon as possible.

However, in other cases, discovery is usually only available once proceedings have commenced. Following the pleadings stage, the parties are obliged to disclose to each other the documents they have in their control relating to the issues in dispute. This discovery obligation extends to the discovery of documents that are both helpful and damaging to one's case. The obligation continues up until trial.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Arbitration is available as a method of dispute resolution provided that the parties agree by entering into an arbitration agreement to refer the dispute in question to arbitration.

The parties can also agree to the mediation of their dispute at any time before or during court or arbitration proceedings.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, time limits do exist.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

The Limitation Ordinance provides that claims based on breach of contract or negligence must be brought within six years from when the cause of action arose. However, claims for damages for personal injury in an action for negligence, nuisance or breach of duty must be brought within three years from the cause of action, i.e. the date of injury or death or, if later, the date of the claimant's knowledge. In personal injury actions, the court may direct that the time limits should not apply to the action where it would be equitable to do so having regard to the degree of prejudice which would be suffered by the claimant and the defendant.

The time limits may be extended where the claimant is under a disability, i.e. is not of sound mind or is an infant.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

The time limits for limitation purposes do not start to run until the claimant has or could have with reasonable diligence discovered the concealment or fraud.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

Monetary compensation, injunctive relief and declaratory relief are all available remedies.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Damages for breach of contract are awarded to put the injured party in the same position he would have been if the contract had been properly performed. They include physical damage caused to person or property; economic loss and consequential loss; and loss which the court might reasonably expect to have been contemplated by both parties in "special circumstances" where such circumstances were known to the parties at the time the contract was formed.

Damages for negligence are awarded to put the injured party in the same position he would have been if the negligent act had not occurred. They include loss arising from personal injury (including mental injury), death or damage to property other than the product itself. Damages in tort for pure economic loss are difficult to recover unless specifically provided for by statute (such as the Fatal Accidents Ordinance), or if the claim is for negligent misstatement or where a "special relationship" exists. The latter is very restricted.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Future economic loss may be recoverable if the claimant can show that the future expense is reasonable and there is a reasonable likelihood that the expense will be incurred. In relation to the costs of medical monitoring, the court may find that they are too remote and refuse to make such an award.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Yes, but only in very extreme cases where the court considers that the defendant's actions were particularly reprehensible and the award of punitive damages is necessary to deter him and others from committing similar acts in the future.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

No, there is no maximum limit on the damages recoverable.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

Court approval is required for the settlement of claims by infants or mentally incapacitated persons and a special procedure applies for approval to be obtained. Otherwise, there are no special rules applying to the settlement of claims in general and a party is free to settle a dispute without the approval of the court.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

No. There is no legal provision by which Government authorities concerned with health and social security matters can make such a claim.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Yes. The court will usually order the losing party to pay the costs (including court fees and legal costs) of the successful party.

7.2 Is public funding e.g. legal aid, available?

Yes, public funding is available.

7.3 If so, are there any restrictions on the availability of public funding?

Legal aid will be granted if the applicant is able to satisfy the statutory criteria as to the financial eligibility and the merits for bringing the legal proceedings.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

No, such funding is not allowed.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Third party funding of claims is, in principle, not allowed for reasons of public policy. This prohibition has relaxed over time to allow the notion of common interest to enable the funding of claims by third parties, for example, in circumstances where legal aid is available, where trade unions use the support of their union or policyholders are indemnified by their insurer.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Hong Kong.

The Law Reform Commission of Hong Kong issued a "Report on Civil Liability for Unsafe Products" in December 1997 to consider the reform of the existing law governing compensation for personal injury and damage to property caused by defective or unsafe goods. The Report recommended giving consumers the right to hold manufacturers, producers, own-branders, importers, wholesalers, distributors and retailers jointly and severally liable for defective or unsafe products. The Report also recommended that consumers should have the right to recover losses arising out of damage to the defective product itself. There is however currently no legislative action to implement such recommendations.

The Law Reform Commission also established a sub-committee in November 2006 to consider whether a scheme for class actions should be introduced in Hong Kong. Publication of the report of the sub-committee is awaited.

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In addition to product liability, Allan deals with a broad range of commercial dispute work, including corporate commercial, judicial review, contentious insolvency, fraud and asset recovery, regulatory, defamation, professional indemnity and other insurance related matters. He also advises parties involved in PRC-related disputes.

He is widely recognised as an outstanding litigator and is named in a number of legal directories, including Asia Pacific Legal 500, the Who's Who in the Law - Hong Kong and China, International Who's Who of Commercial Litigators, PLC Which Lawyer?, Asialaw & Practice, Chambers Asia and Chambers Global. He is also listed as a leading lawyer in IFLR 1000 in insolvency and restructuring practice.

Hungary

Oppenheim

Ivan Bartal

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

All of the above types of liability (i.e. fault based, strict and contractual) exist in the Hungarian legal regime. Act IV of 1959 on the Civil Code (***Hungarian Civil Code***) governs fault based and contractual liability and Act X of 1993 on Product Liability (***Product Liability Act***) provides for strict liability.

Strict Liability

Pursuant to the Product Liability Act, Directive 85/374 EEC has been implemented. The Product Liability Act expressly provides that the producer shall be liable for the damage caused by the defect of its product (Section 3).

Fault Based Liability

Product liability claims can also be enforced by relying on the non-contractual liability provisions of the Hungarian Civil Code. It should be noted that the Product Liability Act expressly authorises the aggrieved party to enforce its claims by utilising the provisions of the Civil Code on contractual and non-contractual liability.

Contractual Liability

As the case of fault based liability, provisions of the Hungarian Civil Code concerning contractual liability can also be applied to product liability claims. It amounts to the breach of contract when a contractual relationship exists between the parties and one of them delivers a dangerous or defective product, hence claims of warranty can be made against the party in breach. There is a four-step system in Hungarian law regarding warranty claims. First the aggrieved party can ask for the repair of the product or its replacement. In case repair or replacement is not possible or the party in breach did not fulfil the claim, the aggrieved party can request a price reduction or it can rescind (terminate with retroactive effect) the contract.

It is important to emphasise that the provisions of the Hungarian Civil Code apply as supplementary rules in questions not determined by the Product Liability Act.

1.2 Does the state operate any schemes of compensation for particular products?

There used to be a compensation system for damage caused by pharmaceutical products, which was terminated and liability for damage caused by such products now falls within the scope of the Product Liability Act. The State shall, however, compensate damage caused by pharmaceutical products used in order to prevent the spreading of pathogenicities, toxins, nuclear radiation and chemical materials under the permission of the competent state agency (Section 21 (4) of Act XCV of 2005).

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

According to the Product Liability Act, the producer (manufacturer) is liable for the damage caused by the product. The Product Liability Act defines the producer as:

- the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part; and/or
- any person who, by putting his name, trademark or other distinguishing feature on the product presents himself as its producer.

In the case of imported products, the same obligations apply to the importer. This does not affect the right of the importer to enforce its claims against the producer. The Product Liability Act defines the importer as:

- a foreign trader; or
- in case of a foreign trade consignment contract: the consignor.

If the manufacturer of a product cannot be identified, all distributors of such product are regarded as manufacturers until such distributors reveal to the injured party the name of the manufacturer or the distributor from whom the product was obtained. The same shall also apply to imported products where the manufacturer is indicated but the importer cannot be identified.

The liability of the above mentioned persons is joint and several.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

There is no general regulation on the duty to recall products. However, special regulations may provide for an obligation to maintain a product recall system (such as Section 22 paragraph (1) b) of Act XLVI of 2008 on Chains of Food Product Traders) but there has not been any general product recall regulation implemented yet. Normally, if the recall of a product is required, the competent authority will issue a resolution to this effect.

1.5 Do criminal sanctions apply to the supply of defective products?

Act IV of 1978 on the Criminal Code (***Hungarian Criminal Code***) contains a provision entitled "Placement into circulation of bad quality products" which prohibits the marketing, placement into circulation and transmission of products for use as "good quality products" where such products do not possess the mandatory attributes specified by national standards or products that cannot be used for their intended purpose. If wilfully committed, the above criminal act is punishable with up to three years of imprisonment; if committed negligently with up to one year of imprisonment. (Section 292 of the Hungarian Criminal Code.)

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

Under Strict Liability

The burden of proof rests with the aggrieved party regarding the damage caused, the defect and that the defect caused the damage. The producer has to prove the exonerating factors.

Under Fault Based Liability

Similarly, in cases of fault based liability, the aggrieved party bears the burden to prove the damage and its value, and that the unlawful conduct of the tortfeasor caused the damage. The tortfeasor carries the burden to prove the exonerating factors.

Under Contractual Liability

The aggrieved party has to provide proof of the breach of contractual obligations. In the case of contracts qualifying as consumer contracts, the consumer has to prove that the goods were not in conformity with the contract.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The Hungarian law on non-contractual liability is a flexible system in which the court weighs different elements in each individual case. Causation and fault as preconditions of liability are flexible concepts, open for judicial interpretation. The increase of risk itself by the defendant does not necessarily establish causation but due to the open character of this system, in cases where the link between the increased risk and the damage is obvious the court may establish that the defendant caused the damage.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

The liability of producers is joint and several, meaning that the aggrieved party can claim full compensation from any or all of them. The liability is shared between the producers by the degree to which each of them contributed to the damage. This is only relevant in how they settle claims amongst themselves. Any of the producers who are liable may be entitled to make a cross claim against the other producers for their contribution. There is no such institution as market share liability in Hungary.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

If there is a statutory or implied obligation to warn others to special attributes of the product or a specific risk that goes with the product, the failure to warn may establish liability. In such a case, failure to warn would establish the causational link and would also be taken into account in considering the liability of the defendant. The question whether only the information provided directly to the injured party, or also information supplied to an intermediary would be taken into account depends on the circumstances of the individual case. If the required standard of conduct under the given circumstances extends only to providing information to the intermediary (e.g. because it is not possible to provide the information directly to the consumer), informing the intermediary may be taken into account as a factor limiting the liability of the producer. In this sense, it may be relevant that the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, although this would not necessarily exempt the producer from liability. The principle of "learned intermediary" has not been generally accepted under Hungarian law theory and practice.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The producer can escape liability by providing proof that:

- it did not place the product on the market;
- the product was not produced for retail purposes, or was not produced or distributed within the framework of regular business activities;
- the product was in perfect condition at the time when it was placed on the market, and the cause of the defect developed subsequently;
- at the time the product was placed on the market the defect could not have been discovered according to the current state of scientific and technological achievements; or
- the defect in the product was caused by the application of a legal regulation or a regulatory provision prescribed by the authorities.

The producer of raw materials or a component shall be exempt from liability upon providing proof that:

- the defect was caused by the structure or composition of the final product; or
- the defect was a consequence of instructions given by the producer of the final product.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

According to the Product Liability Act, the producer can escape liability if, at the time the product was placed on the market, the defect could not have been discovered according to the current state of scientific and technological developments. The general rules of *onus probandi* apply, i.e. the producer has to prove that the defect was not discoverable.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

The Product Liability Act provides that it is an exonerating factor if the producer proves that the dangerous feature of the product is the result of compliance with certain mandatory provisions of law.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

The rules of Act III of 1952 on Civil Procedure (Civil Procedure Act) provide for the principle of *res judicata* so that if a judgment is enforceable, it cannot be contested by the same parties unless there has been procedural irregularities during the trial or a new relevant fact arises which was unknown to the parties. This rule does not prevent other injured parties from litigating in respect of the same defect.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

In accordance with the Product Liability Act, the producer shall not be exempt from liability towards the injured party if the damage incurred was in part due to a reason attributable to a third party. This does not affect the legitimate claims of the manufacturer against a third party. The producer can claim contribution towards any damages payable under the general rules of statutory limitations, which is five years.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

The producer is not liable for compensation for the part of the damage which was caused by any conduct attributable to the injured party. It is also important to note that the injured party bears responsibility for the activity or negligence of all parties whose conduct falls under his responsibility. Therefore, if damages are awarded to the claimant they are reduced by the amount the court considers to be the counter value of the share of contribution of the claimant for the damages.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

The institution of a jury does not exist in Hungary; therefore the trial is always by a judge. Trials of first instance are by a single judge. During appeals the trial is before a panel of three judges. The Supreme Court sits in panels of three judges during revision proceedings but if it is necessary due to the complexity of the matter, the Supreme Court can order that the case should be heard by a panel of five judges.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The court has no such powers. In case certain expertise is needed for the consideration of certain matters or issues, the court can request experts or technical specialists to present their opinion and such opinions will bear the same value as any other evidence.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

Class action does not exist in the Hungarian legal regime. However, in case the defected product caused damage to more than one person they can file a joint claim together against the producer.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Yes. Under Section 39 of Act CLV of 1997 on Consumer Protection (the ***Consumer Protection Act***) the consumer protection authority, non-governmental organisations for the protection of consumers' interests or the public prosecutor may file charges against any party causing substantial harm to a wide range of consumers by illegal activities. This possibility is open only within one year of the occurrence of the infringement.

4.5 How long does it normally take to get to trial?

According to the Civil Procedure Act, the date of the first hearing shall be scheduled to a date no later than four months after the receipt of the statement of claim by the competent court, unless the act determines another date. Should the latter be the case, the hearing cannot be scheduled to a date later than nine months following the receipt of the claim. In case the amount of the dispute is not higher than HUF 1 million, the rules of low amount matters and order for payment shall apply according to which the first hearing shall be scheduled to a date no later than 45 days after the competent court has received the statement of opposition sent by the defendant in connection with an order for payment. (Section 388 (2) of Civil Procedure Act.)

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Hungarian law provides for the possibility of intermediary

judgments. Once the court has rendered such a judgment on the legal grounds of the claim, a judgment on the actual amount of damages can only be made after the intermediary judgment has become enforceable and effective.

4.7 What appeal options are available?

According to the Civil Procedure Act, one ordinary remedy and two types of extraordinary remedies are available against a judgment.

Appeals can be made against the judgment of a court of first instance by the parties to the dispute.

The **revision** of an enforceable judgment can be requested from the Supreme Court by the parties if any provision of law had been breached by the decision or by the procedure.

Finally, as an extraordinary remedy, a request to **reopen the case** can be made against an enforceable judgment, if:

- the requesting party makes reference to a fact, an evidence, enforceable court decision or enforceable decision of another authority, which was not subject to consideration by the court;
- the requesting party lost the case due to a criminal act committed by a judge participating in the decision of the case or a criminal act of the other party or a third party;
- there has been an enforceable judgment regarding the same claim;
- the statement of claim or another document was delivered to a party by way of public announcement but with the violation of the relevant rules; or
- the Supreme Court makes a decision allowing the reopening of a case after the Hungarian Constitutional Court has found a law violating the Constitution of Hungary and a constitutional claim is lodged to this effect.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

In case certain expertise is needed for the consideration of certain matters or issues, the parties may request that the court request experts or technical specialists to present their opinion and such opinions will bear the same value as any other evidence. The parties to the dispute are also free to use "private experts" to testify on their behalf but the statements of those experts will be regarded as statements of the party and not as evidence.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

Pursuant to the provisions of the Civil Procedure Act, there are no pre-trial depositions. Witnesses are heard during the trial. It is not common to file any witness statements prior to trial.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

There is no obligation to disclose such evidence due to the fact that the Hungarian procedural rules do not foresee the concept of deposition or disclosure of documentary evidence before trial.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

According to Section 18 of the Act on Consumer Protection consumers may turn to arbitration boards organised by the Territorial Chamber of Commerce. These arbitration boards are established to attempt to reach an agreement between a consumer and a producer or distributor and settle the dispute out of court proceedings.

The competence of the arbitration boards include the out-of-court settlement of disputes arising out of the application of product liability regulations. Consumers may file the petition with the arbitration board having jurisdiction over the location where the consumer has a permanent or temporary residence. If the consumer has no permanent residence in Hungary, jurisdiction is determined on the basis of habitual residence.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, time limits do apply.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

Under Strict Liability:

Pursuant to the Product Liability Act, damage claims may be enforced within a three-year period (statute of limitation). The term of limitation commences when the injured party learns of, or, with due attention, could have learned of the damage, the defect in the product, or the cause of the defect, as well as of the identity of the producer/manufacturer or the importer.

However, producers/manufacturers shall remain subject to the liability defined in the Product Liability Act for a period of ten years effective from the date of placing the given product on the market, unless the injured party has filed for legal action against the manufacturer in the meantime.

Under Contractual and Fault Based Liability:

The period of limitation for warranty claims arising from breach of contract is six months and two years regarding consumer sales contracts. After the lapse of this period, claims can be enforced by objection or by claiming damages for the breach of contract for up to five years.

The period of limitation for claims arising from non-contractual liability is five years, unless otherwise prescribed by law.

Parties are entitled to agree on a shorter period of limitation, but the agreement is valid only in writing. If the period of limitation is shorter than one year, the parties are entitled to extend it to a maximum of one year in writing; otherwise, an agreement on the extension of a period of limitation is null and void.

The period of limitation commences upon the due date of the claim. If the claimant is unable to enforce a claim for an excusable reason, the claim remains enforceable within one year from the time when the said reason is eliminated or, in respect of a period of limitation of one year or less, within three months, even if the period of limitation has already lapsed or there is less than one year or less than three months, respectively, remaining therein.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Such issues do affect the running of the time limit as the term of limitation commences when the injured party learns of, or, with due attention, could have learned of the damage, the defect in the product, or the cause of the defect, as well as of the identity of the producer/manufacturer or the importer.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

According to Section 355 of the Hungarian Civil Code the aggrieved party may claim "*in integrum restitutio*" or if it is not possible, monetary compensation shall be provided to the aggrieved party for material and non-material damages. In the course of a civil procedure for damages injunctive or declaratory relief may not be claimed.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

The Product Liability Act defines the notion of damage as:

- any pecuniary or non-pecuniary damage incurred by the death, bodily injury or any impairment in the health of a person; and
- any damage caused by a defective product to other objects valued in excess of five hundred Euros as converted to Forints by the official exchange rate quoted by the National Bank of Hungary for the day on which the damage occurs if such object is for private use or private consumption according to its intended purpose and if generally used for such purpose by its owner.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

It can be inferred from the text of the Product Liability Act that only damages that have already occurred can be claimed.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Hungarian law does not recognise the notion of punitive damages.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

No such maximum limit applies.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

No special rules apply.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Costs incurred by health or social security authorities in connection with an alleged injury may not be reimbursed. When the court determines the amount of damages payable to the aggrieved party it also takes into consideration the social security benefits paid, therefore the compensation paid to the aggrieved party is already reduced by social security benefits.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The successful party can recover all reasonable costs incurred during the proceedings such as legal fees and duties paid. Usually the court orders five percent of the overall value of the claim to be paid as the fees of the legal representative in accordance with a law decree issued by the Ministry of Justice.

7.2 Is public funding e.g. legal aid, available?

Under the Act on Legal Aid (Act LXXX of 2003) persons of social need are eligible for legal aid from the Ministry of Justice. Since January 2008, legal aid rules have included trial representation in civil matters such as issues of product liability.

7.3 If so, are there any restrictions on the availability of public funding?

We refer to the answer given to question 7.2.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

We refer to the answer given to question 7.2.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Third party funding is not an accepted institution in Hungary.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Hungary.

The Act on product liability was last amended in 2005. According to this amendment, in case of damage caused by a medicine the producer cannot be exempted from liability stating that at the time when the medicine was placed on the market the deficiency of the medicine that caused the trouble could not have been discovered according to the current state of technological or scientific

achievements, provided that the medicine was used according to the instructions.

Pursuant to a landmark decision published under BH2008.1781, the state may only be held liable for damages caused to personal health by the use of medicines, if the manufacturer is exempted from product liability on the basis that the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the existence of the defect to be discovered.

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The Budapest office of the international law firm Freshfields Bruckhaus Deringer re-established itself as an independent law firm under the brand name 'Oppenheim' in 2007.

Oppenheim currently consists of 41 lawyers who provide advice in all areas of Hungarian business law including general corporate affairs, mergers and acquisitions, banking & finance, competition & antitrust law, real estate law, public procurement law, environmental, planning and regulatory law, IP/IT including data protection, e-commerce, telecommunications and outsourcing, life sciences and has a renowned contentious practice with experience in matters before national and international courts. Oppenheim attorneys provide their legal expertise through a combination of specialised practice groups and sector experience.

Practical Law Company, a leading provider of business know-how for lawyers, ranked Oppenheim as the top choice among independent Hungarian law firms and ranked sixth among all law firms having a presence in Hungary, including international law firms both in 2008 and 2009.

Israel

Norman Menachem Feder

Gad Ticho

Caspi & Co.

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

The Torts Ordinance [New Version] (the "**Torts Ordinance**") is the basis for product liability claims based on negligence or breach of statutory duty. With regard to negligence, a defendant may be held liable if the claimant demonstrates that the defendant had a duty of care toward the claimant, the defendant breached this duty of care and, as a result of the breach, the claimant incurred damage. Generally, a party is considered to owe a duty of care to another if that other may foreseeably be damaged by such party's negligence. With regard to breach of statutory duty, the defendant may be held liable if the claimant shows that the defendant breached a statutory (or sometimes regulatory) duty, the breached duty was designed to protect the type of claimant, as a result of the breach the claimant incurred damage and the damage was of the sort against which the statute was designed to protect.

The Contract Law (General Part), 1973 (the "**Contract Law**") is the basis for product liability claims based on breach of contract. A seller of a defective product has contractual obligations to the buyer, such as an obligation not to deceive and an implied obligation to perform in a customary manner and in good faith, and a breach of these obligations can allow the injured party certain contract law remedies.

The Sale Law, 1968 (the "**Sale Law**") too is a basis for product liability claims. Under this law, warranties, such as satisfactory quality, fitness for intended use and description compliance are generally implied in a transaction between a seller and buyer of goods and the seller breaches its obligations to the buyer if the goods do not conform to the agreement between the parties.

Finally, certain consumer protection laws can also form the basis of product liability claims. The Consumer Protection Law, 1981 (the "*Consumer Protection Law*") prohibits customer deception and allows a breach of an essential duty thereunder to be treated as a tort under the Torts Ordinance. Additionally, the Defective Products Liability Law, 1980 (the "**Defective Products Law**") imposes strict liability on a manufacturer that manufactures a defective product which causes personal injury to the product user.

1.2 Does the state operate any schemes of compensation for particular products?

Under the Insurance for Injured by Vaccination Law, 1989, the State compensates persons disabled as a result of certain vaccinations.

Generally, a no-fault insurance scheme applies in motorised vehicle accidents.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

For liability under the Torts Ordinance, case law establishes that any of a manufacturer, distributor and retailer of a product owes a separate duty of care towards the end user, meaning each is responsible for its own acts or omissions. For liability under the Contracts Law, however, it is not yet settled whether privity between the claimant and the defendant is a necessary element of a successful product liability claim.

The Sale Law addresses only the relation between a buyer and a seller of goods.

The Consumer Protection Law applies to the manufacturer of a product, as well as to its seller. For example, the statute obligates either entity not to mislead a consumer regarding the nature of the relevant product and to disclose to the consumer defects that significantly diminish the product's worth.

Under the Defective Products Law, it is the manufacturer that bears the liability for a defective product. However, this law defines a manufacturer widely. For example, a person representing itself as a manufacturer by providing its name or trademark, an importer that imports to Israel, for commercial purposes, products manufactured outside of Israel or a supplier of a product, the manufacturer or importer of which cannot be *prima facie* identified, is considered a manufacturer under the Defective Products Law. In the event that a product with a defective component causes bodily injury, the Defective Products Law provides that both the manufacturer of the product and the manufacturer of the component can be liable.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Claims for a failure to recall could presumably be brought as a tort or breach of contract claim. Moreover, the Defective Products Law arguably implies a duty to recall unsafe products, as it imposes strict liability for a defective product that causes personal injury.

Additionally, certain regulatory procedures for recall can apply to commercial actors. For example, the Procedure of Recall and/or Prohibition on the Use of Medical Devices promulgated by the Pharmaceutical Administration of the Ministry of Health requires certain recalls by a drug manufacturer, owner of a drug registration or drug importer under certain circumstances. Similarly, the Control on Commodities and Services (vehicle import and vehicle maintenance) Order, 1978, requires importer recalls in certain discovered defects in imported vehicles.

1.5 Do criminal sanctions apply to the supply of defective products?

As a general matter, Israel's Penal Law, 1977 (the "**Penal Law**") criminalises various types of improper behaviour that may apply in a product liability setting, such as negligent manslaughter. Additionally, breach of the Consumer Protection Law can found a criminal action under certain circumstances.

Section 219 of the Penal Law specifically criminalises, under certain circumstances, the sale of, or intent to sell, spoiled or tainted foods or drinks.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

Generally, in civil matters, including product liability claims, the burden of proof falls on the claimant. The Torts Ordinance, however, shifts this burden from claimant to defendant in several situations. One of these is when the claimant alleges that a dangerous object of the defendant caused the damage. When the burden of proof is shifted, the defendant will need to show absence of negligence to avoid liability.

If the defendant destroys documents or fails to document certain matters required by law, and as a result, impairs the claimant's ability to prove its claim, the court can apply the evidential damage doctrine. Generally, when a court applies this doctrine, it shifts the burden of proof for the cause of action to which the destroyed evidence relates from the claimant to the defendant.

Additionally, the Defective Products Law provides for strict liability in the event a defective product causes certain personal injury to the defendant.

When asserting statutory defences, the defendant has the burden of proving those defences.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

Generally, the test applied for proof of causation by claimant in tort law is "*conditio sine qua non*", meaning literally, condition without which it could not. This means direct causation and, if the damage would not have been caused but for the claimant's act or omission, causation will not have been shown. To show causation, the claimant will need to show at least that on the balance of probabilities the damage would not have been caused absent the act or omission of the defendant. Foreseeability of the damage must also be shown to establish fault.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Under the Torts Ordinance, joint tortfeasors are jointly and severally liable to the claimant. The principles of allocation of responsibility between joint tortfeasors are not well established and, accordingly, courts have wide discretion in this area.

To date, Israeli courts have not adopted a concept of "market-share" liability, whereby liability is apportioned to a given defendant according to its share of the market.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

In tort, manufacturers and suppliers who fail to provide adequate warnings and instructions with their products may be negligent or be in breach of a statutory duty. Case law teaches that a manufacturer may be required to warn consumers of the danger of the manufacturer's product and the manufacturer may be negligent if it does not so warn.

Precedent establishes manufacturer liability for failure to provide sufficient instructions for maintenance or use of a product under certain circumstances. Furthermore, the duty to warn runs not only toward the consumer but also toward any person that can be expected to use the product. When the product has a label with instructions or warnings and the user did not abide by the instructions and, as a result, was damaged, the manufacturer will generally have a good defence.

Failure to warn can also give rise to liability under a breach of contract claim.

Under the Defective Products Liability Law, a defective product that can create strict liability includes a product that requires warning or maintenance and use instructions and such warning or instructions are not or are inappropriately given.

In Israel, the learned intermediary doctrine, by which warnings provided by a drug manufacturer to prescribing physicians discharge the manufacturer's duty of care in negligence, is not an explicit exception to the duty to warn in negligence actions.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under the Torts Law, the defendant may argue that the claimant has failed to establish a required element of the claim. Additionally, Israel is a pure comparative negligence jurisdiction, allowing the claimant who is contributorily negligent to recover in the event of the defendant's negligence, but the damages award will reflect a

proportionate reduction from the claimant's losses equal to the claimant's proportionate negligence.

Also, assumption of the risk by the claimant is available as a defence. To show this, the defendant will need to establish that the claimant freely and voluntarily agreed to run the risk of damage in full knowledge of the nature and extent of the risk. This defence defeats liability completely.

In contract, the defendant will not be liable if the claimant fails to establish a contract, a breach of contract or damage due to a breach of contract. The claimant does have a duty to mitigate damage post-breach. Additionally, the Supreme Court has recognised the possibility of using the doctrine of contributory fault as a defence in a contractual action.

Under the Consumer Protection Law, a defendant can defeat civil liability if it shows no causal connection between the defendant's act or omission and the damage the claimant sustained and can defeat criminal liability if it shows that it did not know and should not have known that the sale or the service breached the law.

Under the Defective Product Law, the manufacturer's defences are limited to the following: (i) the defect that caused the damage occurred after the product was released from the manufacturer's control. If the manufacturer shows that the product in question was reasonably checked for safety before it left his control, the presumption will be that the defect incurred thereafter. Courts require, however, that the specific product have been checked - sample checks will not relieve liability; (ii) under the state of the art at the time when the product left the manufacturer's control, the manufacturer could not have known that the product was unsafe; (iii) the product departed the manufacturer's control unintentionally and the manufacturer used reasonable means to prevent he departure and to caution the public about the danger in the product; and (iv) the claimant knew about the defect in the product and the risk inherent to it and willingly exposed himself to the risk.

It is not yet settled whether the defences of contributory negligence and assumption of the risk can be employed under the Consumer Protection Law.

Period of limitations defences are available. See Section 5.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Generally, in negligence, the defendant's acts or omissions in design, development, manufacture, supply and marketing the product, will be judged under a reasonableness standard. This essentially makes the state of art at the time a relevant defence.

In breach of contract, state of the art is not pertinent except where, for example, the contracts provides for a certain standard of behavior, such as "good faith effort".

As noted in question 3.1, the Defective Products Law specifically provides for a state of the art defence. Under this statutory defence, the defendant's conduct is essentially irrelevant as the defendant will not be held liable if there was no technology at the time to identify the defect.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

In negligence, the tortfeasor is not automatically absolved of liability if it shows it complied with laws or regulations applying a standard. Nevertheless, a regulatory standard is often used by defendants as evidence that they met a reasonable standard of care.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Litigants are estopped from litigating again certain matters that have already been resolved by final judgment or order.

Generally, this type of estoppel comprises two forms: (i) cause of action estoppel, which prevents a litigant from relitigating a cause of action that has already been decided between essentially the same parties; and (ii) issue (or collateral) estoppel, which prevents a litigant from relitigating an issue of fact that has already been resolved between essentially the same parties.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

The Civil Procedure Regulations, 1984 (the "**Civil Procedure Regulations**") allow for impleader of a third party where: (i) the defendant seeks participation or indemnification from the third party regarding a prospective award or remedy; (ii) the defendant claims that it is entitled to a remedy that is connected to the subject of the claim and the remedy is, in principle, the same remedy sought by the plaintiff; or (iii) the dispute between the defendant and third party connected to the claimant's claim is, in principle, the same as the dispute between the claimant and the defendant as well and it is appropriate that the disputes be resolved together.

An impleader action must be filed within the time limits imposed on the submission of the statement of defence.

Subsequent proceedings against third parties can be brought (subject to the applicable periods of limitations).

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

A defendant may allege contributory negligence and assumption of the risk in a tort action and contributory fault and failure to mitigate damages in a contract action. See question 3.1.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

The trial is by a single judge. Jury trials are not available in Israel.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

A court cannot delegate its power to judge a trial and assess the evidence, but it can appoint experts. See question 4.8.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

The recently enacted Class Actions Law, 2006 ("**Class Actions Law**"), replaced specific provisions that appeared in various individual Israeli laws, and today, the only way for a claimant to file a class action is pursuant to the Class Actions Law.

Under the Class Actions Law, , the claimant must establish that (i) there is a reasonable possibility that substantial questions of fact and law that are common to the represented class will be adjudicated in favour of the class; (ii) a class action is the most efficient and fairest way to decide the dispute due to the facts involved; (iii) there exist reasonable grounds to assume that the interests of the class members will be represented and handled in good faith, i.e. the representative claimant has no conflict of interest, or is not concealing facts from the court; and (iv) there exist reasonable grounds to assume that the interests of the class members will be represented and handled in an appropriate manner, i.e., the representative claimant is a typical class member with regard to whom the facts and circumstances are similar to the rest of the group. Notwithstanding the foregoing, the court may certify a class action even if the aforementioned conditions (iii) and (iv) are not met, if it believes such conditions can be met in another manner, such as by adding a representative claimant (a claimant authorised by the court to represent a class action). Additionally, class actions cannot be filed with regard to every issue, but rather only with regard to a closed-list of issues that are addressed by various laws, including the Consumer Protection Law, 1981.

A court's certification of a class action must contain a definition of the class. Generally, at this point all the defined class is bound by the claim, unless a putative member specifically opts out by notifying the court. In certain circumstances, a court may certify a class action in the model of 'opt-in', meaning the claim will bind only those who ask to be part of the class.

Class actions are fairly common and more than a few involving product liability have been brought.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Only the following parties are allowed to file a motion to approve a class action: (i) a person who has a cause of action in the matter at hand; (ii) a public agency, regarding a matter that is within the agency's scope of public aims in which it engages; and (iii) an organisation, regarding a matter that is within the organisation's scope of public aims in which it engages, provided that the court is convinced that it would be difficult for a person to bring the claim.

4.5 How long does it normally take to get to trial?

It is hard to estimate without specific circumstances of a case. Moreover, it varies among the type of courts (Magistrate Court -- generally limited to claims of up to NIS 2.5 million -- or District Courts) and the court locales. Generally, it can be expected to take at least one year from the date of filing the action until the start of trial.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Under the Civil Procedure Regulations, a court may strike a Statement of Claim against some or all of defendants if the Statement of Claim fails to allege a cause of action, the claim is a nuisance or is vexing; the value of the claim made is not properly established (the claimant can cure this within a court-provided time period); or the court fee paid is insufficient (the claimant can cure this within a court-provided time period). The Statement of Claim must show each defendant's relation to the claim - failure to demonstrate such relation can serve as grounds for a motion to strike.

Additionally, under the Civil Procedure Regulations, a court may dismiss an action altogether against some or all of the defendants if: *res judicata* is established; the court does not have jurisdiction; or for any other reason for which the court reasons the action can be dismissed at the outset.

Striking out of a claim is without prejudice, whereas dismissing a claim is with prejudice.

The Civil Procedure Regulations allow a court to conduct pre-trial hearings to make efficient, simplify, quicken or shorten the trial or to investigate the possibility of compromise between the parties. Matters that can be addressed at a pre-trial hearing are wide in scope. Absent certain circumstances, a decision made at the pre-trial hearing will be valid for the remainder of the proceedings.

4.7 What appeal options are available?

A party can appeal a final judgment by the trial court as a matter of right. Prior to the final judgment, a party may appeal interlocutory orders and "other decisions" only by leave of the appeal court. Notwithstanding, these orders and other decisions can be addressed in the appeal of the final judgment.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The parties have a right to file expert reports as part of their evidentiary case. There are no substantive, but some procedural, restrictions. The court can appoint experts and usually does so when the parties filed contradicting expert reports or, with the parties' consent, instead of party reports. Experts can be cross-examined.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

Israeli procedure does not include pre-trial oral depositions and witnesses are expected to testify under cross-examination in court. Direct testimony may be, and commonly is, submitted by affidavit. A party may serve interrogatories on opposing parties. Expert witnesses reports are submitted in writing, but the experts can

generally be cross-examined orally in court.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

A party may demand that the opposing party identify documents relevant to the subject matter of the lawsuit. The opposing party then must identify such documents by way of affidavit. The requesting party has a right to examine documents identified in such affidavit. A party may also demand copies of documents referenced in the opposing party's pleadings. Additionally, a party may move the court for an order to disclose a specific document

Certain grounds for refusal to disclose, such as privilege, exist.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Various alternative methods of dispute resolution, such as arbitration or mediation, exist. Courts encourage, but generally cannot compel, use of these methods.

A court is authorised to render a compromise verdict, with the consent of the parties, without the need for the parties to present evidence.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

The Prescription Law 5718-1958 (the "**Prescription Law**") governs limitation periods, absent a specific provision in another applicable law. See question 5.2.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

Under the Prescription Law, the limitations period for civil claims (other than in connection with property) generally is seven years from when the cause of action accrues, unless another law specifically provides otherwise. Generally, some tolling may apply. See below and question 5.3.

For claims under the Torts Ordinance or Consumer Protection Law, the cause of action accrues (i) when the negligent act occurred, or (ii) where damage must be shown to establish liability, when the damage occurred and if the damage was not discovered when the damage occurred, then the date when the damage was discovered. In the latter scenario, the period of limitations nonetheless expires ten years from when the damage occurred.

The limitations period for a given claimant begins only after the claimant reaches the age of majority (eighteen years of age). The period of time in which a claimant is mentally incapacitated and does not have a guardian suspends the period of limitations. If a guardian is appointed for such a claimant, the period of limitations is suspended until the guardian becomes aware of the facts underlying the claimant's cause of action.

Under the Sale Law, the plaintiff is subject to certain time-limited obligations of notice to the defendant.

The Defective Product Law provides that a claim under such law has a limitations period of only three years. Moreover, a claim under the Defective Product Law must be submitted within 10 years from the end of the year that the product left the manufacturer's control.

In a class action, special calculations to the limitations periods apply. For example:

- If the court approved the petition for a class action, each member is considered as if it submitted the claim at the day of the approval.
- If the court rejects the motion for a class action, the limitations period shall end within a year after the decision of rejecting the claim becoming final, on condition that the claim did not expire before submission for the motion for the class action.
- In an opt-out class action, if a member of the class opts out, it may submit its claim within one year of its opting out, on condition that the claim did not expire before submission of the motion for the class action.
- In an opt-in class action, the limitations period of class member opting in expires only after a year after the last date it had to notice of its right to opt-in, on condition that the claim did not expire before submission of the motion for the class action.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

The Prescriptions Law provides that if an action is for fraud or deceit, the limitations period begins from when the claimant learns of the fraud or deceit. The Prescriptions Law further provides, however, that if the claimant did not know of the facts underlying his cause of action, for reasons not of his making and that reasonable care could not have prevented, the period of limitations begins when the claimant learns of these facts.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

Remedies under the Torts Ordinance include monetary compensation and injunctive relief. A claimant in a personal injury case may recover compensatory damages for its actual expenses, including treatment costs and lost profits as a result of the injury. Damages for pain and suffering may also be recovered.

Remedies for breach of contract are awarded pursuant to the Contracts Law (Remedies for Breach of Agreement), 1970 (the "**Remedies Law**"). Under such law, the remedy for breach is either enforcement or cancellation of the agreement and, in either event, damages. The plaintiff does not have a right to enforcement, however, if: (1) the agreement is not capable of being performed; (2) the agreement is for personal services; (3) enforcement would require unreasonable supervision of the court or execution offices; or (4) enforcement would be unjust under the circumstances.

Remedies under the Consumer Protection Law are generally those available under the Torts Ordinance. Under the Consumer Protection Law, a court is authorised to award damages to a consumers association if it assisted the claimant, but the Consumer Protection Law sets limitations of such compensation. If the consumer was misled in a material way, he has the right to cancel the merchandise acquisition agreement and to a return of consideration already paid by him.

Under the Defective Product Liability Law, the monetary compensation for loss of earnings or loss of earning ability may not exceed three times the average wage in the economy and the monetary compensation for non-pecuniary damages may not exceed a statutory amount (as adjusted by the consumer price index and as may be enlarged by the Minister of Justice).

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

The Torts Ordinance addresses damage and defines the concept widely as: loss of life, asset, comfort, physical well-being or reputation. The Torts Ordinance also addresses pecuniary damage and defines that concept as actual loss or expense which can be evaluated and details of which can be provided. Thus, a claimant in a personal injury case may recover damages for pain and suffering and for lost earnings and treatment costs. There are precedents for awarding damages for mental injury only (without physical injury).

The Defective Product Law provides a right for compensation only for personal injury.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

It is not yet settled whether claims may properly be made for medical monitoring in circumstances where the product has not yet malfunctioned and caused injury. See question 6.2.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are rarely, if ever, awarded. While the Torts Ordinance does not specifically grant a court authority to award punitive damages, courts in the past have awarded punitive damages in situations where the tortfeasor acted wilfully, oppressively or maliciously. Notwithstanding, the trend of the last few decades has been not to award punitive damages in tort negligence cases.

"Aggravated damages" are sometimes awarded by Israeli courts, most commonly in libel cases, for non-pecuniary injury, taking into account aggravated harm caused as a result of an aggravated manner in which a wrongful act is committed.

The Consumer Protection Law allows the court to award "exemplary damages", up to a maximum of NIS 10,000, in certain circumstances.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

Generally not, but under the Consumer Protection Law, a court's authority to award exemplary damages is limited to a maximum amount of NIS 10,000.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

Settlement of class action claims require court approval.

Under the Civil Procedure Regulations, an infant is permitted to file a claim via its custodian or by its "close friend". Settlement in such a case requires court approval.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Under the Correction of Civil Tort Rules Law (Amelioration of Corporeal Damages) 1964, (the "**Amelioration Law**") an entity which ameliorates (whether doing so by compulsion of law or voluntarily) certain personal injuries caused to the claimant has the right to compensation for the amelioration from the injuring party.

Additionally, the National Health Insurance Law, 1994 (the "**Health Insurance Law**") provides specifically for the right of an Israeli Sick Fund or other health services provider (as defined in the Health Insurance Law) to compensation from an injuring party for treatment services the fund or provider provided to the injured party.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Under to the Civil Procedure Regulations, the court can obligate a losing party to pay the costs of the successful party. The court has wide discretion in this matter and generally orders the losing party to pay at least some of the successful party's costs, but normally not all such costs.

7.2 Is public funding e.g. legal aid, available?

Under the Legal Aid Law 1972, a party suffering from poor financial means may apply to the Legal Aid Unit of the Ministry of Justice for legal aid. If the application is granted, a registered legal aid lawyer will be appointed to act for such party. The aided party will be required to pay a symbolic fee, according to its payment ability. Rejection of a legal aid application can be appealed.

Court filing fees may be waived for a party in poor financial circumstances.

When awarding costs, the court has a wide discretion in this regard and will consider the legal aid status of the losing party.

7.3 If so, are there any restrictions on the availability of public funding?

Legal aid is granted on the basis of criteria set by the Ministries of Justice and of Welfare, from time to time. The criteria essentially are a means test.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Lawyers may fund civil product liability claims through conditional or contingency fees although, in connection with motorised vehicle accidents, the contingency rate is limited by Israeli bar rules. These types of fees are prohibited in criminal matters.

Lawyers may not accept compensation that is not monetary, although some lawyers take this to mean only that compensation must include some cash.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Champerty is not permitted and a right of action may not be assigned to an uninterested third party. A right pursuant to a judgment, however, may be endorsed to another. Case law on this subject is limited.

Under the Israeli bar rules, a lawyer may not lend its client money for legal expenses (as opposed to legal fees), unless for a reasonable period of time.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Israel.

In 2006, the Ministry of Justice proposed codification of Israeli civil law. The main purpose of the proposed Civil Codex is to harmonise the various civil laws and precedents and provide an omnibus section of definitions for all Israeli civil law. While the proposed Codex generally is considered not to change materially substantive law, it nonetheless does propose certain changes that can significantly affect product liability claims. For example, the Codex would increase the period of limitations for a defective product action to four years from the current three years under the Defective Product Law and proposes a limited form of aggravated damages in tort actions.

The Class Action Law and the Consumer Protection Law are not part of the Codex and therefore would be unaffected if the proposed Codex were to be enacted as law. Currently, the Codex has no legal power, but from time to time claimants invoke it in an attempt to influence the case at hand.

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Note

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Italy

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

In Italy product liability was traditionally based on the general principle of tort law under section 2043 of Italian Civil Code ("**CC**"), providing that any person who by wilful or negligent conduct causes unfair detriment to another must compensate the victim for any resulting damages suffered (the *neminem laedere* principle). Such negligence liability encompasses both the general lack of prudence or diligence and the violation of "Statutes, Regulations, Orders or Rules". It coexists with the strict liability system of the Italian Consumer Code, implementing the Product Liability Directive 85/374/EC (the "**PL Directive**"). Other available product liability systems include, to a limited extent, contractual liability (section 1490 CC) and liability for dangerous activities (section 2050 CC).

Traditional approach (fault based tort liability)

Under the traditional, fault-based tort liability approach (section 2043 CC), consumers may sue in tort manufacturers for damage caused by defective products. Although negligence is to be considered a necessary element in order to establish liability, some Court decisions found that the defective nature of a product *per se* would prove negligence in the manufacturing process. Thus the manufacturer's fault can be proved by the very existence of the defect generating the injury.

Consumer Code, former DPR 224/88 (strict liability)

The Consumer Code introduces a strict product liability regime. It provides detailed definitions of "product", "defective product", "manufacturer" and "supplier", and defines the scope of manufacturers' and suppliers' liability. It explicitly states that the injured party must prove the damage, the defect and causation. Proving the manufacturer's fault is not required. Lately, recourse by plaintiffs to this cause of action has become increasingly frequent (see answer to question 8.1 below). Because the Consumer Code allows consumers to seek (alternatively or cumulatively) other forms of protection provided by law, a product liability case will mostly be brought based on claims under both the Consumer Code and section 2043 CC.

Liability in contract

The law of contract plays a limited role in product liability litigation. The rules governing the sale of goods limit liability to any contractual duties of the seller in cases where the manufacturer or distributor has a direct contractual relationship with the ultimate consumer (which very seldom occurs in relation to mass produced goods). In any such case, the purchaser may claim the seller's liability whenever a latent defect manifests itself following the sale (section 1490 CC).

Dangerous activities (presumption of fault)

Under section 2050 CC, whoever injures another in carrying out an activity which is dangerous *per se* or due to the means used is (strictly) liable for damages unless he proves that he adopted all possible measures to avoid occurrence of the damage. Some court decisions have applied this provision to the marketing and distribution of toxic chemical substances and blood derivatives contaminated with hepatitis-B and C and HIV viruses. Section 2050 has also been applied in tobacco litigation on grounds that cigarette components are inherently dangerous to health. Recent case law, however, has excluded the applicability of section 2050 to tobacco products arguing that the provision applies to "activities" and not to "products".

Theoretically, section 2050 can only apply to activities that are either "hazardous" by express provisions of law, or considered inherently dangerous and likely to cause damage to the user even if appropriately handled.

1.2 Does the state operate any schemes of compensation for particular products?

Yes. State-operated indemnity schemes are promoted in connection with contaminated blood transfusions and blood derivatives, and in favour of victims suffering injuries or illnesses causing permanent impairment of psycho-physical integrity as a result of undergoing a mandatory vaccination. The indemnity also covers people who suffer damage by interacting with vaccinated persons, people who are subject to vaccination for work or travel reasons, and healthcare personnel who are considered "at risk" and are therefore subject to (not mandatory) vaccines. The indemnity offers limited restoration and does not prevent victims from separately seeking damages under the product liability provisions of the Consumer Code, or under sections 2043 or 2050 CC.

In other areas of the law, *ad hoc* state funding may be available where product liability issues arise in the context of natural catastrophes; in connection with operating nuclear plants and in circumstances where damages are caused to individuals by space objects.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Under the Consumer Code, "manufacturers" are liable for the

fault/defect. A "manufacturer" is any manufacturer of goods or supplier of services, or an agent thereof, or any importer of goods or services within the European Union or any other natural or legal person presenting himself as the manufacturer by identifying the goods or services with his own name, trademark or other sign having a distinctive character. Anybody dealing with the sale, lease, hire or any other form of marketing of the product is considered a "manufacturer" as long as it has dealt with transferring the product from the manufacturer to the consumer, including persons in charge of delivering the product for mere advertising purposes.

Product liability also attaches to importers of products coming from outside the European Union (although the importer will be entitled to sue the manufacturer by filing an action for contribution).

As consumers may not be aware of the distinction between a "trademark" and a "brand or merchandise mark", liability is not limited to the manufacturer of the defective product, but is extended to the person or entity who markets the product. If the name of the manufacturer is known to consumers, the former shall be liable to the latter.

When the manufacturer of defective products is not identified, a supplier having distributed the products in the course of his business is equally liable and is *de facto* considered a manufacturer if it fails to provide the consumer with the name and address of the manufacturer (or of the supplier who sold the products to him) within three months from receipt of a written request by the consumer. This way, the supplier has only a subsidiary liability, which can be avoided by informing the consumer of the identity of the person or entity that manufactured the product or sold the product to him. The ECJ has ruled that, in principle, liability for defective products as regulated by the PL Directive lies with the manufacturer, and will rest on the importer and distributor of the product only in limited cases (i.e. when the manufacturer is not identified).

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

A manufacturer's or distributor's duty to inform the competent authorities is triggered whenever it becomes aware (or should be aware, based on the information available in its position as a business entrepreneur) that a product placed on the market or otherwise supplied to consumers presents risks that are incompatible with the manufacturer's/distributor's general duty of ensuring product safety.

The new legislation imposes a number of additional duties on manufacturers and distributors, including that of providing consumers with all the information necessary to evaluate the risks arising from the normal and foreseeable use of the product, adopting measures proportional to the characteristics of the product, so as to enable the consumer to identify the risks and to take any necessary steps to avoid them. Product recalls are regulated in greater detail, and manufacturers and distributors are required to organise direct withdrawal of defective products from the market and, if the case may be, destruction thereof, and to bear all relevant costs.

1.5 Do criminal sanctions apply to the supply of defective products?

Yes. The Consumer Code provides that the competent authorities (i.e. the relevant Ministry according to the product or service in issue) can ban the marketing of dangerous products and take any necessary measure to ensure compliance with such ban.

Manufacturers or distributors placing dangerous products on the market in violation of the ban are criminally liable with imprisonment (from six months to one year) and a €10,000-50,000 fine (if it involves the perpetration of a more serious crime, the relevant criminal provisions will also apply). In the absence of the ban, placing dangerous products on the market is punishable with up to one year imprisonment and the same fine as indicated above.

For products presenting risks under certain conditions, authorities may require that products be marked with suitable, clearly worded and easily comprehensible warnings in Italian, and make their marketing subject to prior conditions so as to make them safe.

Likewise, if a product presents risks for certain individuals, the authorities can require that any such individual be given notice of said risks in good time and in an appropriate form, including the publication of special warnings.

Furthermore, for potentially dangerous products, authorities can temporarily ban their supply, the offer to supply, or their display for the period needed for the various safety evaluations, and can order that products already marketed be adapted to comply with safety requirements within a given deadline.

The failure to comply with any of the above requirements entails a financial penalty ranging from €10,000 to €25,000, and fines of an administrative nature (non-criminal) are inflicted in cases of failure to cooperate with the authorities in carrying out product checks and in acquiring information thereon and samples.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

Under the Consumer Code, in product liability claims the injured party must provide evidence of:

(i) the defect (under the Consumer Code's definition);

(ii) the damage incurred (based upon the general tort rules); and

(iii) the causal relationship between defect and damage (based upon the general principles of causation in tort law, proof of causation often being achieved through presumptions); but

(iv) no evidence of fault is required.

Since the plaintiff has no burden of proving fault, it is up to the defendant to provide any evidence of grounds excluding liability (e.g. by proving that the plaintiff used the product inappropriately). This is why, when dealing with product liability issues under the Consumer Code, authors often speak of shifting of the burden of proof to the manufacturer, distributor, supplier, etc.

In tort, under section 2043 CC, the plaintiff must prove:

(i) the defect;

(ii) the damage suffered;

(iii) the existence of a causal relationship between defect and damage; and

(iv) negligence or fault on the part of the defendant.

It can be particularly difficult for a consumer to provide evidence of fault in connection with products whose manufacturing processes are particularly complex.

In issues connected to damages arising from performing a dangerous activity (section 2050 CC), the injured party must prove:

(i) that the injurer performed a dangerous activity (according to the definition provided by case law);

(ii) the damage suffered; and

(iii) the existence of a causal relationship between the dangerous activity and damage; but

(iv) no evidence of fault is required (fault is presumed from the

very fact of carrying out a hazardous activity).

Therefore, under 2050 CC it is up to the person who carried out the dangerous activity to prove that all possible measures to avoid the damage have been adopted. Once again, authors speak of shifting of the burden of proof to the defendant.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

Causation must be proved by the claimant, and based on standards applied by case law in respect of both product liability claims and tort claims, meaning that the injury shall be, under probabilistic criteria, the direct and immediate consequence of the defendant's act or omission. Although, the claimant is supposed to prove that the injury would not have occurred but for the defendant's act or omission ("but for" test), courts tend to require the defendant to give positive proof that the injury was not, in actual fact, the consequence of its conduct.

In addition, if the defendant is able to prove that an additional cause pertaining either to the claimant (contributory negligence or a pre-existing impairment of the claimant) or to an external factor is the exclusive or concurrent cause of the injuries, liability of the defendant can be excluded or proportionally reduced.

As far as causation is concerned the Joint Divisions of the Supreme Court (no. 281/2008) have recently stated that, while the so-called cause-in-fact (factual causation) is to be assessed on the basis of the "but for" test, when investigating the extent of legal responsibility other tests should apply in order to assess causation, such as that of probability. According to such theory, causation is establish if it is proved that it is "more probable than not" that the harm would not have occurred if the defendant had not acted as he actually did.

With regard to assessment of causation, technical/medical knowledge or skill is often needed, so that, in practice, the court refers to court-appointed experts to determine causation (please see the answer to questions 4.8 and 4.9).

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

According to the Consumer Code, when more than one individual or entity is responsible for damage, they shall be held jointly and severally liable. Each of them shall have a right of recovery against the other(s) based upon the degree of fault and liability ascribed to each. In case of uncertainty in respect of the percentage of liability that each must bear, the obligation to compensate damages is divided equally among them.

The same principles generally apply in tort. Under section 2055 CC, if a tort is ascribable to two or more persons, all are jointly liable to the injured party for damages. Any liable person having fully compensated the damage has a right of recovery against the other persons held liable, according to degrees of their respective fault and to the consequences related thereto. In the event of doubt as to the establishment of the degree of fault of each, all are presumed to be liable for an equal share of debt.

Generally speaking, market-share liability is not a principle applied by Italian courts in product liability issues.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

The assessment of the defectiveness of a product will include an examination of, among other things, its presentation to the public and its instructions and warnings, including any descriptions, manuals, stickers, writing on the package and advertisements [XE "advertising"]. This implies that the manufacturer has a duty to inform consumers of the features (and possible dangers) of the product, and penalties are inflicted upon a failure to comply with any such duty (see the answer to question 1.5). The nature of the information required to be provided will depend on the type and intended use of the product and on the anticipated user's level of awareness.

A consumer will be entitled to recover damages if the instructions or warnings were wrong, incomplete, contradictory or too short.

For products intended for children [XE "product liability: children"], courts have held that the manufacturer's level of attention to instructions and warnings should go so far as foreseeing abnormal behaviour by children in using the product (but not so far as covering uses of the product that are clearly in contradiction with the scope of the product).

With respect to the injured party, the only information that can be taken into account is that which is directly provided to it or publicly available, but not that which is directed to different people. The answer is different if the product can only be obtained through an intermediary who, in his function, assumes the legal liability of e.g. prescribing a medicine (a doctor) or installing a medical device (a surgeon). The principle is valid only where medical professionals have to assess the suitability of a non-defective product: if the product is acknowledged to be defective (and not simply non-suitable for a specific patient or illness), the only liable party is the producer.

Under Italian law there is no principle of "learned intermediary" in relation to defective products.

3 Defences and Estoppels

3.1 What defences, if any, are available?

A manufacturer may avoid liability under the Consumer Code if:

a. "the manufacturer did not place the product on the market" (the product is considered released on the market "when it is delivered to the purchaser, user or an assistant to this, also just for viewing or testing same");

b. "the defect that caused the damage did not exist when the manufacturer released the product onto the market". In this case, the manufacturer's burden consists of proving that the defect did not exist at the time when the product was released on the market;

c. "the manufacturer did not manufacture the product for sale or any other form of distribution against payment of

consideration, and did not manufacture or distribute the product in the exercise of his professional activity";

d. the defect depends on the "compliance of the product with a mandatory legal rule or a binding measure";

e. "the state of scientific and technical knowledge at the time when the product was released on the market did not allow the existence of the defect to be discovered"; or

f. "the manufacturer or supplier of a component part of the product fully complied with the instructions given by the manufacturer who used the component or the defect is fully due to the concept of the product in which the part was incorporated".

In relation to the "state of the art" defence (e. above), the strict view of legal authors excludes the possibility that a defect may be considered unpredictable only because the scientific theses that confirm its existence are not yet fully consolidated or are not directly and immediately accessible, and case law in such cases tends to consider the defect as predictable.

Note that, under the Consumer Code, a manufacturer may be held liable for damages only if the product is defective in relation to its ordinary, intended use.

Under the Consumer Code, if the injured party contributed to the injury, damages shall be assessed according to the seriousness and degree of his contributory negligence and the level of consequences due to his own negligence. No damages shall be awarded if the victim could have avoided the injury by acting with ordinary diligence and duty of care, and there will be no damages award if the consumer was aware of the defect and of the risks connected thereto, but nevertheless accepted being exposed to the danger by continuing to use the product. Recent case law has accepted the "awareness" defence (as in tobacco litigation cases).

Traditional defences in tort to exclude a manufacturer's liability include a variety of arguments are similar to those mentioned above under the Consumer Code.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

See the answer to question 3.1. The manufacturer's liability is excluded if the level of technical and scientific knowledge at the time when the product was placed on the market did not allow the defect to be discovered. The time when the product is placed on the market is either the time when it is delivered to the purchaser, or to the user, or to an agent thereof, including when it is delivered for trial purposes or for inspection.

Any element that may exonerate the manufacturer from liability must be proved by the manufacturer himself. Accordingly, the burden of proving elements exonerating the manufacturer from liability, and of proving that the defect was not known, or capable of being known, at the time the product was placed on the market both lie on the manufacturer (as also confirmed by case law).

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

The manufacturer is exonerated from liability if the defect is due to conformity of the product with a mandatory rule or a binding provision, the reason being the impossibility of sanctioning conduct that is mandatory. However, the legal provisions regulating product safety and the manufacturing process of goods are limited to a few sectors such as the processing of food and beverages, medicines, pharmaceuticals, household electric appliances, and cosmetics.

However, manufacturers are not exonerated from liability for damages caused by defective products placed on the market simply because the manufacturer abided by all existing safety standards or production guidelines. Compliance with such rules may support the manufacturer's position, but if the product is defective the manufacturer shall be liable regardless of compliance with existing rules.

The same rule applies to torts, even though the general definition of faulty conduct includes any form of "negligence, imprudence, lack of skill or failure to abide to existing laws, regulations, orders and guidelines". In practice, compliance with existing rules does not exclude tort liability if the agent is found to have acted with negligence, imprudence or lack of skill as per the definitions of these concepts given by case law.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Yes. Different claimants can litigate issues of fault, defect or damage that had been previously litigated by another claimant in another case in relation to the same product. Procedurally speaking, the cases are considered different because they involve different parties to the dispute, even if they regard the same product and arise out of the very same issues. However, it is most likely that de facto the decision in the subsequent case will be affected by the outcome of the previous one.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

Yes. Defendants can claim that the fault/defect was due to the actions of a third party, and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in separate, subsequent proceedings. The period of limitation in which to commence any such proceedings follows the ordinary rules on statute of limitations as outlined in the answer to question 5.2 below.

In addition, the action of a third party can be such as to break the causal nexus between the defendant's action and the damage, thus entitling the defendant to argue that, failing causation, no liability can be imposed upon him/her.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Yes. If the claimant is the injured party and contributed to causing his injury or damage, the assessment of damages shall be based on the seriousness and degree of his contributory negligence and the level of consequences due to his own negligence. No damages will be awarded if the injured party could have avoided the injury by acting with ordinary reasonableness and diligence. Moreover, no damages

will be awarded if the injured party was aware of the defect and the risks connected thereto, but nevertheless tolerated and thereby accepted exposure to the risk by continuing to use the product.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

Italy belongs to the civil law tradition which does not contemplate trial by jury, so all civil proceedings are governed by a single judge or panel of judges.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Yes. A judge can appoint technical experts (**CTUs**) to assist him or her in specific or technical activities (e.g. medical assessment of certain health damages; causation). The results achieved can be evaluated only by the judge and they do not represent a piece of evidence. See also the answers to questions 4.8 and 4.9 below.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

On 21st December 2007 the Italian Parliament passed an amendment to article 140 of the Consumers' Code introducing a collective/class action system. Only certain consumer associations were entitled to sue collectively for tort liability, unfair trade practice, and anti-competitive behaviour (including antitrust violations) on behalf on consumers and end-users. The 2007 Law provided for a collective action system based on an opt-in mechanism and a two-steps procedure: the first one aimed at assessing admissibility of the collective action and the right to compensation; the second one (extra-judicial) for the quantification of the damage. The amendment should have entered into force on 30 June 2008. However, due to further amendments, entry into force of the law on class actions has been postponed until 1st July 2009. On 23rd December 2008, the Italian Government filed with the Parliament a last draft for amending the former proposed collective/class action system in order to address some of the concerns expressed by stakeholders and resolve several contradictions and gaps.

The draft proposal submitted by the Government in December 2008 shapes a new system based on the following elements:

- Capacity to sue on behalf of class members is granted to a member of the class (also through consumers' associations which- however - do not have an autonomous right to file the class action and need to receive mandate to that effect). Other consumers and users may opt-in not later than the term granted by the Court when it rules on admissibility of the class action.
- The action may relate to:

i. contractual rights of a plurality of consumers and users placed in an identical situation *vis-à-vis* the same company (including rights relevant to standard agreements);

ii. identical rights of end consumers of a product *vis-à-vis* the manufacturer, irrespective of a direct contractual relationship with the latter; and

iii. identical rights of consumers to compensation for prejudice suffered as a result of unfair business practices or anti-trust conducts.

- The two-steps procedure (judicial and extra-judicial) is abolished: upon ruling on the admissibility of the action (which can be denied if the action is manifestly groundless, if a conflict of interest exists, if there is no identity in the individual rights, or if the class representative appears not to adequately represent the interest of the class), the Court gives direction on the proceedings and rules on:

a) the features of the individual rights in dispute and the criteria that must be satisfied to be member of the class;

b) the term within which opt-in is allowed; and

c) if the claim is accepted, the amounts due to the members or the criteria to quantify them.

In deciding, the Court shall take into account the overall amount payable by the defendant, the number of creditors and the difficulties in recovering the amounts in the event where the defendant's appeal is upheld. The Court can rule that the aggregate amount due by the defendant is deposited until the decision is final.

The decision becomes enforceable after 180 days from publication.

No other class actions for the same facts and against the same defendant can be filed after expiry of the term for opting-in. Class actions filed before said date, are consolidated to the one previously commenced. Waivers and settlements between some of the parties do not affect the right of other class members who have not expressly consented thereto. Consumers and users who do not opt-in are entitled to file individual claims.

The law applies retroactively to torts occurring after 1st July 2008.

Finally, as in the former draft bill on class action, unlike in the US, no discovery, no punitive damages and no jury trial are provided for.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Under the current regime, consumer associations are only entitled to act on behalf of consumers and users to obtain an injunction preventing reiteration of a conduct which prejudices consumers and an order for corrective remedies, besides publication of the decision. Please also see the answer to question 4.3 above.

4.5 How long does it normally take to get to trial?

The common law concept of "trial" is unknown to the Italian civil procedure system: Italian proceedings consist of an introductory stage when the statement of claim and statement of defence and the subsequent briefs with specification of the claims and defences are filed; an evidentiary stage when fact witnesses are heard and court-appointed experts carry out their assessments; and a final stage when conclusive briefs are submitted by the parties and the case is reserved for decision by the court. The duration of the proceedings depends on the complexity of the case, on the number of fact witnesses heard and on the time devoted to court-appointed experts. Generally, up to three years may be required to reach a first instance decision. For the duration of collective action proceedings please refer to the answers to questions 4.3 and 4.4 above. As the law of collective actions has not entered into force yet, it is not possible to assess possible duration of these proceedings.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

In principle, the court can try preliminary issues (e.g. lack of jurisdiction) prior to examining the merits of the case. In practice,

however, courts tend to determine the preliminary issue at the end of the case, along with the merits.

Some preliminary issues (such as lack of territorial venue or statute of limitation) must be raised by the defendant in the statement of defence, otherwise they cannot be raised at all. Others (such as lack of jurisdiction or lack of *locus standi*) can be raised *ex officio* by the court without input from the parties and at any stage of proceedings (including the appeal stage).

4.7 What appeal options are available?

Any party to a claim has a right of appeal to the Court of Appeal (second instance) and, on issues of law only, to the Supreme Court of Cassation. Two other "exceptional" appeal options are available: revocation; and third party opposition. No leave to appeal is required.

Appeal

The losing party to a partial or final judgment can challenge the decision before the Court of Appeal, formed by a panel of three judges. The appeal must be filed within thirty days from service of the first instance judgment; failing service, the term to appeal is one year from the date when the judgment is lodged with the court clerk. No leave to appeal is required.

All claims raised in the first instance can be referred to the Court of Appeal and any error the appellant asserts has been committed by the first instance court can be ground for appeal. At the appeal stage, no new objections and claims can be raised and the parties may not produce new evidence. The appellate court issues a new judgment, which replaces that of the first instance court.

Cassation

The second instance judgment can be challenged before the Supreme Court of Cassation. The appeal must be filed within sixty days from service of the judgment; failing service, the term to appeal is one year from the date when the judgment is lodged. The Supreme Court does not re-examine the merits, but only evaluates whether legal principles and procedure have been complied with in the previous instances. When the court ascertains errors, it sets aside the judgment appealed from and remits the case for judgment on the merits to a lower court, which must re-examine the facts in the light of the legal principle fixed by the Supreme Court. In cases where the judgment appealed from is set aside due to a violation or incorrect application of rules of law and there is no need for re-examination of the facts, the court itself issues a new judgment based upon the correct principle of law.

Revocation and third party opposition

Revocation is a proceeding before the court that issued the challenged judgment (e.g. in case of manifest mistake in the evaluation of facts or documents, wilful misconduct of one of the parties or of the judge during the proceedings, judgment issued on the basis of false evidence). Third party opposition may be raised by someone who was not a party to the original proceedings, complaining that the judgment was rendered in his absence and that this has infringed his rights, or has ruled thereon, or has created a right inconsistent with his own rights.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

In the course of proceedings, the judge can appoint a CTU to assist in activities that the judge cannot directly perform (see answer to question 4.2). When the court appoints a CTU the parties can also appoint their own experts who participate in the technical investigations. In product liability claims a technical assessment of the allegedly defective product is often needed and expert investigations can be the core of the action.

In addition, before the commencement of a case, if there is an urgent need to verify the state of a place or an object before they are modified in a way that could hinder their use as evidence in proceedings (e.g. the scene of an accident or an easily deteriorating product), a party can request a pre-trial technical investigation.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

Fact witnesses

Italian civil law does not distinguish between pre-trial and trial as in common law jurisdictions. A party wishing to depose a factual witness in civil proceedings will file the relevant request in the introductory brief or in the statement of defence and in the subsequent briefs on evidence, listing the questions on the factual circumstances of the case that they wish the judge to ask to the witness. The counterpart has the right to list questions in order to counter-depose the witness. The judge has the power to admit or dismiss any such witnesses and to allow or strike off the suggested questions. Witnesses must appear personally at a prescribed hearing scheduled by the judge, who is the only person entitled to ask questions. Depositions constitute full evidence.

Expert witnesses may not be deposed under Italian civil procedure law. Evidence in the form of sworn affidavit is not admissible, although experts may prepare reports in writing that parties are entitled to file with the court as documentary evidence. In this respect, the Parliament is discussing a reform of the Code of Civil Procedure whereby the parties will be allowed to file written witness depositions on questions previously submitted to and approved by the Court (see section 8 below).

Court-appointed experts

See the answer to question 4.8. CTUs are assistants of the judge, they are not witnesses, and their findings are not pieces of evidence. Their report serves the purpose of clarifying technical or medical aspects to the judge, who is not bound to follow any conclusions reached by the expert on specific issues. CTUs are never deposed as witnesses.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

In the Italian procedural system there are no disclosure obligations. The basic principle is that the claimant must prove its claims by submitting to the judge all relevant evidence it possesses. The same applies to the defendant in proving statements made in its defence. Normally the evidentiary phase of a trial is limited to such document production and the hearing of witnesses (if any). If a party fails to submit documentary evidence on its own behalf, it suffers no adverse consequence in the proceedings save that its claims may not be proved to the judge's satisfaction.

The Italian Code of Civil Procedure provides that the judge may order the inspection or disclosure of evidence in the possession of another party or of a third party ("items", like documents, are usually produced in the trial by one of the parties as evidence of its claim, rather than "inspected"). If the request originates from one of the parties to the proceedings, this must specifically indicate the particular document to be disclosed, and there cannot be a "fishing

expedition" for generic classes of documents. The judge may refuse a request for disclosure where the filing might cause serious damage to the party or third person concerned.

If the party refuses disclosure without good grounds, the judge may infer that the document is adverse to that party. If the refusal comes from a third party, the judge can only impose a fine. It must be stressed that a disclosure order cannot be specifically enforced by the judge or by the party for the benefit of whom the disclosure is ordered.

A party may refuse to comply with such an order on the grounds that a document is protected under "professional or official secrecy". The Italian procedural system treats documents as falling within this protection in limited cases only, namely where they are communications with lawyers (in relation to facts learnt in the management of a file and correspondence exchanged with the counterparty's lawyer marked as "privileged and confidential"), CTUs, accountants, public notaries and certain public authorities (e.g. the Bank of Italy), or health professionals, priests and any other professionals. Thus, if one party is in possession of documents not covered by any of these categories, the other party cannot prevent their production by the first party for its own benefit.

All of a party's private or internal documents and correspondence must be considered confidential. The Italian Constitution affords secrecy to correspondence and communications in general, the scope of which can be limited only by means of a reasoned order of the judicial authorities, issued in any case in full accordance with the guarantees provided by the law.

The production at trial of correspondence internal to another company (whether or not it is party to the proceedings) appears not only to be forbidden, but also in violation of the criminal law (the Italian Criminal Code punishes the person who "violates" - i.e. reads or steals - correspondence not directed to him).

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Mediation and arbitration are available but are seldom used in respect of product liability claims. The new law on collective actions provide for mandatory conciliation and mediation procedures. For additional details, please see the answer to question 4.3.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes. The statute of limitation depends on whether the plaintiff is suing in tort or contract or under the product liability provisions encompassed in the Consumer Code.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

Claims brought in tort are subject to the general five-year tort liability limitation period, running from the time when the claimant could exercise his/her rights. The time limit is extended if the tort could also be considered as a criminal offence.

A general ten-year limitation period covers most other areas of the law, including the enforcement of contractual remedies.

Under the Consumer Code, consumers are time-barred from filing an action against manufacturers after a three-year period, running from the time when the victim (should reasonably have) became aware of the damage, of the defect in the product and of the identity of the manufacturer. In any case, the action is foreclosed after ten years from the time when the manufacturer (or the importer in the European Union) placed the product on the market.

Statute of limitations rules are binding and mandatory in Italy. Courts have no discretion to disapply time limits but the relevant objection must be raised by the parties.

The Joint Divisions of the Supreme Court (No. 581/2008) has recently stated that in case of latent damage limitation period, under sections 2935 and 2947 CC, runs from the time when the claimant (by using the ordinary care and the scientific knowledge available from time to time) may have perceived the injury suffered as an unfair damage potentially caused by fraudulent or negligent conduct of the defendant.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

The existence of fraud, if acknowledged, does not affect the running of time limits for the commencement of civil proceedings.

The existence of concealment, however, does affect the running of time limits in that, under the Consumer Code, the period of limitation to file an action against manufacturers starts running from the time when the injured party became aware of the damage, of the defect in the product and of the identity of the manufacturer, or should reasonably have become aware thereof. Hence, if there was any concealment as to the above, this affects the running of the limitation period.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

Remedies available include monetary compensation of damage (see the answer to question 6.2) as well as injunctive relief. Injunctive relief (e.g. an order by the Court enjoining the defendant from carrying out a certain conduct) may be granted both as ordinary remedy (i.e. with the Court decision rendered at the end of the ordinary proceedings in the merits) and as interlocutory remedy, whenever the claimant's rights could be prejudiced during the time required to complete the ordinary proceedings on the merits.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Under the Consumer Code the damages for injury to life or limb, and destruction or deterioration of property other than the defective product itself (if normally intended for private use or consumption and employed accordingly by the injured party) are recoverable. Redress may only be sought if recoverable property damages exceed €387.

If the victim is suing under contract law, recoverable damages resulting from breach of contract include actual damage and lost profit. Damages may be sought for failure to perform a contractual duty as long as the damages are a direct and immediate consequence of the non-performance.

If the victim is suing under tort law, recoverable damages include

both patrimonial and non-patrimonial damage.

Claimants claiming damage in tort, and within the context of a product liability claim, often seek compensation for so-called 'existential' damages, i.e. injuries affecting the victim's personality and capacity to lead a peaceful existence. In this respect, the Joint Divisions of the Supreme Court - by four recent decisions (nos. 26972, 26973, 26974 and 26975 of 24 June 2008) which have settled the dispute on the nature of the so-called "existential damage" - have clearly ruled that the "existential damage" is not an autonomous sub-category of non-patrimonial damage but, not differently from biological and moral damage, merely describes a type of prejudice of which non-patrimonial damage consists. Compensation of non-patrimonial damage "*requires assessment of the existence of all elements of torts*".

Injured parties may claim no more than the damages actually incurred, the purpose of the tort rules being to restore the victim's position prior to the occurrence of the tort. Damage assessment is generally based upon factual evidence, although damages may at times be awarded by the judge based upon statistical criteria and presumptions, or otherwise according to equitable criteria.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

In principle, under Italian law a victim may only recover the damages actually incurred. No specific case law has dealt with damage recovery in respect of the cost of medical monitoring in circumstances where a product has not yet malfunctioned and caused injury but may do so in the future. However, courts have dealt with similar issues allowing recovery of future damages that the victim is likely to suffer as a consequence of damage already incurred as long as signs of the onset of the damage are clearly traceable (as is the case for increasingly deteriorating illnesses after exposure to noxious substances such as asbestos, whereby the symptoms of cancer may very well be detected beforehand although the illness may critically develop at a later stage). In all such cases, courts may seek an estimate and award costs for future medical treatment whenever there is medical certainty or statistical evidence of a high likelihood of having to incur such costs in the future.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

A basic principle of Italian tort law is that a victim may recover nothing more than the damage actually suffered. Hence, punitive damages are not contemplated in the Italian legal system. In addition, foreign judgments allowing for punitive damages have been considered as being contrary to public order and, as such, not recognisable and enforceable in Italy.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no limit on the amount of damages awarded.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

Not for ordinary claims.

For collective/class action please see the answer to question 4.3 above.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

No they cannot, even if there is still a grey area on the issue.

Some guidance is given, in particular with respect to blood derivatives, by some decisions of the Italian Constitutional Court (n. 307 of 1990, n. 118 of 1996, n. 27 of 1998) which clarified that the benefits set out by the law and payable by the State to individuals which have contracted infections as a result of blood transfusions and treatment with blood derivatives are different in nature from compensation for damages. Such benefits are "in addition to" damage compensation and would not imply a "double recovery" by the damaged parties.

Based on the above principle, it can be argued that the State would not be entitled to claim back from the defendant company the money paid on account of benefits.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

During the proceedings each party must pay its own costs. The cost of the acts considered necessary by the judge must be paid by the party who will take advantage of them (e.g. appointment of an interpreter or translator). But according to the Consumer's Code the expenses of the Court Expertise, even if it is requested by the plaintiff, can be debited by the judge in advance to the defendant.

At the end of the proceedings, the general rule in the Italian system is that costs follow the event; however, the judge can decide to "set off" the costs in which case each party shall bear its own costs.

The judge may also impose compensation for the damages suffered by a winning defendant in case of abuse of process by the plaintiff.

7.2 Is public funding e.g. legal aid, available?

Yes. The legal aid system in Italy is called "*gratuito patrocinio*".

7.3 If so, are there any restrictions on the availability of public funding?

Italy has a very limited legal aid system. In order to benefit, a plaintiff must show to have a well-founded case and that he/she has an annual income of less than €9,723.84; legal aid is therefore seldom granted in practice.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Contingency or conditional fees are, since 2006, allowed by the Italian bar rules, provided that the relevant agreement between the lawyer and the client is done in writing.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Third party funding of claims is not used in Italy as a means of funding.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Italy.

The Parliament is currently discussing a wide reform of the Code of Civil Procedure, which - if approved - will affect the procedural system applicable also to product liability claims. The main proposed amendments are, *inter alia*:

(i) Legal fees and disbursements, The Judge may - even *ex officio* - order the losing party to pay not only the relevant legal fees and disbursements, but also an additional amount, which is assessed on equitable grounds, from a minimum of Euro 1,000 to a maximum of Euro 20,000.

(ii) Written fact witness depositions. As noted in the answer to question 4.9 above, under the procedural rules currently in force, witness can only be deposed orally before the Judge. According to the proposed draft, the parties will be allowed to file written witness depositions on questions previously submitted to and approved by the Court. The Judge, upon examination of the written depositions can always call the witness for oral examination.

(iii) Grounds for appeal before the Supreme Court. According to the proposed draft bill, a Court of Appeal decision could be challenged before the Supreme Court on the basis of the following grounds:

a) The appealed decision is not consistent with previous case-law.

b) The appeal relates to issues on which the Supreme Court wishes to confirm or amend its approach or the issue is disputed.

c) There is a *prima facie* grounded claim for violation of the right to a fair trial.

The above grounds stem from (and are reduced in number in respect of) the ones currently provided by the Code of Civil Procedure.

As regards case-law trends, the recent decisions by the Joint Divisions of the Supreme Court (see the answer to question 6.2 above) have set important guidelines on the category of non-patrimonial damage and have clarified that non-patrimonial damage shall be adequately proved by the claimant both as regards its existence and its amount. The decisions by the Supreme Court have already had (and will continue to have) an impact on product liability claims in respect of the damage award.

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

Persons and legal entities (hereinafter "Claimant(s)") may seek compensation for having been injured by a "defective" product through one of several legal avenues. Traditionally, such claims were brought as tort claims under the *Civil Code of Japan* (the "CCJ"), but since 1996, claims have also been able to be brought under the *Product Liability Law* (Law No. 85 of 1994, the "JPLL"). Claims may also be brought under breach of contract theories and, depending on the nature of the product involved, there may exist publicly or privately funded insurance schemes.

Under the JPLL, a Claimant may seek compensation for damages caused by a "defective" product. The JPLL, like its counterparts around the world, alleviated the evidentiary burdens that were placed on Claimants who were forced to bring tort claims for damages against manufacturers and importers of defective products. Under the JPLL, a Claimant is relieved of the burden of proving that the manufacturer or importer owed a duty to the Claimant and negligently or intentionally injured the Claimant. Instead, under the JPLL, the Claimant need only prove that the product was defective and that the defect was the cause of the injuries suffered.

Simply stated, the JPLL imposes liability on a "Manufacturer" (defined in question 1.3 below) of a "Product" for personal injury or property damage caused by a "Defect" existing in the "Product", regardless of whether it was domestically produced or imported by the Manufacturer (JPLL § 1). A "Product" is defined to include any "movable property manufactured or processed" (JPLL § 2(1)) so the scope of the JPLL excludes non-movables such as real estate, energy or unprocessed and unharvested agricultural products.

The JPLL defines a "Defect" as a lack of safety which ordinarily a Product should possess, taking into consideration: (i) the characteristics and nature of the Product; (ii) the ordinarily foreseeable uses of the Product; (iii) the state of knowledge and technology at the time of manufacture and/or delivery; and (iv) any other relevant circumstances relating to the Product. Defects can be broadly categorised into three groups. A design Defect arises when the design of the Product does not sufficiently consider safety issues relating to use, handling or storage of the Product. A warning Defect arises when the Manufacturer does not properly warn consumers of the not readily apparent dangers associated with use of the Product and does not properly instruct the consumer on how to use, handle or store the product to avoid such dangers and risks. A manufacturing Defect arises when a Product is improperly manufactured. Whether a Product is defective is determined on a case-by-case basis and is fact specific to the Claimant's own handling, use and storage of the Product.

Liability of the Manufacturer is *strict* once it is found that they sold a defective Product, but the amount of damages ordered to be paid may be reduced if the court finds that the injured Claimant's own negligence or misconduct played a part in the amount of damage suffered.

In addition to the JPLL, a Claimant may also bring breach of contract or tort claims under the CCJ. Provided a direct contractual relationship exists between the injured party and the seller of the defective product, breach of contract claims or implied statutory warranties may be brought under CCJ Article 415 (Liability for Incomplete Performance of Obligation) and CCJ Article 570 (Warranty against Latent Defect). In most modern consumer transactions, the consumer does not typically have a contractual relationship with the manufacturer so the foregoing causes of action by a consumer against a manufacturer are not typically possible in today's world of e-commerce, having a direct contractual relationship with the importer and seller of a product has become more common.

If no contractual relationship exists and if a claim brought under the JPLL is unsuccessful, an injured party may bring a tort claim under CCJ Article 709. CCJ Article 709 allows Claimants to claim that a third party has infringed upon or violated their "right" or "legally protected interest". A suit brought under this article is akin to a traditional tort action in common law jurisdictions. CCJ Article 709 provides that "[a] person who violates intentionally or negligently the right of another is bound to make compensation for damage arising there from". But while this general right of remedy is available to any person injured by a person or thing, the burdens of proof placed on Claimants are high in the case of a product liability suit, making the chance for success in a product liability context low. As such, Article 709 is viewed as a last resort for persons injured by a defective product.

Finally, the *Consumer Contract Law* (Law No. 61 of 2000 as amended, the "CCL") protects consumers in their dealings with merchants. However, while this law limits the extent to which a seller of a product may disclaim warranties relating to a product or restrict the remedies available to a purchaser injured by a product sold by the seller, this law does not offer a cause of action for damages caused by defective products.

1.2 Does the state operate any schemes of compensation for particular products?

Yes. The Japanese government operates compensation schemes for pharmaceuticals and for products that are deemed to have specific risks. One such scheme is the *Preventive Inoculation Law* (Law No. 68 of 1948 as amended), which compensates the victims of injuries caused by inoculations. This scheme is entirely funded by the Japanese government without contribution by the private sector. Another scheme is the Pharmaceuticals and Medical Devices Agency Law (Law No. 192 of 2002 as amended) which established the *Pharmaceuticals and Medical Devices Agency* (the "MD Agency"). Under this scheme, compensatory payments covering medical and funeral expenses are made to individuals or their families in the event of illness, disability or death caused by side effects of pharmaceuticals. To administer the scheme, the MD Agency charges pharmaceutical companies a contribution amount (*kyoshutsu-kin*). There are two types of contributions: one is a general contribution that is charged annually to all companies that manufacture, import or market drugs, based on sales revenue. A second contribution is made by specific companies involved in the manufacture, import or marketing of drugs that are discovered to be dangerous or cause injury.

Another scheme is found under the *Consumer Products Safety Law* (Law No. 31 of 1973 as amended, the "CPSL"). The CPSL established the Consumer Product Safety Association (*Seihin Anzen Kyoukai*) (the "CPSA") which administers a "safety-goods mark" or SG-Mark programme for certain, classes of products together with a related consumer compensation programme for persons injured by products carrying the SG-Mark. To carry the SG-Mark, a company must have its products conform to the safety specifications and requirements promulgated by the CPSA. The compensation programme is funded by the CPSA through, among other means, the sale of SG-Mark stickers which are attached by the company to all products that meet the SG-Mark standard. Adherence with the SG-Mark standards is voluntary, but for many products, commercial pressures compel adherence. Adherence to an SG-Mark standard does not absolve a company of liability; it only provides a means by which a consumer may seek compensation in the event of an injury. The CPSA will compensate a person up to 100 million yen, depending on the severity of the injury, for claims brought within a defined number of years after purchase of the product by the consumer. The CPSA bases payment on various factors. For example, the CPSA will not pay any compensation in the event that the injured party was contributorily negligent.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Under the JPLL, the classes of persons and entities that may be liable for injuries caused by a defective Product include: (i) any person who manufactures, processes, or imports the Product as a business; (ii) any person holding himself out to be a manufacturer of a Product by putting his name, trade name, trademark or other feature on the Product, or any person who puts his name, etc. on the Product in a manner mistakable for the manufacturer's name; and (iii) apart from any person mentioned in the preceding subsections, any person who affixes his name to a Product and who may be recognised as a manufacturer-in-fact, taking into consideration the manner in which the Product was manufactured, processed, imported or sold, or any other relevant circumstances (hereinafter, the "Manufacturer"). In addition, liability may pass through the final Manufacturer and include subcontractors, raw material providers and part suppliers. In such cases, subcontractors, raw material providers and part suppliers may be jointly and severally liable with the Manufacturer for damages. Nevertheless, subcontractors, raw material providers and parts suppliers have defences to liability. See question 3.1 below. Manufacturers, subcontractors, raw material providers and part suppliers may also be liable under the CCJ. Only a party that breaches a contractual duty and is in privity of contract with the injured party can be liable under contract law.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

The JPLL does not contain a provision that expressly obligates a Manufacturer to recall or repair a Product found to be defective in a product liability lawsuit. However, the aforementioned CPSL grants government ministries the power to promulgate standards applicable to specific classes and types of products, to investigate complaints relating to particular products, compel manufacturers and importers to disclose information relating to allegedly unsafe products, and order product recalls or other remedial actions. For the majority of consumer products, the ministry that has regulatory oversight is the Ministry of Economy, Trade and Industry ("METI").

Under the recently revised CPSL, a company is legally obligated to take some form of remedial action if their product causes a "serious product accident" to stop such accidents from further arising or spreading. Such action could include investigating the nature and cause of the accident, reporting the accident to a government ministry, commencing a recall, repairing the product or making a public announcement to warn consumers. A "product accident" is defined as any accident that is either: (1) a product accident that damages the life or body of a consumer; or (2) a product accident in which a consumer product is destroyed or damaged, potentially causing life-threatening or bodily injury to a consumer; and (3) which could have been caused by a product defect. In other words, in the case where an accident causes injury to a person, property or the Product, unless it is clear that the cause is *not* a defect, the incident is deemed to be a product accident. A "serious product accident" means those product accidents in which the injury that occurs or may occur is serious, and the nature or appearance of the accident fulfils the criteria laid down by regulation. Criteria have since been promulgated by METI to include: (1) fatal accidents; (2) product accidents causing injuries with aftereffects that take more than 30 days to heal or that leave the body permanently disfigured; (3) fires; and (4) carbon monoxide poisoning.

In the event of a "product accident", whether and what steps the company might take are within the discretion of the company, but companies are strongly encouraged to file a report to METI and institute remedial actions that are appropriate under the circumstances.

Under the powers granted in the CPSL, if at anytime a ministry such as METI concludes that the remedial actions being taken by the company are insufficient in light of the potential or foreseeable danger associated with the Product, such ministry may order the remedial actions it deems necessary. Such actions could include ordering the company to conduct a total or partial recall of the Product, offer all purchasers component replacement or repair service, or place advertisements in national media to warn consumers of the danger.

Aside from possible civil liability stemming from the failure to recall, repair or warn consumers of a potential danger, violation of the CPSL or a ministry order carries with it possible criminal fines and criminal prosecution of the company and its directors, officers and employees.

1.5 Do criminal sanctions apply to the supply of defective products?

The JPLL, CCJ and CCL provide only for a civil cause of action for injured persons or entities and do not carry criminal sanctions. However, in addition to the possible criminal sanctions previously mentioned in regards to the CPSL, under the Japanese Criminal Code, it is possible that a company's directors and employees could face criminal penalties if they were criminally negligent in the manner by which they designed, manufactured or supplied a defective Product.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

Under the JPLL, the Claimant has the burden of proving that the Product is defective and that the Defect was the cause of the Claimant's injuries.

For claims brought under CCJ Article 709, again, the Claimant bears the burden of proof and must show that the injury was caused by a Defect in the Product and that the Manufacturer negligently or intentionally breached a duty owed to Claimant and this breach of duty caused damage to the Claimant.

Under contract law, the Claimant must make a showing that the Manufacturer breached the terms of the contract by supplying a product that failed to meet an express or implied warranty of the Product and that the breach caused the injury to the Claimant.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The JPLL does not provide a specific test for causation, so a court will use the standard test for causation found under the CCJ by asking whether, but for the Defect, the injury would not have been suffered. A Manufacturer is liable only to the extent that the damages were generally foreseeable or specifically foreseeable to the Manufacturer based on information known to the Manufacturer. A Manufacturer would not be liable for damages for only having wrongly exposed a Claimant to an increased risk of injury known to be associated with the Product unless the Claimant can prove some sort of physical or mental injury.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Market-share liability does not exist in Japan. When filing suit under the JPLL, CCJ or CCL, it is necessary to specify the Manufacturer that is responsible under the JPLL for the defective Product.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

As mentioned above, a Defect may be found in a case where a Manufacturer fails to properly warn consumers of the latent dangers and risks associated with the product. Japanese courts do not recognise a "learned intermediary" defence whereby distributing a Product through an intermediary or warning an intermediary would absolve the Manufacturer of liability. Warnings must be communicated to the people that will be exposed to the danger of the Product.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under the JPLL, once a Claimant makes a showing that the Product is defective, the Manufacturer may assert one or more of the following defences to either avoid liability or shift part or all of the liability to another party:

- the claim was brought beyond the applicable three or ten-year statute of limitations (see question 5.2);
- the Product is not defective because the manner in which the Claimant handled, used or stored the Product was, under the circumstances, unforeseeable misuse;
- the Product is not defective because its design and manufacture meets or exceeds published safety guidelines and standards (such as the SG-Mark);
- the state of scientific or technical knowledge at the time when the Manufacturer delivered the Product was such that the existence of the Defect identified by the Claimant could not have been known;
- the Defect did not exist at the time the Product was delivered by the Manufacturer;
- in the case of a failure to warn of the Defect, the Claimant is an experienced and knowledgeable user of the Product;
- the Defect was caused by defective components or raw materials supplied by a subcontractor;
- (in the case of a subcontractor) the components or raw materials that are said to have caused the Defect were supplied pursuant to the specifications and instructions given by the final Manufacturer and that the subcontractor was not negligent with respect to the occurrence of the Defect; or
- the Claimant's injuries were not caused by the defective Product.

Under CCJ Article 722, the Claimant's own contributory negligence or assumption of the risk may be a partial or complete defence to liability.

In respect to breach of contract claims, standard defences to breach of contract claims would be available. See also question 3.6.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

A "state of scientific or technical knowledge" defence exists under the JPLL. If the Manufacturer can prove that a Defect in a Product was undiscoverable or unknowable by the scientific and technical knowledge available at the time of delivery to the Claimant, the Product will not be found to be defective. However, this defence is narrowly interpreted by the courts. Courts require a showing by the Manufacturer that none of the established knowledge or technology relevant to the Product provided any suggestion or knowledge that such a danger might have existed. As a result, scientific or technical knowledge is not limited to the knowledge held by the individual Manufacturer, but is deemed to include all scientific and/or technical knowledge at the time. The Quality-of-Life Policy Council under the Prime Minister's Cabinet Office has taken the position that scientific and/or technological knowledge must be judged based on the highest standards of technology available at the time; thus placing on Manufacturers a heavy evidentiary burden.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Under the JPLL and the CCJ, to counter a Claimant's showing that a Product is defective, a Manufacturer may argue that the Product complies with relevant safety standards such as the SG-Mark standard or some other government regulation or guideline. While such a defence may be persuasive to a court, it is not dispositive that no defect exists and the Manufacturer may nonetheless be held liable for having delivered a defective Product.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Because claims brought under the JPLL are specific to a particular factual incident involving injury, injuries involving different Claimants injured by the same Product may be brought in separate proceedings and involve claims and issues litigated previously.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

A Manufacturer in a product liability suit may seek indemnification from a third party for losses that might be incurred in the future if such manufacturer is found liable for having delivered a defective Product. The Manufacturer could accomplish this by filing a suit against such third party and then seeking to combine the proceedings. The combination of the two proceedings is at the discretion of the court.

If the third party was not brought in as a third party defendant in the original suit, a manufacturer could file a suit against the third party after the underlying product liability law suit was decided against the manufacturer.

If indemnification is sought under a breach of contract theory, the law suit for indemnification must be filed within ten years from the date when the Manufacturer paid the court ordered damages to the injured party.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Yes. CCJ Article 722, paragraph 2, empowers courts to take a Claimant's own negligence into account when calculating damages. While not expressly provided in the JPLL, CCJ Article 722 would likewise permit a court to reduce a Claimant's damages in a product liability suit in the case where the Claimant was contributorily negligent. In relation to contract claims, CCJ Article 418 grants courts the additional power to relieve a Manufacturer of any liability where the Claimant has been negligent.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

Trials are by judges only.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

A court may, *sua sponte* or upon petition of one of the parties, appoint an expert to testify and provide evidence, but experts never "sit" with the judge. The judge alone has the authority to decide factual and legal matters at issue in litigation.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

Japanese civil procedure does theoretically allow class action suits where a single Claimant represents other injured parties, but the requirements for the class are so stringent that forming a class is exceedingly difficult in the vast majority of situations and rarely accomplished. However, Claimants with related claims against the same Manufacturer may join the same law suit in some circumstances.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

The JPLL itself does not allow representative bodies to sue on behalf of individuals. However, since June 7, 2007, consumer groups recognised and authorised by the Japanese government may, on behalf of consumers in general, seek injunctions to stop companies violating certain clauses of the CCL.

4.5 How long does it normally take to get to trial?

Under Japanese Civil Procedure, a Court must schedule the first

hearing within 30 days of the filing of the law suit, but this is often delayed due to scheduling conflicts of the court. Trials in Japan are primarily conducted by written submission of the parties and oral arguments are rare. There is no continuous "trial" as one might see in a common law country such as the U.S. or the U.K., but rather interspaced hearings, typically lasting less than 30 minutes, are held primarily to afford the parties opportunity to submit new documents and evidence to the court. As a result, "getting to trial" happens very quickly, but reaching a judgment in the first instance may take a few years, depending on the complexity of the matter.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Japanese civil procedure does not provide for motion practice, so issues of fact or law may not be decided as preliminary issues. For example, there is no motion for summary judgment or dismissal. However, a court may close the trial proceedings and make a final judgment at anytime.

4.7 What appeal options are available?

A dissatisfied party may appeal to an appeals court as a matter of right. The appeals court sits *de novo* over the lower court's judgment. A further appeal may be made to the Supreme Court of Japan, but if the issue involves subject matter other than a constitutional issue or a serious procedural or factual error, it is likely that the appeal will be denied by the Supreme Court. The Supreme Court will only consider matters of law and will not make any factual determinations.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

A court may, *sua sponte* or upon petition of one of the parties, appoint an expert to testify. Additionally, parties may introduce expert testimony as part of their briefs and submissions to the courts. Expert testimony may be introduced as evidence at trial by any of the following methods. First, under the *Kantei* system, a party may make a request to the court for an expert opinion and the court may appoint an expert to testify. Second, each party may provide expert testimony from an expert of their own choosing either by examining the expert as a witness (*Shounin-jinmon*) at a court hearing or by submitting documentary evidence from the expert (*Shoshou*). While each party is free to challenge the qualifications of the expert, the court does not have a *Daubert*-like gatekeeper duty to exclude unreliable expert testimony and is free to consider or disregard any evidence submitted by a party.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

If a witness is presented at a hearing, whether they are a fact or expert witness, the party presenting such witness is required to give to the other party written notice containing a summary of the matter about which the witness will be called upon to discuss. The non-calling party will also have a chance to cross examine at the hearing.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

Unlike common law countries such as the U.S. or the U.K., there is neither a disclosure obligation nor right of discovery in Japan. There are, generally, four ways a party may be able to obtain documentary evidence from the other side: (1) preservation of evidence motion; (2) request through an attorney bar association; (3) court ordered production of documents; and (4) an inquiry by a party. However, a party may refuse to produce documentary evidence where: (1) the document contains information regarding which the holder (or people that are closely related to the holder) has a right to refuse to testify; (2) the document contains information on which the holder owes a professional duty of confidentiality; (3) the document is related to governmental affairs and the production of the document is against public interest or will materially adversely affect the functioning of public duties; or (4) the document was made specifically for the purposes of the holder or relates to a criminal or juvenile delinquency matter. One of the greatest hurdles facing Claimants in product liability cases is that the evidence needed to prove that a Product is defective is held by the Manufacturer and is not easily discoverable. It is believed by many practitioners that this is an important factor as to why product liability lawsuits are not more common in Japan.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Potential civil litigants may agree to refer their case for closed-door civil conciliation (*chotei*) by applying at the local district court. A conciliation board consists of one judge and at least two conciliators. When an agreement is reached, it is recorded and becomes enforceable in the same manner as a judgment of the court, but if the conciliation fails, the plaintiff will have to file a law suit to pursue his/her claim.

Arbitration (*chusai*) is a speedy and economical method for settling disputes, but both parties must agree in advance to be bound by the arbitrator's decision. The arbitrator's decision is enforceable as the judgment of the court.

Negotiated settlement (*wakai*) may be reached by the parties before or during court proceedings. There are organisations which specialise in promoting settlements of product liability and product defect related claims in a certain product area such as the Centre for Housing Renovation and Dispute Settlement Support, the Association for Electric Home Appliances, the Automobile Product Liability Consultation Centre, the Pharmaceutical PL Centre, the General Merchandise PL Centre, and the Consumer Product Safety Association. Only once an arbitration agreement is recorded with the court does it become enforceable as the judgment of the court.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, there are time limits.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

Generally, claims under the JPLL must be brought within a period

of three years from the time when the injured person becomes aware of the damage and the responsible Manufacture or a period of ten years from the time when the Manufacturer delivered the Product in the case where the injury or the Manufacturer is unknown to the Claimant. Claims under CCJ Article 709 follow a similar prescription of three and 20 years, respectively. Generally, contract claims must be brought within ten years, but this period varies with the identity of the parties and nature of the contract.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

A court could toll the statute of limitations if it found that doing so is in the interests of justice in view of fraud or concealment of evidence by the Manufacturer.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

Only monetary compensation is available as a remedy under the JPLL and CCJ. Under the CCL, orders to invalidate contracts entered into with consumers as well as prospective orders to prevent illegal solicitations for new business are also available.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

The JPLL provides that a Manufacturer shall be liable for damages to the life, limb or property of the victim. A Manufacturer is not liable for damage to the Product alone. In addition to physical injuries, compensation for mental damages (pain and suffering) (*isharyou*) caused by the injury caused by the defective Product are also recoverable within the discretion of the court and are commonly awarded. Medical expenses and lost wages are also recoverable.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

No. Recovery is only possible once a defective Product causes damage.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are not recoverable in Japan.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no maximum limit on the damages recoverable.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

No special rules apply.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Japanese government social welfare organisations may not claim a portion of damage compensation that a Claimant receives as the result of a product liability law suit.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

As a general rule, court costs such as filing fees, the prevailing party's travel expenses and document preparation fees, etc. are borne by the loser of the suit. Otherwise, each party covers its own expenses. It is within the discretion of the court to award a reasonable portion of the prevailing party's lawyer fees as part of the damages. By U.S. or U.K. standards, awards of attorney fees are not generous.

7.2 Is public funding e.g. legal aid, available?

There exists a public entity called the Japan Judicial Support Center (*Nihon Shihou Shien Sentaa*) that may assist with attorneys' fees and court costs for some Claimants.

7.3 If so, are there any restrictions on the availability of public funding?

To receive public funding from the source mentioned above, there must be some possibility of the requesting party winning the suit.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

The Japanese Bar Association allows Japanese lawyers to structure their fees so that a portion of compensation to be paid at the conclusion of the suit is dependent on the outcome of the law suit. However, lawyers are not allowed to bear litigation costs of their clients until a judgment is entered.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

A third party is not prohibited from providing funds to a Claimant in order to commence a product liability law suit, however, the Claimant's lawyer may not fund the claim, but may work on a success fee basis. In the case of working on a success fee basis, the Claimant would have to pay his/her share of court costs as they arose and became due.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Japan.

The most notable, recent development in the field of product safety has been the considerable revision of the CPSL which went into effect on May 14, 2007. While not creating a private cause of action for injured persons, the revised CPSL does place on all companies a duty to collect information about accidents involving their products, report such accidents under certain circumstances to the government, and to undertake remedial measures to eliminate any unsafe conditions or properties of their Product. There is also a duty placed on retailers to report up the distribution chain any incidents that come to their attention. From April 1, 2009, for products that can become especially dangerous due to deterioration over time (such as kerosene heaters), the CPSL will require Manufacturers/importers to notify consumers that the manufacturer/importer will inspect the product upon request, keep a database of the owners of such products, and inspect such products when so requested by a product owner. Also from April 1, 2009, the CPSL will require Manufacturers/importers to affix a warning label to products for which prolonged use often results in minor accidents (products such as electric fans and air conditioners). METI advises that such a warning label should state the intended life of the Product and possible accident scenarios.

As of the time of writing of this chapter, two bills regarding consumer safety are under consideration by the Diet. One would create a Ministry of Consumer Affairs to be in charge of Japan's product liability policy. The other would give the Prime Minister power to order recalls and take other measures. The passage of both of these bills is uncertain.

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Korea

Kyu Wha Lee

Sedong Min

Lee & Ko

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

Broadly speaking, a party may seek compensation for death, injuries or property damage due to a defective product through 3 legal methods under Korean law. Conventionally, a party injured by a defective product would bring a claim under tort or a breach of contract, with a tort claim being even more common. However, the Product Liability Act of Korea ("PLA"), increasing consumer protections, became effective on July 1, 2002 and since then, claims for defective products have been brought under the PLA rather than the other 2 theories.

A party may bring a claim and seek compensation against the manufacturer for damages caused by a defective product under the PLA. In case a claim is brought under the PLA, the claimant would need to establish the existence of a defect in the product, and the causal relationship between the defective product and damages. However, the claimant would not have the burden of proving that the manufacturer had intentionally or negligently caused the defect. In order for the manufacturer to defend itself from such claim of product liability, it would need to prove one of the affirmative defences as provided for under the PLA (please see question 3.1). From the foregoing, it is deduced that the PLA imposes strict liability on a manufacturer of a defective product.

The PLA provides that a "manufacturer" (as defined in question 1.3) would be liable for either damage leading to death or personal injuries, or damage to any item of property (other than the defective product itself), which is suffered by any person, due to a "defect" of the "product" (Article 3(1) of the PLA). "Product" as defined therein means all movables, industrially manufactured or processed, even though incorporated into another movable or into an immovable product (Article 2(1) of the PLA). In this definition of "product", electricity and energy are included, but real property, non-processed agricultural products, software, and information are excluded. "Defect" as defined therein means the lack of safety in a product given the science and technology available at the time of manufacture thereof. The PLA categorises a "defect" into 3 types, namely, "manufacturing defect", "design defect", and "indication defect" (Article 2(2) of the PLA).

A manufacturing defect means the lack of safety caused by manufacturing or processing of any product deviating from the originally intended design, regardless of whether the manufacturer faithfully performs the duty of care and diligence with respect to the manufacturing or processing. A design defect means the lack of safety caused by the failure of the manufacturer to adopt a reasonable alternative design in a situation that any damage or risk caused by the product would otherwise be reduced or prevented. An indication defect means conditions that the manufacturer fails to give reasonable explanations, instructions, warnings and other indications on the product, while the occurrence of damage or risk caused by the product that would otherwise be reduced or prevented.

Before the enactment of the PLA, a party injured by a defective product would generally bring a tort claim under Article 750 of the Korean Civil Act ("Civil Act"), which provides that a person who causes losses to or inflicts injuries on another person by an unlawful act, intentionally or negligently, would be bound to compensate for damages arising there from. However, in order to receive compensation for a tort claim, the claimant bears the burden of proving (i) the existence of a defect in the product, (ii) the defect was intentionally or negligently caused by the manufacturer, (iii) damages, and (iv) causation between the defect and damages. Thus, liability for a tort claim would be fault based, and when compared with the theory of claim under the PLA, it is disadvantageous to the consumer resulting in fewer claims in tort over defective products.

Further, a party injured by a defective product may bring a claim against the seller for the sale of a defective product (Articles 393 of the Civil Act), or a breach of contract. However, in order to bring a claim of breach of contract against the seller of the defective product, the rule of privity of contract would apply, but consumers in general would not have a contractual relationship with the manufacturer of the defective product. As such, a claim of breach of contract under the Civil Act would be rarely brought.

1.2 Does the state operate any schemes of compensation for particular products?

The Korean government does not operate any compensation schemes for particular products. However, the fundamental Framework Act on Consumers ("FAC") provides for the broad protection of consumers against the potential of death, bodily harm, or property damage caused by a defective product. For instance, the FAC provides that if the defect in the product has the potential of death, bodily harm, or property damage, then the enterpriser would have the duty to report thereof to the relevant governmental authorities, to provide necessary measures for the prevention thereof by conducting a recall of the defective products, and other measures for the safety of the consumers.

Under the FAC, consumers may request compensation for damages due to a defective product to the Korea Consumer Agency ("KCA") (Article 55(1) of the FAC), which is created pursuant to the FAC. Upon receiving the request, the Head of the KCA may recommend the parties of a claim for the settlements of the claim (Article 57 of the FAC), or if the request is unsuitable to be settled by KCA, then the Head of the KCA may discontinue the settlement process of the case (Article 55(4) of the FAC). If the concerned parties fail to reach an agreement by recommended conciliation of the KCA, then the party or the Head of the KCA may request a mediation of dispute to the Consumer Dispute Mediation Commission ("Mediation Commission") of the KCA. When the Mediation Commission receives a request for dispute mediation under the FCA, it will complete the mediation process within 30 days (Articles 65 and 66 of the FCA). When the mediation process is completed, the Mediation Commission would promptly notify the parties of the result of mediation without delay. Upon notification of the results, the parties shall notify the Mediation Commission of their intentions to accept the result within 15 days thereof, otherwise, the parties will be considered to have accepted the result of mediation. If the parties accept or are considered to have accepted the result of mediation, then the Mediation Commission will prepare an official record regarding the settlement of the dispute in accordance with the result of mediation, which shall be regarded to have the same legal effectiveness as final judgment rendered by courts (Article 67 of the FAC). However, if the parties have not accepted the result of mediation and make an objection to the results within 15 days, then such result of mediation would have no legal bearing on the parties.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Under the PLA, a manufacturer is strictly liable for its defective product. The term manufacturer includes (i) a person that is engaged in the business of manufacturing, processing or importing any product, and (ii) a person who presents itself as a manufacturer, processer or importer of such product by putting his name, firm name, trademark or any other distinguishable feature on the products or a person who puts any distinguishable feature on the products, which makes that person mistaken for a manufacturer, processer or importer of such product.

With respect to any product the manufacturer of which cannot be identified, a person who, for profit, supplies it in a form of sale or lease, etc. would be liable for damages by defective products, if, in spite that he knows or would be able to know the identity of the manufacturer or the person who has supplied it to himself, and he fails to inform any injured person of said identity within a reasonable period (Article 3(2) of the PLA). Also, where 2 or more persons are liable for the same damage by defective products, they would be liable jointly and severally (Article 5 of the PLA). Further, any special agreement intended to exclude or limit any liability for damage under the PLA would be null and void; provided, that this would not apply to cases where a person who is supplied with a product to be used for his own business concludes such special agreement with respect to any damage to his business property caused by the product (Article 6 of the PLA).

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

The PLA does not provide for provisions on recalls. However, the FAC provides provisions on the duty to report, voluntary recalls, etc. Specifically, if any enterpriser discovers the existence of any serious defects in the manufacture, design or indication defect of the products provided to the consumers which can or potentially can cause danger to the lives, bodily harm or property damage, then the enterpriser must promptly report the defects to the head of the competent central governmental authorities (Article 47(1) of the FAC). After such report, the enterpriser must recall, destroy or repair the defective product, or exchange them for other products, or refund their costs, or cease manufacturing, importing, or selling of such products, or take other necessary measures accordingly (Article 48 of the FAC).

In case the head of the central governmental authorities deems that the products provided by an enterpriser can or potentially can cause any danger to the safety of consumers' lives, bodies, or damage to property due to their defects, he may recommend or order the enterpriser to recall, destroy or repair the defective product, or exchange them for other products, or refund their costs, or prohibit the manufacturing, importing, or selling of such products, or take other necessary measures (Articles 49 and 50 of the FAC). The failure or breach of the duty to report or comply with the order of the head of the central governmental authorities carries with it administrative and/or criminal penalties (please see question 1.5).

Aside from civil litigation cases involving damages arising out of the enterpriser's knowingly failure to recall the defective product, a recall of defective products would be carried by voluntary recall or by recommendation or order for recall by the central governmental authorities under the FAC.

1.5 Do criminal sanctions apply to the supply of defective products?

The PLA provides only for a civil cause of action for injured persons and not criminal penalties. As abovementioned, the central governmental authorities pursuant to the FAC is empowered to recommend or order the enterpriser to recall, destroy or repair the defective product, or exchange them for other products, or refund their costs, or cease manufacturing, importing, or selling of such products, or take other necessary measures. In case the enterpriser violates an order by the central governmental authorities, the enterpriser could be punished by imprisonment for not more than 3 years or by a fine not exceeding 50 million Korean Won. In case the enterpriser breaches its duty to report or reports falsely, the enterpriser could be punished by an administrative penalty not exceeding 30 million Korean Won. (Articles 80, 84, 86 of the FAC.)

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

Under the PLA, the claimant bears the burden of proof of existence of the defect in the product, damage, and causation between the defect and damages, but does not bear the burden of proving that the manufacturer had intentionally or negligently caused the defect. If the manufacturer fails to prove any of the affirmative defences provided for under the PLA (please see question 3.1), then the manufacturer would be held liable for the defective product.

In case of tort claims under Article 750 of the Civil Act, the claimant would bear the burden of proving that the manufacturer had intentionally or negligently caused the defect as well as burden of proving the defect, damage, and causation between the defect and damages (please see question 1.1).

In case of breach of contract claims, the claimant would bear the burden of proving that the manufacturer had breached the contract due to its supply of products not conforming to the terms of the contract, and as a result, the claimant had suffered damages.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The standard of causation is not specifically provided for under the PLA. However, the recent trend by the Korean courts is to shift the burden of proof to the defendants regarding the existence of defect and causation. For instance, the consumer would only need to prove that the accident were to happen within the realm of manufacturer's control and the accident would generally not happen without someone's fault. If the consumer proves such facts, then the court would presume that the product was defective and the damage was caused by such defect to alleviate the burden of consumers. Further, the wrongful exposure of a claimant to an increased risk of injury that is known to be associated with the product alone would not make the manufacturer liable for damages, unless some sort of injury such as physical or mental injury is proved by the claimant.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Market-share liability is not recognised under Korean law. In order to impose product liability, the manufacturer of the defective product would need to be identified. In case the manufacturer cannot be identified, the supplier or lesser might be liable under certain requirements (please see question 1.3).

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

As abovementioned in question 2.2, the PLA requires reasonable explanation, instruction, warning, and other indications regarding the product directly for the consumer. The learned intermediary defence would not be recognised by Korean courts.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Affirmative defences may be proved by manufacturers in product liability suits to be exempted from liability:

(1) the claim was brought beyond the 3- or 10-year statute of limitation;

(2) the manufacturer did not supply the product;

(3) the state of scientific or technical knowledge at the time when the manufacturer supplied the product was not such as to enable the existence of the defect to be discovered;

(4) the defect in the product is due to compliance with applicable laws at the time when the manufacturer supplied it; or

(5) (in case of subcontractor) the components or raw materials claimed to be the cause of the defect were supplied pursuant to the specifications and instructions given by the final manufacturer.

However, where, in spite of the fact that the manufacturer knows or should have known the existence of any defect in the product after it has been supplied, the manufacturer fails to take appropriate measures to prevent the damage caused by the defect from occurring, then the manufacturer shall not enjoy from exemptions #3 and #5 above (Article 4 of the PLA).

Further, if the negligent actions of the claimant contributed to the overall damage, then the amount of damage compensation attributable to such negligence of the claimant may be deducted (please see question 3.6).

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

As abovementioned in question 3.1(3), a "state of scientific or technical knowledge" defence is recognised under the PLA. The manufacturer would have the burden of proving that the state of scientific or technical knowledge at the time when the manufacturer supplied the product was not such as to enable the existence of the defect to be discovered.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

As abovementioned in question 3.1(4), in case the defect in the product is due to compliance with applicable laws at the time when the manufacturer supplied it, and the manufacturer asserts this affirmative defence, liability may be avoided. However, this affirmative defence may only be applied in case where the government has mandated certain regulatory standard onto the manufacturer and the manufacturer had no other choice but to comply with such regulatory standard. Meaning, a mere showing of the manufacturer's compliance with minimum regulatory standards does not provide for this defence under the PLA.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

A claim for damages due to a defective product can be re-litigated even if the issues have been contested and finally resolved in different cases, because the effectiveness of final judgement covers only the parties to the litigation under Korean law. However, in

practice, courts tend to give deference to the decisions of other similar cases rendered by another court.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

In a product liability suit, the manufacturer may seek indemnification from a third party for losses incurred due to such third party, or if such third party had contributed to the compensation liable by the manufacturer. In such case, the manufacturer would need to first file an indemnification suit against such third party, and then seek to combine the proceedings. However, if such proceedings cannot be combined, then the proceedings can be carried out separately. Also, the manufacturer may file an indemnification suit against such third party (or joint tortfeasor) after the product liability suit against the manufacture has been decided against the manufacturer. Such indemnification suit must be filed within 10 years from the date when the manufacturer paid the court ordered damages to the claimant.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

The PLA does not provide for provisions on contributory negligence of the claimant. However, under the Civil Act, in case the claimant's actions caused or contributed towards the damage, then the amount of damage compensation may be reduced by a proportionate amount attributable to the claimant's negligence.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

In Korea, trails are by judges only.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Upon the petition of either party or *ex-officio*, the court may appoint an expert possessing the required expertise and experience to provide his expert opinion in the form of a report to assist the judge. The expert will not be allowed to sit with the judge.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

There is no legislation in Korea providing for class action in product liability suits. Even if a large group of consumers have common cause of action for damages from a common defect of a product, each of the consumers individually would need to be claimants in product liability suits.

However, the FAC provides for the collective dispute mediation procedure for a large number of consumers having identical or similar damages from a defective product, and common legal or factual issues. Specifically, the state, municipality governments, the KCA, certain consumer association or an enterprise may request or file for collective dispute mediation to the Mediation Commission (Article 68 of the FAC). If such request for collective dispute mediation is accepted by the Mediation Commission, then the Mediation Commission must inform the consumers or enterprises at least 14 days from the initiation of the collective dispute mediation procedure through proper channels such as public notice in the KCA website or in newspapers of nation-wide circulation. Through this public notice, the parties to the collective dispute mediation may be added. The Mediation Commission may nominate 1 or more persons among the parties of the collective dispute mediation suitable to represent the group's interest. The Mediation Commission may, if the enterpriser accepts the results of the collective dispute mediation by the Mediation Commission, recommend a compensation plan for the consumers not being parties of the collective dispute mediation. If consumers being the parties of the collective dispute mediation file a lawsuit, then such consumers shall be excluded form the procedure.

As abovementioned in question 1.2, if no agreement is reached as a result of the collective dispute mediation, or a party would not accept the results of the collective dispute mediation, then disputes shall go to court and be finally decided by the courts.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

A consumer association may not file a suit on behalf of consumers seeking compensation for damages derived from defective product.

Under the FAC, however, certain consumer associations, the Korea Chamber of Commerce and Industry, the Federation of Small and Medium Business, Federation of Korean Industries, or Korea International Trade Association may file a lawsuit to courts requesting suspension or prevention of a certain action of an enterprise infringing consumers' rights such as suspension or prevention of being sold defective products in the marketplace (Article 70 of the FAC). But the FAC does not allow the consumer associations or any entities above to file a lawsuit seeking compensation for damages derived from defective products.

4.5 How long does it normally take to get to trial?

Once a complaint has been filed with the court and the complaint is delivered to the defendant, the defendant is required to submit a response within 30 days of receipt thereof. Subsequently, several exchanges of briefs usually take place prior to the first hearing. The first hearing is usually scheduled 4 to 5 months from the filing of the complaint, but it varies on a case-by-case basis. Traditionally, in civil actions, the case at the court of first instance would take approximately 8 to 10 months, approximately 6 to 8 months at the court of second instance, and 4 to 5 months at the Korean Supreme Court. However, in case of product liability suits, there are usually much more issues and fierce arguments between the parties than regular suits, therefore it would take a longer time to hear the judgment than regular suits. For example, a product liability case regarding tobacco was filed in 1999, but the court of first instance rendered its decision only in 2007.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

If the court decides that preliminary issues are needed to be tried

and judged, the court may render an interim judgment on the preliminary issues, which could be related to matters of law and fact. For example, the court may preliminarily examine and render interim judgments on the existence of product liability, and then examine the amount of compensation and damage and make a final judgment. However, in practice, such discretion of the court to preliminarily try certain issues and interim judgments is not exercised by the courts *per se*, but rather such trying of issues is conducted as part of the regular trial and determination on such issues are made in the final judgment.

4.7 What appeal options are available?

If a party is dissatisfied with the judgment of the court of first instance, then such party may appeal to the court of second instance (usually the High Court). At the High Court, the parties may introduce new evidence and arguments. If a party is dissatisfied with the judgment of the High Court, then such party may appeal to the Supreme Court. At the Supreme Court, the grounds of appeal are strictly limited to questions of law.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The court may, upon the petition of a party or *ex-officio*, appoint experts possessing the required expertise and experience in connection with technical issues. The parties may also present expert opinions as part of their case.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

In Korea, factual or expert witnesses are not required to be present for pre-trial deposition. Such witnesses will be present at the hearing to present their witness statements. Further, the party would need to present to the opposing party the list of questions the party will be asking the witness at the hearing, and the opposing party would also have an opportunity to question the witness.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

As a civil law country, Korea is different from common law jurisdictions such as the U.S. and U.K., in that Korean law does not provide for extensive discovery as part of the pre-trial procedures. However, a party may file an application requesting the court to order the holder of evidentiary documents to produce such document to the court. Such request for the production of documents may be made in case (i) the other party possesses the document it had referenced during the trial, (ii) the requesting party has the legal right to inspect such document, or (iii) when the document has been prepared for the benefit of the applicant, or prepared due to the legal relationship between the applicant and the holder of such document. In case the court order to produce documents is ignored, then the requested party may be subject to a maximum administrative penalty of up to 5 million Korean Won or a maximum of 7 days' detention.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

About the mediation process with the KCA please see question 1.2. In addition, an application for civil mediation may be filed with the court, which will be handled by the judge assigned or by the civil mediation committee (consisting of 1 judge and 2 members of the civil mediation committee). The settlement reached through the civil mediation will be officially recorded and become enforceable with the same legal effectiveness as a judgment from the court. However, if no settlement is reached, then the claimant would have no choice but to file a suit to get compensation for damage.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

With regard to the statute of limitation for product liability suits, please refer to question 5.2.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

Under the PLA, a claim is barred by the statute of limitations if the claim is not filed within 3 years of becoming aware of the occurrence of the damage and of the identity of the person liable, or within 10 years from the date the defective product was delivered, whichever comes first; provided, however, that with respect to the damage caused by any substances which are accumulated in the human body and in turn, harm his health, or any other injuries or damages of which the symptoms thereof appear a lapse of a certain latent period, the 10-year period shall be reckoned from the date on which the damage occurs actually. Also claims under tort theory would be barred by a statute of limitation of 3 years or 10 years similar to those under the PLA. Claims under a breach of contract theory would have a statute of limitation of 10 years from the breach of contract in general, however it might differ depending on the parties to the contract (i.e., whether the parties are merchants or not) or the kind of contract.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Under the PLA or civil code, concealment or fraud do not affect the running of any time limit. However, courts generally understand that the statute of limitation of 3 years as mentioned above would start from the date when the claimants become aware of the illegality in the manufacturing and causation between the damage and defective products as well as the occurrence of the damage and of the identity of the person liable. Under such interpretation regarding the statute of limitation, the court might construe that the statute of limitation would not reckon because of the concealment or fraud.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

In product liability suits, only monetary compensation is recognised. However, as abovementioned, according to the FAC, an injunctive relief may be sought by a consumer organisation or other institutions (please see question 4.4).

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

According to the PLA, a manufacturer shall be liable for damages for bodily injuries or damage to property. In addition to physical injuries, damages for mental pain and suffering caused by the injury due to the defective product is recoverable at the discretion of the court as well as medical costs and lost wages. However, a manufacturer would not be liable for damage to the product itself.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Damages cannot be recovered in respect of the cost of medical monitoring in circumstances where the product has not yet malfunctioned and caused injury. The PLA only allows for compensation if a casual relationship is present between the injury and the defective product.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Korean law does not allow punitive damages.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no maximum limit on the damages recoverable from one manufacturer.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

There are no special rules applicable to the settlement of claims/proceedings.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Government authorities may not claim any portion of the compensation a claimant receives from a product liability suit.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Upon the completion of the litigation, the court will also issue a judgment in connection with the cost involved in the litigation. In general, the winning party is entitled to recover the stamp tax, service of process, witness fees, and any other litigation costs paid to the court. However, attorney's fees of the winning party might not be fully recoverable pursuant to court regulations.

7.2 Is public funding e.g. legal aid, available?

There is no public funding, or any type of legal aid, specifically established for product liability suits. However, the government does operate a Legal Relief Foundation that provides for legal assistance at little or no cost to indigents, disabled persons or minors etc.

7.3 If so, are there any restrictions on the availability of public funding?

Legal assistance through the Legal Relief Foundation is limited to indigents, disabled persons or minors etc. If eligible, then legal assistance is provided at little or no cost.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Currently, Korean law allows for attorneys to represent clients in civil matters on a contingency or success fee basis, and are frequently used in practice.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

There is no specific provision under relevant Korean law prohibiting a third party from providing funds to a claimant in order to commence a product liability suit. However, the business of taking over claims, or pretending to take over claims, to bring a lawsuit is prohibited, and it could be punished by imprisonment for up to 3 years or by a fine not exceeding 20 million Korean Won (Article 112 of the Attorney-at-Law Act).

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Korea.

Almost 7 years have passed since the effectuation of the PLA. Over those years, the courts have developed precedents regarding the PLA for the consumer protection especially with regard to manufacturing defects. Courts are in the process of developing precedents for design and indication defects (please see question 2.2 for discussion on tests for manufacturing defects).

The FAC and the Enforcement Decree thereof have been amended

on March 28, 2007 opening the doors for consumer interest organisations to file suits for injunctive relief against enterprisers for defective products and collective dispute mediation. In July 2008, a consumer association filed suit against a telecommunications company to prevent the sharing of private information of subscribers with third parties without consent. Also, in April 2009, there was a news release that asbestos containing ingredients were used in baby powder of a major brand, and a consumer association is contemplating on filing suit against the manufacturer of the baby power for an injunctive relief preventing the manufacturer from using such harmful ingredients. According to recent KCA publications in 2009, since the introduction of collective dispute mediation by amendment of the FAC on March 28, 2007 and until now, there have been 42 collective dispute mediation cases, and 32 of those cases have been completed through the collective dispute mediation process with approximately 2,012 consumers benefiting therefrom.

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

In Luxembourg, product liability is mainly governed by:

(i) specific legislation on defective products;

(ii) contractual and tortious liability; and

(iii) specific legislation on sale agreements concluded by consumers.

I. Legislation on defective products

Product liability is governed by the Luxembourg act dated 21 April 1989 on the civil liability for defective products, as amended (the **Defective Products Act**), implementing Council Directive 85/374/EEC, as amended.

Under the Defective Products Act, producers are liable for damages caused by defects in their products.

A product is defective when it does not provide the safety which the user is entitled to expect. The victim must prove the defect, the damage and the causal link between the defect and the damage.

The Defective Products Act does not affect other rights the user may have according to the general principles of contractual or tortious liability.

II. Contractual liability

Pursuant to article 1603 of the Luxembourg Civil Code (**LCC**), sellers must fulfil two main obligations: (i) deliver the goods; and (ii) warrant the goods that have been sold.

(i) Under Luxembourg law, the seller must deliver goods that correspond to the terms stipulated in the contract. The delivery duty implies the transfer of property to the purchaser but also accessory duties such as the obligation to ensure the safe use of the goods (i.e. by giving the purchaser complete and clear instructions or warnings).

- Where the seller does not deliver products in conformity with the contractual specifications, the purchaser is entitled to request either the compulsory performance or the rescission of the contract.
- Where a purchaser is the victim of an injury caused by a product, the seller may be liable if the injury is a consequence of a breach by the seller of his information and security duties.

(ii) Under Luxembourg law, the seller is liable for the hidden defects of the product he sells.

The corresponding warranty is governed by articles 1641 to 1649 of the LCC. According to case law, the scope of this warranty is not limited to sales but also encompasses other types of contracts (e.g. lease agreements).

The purpose of this warranty is to ensure that products sold to the purchaser are fit for proper use. Should the products be unfit for their purpose or should the defect be of such a nature that it diminishes the use of the products to the extent that the purchaser would have paid a lower price for them had he been aware of the defect, the warranty may be invoked.

In order for the purchaser to succeed in his action, the latter must prove that the defect existed before the sale and that this defect could not reasonably have been discovered. The defect must also be sufficiently serious.

The warranty will be ineffective if the defect was either obvious or known to the purchaser.

III. Tort liability

1. The producer or the manufacturer of a product may also, in accordance with the principle of tort liability set out in articles 1382 and 1383 of the LCC, be liable for the damage caused to a victim as a consequence of his fault or negligence. In order to succeed in his action, the victim must prove that it has suffered a damage which is directly linked to a fault or a negligent act of the producer or the manufacturer.

2. Pursuant to article 1384, first indent of the LCC, the holder of goods that are under his control is liable for the damage caused by the said goods.

Contrary to the liability based on articles 1382 and 1383 of the LCC, which require proof of a fault, article 1384, first indent establishes a presumption of liability of the holder of the product that caused the damage.

Luxembourg case law defines the "holder" (*gardien*) as the person having the powers of use, command and direction of the product. The presumption of liability applies if (i) there was contact between the object causing the damage and the damaged good and (ii) the object was in motion at the time of contact. In the absence of contact or if the product was inert, the victim must prove that the object was at least in part instrumental to the realisation of the damage.

IV. Specific legislation on sale agreements concluded by consumers

The act dated 21 April 2004 on the conformity guarantee due by the seller of moveable property, implementing Council Directive 1999/44/CE, governs sale agreements whereby a professional sells moveable property to a consumer.

Pursuant to this act, the seller must deliver the moveable property

as agreed upon by the parties in accordance with the sale agreement. In addition, the seller is liable for any material defects.

No guarantee is due where the purchaser could not ignore the material defect at the moment of delivery.

1.2 Does the state operate any schemes of compensation for particular products?

The Grand-Duchy of Luxembourg (**Luxembourg**) has not created compensation schemes for particular products.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

I. Legislation on defective products

Under the Defective Products Act, the manufacturer, the producer and, in the case of products manufactured outside of the European Union, the importer, may be liable for damages caused by the defects of their products. Any person that presents itself as the producer or the manufacturer of the product, e.g. by affixing its name, trademark or another distinctive sign on the product, may be regarded as the product's producer or manufacturer.

II. Contractual liability

The manufacturer or the seller of the defective product are generally liable *vis-à-vis* the injured party.

III. Tort liability

1. The manufacturer of the product may be liable on the basis of tort liability.

2. Pursuant to article 1384, first indent of the LCC, the holder of the defective product that caused the injury is presumed to be liable. The holder can be the manufacturer, the seller or the owner of the product.

IV. Specific legislation on sale agreements concluded by consumers

The seller may be liable.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Under the Act dated 31 July 2006 relating to General Product Safety, as amended (the **General Product Safety Act**) implementing Council Directive 2001/95/EC, producers have the obligation to ensure that they put only safe products on the market. The General Product Safety Act applies if no specific provisions exist governing the safety of the products concerned.

According to article 6 of the General Product Safety Act, the Minister of Economy can (i) order the withdrawal of dangerous products already placed on the market and (ii) order, coordinate or organise, with the cooperation of the producer and the distributor if needed, the recall of dangerous products already supplied to consumers.

1.5 Do criminal sanctions apply to the supply of defective products?

The General Product Safety Act sets forth criminal sanctions against producers who market products for which they know or should have known did not meet the safety standards imposed by Luxembourg legislation, including fines between EUR 251 and EUR 25,000.

In the event of non compliance with the decisions taken by the Ministry of Economy, producers and distributors may be sentenced to imprisonment for a period of between eight days to one year and imposed fines of between EUR 251 and EUR 125,000.

Furthermore, this act imposes fines between EUR 25 and EUR 250 for distributors who put into circulation products that are not safe.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

I. Legislation on defective products

Pursuant to article 3 of the Defective Products Act, the victim must prove the defect, the damage as well as the causal link between the defect and the damage.

II. Contractual liability

- The purchaser must demonstrate that the seller failed to deliver products in conformity with the contractual specifications.
- The seller will also be liable towards the purchaser in case of failure to respect its information and security duties.
- In case of an action based on hidden defects, the purchaser must prove that the defect (i) existed before the sale, and was hidden at the time of the sale and (ii) is sufficiently serious.

III. Tort liability

(i) Articles 1382 and 1383 of the LCC:

The victim must prove the fault, the damage and the causal link between the fault and the damage.

(ii) Article 1384, first indent of the LCC:

The victim is not required to prove that the product was defective, but that the product had an active role in the occurrence of the damage.

IV. Specific legislation on sale agreements concluded by consumers

The purchaser must prove that the seller failed to deliver the goods in conformity with the terms of the sale agreement.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

Luxembourg courts generally retain the theory of adequate causation (*théorie de la causalité adéquate*). This theory attempts to link the damage to the past event that was normally likely to cause it, unlike other events preceding the damage that would only have caused it under exceptional circumstances. In other words, a fault preceding the occurrence of a damage is in causal link with the damage if according to general life experience, such a fault would normally give rise to such a damage.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

I. Legislation on defective products

According to article 2 of the Defective Products Act, the supplier of the defective product may be liable where the producer of the said product cannot be identified.

II. Contractual and tort liability

According to Luxembourg case law, if several producers are liable for the same damage, they will be declared jointly and severally liable towards the victim (*responsabilité in solidum*).

There is no "market-share liability" in Luxembourg.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

As previously mentioned (see the answer to question 1.1), a duty of information lies with the manufacturer or the seller of a product. The manufacturer or the seller must generally provide consumers with relevant information on the product, on the means of use and on the dangers involved (*obligation d'information et de conseil*).

A specific duty of information lies with the manufacturer or seller of medical products, who must provide information on such products to users and doctors, in particular as to the possible harmful side effects. Otherwise they may be held liable (both contractually and in tort) to the extent the breach of the information duty is directly linked to a damage suffered by the victim.

There is no principle of "learned intermediary" in Luxembourg.

3 Defences and Estoppel

3.1 What defences, if any, are available?

I. Legislation on defective products

(a) Pursuant to article 4 of the Defective Products Act, the producer shall not be liable if he proves:

(i) that he did not put the product into circulation;

(ii) that, having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation or that this defect came into being afterwards;

(iii) that the product was neither manufactured for sale nor for any other form of distribution for economic purposes, nor manufactured or distributed in the scope of the producers' business;

(iv) that the defect is due to compliance of the product with mandatory regulations issued by the public authorities; or

(v) in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product.

(b) According to article 5 of the Defective Products Act, the liability of the producer can be reduced if the damage is caused jointly by a defect in the product and by the fault of the victim or any person for whom the victim is responsible.

The liability of the producer is not reduced where the damage is caused both by a defect in the product and by the fault of a third party.

(c) The liability of the producer *vis-à-vis* the victim under the Defective Products Act cannot be contractually limited or excluded.

II. Contractual and tort liability

(a) Where a fault must be proved by the victim (in both contractual and tort liability), the manufacturer or the seller may avoid or limit his liability if he proves a case of absolute necessity (*état de nécessité*) or a fault of the injured person.

Where a presumption of liability exists (i.e. article 1384, first indent of the LCC), the manufacturer or the seller may avoid his liability if he proves (i) a case of unforeseeable circumstances (*force majeure*), (ii) a fault of the victim or (iii) a fault of a third party, provided that this fault presents the characters of *force majeure* (i.e. is unforeseeable, unavoidable and beyond his control).

(b) In principle, Luxembourg law recognises the possibility for parties to contractually exclude or limit their liability for breach of contract or negligence. However, liability for death, personal injury, gross negligence or fraud cannot be excluded or limited by way of contract.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

The Defective Products Act has not implemented into Luxembourg law the provision of the EU Directive on defective products whereby the producer cannot be held liable if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered. Hence, the Defective Products Act does not consider development risk as a means of defence for the producer.

There are no Luxembourg case law precedents on this specific issue.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

The producer shall not be held liable under the Defective Products Act, in contract or in tort, if he proves that the defect is due to compliance of the product with mandatory regulations issued by public authorities.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Pursuant to article 1351 of the LCC, the authority of *res judicata* (*la chose jugée*) does not allow a challenge to what was definitely judged between the same parties. Consequently, the same parties cannot initiate new legal proceedings based on the same grounds and the same subject matter.

However, it is possible for another victim to sue the same producer

for the same defective product. In this case, the court is not bound by the former judgment.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

As previously mentioned (see the answer to question 3.1), the Defective Products Act does not allow the producer to reduce his liability if the damage is due to the fault of a third party and to the default of the product.

Where the liability is sought on the basis of article 1384, first indent of the LCC, the fault of a third party may exonerate the defending party from its liability if the said fault presents the characters of *force majeure*.

In any case, the defendant can claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

See the answer to question 3.1.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

In Luxembourg, there is no jury in civil and commercial matters. Depending on the value of the claim brought before the court, the case will be submitted for hearing before either one judge (*juge de paix*) or three judges (*tribunal d'arrondissement*).

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The New Code of Civil Procedure (**NCPC**) does not allow a court to appoint an expert or technical specialist to sit with the judge (expert assessors). However, Luxembourg courts are entitled to appoint an expert in matters for which technical advice is required.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

A class action procedure is not permitted under Luxembourg law.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

A consumer organisation is not entitled to start legal proceedings for the damages suffered by its members. Each consumer must file his own claim against the manufacturer and/or the seller.

However, a consumer organisation may initiate an action for its own personal damage suffered or for the injury caused to the collective interest (*intérêt collectif*) defended by the said organisation.

A consumer organisation may also initiate actions before the President of the District Court to obtain the cessation of practices infringing the provisions of the act dated 21 April 2004 on the conformity guarantee due by the seller of moveable property.

4.5 How long does it normally take to get to trial?

The *Justice de paix* has jurisdiction for civil and commercial matters not exceeding EUR 10,000. It can take three months to one year to obtain a court decision.

For matters exceeding EUR 10,000, the proceedings before the District Court (*Tribunal d'Arrondissement*) generally last between one to four years. The duration of the procedure depends largely on the complexity of the case, the diligence of the lawyers instructing the case, the potential appointment of experts and witness hearings.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The courts can rule upon the question of jurisdiction as well as any procedural issues and judgments can be appealed before the Court of Appeal.

In a preliminary judgment (*jugement avant dire droit*), a court may order a witness hearing, the appointment of an expert, or a third party to provide evidence. This judgment does not rule on the merits of the case and thus cannot be appealed without the decision rendered on the merits.

4.7 What appeal options are available?

Pursuant to article 2 of the NCPC, the decision of the *Justice de paix* cannot be appealed where the amount of the claim does not exceed EUR 2,000.

Except in case of a *jugement avant dire droit* (see the answer to question 4.6), a party may appeal a court decision. The appeal must be lodged within forty days of the service of the decision, before the District Court (for claims under EUR 10,000) or before the Court of Appeal (for claims above EUR 10,000). On appeal, both matters of fact and matters of law are judged.

Finally, a party may lodge proceedings before the Luxembourg Supreme Court (*Cour de cassation*) within a period of two months of the service of the decision. The Supreme Court does not rule on matters of fact but only on matters of law.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

As previously mentioned (see the answers to questions 4.2 and 4.6), a court may appoint an expert for technical advice. Pursuant to article 446 of the NCPC, courts are not bound by the expert's advice. The expert is not entitled to give an opinion on the merits of the claim.

Each party may also appoint its own expert. According to Luxembourg case law, a court may only rely on a unilateral report provided that the report had been duly communicated to the other

party and that this other party was able to comment on it.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

There is no pre-trial deposition in Luxembourg or formal prior disclosure procedure.

However, in accordance with article 64 of the NCPC, each document, technical report, witness statement and generally all evidence must be exchanged by the parties during the proceedings. The court may reject evidence submitted if it considers that it has not been communicated (to the other party) in due time.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

There are no obligations to disclose evidence before court proceedings.

During the proceedings, each party must exchange its evidence (see the answer to question 4.9).

The court may order a party to the dispute or a third party to disclose documents under penalties.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

(i) Arbitration may be used to resolve civil and commercial disputes. Luxembourg law distinguishes between a submission to arbitration (*compromis d'arbitrage*, which is a contractual agreement whereby the parties refer an existing dispute to one or more arbitrators) and an arbitration clause (*promesse d'arbitrage* or *clause compromissoire*, which is a contractual agreement whereby the parties agree to submit to arbitration, future disputes arising pursuant to their contract).

Article 1244 of the NCPC provides that the arbitral award may only be challenged before the court by means of an annulment action on the basis of a limited list of annulment grounds.

(ii) Mediation may also be used to resolve conflicts in civil and commercial matters, whereby parties agree to ask an impartial third party, the mediator, to help them find a solution to their dispute. Contrary to arbitration, the mediator does not impose a decision on the parties; he simply offers a private and confidential assistance.

There is no specific legislation on mediation for civil and commercial matters in Luxembourg.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

There are time limits on bringing proceedings (see the answer to question 5.2).

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

I. Legislation on defective products

The Defective Products Act provides that proceedings for the recovery of damages must be brought within three years from the day on which the plaintiff became aware, or should reasonably have become aware of the damage, the defect and the identity of the producer (article 7). This period may be interrupted or suspended.

Pursuant to article 7(2) of the Defective Products Act, the producer may only be held liable for damages that occur within ten years from the date on which the product that caused the damage was put into circulation, unless the victim has filed an action against the producer in the meantime.

II. Contractual liability

In accordance with article 1648 of the LCC, the statute of limitation applicable to actions on grounds of hidden defects is divided into two time limits: (i) a short period to denounce the defect (without providing a strict limit for the first time period which is left to the court's discretion); and (ii) upon expiry thereof, a period of one year to initiate legal proceedings. This one-year period may be interrupted by negotiations or by summary proceedings.

III. Tort liability

In accordance with article 2262 of the LCC, a tort action becomes time barred after thirty years from the date the damage occurred.

Courts do not have a discretionary power to disapply the statute of limitation.

IV. Specific legislation on sale agreements concluded by consumers

The purchaser must by any means notify the seller of the material defect within two years of the delivery of the moveable property and must initiate his action for warranty within two years of such notification.

This strict time limit does not apply where the seller has deceived the purchaser in order to prevent him from initiating his action for warranty or where the parties have entered into negotiations or where a court action is pending.

Time limits are suspended against (non-emancipated) minors according to article 2252 of the LCC.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

The grounds to interrupt or to suspend time limits are exclusively enumerated in articles 2242 to 2259 of the LCC. However and according to Luxembourg case law, fraud or concealment may affect the running of time limits.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

I. Legislation on defective products

Article 7 of the Defective Products Act allows the victim of the defective product to recover damages.

II. Contractual liability

- In case of lack of conformity, the purchaser may choose either to return the moveable property and to get a refund or to keep the moveable property and to reclaim part of the sale price. Where the seller replaces or repairs the moveable property, the purchaser cannot obtain rescission of the sale or the reduction of the sale price (article 1610 of the LCC).
- Article 1644 of the LCC gives the purchaser the possibility to rescind the contract by means of an action to set aside the sale on account of a material defect (*action rédhibitoire*) or

to obtain a partial repayment by means of an estimatory action aimed at ascertaining the value of the defective product (*action estimatoire*). In addition, damages may be allocated to the victim to cover the loss resulting from the purchase of the defective product.

- In the event of breach by the seller of his information and warning duties, damages may be allocated to the victim of the defective product.

III. Tort liability

Tort liability allows the victim of the defective product to recover all damages suffered.

IV. Specific legislation on sale agreements concluded by consumers

In case of lack of conformity, the purchaser can either choose to return the moveable property and to get a refund or to keep the moveable property and to claim part of the sale price.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

I. Legislation on defective products

The Defective Products Act does not apply to damages caused to the defective product itself nor to damages or destruction of any item of property if the item is of a type which is not ordinarily intended for private use or consumption and if it was not used by an injured person mainly for his own private use or consumption.

Material damages to goods exclusively are only indemnified up to a threshold of EUR 557.76.

The liability is unlimited in case of physical injury, and may include damages for moral and material prejudice.

II. Contractual and tort liability

Contractual and tort liability allow victims to claim all damages suffered (material and moral damages) that are licit, personal, certain and direct. For contractual liability, the damage must additionally be foreseeable (*prévisible*).

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

As previously mentioned (see the answer to question 6.2), the damage must be certain to be indemnified. According to case law, future damages (*dommage futur*) can be indemnified when they are expected to occur with an adequate degree of certainty that can be estimated.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are not admissible under Luxembourg law.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no maximum limit applicable for recoverable damages. The manufacturer must indemnify the victims for all damages suffered.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

Parties are entitled to settle on claims and rights (articles 2044 to 2058 of the LCC).

According to case law, it is not admissible to settle on potential (i.e. non actual) rights. Such settlement agreement is null and void.

In order for the settlement agreement to be valid, parties must agree on mutual concessions (*concessions réciproques*).

Except for minors (which require the approval of the terms of the settlement agreement by the family council (*conseil de famille*), article 467 of the LCC), there is no obligation for a court to approve the settlement.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

The law must define the cases in which social security organisms are entitled to claim from the liable party the refund of the allowance or medical expenses paid to the victim in relation to the defective product that caused the damage. A potential share of liability between the author of the damage and the victim is opposable to social security organisms.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Pursuant to article 238 of the NCPC, judicial expenses (*frais et dépens*), including bailiffs' fees and experts' costs, are payable by the losing party. Furthermore, the court may order the losing party to pay an indemnity in accordance with article 240 of the NCPC, in order to compensate the successful party for expenses incurred (such as lawyers' fees). The amount of this indemnity is determined at the court's discretion.

7.2 Is public funding e.g. legal aid, available?

Legal aid is available in Luxembourg and is governed by the Legal Assistance Act dated 3 October 1995.

7.3 If so, are there any restrictions on the availability of public funding?

Legal aid is allocated to Luxembourg residents or foreigners legally residing in Luxembourg. In order to obtain legal aid, the applicant must justify an insufficient income.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Lawyers' fees are determined according to the importance of the

case, its complexity and its outcome. Success fees are valid only if they are not exclusively based on the outcome of the case.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

A third party funding of claims is not permitted in Luxembourg.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Luxembourg.

There are no recent cases, trends or developments concerning product liability in Luxembourg.

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Malta

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

The Maltese Civil Code clearly states that the seller is bound to warrant the thing sold against any latent defects which renders the thing sold unfit for its intended use or which diminishes the goods value to the extent that the buyer would not have bought it or would have tendered a smaller price had he been made aware. Whilst the seller is in no way answerable for apparent defects under the Civil Code he is answerable for latent defects even though they may not have been known to him.

Furthermore the Consumer Affairs Act, Chapter 378 of the Laws of Malta, imposes liability upon the producer for damage caused wholly or partly by a defect in his product and the Product Safety Act also imposes, in certain circumstances stricter, liability upon the Producer. The relative provisions governing liability for defective products have been adopted from EU Directive 85/374 on the liability for defective products. Any producer of a defective movable must compensate any damage caused to the physical well being or property of individuals, independently of whether or not there is negligence on the part of the producer. The producer's civil liability is strict.

1.2 Does the State operate any schemes of compensation for particular products?

The Civil Code provides the buyer with two alternative actions. The buyer may opt to restore the thing to the seller and have the price repaid to him. Alternatively the buyer may choose to retain the thing and have a part of the price repaid to him as determined by the Court.

If the defects of the thing sold had been known to the seller, further to being bound to repay the amount received by him, he shall also be liable for damages towards the buyer.

Whilst there are Tribunals set up by the State for the purpose of liquidating compensation when found to be due there are no specific schemes operated by the State for compensation relating to particular products.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Generally speaking it is the producer who bears responsibility for any fault or defect. The definition given to the term "Producer" is a wide one and is such that it is primarily the manufacturer of the product in question who is to bear the relative responsibility for the fault or defect. This is only possible when the said manufacturer is established in Malta. Alternatively the manufacturer, when not present in Malta, is substituted by any other person in Malta who as a result of affixing to the product his name, trade mark or any other distinctive mark, presents himself as the manufacturer. The latter person could be, albeit not necessarily, the manufacturer's representative.

Any person who has been known to have reconditioned the product may also be found to be responsible for any faults and defects in the product.

In the circumstances that the manufacturer is not present in Malta, and furthermore there is no representative for the manufacturer established in Malta, it is the importer who is to bear responsibility for any fault or defect.

Also responsible for any fault or defect may be anyone involved in the supply chain of the relative product in so far as their activities may have affected any of the safety aspects of a product that has been placed on the market.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

The Head of the Market Surveillance Directorate within the Malta Standards Authority (hereinafter the 'Director') may adopt measures aimed at achieving the return of a dangerous product, and that is one that does not conform to the definition of a safe product, that has already been supplied or made available to consumers by the producer or distributor.

The Law imposes an obligation upon the producer to adopt measures commensurate with the characteristics of the products which they supply so as to make consumers aware of any risks which these products might present. Furthermore the producer is obliged to take appropriate action including, if necessary, withdrawing the product from the market.

The Director is further empowered to take appropriate measures imposing restrictions on the way a product is placed on the market or requiring its withdrawal from the market if he has reason to believe that the product could be dangerous to the health and safety of

consumers. It is merely through an order in writing that the Director can request the immediate withdrawal of unsafe products from the market and, whenever he deems it necessary, to order the destruction of such products under such conditions as he may deem fit.

Upon receipt of a notice in writing ordering the producer to withdraw the product in question, until such time as the notice is withdrawn, the product shall not be used, sold, offered for sale or traded or shall not be removed except to such place as the notice may specify. Breaching such written notice will result in a criminal offence.

1.5 Do criminal sanctions apply to the supply of defective products?

The Product Safety Act, Chapter 427 of the Laws of Malta, imposes upon distributors, and that is upon any person in the supply chain whose activity does not affect the safety properties of a product, including wholesalers, retailers, commission agents and other intermediaries, the requirement to act with due care in ensuring that compliance with general safety requirements is held. Distributors may not supply products they know, or should reasonably know, not to be compliant with such safety requirements.

Distributors supplying products known to them not to be in conformity with the established safety requirements shall be prosecuted in a Court of Magistrates sitting as a Court of Criminal Judicature. Upon being found guilty the criminal sanctions applicable in this regard range from a minimum fine of €1,164.69 to a maximum fine of €23,293.73 and imprisonment not exceeding four years.

Furthermore the Court may order the suspension or cancellation of any licence or licences issued in favour of the person charged or convicted or in respect of the premises involved in the proceedings.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The onus of proving any defect and any possible damage that has resulted from the said defect shall rest upon the claimant. It is the causal relationship between the defect and the resulting damage that must be shown by the injured party.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

It is enough for the claimant to show that his association with the product resulted in the injury. There shall not lie upon the injured person the burden of proving the fault of the producer. A product will be considered to be defective if it does not provide the safety which a person is entitled to expect. In this regard consideration shall be given to the presentation of the product, how it was marketed and any directions and warnings that may have been provided and to the use to which the product could reasonably be expected to have been put. Whilst a product shall be considered defective if it does not provide for the safety which is usually provided for by other models of the same type a product shall not be considered defective only because a better product is subsequently put on the market.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Whilst there are no provisions for market share liability the law states that whenever two or more persons are liable for the same damage (liability must thus first be established) they shall be liable jointly and severally.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

When considering whether or not a product is defective consideration is given to, amongst other things, the product information and warning supplied with or for the product, the product's labelling information and data sheet, marketing material and any statements that may have been made in relation to the product throughout the marketing process and by sales representatives.

Article 77 of the Consumer Affairs Act, Chapter 378 of the Laws of Malta, provides that where the trader as a final seller of goods is liable to the consumer because of a lack of conformity resulting from an act or omission by the producer, by a previous seller in the same chain of contracts or by any other intermediary, the final seller shall be entitled to pursue remedies against the person or persons liable in the contractual chain.

3 Defences and Estoppel

3.1 What defences, if any, are available?

In relation to liability for defective products the Producer shall not be liable if he brings as proof one of the following defences:

(a) that he was not the person to have put the product into circulation;

(b) that it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that the defect came into being afterwards;

(c) that the product was neither manufactured by him for sale or for any form of distribution for an economic purpose nor manufactured or distributed by him in the course of his business or trade;

(d) that the defect in question is due to compliance with a mandatory requirement imposed by law or by a public authority;

(e) that the state of scientific and technical knowledge at the time when the producer put the product into circulation was not such as to enable the existence of the defect to be discovered; or

(f) in the case of the manufacturer of a component or the producer of a raw material, that the defect is attributable to the design of the product in which the component has been fitted or the raw material has been incorporated or to the instruction given by the manufacturer of the product.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Considered to be one of the most important defences as far as most manufacturers are concerned is the "state of scientific and technical knowledge" or "development risk" defence. This defence excludes a producer from liability, if he can prove that the state of scientific and technical knowledge, at the time when he put the product into circulation, was not such as to enable the existence of the defect to be discovered.

The injured party shall under no circumstances be expected to prove the fault of the producer and thus it is up to the same producer to prove that he had no control over the discovery of the fault or defect.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

The only defence is if the manufacturer manages to prove that the defect in question is due to compliance by the manufacturer with a mandatory requirement imposed by law or by a public authority.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

There is no law prohibiting separate proceedings by a different claimant in relation to product liability.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

It is not possible for defendants to have their liability reduced on the mere fact that the damage, apart from there having been a defect in the product, also resulted through an act or omission of a third party. Nonetheless there is nothing prohibiting the defendant from claiming damages from the third party through separate proceedings, in which case such action would be barred by a two-year prescriptive period. Furthermore there is also the possibility of asking the Court to call in such third parties into the same proceedings.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

The defendant can argue that the product was misused or that it was used for purposes other than those for which it was intended.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

Proceedings are usually held either within the Consumer Claims Tribunal or, in the case where there is a breach against product safety legislation, within the Court of Magistrates sitting as a court of criminal judicature. The Consumer Claims Tribunal is presided by an Arbiter while the Court of Magistrates is presided by a Magistrate.

Furthermore it is to be noted that the Tribunal shall only have jurisdiction to hear and determine claims made by consumers against traders where the value of the claim, excluding interest and costs, does not exceed €3,494.06. Nonetheless the jurisdiction of the Tribunal shall not be exclusive and it shall be at the option of the consumer whether to bring an action against a trader before a tribunal or before the ordinary courts.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The Arbiter presiding over the Consumer Claims Tribunal is, as far as is possible, expected to refrain from appointing technical referees to give expert evidence and shall where experts are appointed make out a list of points upon which the expert is to give evidence. The Magistrate presiding over the Court of Magistrates has all the powers to appoint technical experts as he best deems fit.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

There are no specific provisions under Maltese law for multiple claims in relation to product liability. Nonetheless there is no limit to the number of claimants who can bring an action and any amount of claimants could be added in one action. All that is required by the law in this regard is that there is sufficient connection between the claims of the different claimants.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Generally speaking it is one of the roles of Consumer Associations to report or submit complaints to the Authority. In this regard Association representatives shall be called to give evidence on the facts known to the Association in relation to the complaint or report.

Furthermore there is no prohibition towards having a number of claimants represented through a representative body as long as the latter is authorised to do so in terms of Law.

4.5 How long does it normally take to get to trial?

Tribunal proceedings are usually concluded without delay so much so that the Consumer Affairs Act encourages, as far as is reasonably possible, that a case is decided on the same day of the hearing.

Court proceedings are usually lengthier and it can sometimes take months between one sitting and the next. Court proceedings make it more possible for either of the parties to prolong a decision being pronounced.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Prior to examining the merits of the case the Court can try preliminary issues which are raised by the defendants such as for example issues relating to prescription (time bar) and the lack of jurisdiction of the particular tribunal. More often than not the preliminary issues are procedural and the magistrate shall elect whether to decide upon these issues prior to the hearing of the facts or whether to postpone these decisions which shall be determined at the end of the case together with the decision relating to the merits. Preliminary issues are divided between issues which must be brought by the defendant in the statement of defence and other issues which may be brought at any stage in the proceedings.

4.7 What appeal options are available?

Appeals from decisions of the Consumer Claims Tribunal can be filed within twenty days from the date of the decision by means of an application to the Court of Appeal sitting in its inferior jurisdiction.

The right to appeal shall always lie on any matter relating to the jurisdiction of the Tribunal, on any question of prescription, and where the tribunal has acted contrary to the rules of natural justice and such action has prejudiced the rights of the appellant. Furthermore there shall also be the right to appeal where the amount of the claim in dispute exceeds €1,200.

The Consumer Affairs Act provides for a Consumer Affairs Appeals Board. A trader upon whom an interim measure has been served, or upon whom a compliance order has been made, may within fifteen days of notification of the measure appeal from the said measure or order by application before the Appeals Board.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The Code of Organisation and Civil Procedure provides for the Court to appoint one or more experts to assist in considering technical issues.

Expert evidence can also be brought in by the parties in which case the Code of Organisation and Civil Procedure states that where a person is called as a witness, his opinion on any relevant matter on which he is qualified to give expert evidence shall be admissible in evidence only if, in the Court's opinion, he is suitably qualified in the relevant matter.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

A party wishing to present witnesses, factual or expert, will file the request in the sworn declaration leading to the commencement of the civil proceedings or in the statement of defence. It is common practice to have witnesses presenting themselves in persona. All persons giving witness can be examined and cross-examined in Court. It is also common for experts to prepare reports in writing that are in turn filed with the court as evidence.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

All documentary evidence, by law, is to be presented on the commencement of court proceedings. Nonetheless the Court may permit both the plaintiff and the defendant to present such other documentary evidence which was not available or could not have been obtained at the time of commencement of proceedings.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

The Arbitration Act, Chapter 387 of the Laws of Malta, encourages and facilitates the settlement of disputes through arbitration and establishes the Malta Arbitration Centre as a centre for domestic arbitration and international commercial arbitration.

The Mediation Act, Chapter 474 of the Laws of Malta, came into force towards the very end of December 2004 and established the Malta Mediation Centre as a centre for domestic and international mediation.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

The Law provides strict time limits in relation to the institution of proceedings after which actions may not be commenced.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

Actions provided by the Civil Code as referred to in question 1.2 above are barred by the lapse of one year as from the day of the contract in regard to immovables, while in regard to movables actions are barred by the lapse of six months from the day on which it was possible for the buyer to discover such defect.

Criminal actions in relation to proceedings relating to offences concerning product safety are barred by the lapse of two years from when the offence is committed.

The Consumer Affairs Act stipulates that actions for damages in relation to defective products are to be barred by the lapse of three years commencing from the day when the injured party becomes aware or was in a position to reasonably become aware of the damage, the defect and the identity of the producer or his representative. Furthermore the possibility for such actions shall be extinguished upon the expiration of ten years from the date on which the producer put the actual product into circulation unless legal proceedings against the producer had already been instituted.

Time limits are fixed by the Law and unless there are issues of concealment or fraud the Court shall not vary the time limits.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

In situations wherein the buyer, for any reason beyond his control including concealment or fraud, was unable to identify any existing defects in the product purchased, such time limits shall not start

running against him but shall only start running when the buyer was in a situation wherein he could have identified the defect.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

Remedies available to successful claimants include monetary compensation.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Other than compensation for the defective product itself, damages that may be recovered include all damages caused by death or by personal injury, and loss of, damage to, or destruction of any item of property. Personal injury includes any disease and any impairment of the physical or mental condition of a person. There is therefore no upper limit on the damages which can be claimed and these will have to be computed according to the normal rules of civil law.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Under Maltese Law damages that may be recovered must be damages that have actually been suffered.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Our courts grant only real or material damages and thus punitive damages are not considered.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no such limitation imposed by the Law.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

No such rules have as yet been developed under Maltese Laws.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Government Authorities can in no way claim from damages awarded or settlements paid to the Claimant.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

In relation to proceedings within the Consumer Claims Tribunal the Arbiter shall determine the costs that any of the parties is to pay to the other and unless special circumstances so warrant, the losing party shall be ordered to pay the costs of the party in whose favour the decision is awarded. In this regard costs shall be limited to expenses made directly in connection with the case by the party in whose favour the payment of costs is awarded but shall not include any form of legal fees or fees paid out to persons assisting the parties before the tribunal. Furthermore where the Arbiter is satisfied that a claim presented before the Tribunal or any defence offered in respect thereof is vexatious or frivolous, he may order the claimant or the defendant to pay to the other party a penalty of not more than €116.47.

In a Court of Magistrates and in a Court of Appeal, further to the same expenses that can be recovered under the Consumer Claims Tribunal, legal fees can also be recovered.

7.2 Is public funding e.g. legal aid, available?

Legal aid is available to parties both in the superior courts and in the inferior courts but such legal aid is not available to parties for proceedings being held under the Consumer Claims Tribunal.

7.3 If so, are there any restrictions on the availability of public funding?

Not Applicable.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Not Applicable.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Not Applicable.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Malta.

It was in 2001 when Malta started introducing various laws to align local legislation with the mandatory EU Acquis. Product Liability rules were first added to the Consumer Affairs Act way back in 2002. This meant that for the first time ever Maltese Law specifically provided for the civil responsibility of manufacturers and distributors who placed on the market unsafe or dangerous products which could cause damage to persons or property. The new provisions, the first of their kind and modelled on EU Directive 85/374 EEC, were brought into force on the 28th January, 2003 by virtue of Legal Notice 46 of 2003.

Throughout the more recent years the Consumer Affairs Act has

been amplified and strengthened and now contains rules emanating from several EU consumer directives including rules on product liability, unfair contract terms, misleading and comparative advertising, as well as administrative measures for the better enforcement of these rules. The Consumer Affairs Act can be seen to be a declaration of fundamental consumer rights.

Malta is currently discussing the European Commission's proposed legislation directed towards making safety requirements more stringent and strengthening the manufacturer's and importers responsibility for the marketing of toys.

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

In Mexican law, liability arising out of an illegal act is regulated by a variety of laws that must be interpreted and applied in a harmonious manner. Examples of the most important are: the Federal and State Civil Codes; the Federal Consumer Protection Law; the General Health Law; the Federal Labour Law; and the Ecological Balance and Environmental Protection Law.

The Mexican provisions regulating liability arising out of illegal acts provide the injured party the option to claim from the offender to: a) do what is necessary to revert to the original condition (restore things as they were before the harmful result occurred) whenever possible; or b) pay damages to the victim.

Considering that product liability is the subject matter of this legal guide, it must be noted that said concept did not exist as such in Mexican legislation until the most recent amendments to the Federal Consumer Protection Law (May 4, 2004), and therefore, the actions arising from a defective product were based on the general principles regulated by the Federal and State Civil Codes, whereby anyone who causes injuries or damages to another is obligated to indemnify the victim, unless it is proven that the harmful result was due to the inexcusable fault or negligence of said victim.

Furthermore, liability requires that the injury or damage derives as a direct and immediate consequence of the illegal act, either for breach of contract, or an obligation arising from the law.

It should be noted that liability as a result of the use of a product or service, depends on the following:

i) Existence of an obligation (whether by agreement or imposed by law).

ii) Breach of a legal obligation or contractual (acting in a manner contrary to law or proper customs).

iii) Causation between the illegal act and the injury or damage suffered by the victim.

iv) Damages are not the result of the inexcusable fault or negligence of the victim.

Breach of statutory obligations can in fact be the ground for imposing administrative penalties to the offender; however, if there is no actual damage to a consumer, liability cannot exist for lack of causation.

1.2 Does the state operate any schemes of compensation for particular products?

No, the Mexican Government does not have any schemes of compensation for particular products.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

The Federal Consumer Protection Law establishes that: "*…The enforcement of warranties is claimable, without distinction, from the manufacturer, the importer-exporter, or from the distributor unless one of them, or a third party, expressly accepts the obligations in writing…*"

The aforementioned Law allows consumers to "*…choose to file [a claim], without distinction, against seller, manufacturer, or importer-exporter…*"; however, in the event of injury and/or damage caused by a product, determination of actual liability has to be made in each case, since several individuals and/or companies may be sued, but one or more may not be liable, even though they have participated in the chain of supply.

The previous statement is based on the fact that liability should be attributed to the person who actually causes the damage, since the Mexican legal system applies the theory of causation, which means that the alleged damages must be the direct and immediate consequence of the illegal conduct of certain individual or company.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

In Mexico, the Consumer Protection Agency and the Health Department have authority to secure goods and products which may negatively affect the life, health and safety of consumers.

Once the proceedings established in the respective Law have been completed, if the manufacturer and/or importer and/or distributor do not recall the goods and products, they can be subject to additional administrative penalties, but besides the right to denounce such omission, consumers do not have the right to file an individual claim, unless they have suffered an injury or damage to their property.

1.5 Do criminal sanctions apply to the supply of defective products?

The response is negative, since manufacturers do not intentionally produce defective products. However, if: a) a defective product is

found; b) the defect is identified; and c) those responsible to cure such defect do not correct it, they (or the directors of a corporation, as the case may be) can be held criminally liable for injuries and/or damage to property.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

In judicial proceedings the plaintiff (consumer) has the burden of proof of fault/defect and of the consequent damages.

The above mentioned is corroborated by the provisions of the Federal and State Codes of Civil Procedures which provide that "*the parties have the burden of proving the facts on which their claims are based*".

In turn, the defendant is entitled to prove that the harmful result was not caused by its product or service, or that it derived from the recklessness, negligence, or lack of ability of plaintiff.

In any event, taking into account the Mexican reality (Mexican consumers often do not have the means to file claims for damages) and as an example of the legal protection of the consumer the Consumer Protection Agency and the National Commission on Medical Arbitration provide counsel at the administrative level to them. Thus, in Mexico there are many administrative complaints, and a very small amount of lawsuits.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

As mentioned above, according to Mexican law, injury and/or damage must be the direct and immediate consequence of an action contrary to law or a breach of a contractual obligation, and the mere increase of risk would not be sufficient to prove causation.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Considering that, under Mexican law, liability is based on the principle of causation (illegal conduct-harmful result), assuming that such a scenario occurs, none of those manufacturers would be held liable.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Yes. If the manufacturer fails to establish and specify the applicable and adequate warnings that apply to its product, and such product causes injury and/or damage, the manufacturer will be held liable.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The Federal and State Codes of Civil Procedures provide procedural defences that a defendant may invoke, in addition to those based on substantive issues.

Mexican law does not limit defences that may be raised by a defendant. Article 14 of the Mexican Federal Constitution grants a defendant the right of due process of law in which it may argue and try to prove all available defences in order to answer the claim.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

No. There is no regulation which allows a state of the art/development risk defence, since, as previously mentioned, the theory of causation governs liability.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

A supplier should defend itself by proving that the product and/or service did in fact comply with the official legal standards in effect at the time; however and considering that such compliance is compulsory, he will not be exonerated if the defence is based only on these grounds.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

The response is affirmative; different plaintiffs may file different claims based on the same issues.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

Yes, defendants can and should argue such a defence, considering the principle of causation adopted by Mexican law.

Moreover, if the defendant is a manufacturer, let us say of cars, and damage is caused by a defective component supplied to such manufacturer, the answer depends on the nature of the defect and fault, since the car maker is deemed to be an expert in this field.

Regarding the question as to the time in which the defendant can seek contribution from the third party, the answer is twofold:

i) if the problem is known before the response to the claim is due, Mexican procedural rules authorises the defendant to name such third party as co-defendant (third interested party); and

ii) if the defendant gains such knowledge thereafter, it has the right to file a separate claim against its supplier, and the statute of limitations allows it to sue within 10 years counted from the date in which the supply agreement became effective.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

The response is affirmative. See the answer to questions 1.1, 2.1, 2.2 and 2.3.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

The Mexican legal system does not contemplate trial by a jury; therefore a judge is the one who rules the case.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The Mexican legal system does not allow courts to appoint technical specialists to sit with the judge, this right is granted to the parties; however, when the experts appointed by the parties disagree in their opinions, the courts appoint a third (official) expert. The legal principle is that judges are to assess and appraise the evidence presented by the parties.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

Although the Federal Consumer Protection Law authorises the Consumer Protection Agency to file a group or class action with the courts as consumers' representative, in the Mexican legal practice, group or class actions are not common. It is also possible that several plaintiffs file the same claim and also appoint the same attorneys to represent them in a joint complaint.

Class actions are processed in accordance with the rules of civil procedures, in what is called an "Ordinary Civil Action".

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

The response is affirmative. See the answer to question 4.3.

4.5 How long does it normally take to get to trial?

A civil action is formally initiated when a plaintiff files its claim. The claim is entered immediately, unless the judge considers that plaintiff must clarify certain issues. The same applies to administrative proceedings with the Consumer Protection Agency.

A claim for damages usually takes from 12 to 18 months to be decided by the trial court, depending on the complexity of the matter. The appeal against the judgment may take from 4 to 6 months. The decision on appeal can be contested through "constitutional proceedings" (*juicio de amparo*) before Federal Courts.

Conciliatory proceedings before the Consumer Protection Agency will usually take up to 6 months; however, this proceeding is optional and not the means to obtain a judgment declaring liability and an award for damages. This conciliatory proceeding is not a prerequisite for a consumer to file a claim for damages before the trial court. Nevertheless, in practice, this conciliatory proceeding is the normal course followed by consumers.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The Mexican legal system does not allow the courts to decide preliminary issues other than those of a procedural nature such as the authority of a party's representatives, jurisdiction, etc.

Other matters which may be dealt with prior to trial includes (but is not limited to) requesting the indebtedness recognition of witness examination due to old age, threat of imminent, death or the proximity of a prolonged absence. This may take place if such evidence is essential to the case.

4.7 What appeal options are available?

Procedural decisions and judgments can be appealed before Appeal Courts, and decisions on appeal may be contested again through constitutional proceedings before Federal Courts.

The subject matter of these proceedings is to review the constitutionality of the decision on appeal and/or the constitutionality of legal provisions applied to the case. In the latter scenario the decision of the Federal Court is reviewed by the Supreme Court of Justice.

In respect to the decisions of the Consumer Protection Agency, be it the conciliatory proceeding or an administrative proceeding for infringement, the decision may be challenged in a motion to review.

It is important to note that the motion to review is an optional remedy to challenge the decisions of the Consumer Protection Agency. Said motion is filed before the authority that issued the decision in the conciliatory or administrative proceeding and it is resolved by its immediate superior.

Penalties imposed by the Consumer Protection Agency can be challenged through an annulment action before the Federal Tax and Administrative Justice Tribunal, and its decision may be contested again before Federal Courts through constitutional proceedings.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

As expressed in the response to question 4.2, the parties have the right to appoint experts, and if their opinions differ, the courts can designate a third expert.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

Evidence must be submitted at the appropriate stage of the proceedings, except for the request to examine a witness, as set forth in the answer to question 4.6.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

Except as mentioned in the answer to question 4.6, our legal system does not contemplate pre-trial proceedings. Each party is obligated to submit all relevant documents as exhibits of the claim or the response, as the case may be, and allow court officials and experts to examine other documents in their possession, at the request of the other party. In this regard, it is important to point out the fact that our procedural rules do not accept "discovery"; the interested party must identify the accounting, corporate records, correspondence and other documents belonging to its counterpart and/or third parties which are relevant to the case.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Yes. Mexican Law allows the parties to settle their disputes under arbitration or mediation proceedings.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Mexican legislation does establish specific time limits to file a claim for damages, as well as for other causes of action.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

The limitation periods are as follows:

a) Administrative proceedings heard by the Consumer Protection Agency, brought by consumers against suppliers have special rules on limitation periods, but the general period is of 1 year.

b) Claims for damages lapse in 2 years, counted from the date in which the damage was caused, and those for breach of a contract in 10 years, counted from the date on which the obligation was to be fulfilled.

The age and specific condition of the plaintiff cannot be taken into consideration to waive or extend the limitation periods, except, for instance, in the case of minors and mentally handicapped individuals.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Issues of concealment or fraud do not affect the running of the statute of limitations.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

Damages and lost profits indemnity are available as remedies.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Damage to the product itself and to property of the victim are recoverable, as well as the indemnity for personal injuries.

The concept of "mental" damage may be assimilated to that of "moral" damage in Mexican Law.

Moral damage can be defined as the negative consequences which a person may suffer in its feelings, beliefs, honour, reputation, private life, or appearance. In this case, the amount of damages will be determined by the judge, which must consider the nature of the damages, the degree of liability, the financial standing of the liable party and that of the victim, and any other particular circumstances of the case.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

The response is negative. As stated above, damages must be the direct and immediate consequence of an illegal act. The possibility for a product to cause damage or injury in the future cannot be the basis of an action for payment of costs of medical monitoring.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

The response is negative.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

The amount of damages for personal injuries is set out in the Federal Labour Law. The amount of damages for medical expenses and pecuniary damages are determined by the court, based upon "actual damages".

The amount of indemnity for moral damages is determined by the court, as set forth in the answer to question 6.2.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

Settlements are not subject to special rules. Nevertheless, the settlements agreements must be approved by the court, in which case they will have the same effect as a court ruling (*Res Judicata*).

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

The response is negative.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

In ordinary civil actions, the successful party may recover legal expenses. The Federal and State Codes of Civil Procedures establish the bases to liquidate such expenses and the conditions to award them to a party.

7.2 Is public funding e.g. legal aid, available?

The Consumer Protection Agency is a government agency created to protect the interests of consumers, without charge. In addition, the government provides free legal assistance to those who have no means to hire the services of an attorney. Also, there is a wide network of law firms that provide free legal counsel to those unable to afford a lawyer. These law firms are mostly sponsored by universities, associations, or non-governmental organisations.

7.3 If so, are there any restrictions on the availability of public funding?

See the response to question 7.2 above.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

See the response to question 7.2 above.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Yes. Mexican Law allows a third party to found the claim.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Mexico.

Please be advised that there have not been any new cases or amendments to the Federal Consumer Protection Law and/or the Federal and State Civil Codes in relation to product liability.

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Portilla, Ruy-Diaz & Aguilar, S.C. is a law firm with enormous experience gained by its members in serving clients, based on superior ethics, quality and professionalism. Some of our clients are the largest and best-known companies in the world, including international and domestic law firms, as well as financial institutions, and of course, smaller firms and individuals.

The Firm offers services in various areas of the law including: administrative; bindings and privatisations; arbitration; civil and commercial litigation; consumer protection; corporate and contracts; criminal litigation; franchising; health; immigration; labour; mergers and acquisitions; real estate; social security; tax; and trusts.

Our Firm currently has four partners and 15 associates, and a supporting staff including paralegals, translators, technical specialists and administrative staff, with offices in Mexico City and Queretaro, Mexico.

The specialisation and development of each of the Firm's practice areas, the support provided among different areas, and our deep knowledge of Mexico, its legal system, markets and industry, enables the Firm to offer clients innovative, timely, and comprehensive solutions to their needs, at very good and competitive prices. In order to prevent problems before they develop, we take a preventive, coordinated, and strategic approach to advise our clients.

The Firm and its lawyers actively participate in various public and private organisations at an international level, keeps us attuned to what is happening in the community and in the world at large. It enables us to not only better understand and be closer to client needs, but also to participate in and have an influence upon the changes affecting them.

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

The law of product liability in the Netherlands is based on three grounds: contractual liability; tort-based liability; and the Netherlands Product Liability Act. The EC Product Liability Directive (European Directive 95/374/EEC on liability of defective products) ("**the Directive**") is implemented in the Netherlands Product Liability Act of 13 September 1990, which entered into force on 1 November 1990. This act is now found in Articles 6:185-6:193 Netherlands Civil Code ("**NCC**").

The Directive has not superseded or replaced systems of liability that existed prior to its implementation. Product liability cases may still be based on the contractual relationship between the consumer and the producer/supplier or on an unlawful act (tort) on the part of the producer/supplier.

Contractual liability only plays a role if a sales agreement between the consumer and the supplier exists (Article 7:24 NCC). The buyer may claim any damages if the product which has been delivered does not possess the qualities which the buyer was entitled to expect. The buyer may expect that the product possesses the qualities necessary for its normal use and the qualities necessary for any special use provided in the contract (Article 7:17 NCC). Supply of a product other than the one agreed does not conform to the contract. The same applies if what has been delivered varies in quantity, size or weight from what has been agreed. Further, where a sample or model was shown or given to the buyer, the product must conform to this sample or model, unless the sample or model was provided only for indicative purposes.

However, if the failure in performance consists of a defect referred to in Articles 6:185-6:192 NCC, the seller is not liable for the damage referred to in those articles unless:

- he was aware or ought to have been aware of the defects;
- he has promised freedom from defects; or
- it relates to damage to things for which pursuant to Articles 6:185-6:192 NCC, there is no right to compensation on the basis of the threshold provided for in these articles, without prejudice to his defences pursuant to the general provisions for damages.

Under contractual liability law, liability to non-commercial consumers cannot be excluded or limited by contractual provisions (Article 7:6 NCC). Although the seller may use general terms and conditions, the other party is only bound by the general terms and conditions if he knows or should have known their contents (Article 6:232 NCC). A clause in a set of general terms and conditions can be annulled if the wording and the content of such clause are unreasonable for the other party (Article 6:233 NCC). Articles 6:236 and 6:237 NCC set out contractual stipulations which are strictly forbidden ("**black list**") and which are presumed to be unreasonably onerous ("**grey list**") respectively.

The "black list" includes:

- a stipulation which totally and unconditionally excludes the other party's right to enforce performance;
- a stipulation which limits or excludes the other party's right to set the contract aside; and
- a stipulation which limits or excludes the right which, pursuant to the law, the other party has to suspend performance or which gives the user a more extensive power of suspension than that to which he is entitled pursuant to the law.

The "grey list" includes:

- a stipulation which, taking into account the circumstances of the case, gives the user an unusually long or an insufficiently precise period to react to an offer or another declaration of the other party; and
- a stipulation which materially limits the scope of the obligations of the user with respect to what the other party could reasonably expect in the absence of such stipulations, taking into account rules of law which pertain to the contract.

Before the implementation of the Directive in the Netherlands, product liability claims were generally based on Article 6:162 NCC. This provides that any person who causes injury to another by means of an unlawful act is liable to pay compensation. The term "unlawful act" includes violation of any right or a statutory duty, as well as any act or omission which violates a rule of unwritten law "pertaining to a proper social conduct". The cases in this respect fall into three categories: manufacturing defects; inadequate warnings or instructions; and design defects.

The relevant difference between the strict liability and tort-based liability lies in the "standard of care". Under the Netherlands Product Liability Act the producer is liable unless he can exonerate himself by way of certain specific defences. Under general tort principles the possibilities of exoneration are in theory wider, but it is generally believed that it will make no difference in practice.

Since the Directive was implemented in the Netherlands, product liability cases have generally been based on the strict liability system. As a rule, the principles of the directive can only be used with respect to products being put into circulation since 30 July

1988, i.e. the date on which the Directive should have been implemented.

1.2 Does the state operate any schemes of compensation for particular products?

No, the state does not operate any such schemes.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

A producer or anyone who might be said to appear to be a producer may be liable for supplying a defective product. In Article 6:187 (2) NCC the definition of producer is given. "Producer" means the manufacturer of the finished product, raw material or other component parts. In addition, a person who presents himself as the producer of the product is considered as a producer. An entity which connects its name to a product by printing its name or trademark or any other sign on it also falls within the scope of the definition of "producer". A licensee is regarded as a "producer" if he presents himself as such. Otherwise, he is not a producer in the sense of the product liability regulations. Also the importer may be held liable in respect of defective products. A supplier will not be liable unless he fails to inform the injured person within a reasonable time of the identity of the producer or of the person who supplied him with the product. In the event the person who supplied the product to the supplier is insolvent, liability will not revert to the supplier himself. If the producer is not known, the supplier may be held liable.

Duty of care in tort can rest on all persons who cause injury to another and may be held responsible for the damages.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Pursuant to the Commodities Act Decree producers and suppliers are not allowed to supply any products that they know, or should presume to be dangerous. To the extent to which it can be determined, the producer and supplier must immediately inform the Food and Consumer Product Safety Authority if they have placed a dangerous consumer product on the market, and they should include, in their notification, details of their plans to deal with the dangerous products. Possible responses are issuing a warning to consumers or effecting a product recall. Which action should be taken can be determined on the basis of the Commission publication "Product Safety in Europe: A guide to corrective action including recalls".

If the producer and supplier fail to take appropriate action voluntarily, the Food and Consumer Product Safety Authority can order them to do so or can initiate a product recall by itself.

In addition, under Dutch law it is considered to be unlawful not to recall products from the end-users for example when other measures are inadequate.

1.5 Do criminal sanctions apply to the supply of defective products?

The supply of a defective product is an offence under the Economic Offences Act and a criminal offence. Pursuant to the Economic Offences Act the penalties for placing unsafe products on the market consist of six months in prison or a fine of up to €16,750 for individuals, or a fine of up to €67,000 and a possible one year ban on trading for businesses. If it can be established that there is a criminal offence the penalties are more severe. If a defective product causes the death of a consumer, then if the person who sold the product knew that it constituted a danger to the health of consumers, he can be imprisoned for life or he can be imprisoned for a maximum of thirty years. A fine up to a maximum of €67,000 can also be imposed.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

In general, the party claiming damages bears the burden of proof (Article 150 Court Civil Proceedings ("**CCP**")). However, in some circumstances the Courts have lessened the burden on the claimant, or shifted it to the defendant, while still requiring the element of fault.

For liability based on tort, fault is required. The claimant has the obligation to provide *prima facie* evidence that the offender was at fault. A shift of the burden of proof from the claimant to the defendant has been accepted previously in among others, the "Lekkende Waterkruik"-case, where the Supreme Court ordered that the producer of the hot water bottles had to show that sufficient precautions were taken.

However, more recently in the "Du Pont/Hermans"-case the Netherlands Supreme Court did not accept the shift in the burden of proof as such, but ruled in favour of the claimant by stating that the question of fault could only be answered based on the circumstances submitted by the defendant to demonstrate its point of view. This included "evidence put forward by the defendant as to its actions and the reasons for those actions".

In the "Asbestos"-case, the Supreme Court gave an indication of the extent to which the producer has the duty to investigate risks associated with the product. In this case an employee became ill because of the use of asbestos in the factory of his employer. The decision related to an employer, but it is generally believed that it can also be applied to producers. According to the decision, an employer must explain how he fulfilled his duty of care with respect to the safety. If legislation in that respect is lacking or is insufficiently precise, the danger of any substances to be processed or produced must be investigated. The employer must make enquiries, including if necessary, consulting experts.

For the purposes of an action brought under the provisions of the contractual liability, Article 6:188 NCC stipulates that the claimant bears the burden of demonstrating that the product was defective and that the defect caused the damage to the claimants. Once the claimant has shown that the product was defective, the burden is on the producer/supplier to prove that the defect did not exist when the product was put on the market.

The stipulations of burden of proof apply to both contractual and non-contractual situations. Article 6:192 NCC determines that the liability of the producer cannot be contractually limited. The same applies for sales agreements and general terms and conditions subject to these agreements.

Liability based on stipulations for product liability under Articles 6:185-6:193 NCC is mainly risk liability (i.e. strict liability), but it can be seen to include some "fault" elements. One of those is the issue of the reasonably expected use of a product. This concerns the use that the producer could reasonably expect. The producer has to take into account the fact that the product may be used wrongly or for other purposes than those for which it is meant. Another fault

element is found in the question of the level of safety one could reasonably expect. In case of design defects the circumstances such as the aim of the product, the seriousness of the injury, the expected frequency of injuries and the possibility of an alternative design must be taken into account. With respect to these fault elements, the burden of proof that there has been no fault rests on the producer/supplier.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

One component required for proving a tort has occurred is causation between fault/defect and damage. This causation is established through the test of '*condicio sine qua non*'. The claimant has to prove that there is causal relationship between the fault/defect and the damage. The Courts may shift the burden of proof to the defendant. The claimant also has to prove to what extent the defendant is liable. The defendant has only to compensate for damage that can be attributed to the defendant. Whether damage can be attributed is decided on the basis of the nature of the liability or the nature of the damage (Article 6:98 NCC).

Article 6:99 NCC stipulates that if the damage results from two or more events, for each of which a different person is liable, and it has been established that the damage is arisen from at least one of the events, the obligation to compensate for the damage is imposed on each of such persons. A person will only not be held liable if he proves that the damage is not the result of an event for which he is liable.

As stated under question 2.1, the claimant normally bears the burden of proof. The claimant has to prove that there was a fault/defect, that damage occurred and that a causal relationship exists between the defect/fault and the damage. As set out under question 2.1, the Courts may lessen the burden on the claimant or shift it to the defendant.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

In Article 6:189 NCC it is provided that if, based on 6:185 NCC, more than one person is liable for the same damages, each of them shall be liable for the whole. Thus, all defendants are jointly and severally liable. The same is provided in the general provisions in Article 6:102 NCC. In this respect, it is required that the liability relates to the same type of damage.

Suppliers of "trademark-less" products are considered as producers of the products. Suppliers of these products can only pass on their liability if they inform the injured party within a reasonable time of the identity of the producer or of an upstream supplier (Article 6:187, (4) NCC). The general principles will also apply to trademark-less products.

A producer is only partly liable (i.e. not jointly and severally liable) in situations in which damages can be "divided", for example if it can be shown that the particular producer only caused one particular part, or type, of the damages.

In the "Des"-case the Supreme Court of the Netherlands rejected the concept of assigning liability by market share and imposed the burden concept of joint and several liability. Thus, regardless of proof that the defendant's product caused the injury, and regardless of the particular defendant's share of the relevant Des hormone market at the pertinent time, any prior Des manufacturer can now be held liable in the Netherlands on the basis of joint and several liability for the entirety of the plaintiff's injury.

As noted above, the liability of the producer may not be limited or excluded with respect to consumers and Article 6:192 NCC. The same applies in general national law.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Under Dutch case law a producer is obliged to warn if he knows or ought to have known that the product can cause damage. If he fails to warn he can be held liable.

In the "Rockwool"-case, the Supreme Court ordered that a manufacturer in general ought to take such measures, which can be required of a "careful manufacturer", in order to prevent the product he brought into the market causing any damage. In Rockwool it was also decided that the producer of a semi-finished product has the obligation to warn both the purchasers of the semi-finished product and the purchasers of the end product.

In the "Halcion"-case the Supreme Court decided that a medicine is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account. The consumer is not required to expect additional effects for which he is not warned. The producer is liable if an additional effect arises that was, or could have been, foreseeable and whereby he failed to warn the consumer for the danger of an additional effect occurring.

In the Netherlands the doctrine of the 'learned intermediary' theory is not recognised. In the "Halcion"-case the Court decided that Halcion should have warned not only the doctors who prescribed the medicine but also the consumers. Halcion should not have relied on doctors to have sufficient knowledge of the pharmacy to warn the consumers by themselves.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The producer is, according to Articles 6:185-6:192 NCC, not liable if he proves:

- that he did not put the product into circulation;
- that it is to be assumed that the product did not have the defect which caused the damage at the time when the producer put it into circulation;
- that he manufactured the product neither for sale nor for any other form of distribution for economic purposes;
- that the defect is due to compliance of the product with mandatory regulations issued by public authorities;

- that the state of scientific knowledge at the time when the product was put into circulation was not as to enable the defect to be discovered; or
- in the case of the manufacturer of a component, that the defect is due to the design of the finished product or that the component was made according to the instructions of the producer of the final product.

Sellers having a contractual relationship with the consumer may include the defence that the breach of contract consists of a defect referred to in Articles 6:185-6:192 NCC in circumstances in which the seller was not, and ought not to have been, aware of the defect, and had not promised that the product is free from defects.

Producers/suppliers who are sought to be held liable in tort (i.e. based on an unlawful act) can argue that there was no negligence. This argument could succeed if, for example the defect was hidden or latent or otherwise undiscoverable by the producer/supplier at any relevant time prior to the injury.

The general provisions for damages in book 6 NCC provide that in all actions in which there is a failure in the performance of an obligation, damages may be limited or even excluded entirely if the injury was caused by the fault or negligence of the consumer.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

The development risks defence has been incorporated in Article 6:185 NCC (see question 3.1 above). In the "Sanquin Foundation"-case, the development risks defence was in discussion. The District Court held that for the purposes of assessing whether a blood product is defective, a Court must take into account "the extent of safety the public may expect of blood products". The Court decided that the public may expect that blood products are free of HIV in the Netherlands, taking into account the vital interest in such products and the fact that in principle no alternatives exist. (In this context, it was held that the fact that the Foundation had complied with applicable regulations could not support a different conclusion.) However, the District Court also held that the Foundation had acted in compliance with the scientific and technical learning available at the moment of the blood donation and the delivery of it to the claimant, and it was therefore entitled to rely on the "development risks" defence under Article 6:185 section e.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Compliance with regulatory and/or statutory requirements may be a defence (reference is made to question 3.1). See also the "Sanquin Foundation"-case above.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Although no specific rules exist that state that it is not possible, it is generally believed that a claimant cannot bring the same claim again based on the same set of facts.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

The producer will not be liable if he can raise one of the defenses as set out in the answer to question 3.1. If the producer is liable because he has put into circulation a defective product but the damage is also caused by the behaviour of a third party, then the injured party can claim against both the producer and the third party. If the injured party only claims damages from the producer, then the producer is entitled to take recourse against the third party. This action should be brought in subsequent proceedings. The time limits that apply are set out in question 5.2.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

The producer can allege that the damage is caused by the fault of the injured party. The obligation to pay compensation can be reduced or can be lifted if the damage can also be attributed to the behaviour of the injured party taking into account all the circumstances of the case (Article 6:101 and 6:186 (2) NCC).

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

There is no jury system in the Netherlands.

In the Netherlands, claims must be brought in first instance before the competent District Court, unless the parties have agreed upon a different form of dispute resolution. If the amount claimed is €5,000 or less, a special division of the District Court (the Cantonal division) will deal with the case. In first instance, a case is usually decided by a single judge.

Decisions from the District Courts (including those of the Cantonal division) are subject to appeal to the Court of Appeal as of right, unless the amount claimed is less than €1,750 in which case the decision cannot be appealed at all. Usually, a case before the Court of Appeal is decided by a majority decision of a panel of three judges.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

In the course of Court proceedings, the Court can appoint experts, either *ex officio* or at the request of a party (Article 194 CCP). Before Court proceedings are under way, a party can request that the Court allows preliminary expert advice on a certain issue (Article 202 CCP). In addition, each party is free to file opinions of its own experts. However, such opinions are considered as coming from party experts (i.e. are taken to be partisan). In the case of conflicting opinions of the party experts, the Court usually appoints its own expert. The Court can also hear witnesses (Article 163 CCP). In addition, a party can request the Court to allow the preliminary hearing of witnesses before Court proceedings are under way (Article 186 CCP). However, it is for the judge to assess the evidence.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

There are no specific provisions under Dutch law for class actions, group litigation orders or group management proceedings as such. However, multi-party actions are in fact available by a number of means.

As a matter of law, there is no limit to the number of claimants who can bring an action and an enormous amount of claimants could simply be added in one action. This will be permitted if there is sufficient connection between the claims of the different claimants. The criteria for determining whether there is "sufficient connection between the claims" are, *inter alia*, the point in time at which the claim arose and whether the claims concern the same subject matter. Furthermore, the judges take the question of efficiency into account when determining whether the claimants can jointly take action.

Collective actions can be brought by an interest group in the form of a foundation or union, so long as the foundation or union is a legal person and its articles of association provide that one of its objectives is to take care of the (similar) interest of people having suffered damages as a result of a defective product (Article 3:305a NCC). A settlement must be attempted before such an action can be brought, and monetary damages are not available directly through these means. However, the foundation or union can seek a declaration that the producer is liable for damages. On the basis of such a declaration the individual injured persons can then negotiate with respect to their compensation or initiate proceedings before a District Court. In such proceedings, the individual has only to prove that he suffered damages. Furthermore, a group of claimants can give a power of attorney to one party to file the claim on their behalf.

Also test cases do happen, although there is no specific provision for such cases. In such cases the claim will usually be brought by a limited number of injured persons, while for example a consumer organisation co-ordinates the action and pays the costs.

The law does not provide for a formal consolidation of multiple claims. However, if a number of claims regarding the same subject matter is pending before the same Court, the Court can consolidate the cases on the docket, which means that the various steps in the litigation will take place on the same dates.

Another option for an organisation that represents complaining individuals, is to reach a collective settlement that can be declared binding by the Court of Appeal in Amsterdam. Pursuant to the Act on Collective Settlement of Mass Damages 2005 (*Wet collectieve afwikkeling massaschade*) (the "**WCAM**") the Court of Appeal in Amsterdam has the authority to declare this collective settlement binding (Article 7:907 NCC). The settlement should be first reached between the association representing the individuals who suffered damage, and the party that caused damage. If these requirements are met, the collective settlement can be declared binding by the Court of Appeal in Amsterdam for all the individuals falling under the settlement. Those who do not want to be bound by the settlement can *opt out*, although they must do so within a limited timeframe.

Since the introduction of the WCAM it has been applied in two significant cases, namely the collective settlements in the DES and the Dexia cases. A further three cases, concerning settlements in cases against Shell, Vedior and Vie d'Or are pending.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

As set out before, collective actions can be brought by an interest group in the form of a foundation or a union such as a consumer association. However, in such action no claim for monetary damages can be made. The claim against pharmaceutical companies over birth defects allegedly caused by the antimiscarriage drug diethyl-stilbestrol (DES) is an example of a collective action, brought by the DES foundation. As said under 4.3 the WCAM was applicable and the Amsterdam Court of Appeal declared the DES settlement binding.

4.5 How long does it normally take to get to trial?

It is difficult to estimate the length of time to progress a product liability claim in the first and second instances, because the length of time a case can take before the District Court and the Court of Appeal is highly dependent on whether the Court wants to hear witnesses and/or takes expert advice. These are usually the delaying factors.

It is important to know that in Dutch litigation no such thing as a trial (a hearing in which all evidence is presented to the Court, followed by a final decision) exists. A hearing before the Dutch Courts usually consists only of the oral arguments of both parties summarising their cases. The Courts can render interim decisions, which may include partial decisions and/or instructions to the parties regarding the further conduct of the litigation such as an order to prove certain statements, an order that expert advice will be taken etc. However, each case must sooner or later end with a final decision, allowing or denying, in whole or in part, the relief sought. If a lot of witnesses are to be heard and/or extensive expert advice is ordered, a final decision might be rendered within one to two years after service of the writ.

In practice, the length of time of the appeal procedure is usually shorter than in first instance. This is because most of the time no new evidence is introduced in appeal.

With the above in mind, the following estimates can be given:

- first instance: final decision within one to two years after service of the writ; and
- appeal: final decision within one to one and a half years after service of the appeal writ.

A Supreme Court appeal takes approximately one and a half to two years after service of the Supreme Court appeal writ until the first decision. This is usually also the final decision. The Supreme Court rarely renders interim decisions.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

There is no trial about preliminary issues in the Netherlands.

4.7 What appeal options are available?

As set out above, claims must be brought in the first instance before the competent District Court (*Rechtbank*), unless the parties have agreed upon a different form of dispute resolution. There are nineteen District Courts in the Netherlands. Which of those has jurisdiction in a given case will depend on where the defendant resides.

If the amount claimed is €5,000 or less, a special division of the District Court (the Cantonal division) will deal with the case. Decisions from the District Courts (including those of the Cantonal division) are subject to appeal to the Court of Appeal (*Gerechtshof*)

as of right, unless the amount claimed is less than 1,750 in which case the decision cannot be appealed at all.

There are five Courts of Appeal in the Netherlands and which of those has jurisdiction to hear an appeal depends on which District Court rendered a first instance decision.

Decisions from the Court of Appeal are subject to appeal to the Supreme Court (*Hoge Raad*). The Supreme Court appeals are limited to points of law and points of insufficient motivation (that is: allegations that the Court of Appeal did not provide sufficient reasons for their decision, or that their reasoning was incomprehensible).

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Every issue in dispute, legal or factual, must be decided by the Court. In the course of proceedings the Court may order either *ex officio* or at the request of a party that expert advice must be taken on certain issues (usually technical or medical issues if it is a product liability case). Before Court proceedings are under way, a party can request that the Court allows preliminary expert advice on a certain issue. In addition, each party is free to file the opinions of its own experts. However, party experts are taken to be partisan. In the case of conflicting opinions of the party experts, the Court usually appoints its own expert, although the Court will not be bound by that experts' advice.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

There is no formal pre-trial in the Netherlands or other kind of discovery as such.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

Under Dutch procedural law each party has the obligation to disclose the entire truth. A party can request the production of certain documents, and the Court may draw adverse inferences from non-disclosure or incomplete disclosure. The Court may also order a party to submit certain evidence. Usual forms of evidence include documents, witness statements and expert opinions.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Under Dutch law the alternative methods of dispute resolution available are arbitration, binding advice and mediation.

Arbitration can be agreed in advance as well as at the moment the dispute is already arisen. Arbitration leads to a judgement that will be capable for enforcement. Parties can also choose for the method that a third party will give a *binding advice* on the dispute. In The Netherlands this usually will be a disputes committee, such as the consumer conciliation board. Finally, parties can choose for mediation. *Mediation* is a method of reaching a resolution of the dispute without recourse to judicial procedures. The parties will be supported in their negotiations by an independent party until a mutually acceptable solution is found.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, time limits do exist.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

A cause of action for damages based on a contract of sale cannot be brought after two years from the time the buyer informs the seller that the product is not in compliance with the contract (Article 7:23 NCC). The general limitation period for failure to perform a contractual obligation is five years.

The cause of action for damages on the basis of an unlawful act cannot be brought after a lapse of five years after the commencement of the day following the day on which the aggrieved party became aware of both the damage and of the person or legal entity liable. In any event an action cannot be brought after a lapse of twenty years following the event that caused the damage.

In cases in which the damage results from air, water or soil pollution or from the realisation of a danger as defined in Article 6:175 NCC, the limitation period is extended to 30 years.

In cases brought under the product liability provisions, often several persons can be considered "producers" of one and the same product. Then, the question arises whether each product can invoke expiry of the limitation period if the injured person "became aware, or should reasonably have become aware" of the identity of at least one of them more than three years previously, since the cause of action against the producer becomes barred by the lapse of three years (Article 6:191 NCC). The broad definition of "producer" and the fact that the product liability provisions allow the injured person to claim from any of several producers, compensation for the whole of his damages means that the answer is generally favourable for the injured person.

Article 6:191, (2) NCC provides that an injured person's right to compensation from a producer is forfeited upon the expiry of ten years from the time the producer puts the offending product into circulation. It is worth noting that the ultimate limitation period under the usual tort rules is 20 years, so to that extent the Netherlands product liability act provisions could be said to offer less protection to consumers.

It is also important to note, that under Dutch law, limitation periods are distinct from forfeiture. The expiry of a limitation period means that a cause of action can no longer be brought, whereas forfeiture effectively extinguishes the underlying right to the compensation. General limitation rules do not apply to forfeiture. Thus, whereas a limitation period may be interrupted by the commencement of legal proceedings, such proceedings cannot in effect postpone a forfeiture provision. Also, under the general rules, the defence of the expiry of a limitation period must be specifically raised by the defendant. The ten-year forfeiture period under the Product Liability Act can be raised *ex officio* by the Court.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

In the case of concealment or fraud it is likely that the Courts will

order that it is contrary to reasonableness and fairness to invoke a time limit.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

In this context, pursuant to Dutch law, distinction must be made between an agreement between a consumer and a supplier on the one hand and, on the other hand an agreement between two professional parties.

In the event that the product does not conform to the contract, the consumer will have the following rights (Articles 7:21 and 7:22 NCC):

- delivery of which is lacking;
- repair;
- replacement; and
- in the event that repair or replacement will not be possible or cannot be reasonably required, the consumer may claim dissolution of the contract or reduction of the price.

The rights mentioned above can be used together with and without prejudice to the rights which may be used on the basis of the general contract law (Article 7:22 paragraph 4 NCC), such as compensation for damages, dissolution of the contract on the basis of 6:265 NCC and/or the right to suspend performance.

In the event that the non-conformity relates to a *safety defect* pursuant to Part 6.3.3 NCC (Articles 6:185-6:192 NCC), then, in principle, the seller will not be liable for the damage as mentioned in Part 6.3.3 (Article 7:24 paragraph 2 NCC).

As said under question 1.1, this will only be different in the following exceptions:

- the seller was aware or ought to have been aware of the defects;
- the seller has promised freedom from defects; and
- the damage relates to things for which pursuant to Articles 6:185-6:193 NCC, there is no right to compensation on the basis of the threshold provided for in these articles, without prejudice to his defences pursuant to the general provisions for damages.

If the non-conformity does not relate to a safety defect the seller will be liable under the general principles of Book 6 NCC (Article 7:24 paragraph 1).

Pursuant to the Product Liability Act (Article 6:190 NCC), the producer will only be liable for two kinds of consequential damages, such as personal injury and/or property damage caused to another product which is normally used for private use and from which the amount of the loss exceeds a sum amounting to the franchise of €500.

In the event that the consumer has suffered damages different from those as set out above, then the seller will be liable under the general principles of Book 6 NCC (Article 7:24 paragraph 1). Do note however that pursuant to Article 7:25 NCC the seller then in principle will have the right of recourse against the producer.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Claimants can recover what is known as damages in kind (for example replacement of products). They can also, in certain circumstances, get advance payment of damages in summary proceedings. Advance payment might be awarded by the judge in the summary proceedings if the view is that it is likely that damages will be awarded in the proceedings on the merits and if the claimant has an urgent interest in obtaining advanced payment.

Damages for death can be claimed only by those persons referred to in Article 6:108 NCC. These include the spouse, the registered partner and the children of the deceased, at least up to the amount of the maintenance to which they are entitled by law; other relatives by blood or marriage of the deceased can claim damages provided that at the time of his death the deceased maintained them.

Damages for personal injury, which include physical and mental injury, are recoverable under Article 6:107 NCC. These include, for example, hospital costs and costs for future care. In principle, only the injured person should be compensated for such damages. However, a third party (other than an insurer), who has incurred such costs for the benefit of the injured person is also entitled to compensation, provided that the costs would have been recoverable by the injured person himself.

Mental injury refers to illness and harm which is not triggered by physical injury. Damages for mental injury can be claimed only in respect of unlawful acts (that is in tort).

Article 6:190 NCC (the Netherlands Product Liability Act) is limited to personal injury of a physical nature and does not include mental injury. However, the term "personal injury of a physical nature" is construed to include illness and harm which is a consequence of a physical injury, and could include pain and suffering related to that physical injury.

Non-material damages can also be claimed in the Netherlands in respect of unlawful acts, pursuant to Article 6:106 NCC. The damages should be "fairly assessed" and largely relate to damage to the claimant's honour, reputation or right to privacy. Generally, very modest amounts are awarded for non-material damages in the Netherlands.

Reasonable costs made to avoid or limit damages (costs of mitigation) can also be claimed based on Article 6:96 NCC.

Punitive damages are not available in the Netherlands.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

No case law exists in this respect in the Netherlands. It is unlikely that a Court would grant a claim in the Netherlands in such a case, unless one can prove that the reasonable costs of medical monitoring are the consequence of the damages.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Under Dutch law punitive damages are not recoverable.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

The Netherlands did not limit the level of damages recoverable for death or personal injury under the provisions of the Netherlands Product Liability Act and there are no set limits on recovery under national provisions.

However, based on Article 6:109 NCC, the Court can limit damages, taking into account the type of liability at issue, the legal relationship between the parties and the financial capacity of both parties. It is generally accepted that the Courts must be very restrictive in applying Article 6:109 NCC to limit recovery. As the Courts have freedom to determine the level of damages to be paid, there can be no real indication of the level of damages to be expected. The Court will consider what is reasonable in the circumstances.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

No special rules do apply. Under the WCAM there is no court necessary for the formation of the settlement. The Court of Appeal in Amsterdam comes into play not until the parties have reached the settlement. However, the court does have the power to reject a request to declare a collective settlement binding. This will be the case if the settlement does not comply with the specific requirements. So although there is no court approval required for the settlement itself, for the consequences parties will need the approval of the court of Appeal in Amsterdam.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

No. There is no Government authority under Dutch law who will have the power to do so. Concerning consumer goods a relevant Government authority under Dutch law is The Food and Consumer Product Safety Authority ("**VWA**"). As said under question 1.4, the VWA monitors compliance with the Commodities Act and the Commodities Act Decree. The VWA will take measures if a company does not fulfil his obligations out of these two statutory regulations. The VWA can prohibit the company to place consumer products on the market which are considered as dangerous, can order the company to undertake a product recall or can initiate a product recall by itself. If the VWA incurred costs for taking one of these measures, then it will have the right to recourse this loss against the company responsible.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The unsuccessful party is usually ordered to pay the legal costs of the successful party (Article 237 CCP). The costs to be paid are fixed by the Court, according to a scheme, which is based on the "value of the case", i.e. the amount claimed. The costs as fixed by the Court are usually much lower than the actual costs. The successful party has no action at his disposal to claim the remaining part of his legal costs. This system has been criticised for a long time, but it is not expected to change in the near future.

7.2 Is public funding e.g. legal aid, available?

Pursuant to the Acts on Legal Aid (*Wet op de Rechtsbijstand*), distinction must be made between single householders and people who run a joint household with one or more persons. Single householders with an income of less than approximately €22,900 per year and people who run a joint household with one or more persons with an income not more than €32,400 per year have a right to legal aid paid by the State if certain criteria are met (Article 12 in conjunction with Article 34 Acts on Legal Aid). Those criteria are *inter alia*: the legal interests must concern the Netherlands and the costs of the legal aid must be in reasonable proportion to the interest of the case. The aid consists of the payment of most of the individuals own legal fees. The individual always has to pay a small amount himself. In addition, he has to pay the Court fees and, in the event he loses the case, the other party's costs, as ordered by the Court.

7.3 If so, are there any restrictions on the availability of public funding?

See question 7.2 above.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Contingency and conditional fee arrangements and even "no win no fee" arrangements with lawyers are to some extent allowed, particularly in personal injury cases. However, in practice only a limited number of lawyers will accept these arrangements. The vast majority of lawyers work on the time-spent fee basis only.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

No third party funding of claims is not permitted under Dutch law.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in the Netherlands.

On 17 December 2008, the first decision in The Netherlands regarding liability of tobacco manufacturers was given. In this case ex-smoker, Mr Romer, summoned the tobacco manufacturer British American Tobacco ("**BAT**") for alleged damages to his health caused by the cigarettes of BAT. The case has been decided in favour of BAT. The District Court in Amsterdam decided that for a manufacturer to be liable it is insufficient that smoking causes damages to the health, and that the damages to Mr Romer's health in this specific case were caused by smoking. In the event that the risk of smoking and the damages it may cause to one's health are generally known by the average consumer, it cannot be said that cigarettes are defective products. The Court decided that the risks of smoking were generally known since ate least 1963. This conclusion from the Court was based on several scientific reports which were published since 1950 and the large attention which was given to these reports and the debate thereof in the press.

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Lovells has an outstanding product liability practice covering all aspects of product liability including risk prevention and management, compliance with product safety regulations, product recalls and personal injury claims, with particular emphasis on multi-party and cross-border litigation. The practice operates in all key jurisdictions with over 90 highly experienced practitioners globally.

Our lawyers have been closely involved in many of the major product liability issues over the last decade, having advised on a wide range of products including pharmaceuticals, food and drink, motor vehicles, tobacco, mobile phones, aircraft, trains, vaccines, cosmetics, blood products, medical devices and asbestos.

Lovells' product liability lawyers are supported by dedicated Science and Project Management Units.

To find out how Lovells can help you around the world, please contact:

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

New Zealand has an internationally unique regime in the field of product liability. The New Zealand regime combines traditional concepts of tort, contract and criminal law based on the English common law model with wide-ranging statutory departures - notably New Zealand's distinctive accident compensation legislation. The accident compensation regime effectively bars claims for compensatory damages for most types of personal injury, while still allowing claims for exemplary damages, compensatory damages claims for some breaches of the New Zealand Bill of Rights Act 1990, damages claims for mental injury not associated with physical injury or work or certain criminal offences, damages claims for property damage and business losses, some damages claims resulting from events before the accident compensation regime came into force, and some claims resulting from personal injuries arising under approved clinical trials.

(a) Accident Compensation

The accident compensation legislation initially passed in 1972, and in effect in various forms since 1974, effectively abolished the right to sue for compensatory damages for most types of personal injury suffered after 31 March 1974. Where the legislation applies, state-funded "no fault" compensation is provided and claims for compensatory damages are barred. However, where cover under the accident compensation regime does not apply, product liability claims seeking compensatory damages for personal injury may still be brought.

Cover under the accident compensation regime is available for personal injuries caused by accidents, various occupational diseases and various treatment injuries. The cover for various occupational diseases has also been extended to include periods prior to the inception of the accident compensation regime.

Efforts to circumvent the accident compensation regime by issuing proceedings overseas for torts committed in New Zealand have generally been unsuccessful when tested at appellate level - see for example *Amaca v Frost* [2006] NSWCA 173, (2006) 4 DDCR 88.

Personal injury claims that are not covered by the accident compensation regime, and are not therefore barred, include, amongst others, claims for exemplary or punitive damages (as they are non-compensatory) and most claims for mental injury where the claimant has not also suffered physical injury. The scope of cover was increased in 2005 in relation to victims of crime and injuries caused by medical treatment.

The questions of whether exemplary damages should be available in negligence cases and, if so, whether conscious wrongdoing or subjective recklessness must be proven, are under consideration by the Supreme Court following the second hearing before that Court in the *Couch v Attorney-General* litigation (in March 2009).

(b) Contract

New Zealand contract law has its origins with the common law of England. The general law of contract has, however, been significantly amended in New Zealand by legislation such as the Contractual Remedies Act 1979 and the Contracts (Privity) Act 1982. In sale of goods situations, additional liabilities are also imposed by the Sale of Goods Act, the Fair Trading Act, and the Consumer Guarantees Act (all discussed later). Despite the addition of various statutory bases for claim, contract law remains one of the most important bases for product liability claims in New Zealand.

The Contractual Remedies Act 1979 amends the common law in relation to pre-contractual misrepresentations and in relation to remedies available for breach of contract and wrongful cancellation. Under the discretion conferred on the court, a range of factors may be taken into account.

The Contracts (Privity) Act 1982 confers contractual rights on third parties for whose benefit the contract has been entered into. This enables these third parties to proactively enforce a contract made by others. It does not, however, give the parties to the contract the right to impose aspects of their contract on third parties.

(c) Tort

As with contract law, New Zealand tort law has its origins with the common law of England. Differences between New Zealand and English tort law have progressively widened as a result of court decisions and statutory changes in each country. The most significant tort in the product liability field is the tort of negligence. Liability in negligence arises where, as a result of the relationship between two parties, one owes a duty of care to the other and the duty is breached in a manner which causes damage that is not too remote. The Supreme Court in *Couch v Attorney-General* [2008] 3 NZLR 725 indicated that the Courts should be prepared to consider duties of care in novel circumstances, particularly where the law is confused or developing, without being too ready to strike out a claim before trial.

Negligence liability may arise not only in respect of a defect in a product, but also for a failure to warn or for a misleading statement. A claim for negligent misstatement must be founded on a special relationship denoted by the interdependent concepts of assumption of responsibility and reliance.

Where negligence of the plaintiff and negligence of the defendants materially contributed to a loss, the Contributory Negligence Act 1947 provides for apportionment of responsibility.

(d) Statutory Liability

In addition to tort and contract systems, product liability can also arise under statute. The three most important statutes in this regard are the Sale of Goods Act 1908, the Fair Trading Act 1986, and the Consumer Guarantees Act 1993.

The Sale of Goods Act 1908 is based upon English legislation. It supplements existing contractual relationships between contracting parties by implying terms as to the merchantability or fitness for purpose of goods sold by one person to another. The first major type of statutory implied term arises if a buyer, expressly or by implication, makes known to the seller a particular purpose for which the goods are required, in such a way as to show that the buyer is relying on the skill or judgment of the seller. If the goods are of a description which it is in the course of the seller's business to supply, then there is an implied condition that the goods shall be reasonably fit for their intended purpose. The second major type of statutory implied term arises where goods are bought by description from a seller who deals in goods of that description; a condition is implied there that the goods will be of merchantable quality.

New Zealand has also enacted legislation bringing into effect in New Zealand the Vienna Convention on the International Sale of Goods - see the Sale of Goods (United Nations Convention) Act 1994. Different implied terms may arise as a consequence in international sale transactions. The Convention does not apply to claims for death or personal injury.

The Fair Trading Act 1986 prohibits misleading and deceptive conduct in trade. Part III of the Act contains special provisions relating to product safety including powers enabling the government to set product safety standards and to declare goods "unsafe". Section 32 of the Act enables the relevant government minister to require a supplier to recall goods, and to take other steps described later. The Act also contains a variety of statutory remedies available through the courts, including injunctive relief and compensation.

The Consumer Guarantees Act 1993 imposes additional obligations on manufacturers and sellers. These obligations are referred to in the Act as "guarantees". The guarantees implied by the Act cover acceptable quality, fitness for purpose, compliance with description, compliance with sample (and sales by sample), reasonableness of price, willingness to repair or supply spare parts, and as to title.

Although these statutory provisions have augmented conventional tort and contract systems, the accident compensation legislation has effectively prevented these other statutory measures being utilised in most personal injury situations.

(e) Criminal Liability

In New Zealand criminal liability is imposed by statute, rather than being governed by the common law. In relation to defective products, criminal liability can arise either under the specific provisions of the Fair Trading Act or under the wide-ranging provisions of the Crimes Act.

Contravention of Part III of the Fair Trading Act is an offence against that Act. Maximum fines of NZ$30,000 for individuals and NZ$100,000 for corporations apply. Part III of the Fair Trading Act includes the sections discussed earlier that deal with product safety standards, goods declared to be "unsafe" and compulsory product recalls.

Under the Crimes Act 1961, criminal liability applies in instances of criminal nuisance and for breach of duties applicable to persons in charge of dangerous things or required to avoid omissions dangerous to life.

A criminal nuisance is committed when a person does an unlawful act or omits to discharge a legal duty, and the act or omission was known by the person to be one which would endanger the life, safety or health of one or more individuals. Imprisonment for a term not exceeding one year may result.

If a product fault or defect resulted in a person dying, then this could constitute murder or manslaughter. Criminal responsibility for murder or manslaughter arises only where the omission or neglect is a major departure from the standard of care expected of a reasonable person in the circumstances.

There are also a range of offences applicable in specific areas e.g. the Food Act.

Product liability matters do not often give rise to criminal proceedings in New Zealand.

1.2 Does the state operate any schemes of compensation for particular products?

The uniquely comprehensive accident compensation regime in New Zealand provides statutory compensation for most types of accidents, for various occupational diseases, and for various treatment injuries. The wide-ranging coverage of the accident compensation scheme means that it applies to most (but not all) situations where personal injury results from the supply of defective or faulty products. Consequently, the state does not operate schemes of compensation applicable solely in relation to particular products.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

The manufacturer, the importer, the distributor, and the "retail" supplier are all potentially liable where damage results from the supply of defective or faulty products. Contractual liability will apply as between the parties to a contract, and third parties for whose benefit the contract was made may also sue on the contract under the Contracts Privity Act. Liability in tort depends on the existence of a duty of care, and can certainly be imposed on other parties in the "supply chain" such as manufacturers. In relation to special statutory liabilities: the Sale of Goods Act follows contractual relationships; the Fair Trading Act requires only misleading or deceptive conduct in trade and can apply to a range of parties including manufacturers; and the Consumer Guarantees Act is specifically designed to cover a range of parties in the "supply chain". Criminal liability too can apply in a wide range of relationships.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

An obligation to recall a product may arise under the Fair Trading Act or under the general law.

Section 32 of the Fair Trading Act applies where a person has in trade supplied goods that either:

- do not comply with a product safety standard; or
- are of a kind which will or may cause injury to any person.

If a supplier has not recalled such goods or taken satisfactory action to recall them, then the relevant government minister may require the supplier to take various types of action. Relevant types of action that the supplier may be required to take include recall of the goods, public disclosure of information, repair or replacement of the goods, or refunding all or part of the price paid.

In New Zealand manufacturers may, depending on the circumstances, have a duty to warn consumers and possibly recall products when they learn of risks - even after the products have been sold and even though the product was not defective at the time it was sold.

A claim for failure to recall might be brought by way of action for damages, provided it was not of a type barred by the accident compensation legislation. If breach of the Fair Trading Act were alleged, either civil or criminal proceedings could be brought.

1.5 Do criminal sanctions apply to the supply of defective products?

This is addressed in question 1.1 above, under the subheading "(e) Criminal Liability".

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

Generally speaking the claimant in any particular case will have the burden of proving the elements of the claim including matters of fault and damage. In accordance with the usual rules, the claimant in a civil action must prove the claim on the balance of probabilities and the prosecution in a criminal action must prove the offence beyond reasonable doubt.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

Usually a "but-for" test is applied, i.e. whether the claimant would have suffered the particular loss without or "but-for" the defendant's wrongful actions. The test has also been expressed as requiring the plaintiff to prove that it is more likely than not that the product in question contributed materially to the development of the relevant condition.

There are possible exceptions in various special cases. One such exception concerns proof of an increased risk of the relevant type of injury - following English decisions on the topic. However, in New Zealand there is limited scope for such exceptions, and in a product liability context the New Zealand High Court has held that the exceptional approach of the House of Lords in the English medical negligence case of *Chester v Afshar* [2005] 1 AC 134 does not apply.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Market-share liability is not a recognised doctrine in New Zealand. Broadly speaking, the claimant will be required to establish the claim against each particular defendant - rather than proving only that the relevant goods were produced by one of a group of potential manufacturers.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

It has been recognised in New Zealand that a duty to warn will exist in numerous different circumstances - traditionally where the manufacturer has knowledge about a danger that the consumer could not reasonably be expected to possess. The purpose of the duty to warn is to address, or ameliorate, this imbalance (see *Pou v British American Tobacco*, 3 May 2006). In relation to products distributed to a mass market, the duty is to warn of the relevant risk in a manner that could be expected to come to the attention of the reasonable consumer. An adequate warning to a learned intermediary, who can reasonably be expected to explain a risk, should be sufficient to protect a manufacturer.

3 Defences and Estoppel

3.1 What defences, if any, are available?

A range of different defences are available depending on the type of claim being made.

In negligence claims, contentious issues tend to include:

- the existence, nature and extent of any duty of care;
- whether any duty of care has been breached;
- causation;
- the nature and extent of damage;
- whether damage is too remote; and
- any contributory negligence.

Special defences available to a defendant include voluntary assumption of risk (*volenti*), the Limitation Act time bar, and the accident compensation legislation which bars most claims for compensatory damages for personal injury. While they may not strictly constitute defences, issues regarding the existence or likelihood of intermediate examination of the goods and economic loss may also assist a defendant.

In contract claims relevant issues will include:

- the existence and terms of the contract;
- whether the contract has been breached;
- causation;
- the nature and extent of damage; and
- whether the damage is too remote.

Again the Limitation Act and the accident compensation legislation may bar a particular claim.

Defences to the various grounds for liability by statute will of course depend on the wording of the particular statutory provision relied upon by the claimant. Broadly speaking the most important special defences will again be the Limitation Act and the accident compensation legislation.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Where issues concerning the state of scientific and technical knowledge at the time of supply are relevant, they are ordinarily considered as part of the elements of the claim which the claimant must prove, rather than constituting a distinct defence which the manufacturer is required to prove. In a negligence claim, for example, issues concerning the nature and extent of a duty of care depend upon what the defendant knew or ought to have known at the relevant time.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Again, where compliance with regulatory and/or statutory requirements is relevant, this will normally be addressed as part of the claim which the claimant must prove rather than as a separate and distinct defence which a defendant manufacturer must prove. An exception is the defence of statutory authority, where the defendant alleges that the defendant was authorised by statute to carry out the actions in question.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Factual findings on these types of issues can be re-litigated in separate proceedings brought by a different claimant. Factual findings in one case will not normally bind others who were not party to the particular proceedings in which the factual findings were made.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

Generally, a defendant can seek a contribution or indemnity from a third party, either in the same proceedings or in subsequent proceedings - section 17 Law Reform Act 1936. A claim for contribution or indemnity from a third party must usually be brought within six years after "everything has happened which would have to be proved to enable judgment to be obtained for a sum of money in respect of the claim" - section 14 Limitation Act 1950. In practical terms, a contribution or indemnity claim must usually be brought within six years after either the plaintiff gets judgment against the defendant or the plaintiff and the defendant agree on a compromise. Claims relating to building work may also be subject to the long stop time limit in the Building Act preventing claims being made ten years or more after the date of the act or omission on which the proceedings are based.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Defendants can allege that the claimant's actions caused or contributed towards the damage. This can be alleged by a defendant in denying liability and also in seeking to have any award of damages reduced because of the contributory negligence of the claimant.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

Major product liability claims are normally brought in the High Court. Judges in the High Court regularly sit with juries in criminal trials and rarely sit with juries in civil trials.

Some product liability claims can also be heard in the Disputes Tribunal or the District Court. A Disputes Tribunal can hear various types of civil claims up to a financial limit of NZ$7,500, which can be extended to NZ$12,000 by agreement between the parties. The limits of NZ$7,500 and NZ$12,000 would increase to NZ$15,000 and NZ$20,000 respectively from 1 August 2009 under legislation currently being considered by the New Zealand Parliament. The District Court has a wide-ranging jurisdiction to hear general civil claims for amounts up to NZ$200,000 and to hear various types of criminal claims. Jury trials are available for some District Court criminal hearings, but are not available for civil hearings in the District Court or the Disputes Tribunal.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The High Court can sit with technical specialists in some types of proceedings (e.g. proceedings under the Commerce Act 1986), but the High Court does not sit with expert assessors in product liability claims.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

New Zealand does not have a wide-ranging class action procedure akin to that used in the United States or Australia. True class actions brought on behalf of unnamed claimants can be brought under the Human Rights Act (in relation to discriminatory practices) and under the Health and Disability Commissioner Act 1994. A type or variation of the class action procedure, but not a true class action, can be brought in the product liability context under section 43 of the Fair Trading Act for misleading or deceptive conduct - see the High Court decision in *Commerce Commission v Carter Holt* [2008] 1 NZLR 387 (subsequently overturned on a different point by the Court of Appeal [2009] NZCA 40).

Representative actions and "relator" proceedings have been more widely used than class actions. In a representative action one or more persons with the same interest in the subject matter of a proceeding can sue or be sued on behalf of or for the benefit of all persons interested in the proceedings. The representative must have the consent of the other persons with the same interest or obtain a direction of the Court ordering that the representative be appointed.

Identity of interest is required. Where the class proposed to be represented includes diverse interests, and particularly where members may have available different defences, the procedure is not available. Members of the class represented are bound by any judgment given in the representative action, even though the members may not themselves be individually named as parties. Essentially, conduct of the representative proceeding rests with the named representative party.

The High Court may also appoint a variety of other people to act as representatives of a group.

Opt out orders are not well-recognised. In *Houghton v Saunders* (2008), it was common ground that opt out orders had not previously been made in other representative proceedings in New Zealand, and the High Court judge ruled that an opt in process should be used in that case.

Although class actions and representative action procedures have not historically been widely used in product liability claims in New Zealand, the Rules Committee of the High Court is seeking to introduce new class action rules which in all likelihood will increase the availability and use of class action procedures for product liability claims.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Under currently available processes the High Court may allow a representative body to bring a claim on behalf of a class of persons. The objective is to avoid duplication. It is unlikely that representation would be ordered in respect of a class of persons whose interests contained substantial internal conflicts. This approach is not common in product liability claims in New Zealand, but this may well change if and when new class action rules are introduced.

4.5 How long does it normally take to get to trial?

The time from filing to the commencement of a trial will vary a great deal between cases. A relatively straight-forward civil claim requiring a trial will ordinarily take between nine and 24 months from filing until trial.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The High Court has the power to hear and determine preliminary issues which may determine whether the remainder of the trial proceeds. Preliminary questions can cover matters of fact, matters of law, or matters of mixed fact and law. Preliminary questions are, at least in practice, determined by a judge without a jury. If the preliminary question is a question of law, the High Court may order that the question of law be removed into the Court of Appeal, but this jurisdiction is used very sparingly.

Applications for summary judgment can be made in civil cases in the District Court and the High Court.

4.7 What appeal options are available?

An appeal against a District Court decision at trial will ordinarily lie to the High Court. In exceptional cases the Court of Appeal will provide a second tier of appeal from decisions originally made in the District Court. Some appeals from District Court criminal decisions go direct to the Court of Appeal.

Appeals from High Court decisions at trial can be brought in the Court of Appeal. In some cases a second tier of appeal is available by way of appeal to the Supreme Court (subject to leave being granted).

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Technical issues are ordinarily covered by expert evidence presented by the parties. The court is also able to appoint experts, but this procedure is not widely used.

The High Court Rules contain a code of conduct for expert witnesses. Expert witnesses are for example made subject to an overriding duty to assist the court impartially in relevant matters within the witness' area of expertise. Expert witnesses are not permitted to act as an advocate for the party who engages the witness.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

In civil proceedings, factual or expert witnesses are not usually required to present themselves for pre-trial deposition, but witness statements and expert reports are normally exchanged prior to trial.

In criminal proceedings to be heard before a judge sitting with a jury, factual and expert witnesses to be called by the prosecution may be required to present themselves for pre-trial deposition and/or to provide a statement or reports to the defence prior to trial.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

In civil proceedings the District Court Rules and the High Court Rules provide for parties to obtain access to detailed information about documents (including tape, video and electronic records) relevant to the matters at issue. Parties to civil proceedings and non-parties may be required to list on oath the relevant documents which they may have held at any time and to produce those documents where possible. In preparing a list of documents, the party preparing the list must identify which documents it has in its possession, custody or power and which documents it objects to disclosing. The grounds upon which disclosure may be resisted are limited. The main types of privilege which allow disclosure to be resisted are: privilege against self-incrimination; non-litigious legal professional privilege; litigation privilege; and professional/ indemnity insurers' privilege. In some circumstances disclosure of confidential documents may not be required or may be subject to conditions limiting access.

In criminal proceedings the prosecution is ordinarily required to provide copies of its non-privileged documents to the defence.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

The High Court Rules explicitly provide for judicial settlement conferences (where a judge can assist the parties' negotiations), arbitration, mediation, and other forms of alternative dispute

resolution. The consent of the parties is required for each of these mechanisms except a pre-hearing judicial settlement conference.

The Rules also require consideration at routine case management conferences of whether some form of alternative dispute resolution (i.e. other than a court trial) is appropriate.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

There are a variety of different time limits that can prevent proceedings from being brought or issued.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

In civil proceedings the relevant time limits are generally set out in the Limitation Act. There are some exceptions e.g. equitable claims for breach of fiduciary duty.

In contract cases, the time limit will ordinarily expire six years after the "start point" for contract claims: the date of the breach of contract. In negligence claims, there are different "start points" for different types of claims. Ordinarily the relevant start point will be the date when the relevant damage has occurred. In the context of a claim for personal injury caused by negligence, the time limit will ordinarily run from the time when bodily injury of the type complained of was discovered or was reasonably discoverable as having been caused by the acts or omissions of the defendant - see *Trustees Executors v Murray* [2007] 3 NZLR 321 (SC). Once the applicable "start point" is reached, a claimant in a negligence action ordinarily has six years within which to commence proceedings, but a shorter two-year time frame normally applies where the negligence action is for personal injury. In claims for accident compensation, a claimant is required to lodge a claim within 12 months, but the Accident Compensation Corporation is not entitled to refuse a claim because of lateness unless the claim's lateness prejudices the Corporation in its ability to make decisions. The general time limit under the Fair Trading Act is three years after the matter giving rise to the contravention or application occurred, and the Building Act contains a special "long stop" ten-year limitation period.

The Limitation Act also contains additional provisions that apply to people under disabilities at the time when the cause of action accrues. People under the age of 20 or detained under the Mental Health (Compulsory Assessment and Treatment) Act 1992 are disabled for this purpose. Where a claimant is a person under a disability in these terms, the normal period of limitation is extended. The ordinary time limits will also not apply in cases of fraud or concealment.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Section 28 of the Limitation Act postpones the "start point" from when the period of limitation (e.g. of six years) begins to run in claims based on fraud or where the right of action is concealed by fraud. In such cases the period of limitation does not begin to run until the plaintiff has discovered the fraud or could with reasonable diligence have discovered it.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

A variety of different remedies is available in different types of civil cases - subject to bars in specific instances. Common law causes of action can result in remedies such as orders for damages, injunctions, declarations, payment of interest, taking of accounts, inquiries, and costs. Statutory causes of action are often accompanied by specific statutory remedies, e.g. orders under the Fair Trading Act for payment of amounts of loss or damage, or to disclose information or publish advertisements.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

As explained earlier, the accident compensation legislation bars civil claims for compensatory damages for most types of personal injury and provides statutory compensation instead. Subject to that major exclusion, damages are recoverable for bodily injury, mental damage, damage to the product itself, and damaged property. A wide variety of types of damages can be awarded.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

It is unclear whether damages could be recovered for medical monitoring costs at a time prior to a product malfunctioning. Ordinarily a claimant will need to demonstrate that a cause of action has accrued.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

The availability of punitive or exemplary damages in New Zealand was addressed in *A v Bottrill* [2002] 3 WLR 1406, [2003] 2 NZLR 721. It was held by a majority decision that, under the common law of New Zealand, in exceptional and rare cases inadvertently negligent conduct which was so outrageous as to call for condemnation and punishment could fall within the scope of the jurisdiction to award exemplary damages - even though the defendant had not intended to cause the harm or being consciously or subjectively reckless as to the risks involved. As indicated above, questions of whether exemplary damages are available in negligence cases and, if so, whether conscious wrongdoing or subjective recklessness are necessary elements, are under consideration by the Supreme Court following a hearing in March 2009 in the *Couch v Attorney-General* litigation. The unresolved issues in the Couch litigation, the continuing controversy in Australia and England on the fundamental question of whether exemplary damages should be awarded and the contrasting approaches of the majority and minority in *Bottrill*, together mean that the law in this area should be regarded as unsettled at least until the Supreme Court's decision on the issue in the *Couch* litigation is released.

In New Zealand the amounts awarded by way of exemplary or punitive damages are modest by international standards.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no maximum limit prescribed in New Zealand law, but as noted above the amounts awarded in New Zealand as exemplary or punitive damages are modest by international standards.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

The underlying general principle is that a plaintiff cannot be compelled to continue with a court proceeding against the plaintiff's will. There are, however, a number of exceptions, e.g. where discontinuance would be an abuse of the process of the Court. The Court may set aside a step in a proceeding if an incapacitated person did not have a litigation guardian when that step was taken and the Court considers that the incapacitated person was unfairly prejudiced.

In relation to settlement of money or damages claims by or on behalf of minors, the Minors Contracts Act 1969 contains provision for Court approval to make settlements valid and binding. The Act also enables the Court to impose conditions eg for all or part of the amount paid to be held on trust for a period.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

In some instances Government authorities can claim reimbursement from damages awards and settlement payments paid to a Claimant.

The best example is the ability of the Accident Compensation Corporation in such circumstances to make deductions from amounts of accident compensation it would ordinarily pay, and to recover from the Claimant amounts of accident compensation that have previously been provided.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

In civil litigation an unsuccessful party is ordinarily required to pay a contribution to the legal costs and related expenses of the successful party. A scale for calculation of contributions to legal costs is set out in the High Court Rules. Although the courts still have a discretion in relation to costs, the courts tend to rely heavily on the provisions of the scale.

Court fees will ordinarily be recoverable by the successful party from the unsuccessful party.

In criminal cases a successful defendant will normally recover little if any of its legal costs.

7.2 Is public funding e.g. legal aid, available?

New Zealand parties to litigation can obtain legal aid if they are private individuals, have sufficiently limited resources, and have a sufficiently strong claim or defence. Different schemes apply for civil and criminal proceedings. Changes to the legal aid system are proposed.

7.3 If so, are there any restrictions on the availability of public funding?

A variety of restrictions limit the availability of legal aid. The principal restrictions relate to the nature and financial resources of the legal aid claimant and the strength of the legal aid claimant's claim or defence.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Lawyers in New Zealand may now enter into a conditional fee agreement with a client in the circumstances and manner set out in sections 333 to 335 of the Lawyers and Conveyancers Act 2006. These new provisions came into force on 1 August 2008.

Where a lawyer enters into a conditional fee agreement with a client, the lawyer must ensure that the client has been informed of any other appropriate arrangements that may be available, including, where relevant, the possibility of legal aid. The total fee charged at the conclusion of the matter must be fair and reasonable in accordance with Rule 9 of the Lawyers and Conveyancers Act (Lawyers: Conduct and Client Care) Rules 2008. A conditional fee arrangement must be in writing and must comply with the requirements of Rule 9, including, but not limited to, specifying the method by which the fee is to be determined, the condition(s) that will amount to success and upon the occurrence of which the fees or any part will become payable, the method by which the fee is to be determined in the event that an offer of settlement or compromise is made which the client declines to accept against the advice of the lawyer, and that the client may give notice cancelling the conditional fee agreement within 5 working days after it has been entered into on the basis that the lawyer may charge a normal fee for any work done during that period.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Third party funding of claims is now possible in New Zealand.

Although the tort of champerty has not been abolished altogether in New Zealand, judicial attitudes have changed dramatically and the Courts are more readily accepting that litigation funding is a reality of commercial life. Following the *Fostif* decision of the High Court of Australia, litigation funding is no longer seen as objectionable as a matter of public policy, as the Courts consider they have ample jurisdiction to prevent an abuse of Court processes and to address exploitation of vulnerable litigants. Key reasons for the change have been concerns surrounding access to justice and acknowledgement that the costs of litigation are beyond the means of many people - see *Auckland City Council as Assignee v Auckland City Council* [2008] 1 NZLR 838, and *Houghton v Saunders* (2008, but subject to appeal).

A funding arrangement will not be held to be an abuse of process or objectionable as a matter of public policy simply because a litigation funder has sought out a piece of litigation in which to invest for profit.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in New Zealand.

With one potential exception, recent developments point to a likely increase over time in product liability litigation in New Zealand.

Factors pointing to a likely future increase in product liability litigation include:

(a) the provisions of the Lawyers and Conveyancers Act 2006 (in force from 1 August 2008) that now permit conditional fee agreements between lawyers and clients;

(b) increased concerns about access to justice - see *Auckland City Council as Assignee v Auckland City Council* [2008] 1 NZLR 838 (HC);

(c) influenced by increased concerns about access to justice, increased acceptance of litigation funding as legitimate (as, for example, in the *Fostif* litigation in Australia and in *Houghton v Saunders* in New Zealand);

(d) increased recognition of the potential of the limited existing mechanisms for class actions and representative actions (e.g. *Commerce Commission v Carter Holt* [2008] 1 NZLR 387 (HC) on class actions, and *Houghton v Saunders* on representative actions);

(e) the reluctance of the Supreme Court to strike out before trial new types of claims in areas where the law is confused or developing, that may prove to be arguable (see *Couch v Attorney-General* [2008] 3 NZLR 725); and

(f) the Rules Committee is seeking to introduce new class action rules in the High Court that would significantly expand the potential for class actions beyond the limited mechanisms currently in place.

The potential "exception", which could perhaps lead to a decrease in claims for exemplary damages, is the *Couch v Attorney-General* litigation. In the second part of the appeal to the Supreme Court, the Crown argued in March 2009 that the availability of exemplary damages should be further reduced (as explained above). If the Crown succeeds on this part of the appeal, this could significantly limit the exemplary damages "exception" to the accident compensation bar on most damages awards in personal injury litigation.

Taken overall, recent developments indicate a likely future increase in product liability litigation in New Zealand. The extent of the likely increase, however, remains uncertain.

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Robert Gapes is a litigation partner in the Auckland office of Simpson Grierson and has over 25 years' experience as an adviser and advocate.
He has long-standing specialist expertise in product liability, and has acted on numerous product liability matters involving a very diverse range of products such as asbestos, building products, chemicals, electronics, food and beverage products, medical equipment and pharmaceuticals. He has also co-authored international books, written articles for publication in New Zealand and overseas, and presented conference and seminar papers (eg to the International Bar Association and the Auckland District Law Society) on product liability topics (see www.simpsongrierson.com).
The International Who's Who of Product Liability Defence Lawyers (2008) named Robert as the number one practitioner in New Zealand for product liability expertise.
Robert's advocacy work has included appearing in the Court of Appeal and in the Supreme Court as lead counsel for Mrs Lai, one of the successful parties in the landmark Lai v Chamberlains case. In Lai, the long-recognised defence of barristers immunity was abolished in New Zealand. The Supreme Court decision, released in September 2006, was described by the leading New Zealand commentator, Professor Todd, as the Supreme Court's "first major decision in the area of torts" (see [2006] NZ Law Review 793).

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

Product liability can be based both on negligence, a customary norm derived from judicial decisions and legal theory, and strict liability under the Product Liability Act, "PLA", (104/1988). This article will deal mainly with the rules in the PLA.

Furthermore, product liability can rest on a breach of contract. If a product is defective and does not possess the contractually promised properties, it may lead to strict or fault-based liability under the Purchase Act (27/1988).

A claimant may choose between these three systems. Neither legal basis precludes the use of another, but the different systems may not cover all kinds of damages. In some instances, the claimant must establish that the "manufacturer" acted negligently, *cf.* PLA section 1-3 (1).

1.2 Does the state operate any schemes of compensation for particular products?

Yes. In accordance with the Protection from Infection Act (55/1994), the Government may be obliged to pay standardised damages caused by vaccinations. Compensation for damages caused to patients during medical treatment in the public health care system is regulated in the Patient Injury Act (53/2001). Under the same act private health care institutions must provide insurance for claims related to medical treatment. Compensation for damages caused by vehicles is established in the Liability for Vehicles Act (1/1961). In Chapter 3, the PLA lays down a separate compensation scheme for damages caused by the use of and the testing of medicines.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

The PLA sets out that nearly everyone in the chain of distribution may be held responsible, including the manufacturer, the importer, and the supplier of the product, *cf.* the PLA section 1-3 (1).

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Under the Product Control Act (79/1976) section 6a, there is an obligation to recall products if they constitute "an unacceptable risk" of causing damage to people's health or the natural environment, and the government issues a binding order of product recall. A failure to comply with this order may result in a fine. In addition, the government may request a court to issue a compliance order in the event of the "manufacturer" is in non-compliance, or choose to permanently uphold the order in the court system.

1.5 Do criminal sanctions apply to the supply of defective products?

A negligent or intentional violation of the Product Control Act (79/1976) section 6a is sanctioned with a fine or imprisonment for up to 3 months, or both. In cases of gross negligence, the Penal Code (10/1902) applies.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

As a general rule the claimant has the burden of proof and must establish the factual basis for his claim under all three systems of liability: the PLA, fault-based liability, or contractually based liability in accordance with the Purchase Act, (27/1988).

If a claimant submits evidence that the court considers *prima facie* proof of a fact relating to any of the conditions for liability, this creates an evidentiary burden upon the opposing party. He must present evidence to refute the presumption. In relation to claims based on the PLA, the "manufacturer" must refute, *cf.* section 1-3 (1).

Norwegian courts are free to weigh the evidence in the particular case as they see fit.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

Under the PLA section 2-1, the manufacturer is obliged to compensate for damages caused by the product having a "safety deficiency". A "safety deficiency" exists when the product does not

provide the user or general public with the level of security which may be reasonably expected.

Consequently, the claimant must prove beyond a balance of probabilities that the product has caused the damage in question, and that this damage must be the result of the "safety deficiency".

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

For a claim to be successful, the claimant must prove that each individual defendant is responsible in accordance with the standard rules of assessment of evidence. Norwegian product liability law does not recognise market-share liability.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

In determining the degree of safety which could be expected from the product, due account shall be taken of all matters relating to the product, its presentation, marketing and foreseeable use. A failure to warn can give rise to liability for both for the manufacturer and any intermediaries. They are all considered as "manufacturers" under PLA section 1-3 (1), which provides a very broad definition of parties that can be held liable.

The described principle of "learned intermediary" is not recognised in Norwegian law.

3 Defences and Estoppel

3.1 What defences, if any, are available?

In accordance with PLA section 2-2, the "manufacturer", *cf.* section 1-3 (1), is free from liability if he can show: (a) that he did not supply the product for sale as part of his activities; (b) the "safety deficiency" did not exist at the time when the product was supplied for sale, and that no obligation applied to avert the damage or to minimise it afterwards; or (c) the reason for the safety deficiency was that the product satisfied peremptory rules issued by a public authority.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

The "manufacturer" incurs strict liability under the PLA if the "safety deficiency" existed prior to and at the time the product was supplied for sale. Consequently, there is no general development risk defence under the PLA. If the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply, this may be deemed as a defence against a claim based on negligence.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

See my translation of the PLA section 2-2 (c) under question 3.1.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Yes. Separate proceedings concerning product liability attached to the same product may be instituted by different claimants. In such instances, the reasoning and result in the first judgment may often influence any following judgments, but there is no formal issue estoppel.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

In the event that damage is caused by both a "safety deficiency" and an act or omission of a third party, the defendant is obliged to provide full compensation. In subsequent proceedings, the defendant may seek indemnity from the third party based upon general tort law. Many times, it is practical to join all claims and parties in relation to the same product liability matter in the same proceedings. The defendant will usually want to bring in any responsible third parties. As a rule, an indemnity claim against the third party must be raised within one year after the defendant paid damages to the claimant.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Yes, as set out in section 5-1 in the Tort Act (26/1969), "TA", his claim for damages may be cut short or be reduced to zero.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

The court consists of one or more judges. They may be professional judges or summoned as judges by the parties because they are experts in a field relevant to the particular case. The trial is never by a jury.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Yes, the court may appoint technical specialists as judges. The parties may also request this.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

Chapter 35 in the new Civil Procedures Act (90/2005), "CPA", effective from January 1, 2008 lays down rules in relation to group actions. The claims must be based on the same or essentially the same factual and legal basis. The court must accept the claim as a group action, and decides whether the action shall be treated under an opt-in or opt-out procedure. As a main rule, the procedure is opt-in. Group actions can be instituted by individuals or groups/associations/organisations. At this date, we do not know of any such actions in Norway, but there are rumours that several group actions are currently being prepared.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Yes, both in individual and group actions, claims may be brought by a representative body, provided that the action falls within the purpose of the organisation or body.

4.5 How long does it normally take to get to trial?

The new CPA sets out that a case shall normally go to trial within 6 months after the claim was submitted to the court. This applies for the court of first instance, the appeals court and the Supreme Court.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

In a preliminary stage, the court tries whether the case is admissible. Some grounds for dismissal must be taken into account by the court regardless of its own volition, and some must be invoked by the parties. The preliminary decision will be based on the facts provided by the parties. In accordance with the CPA, the material questions will not be the subject of a preliminary hearing. However, the court may determine the basis for a claim after a simplified trial, if it is clear that the claim or the objections to the claim are untenable.

4.7 What appeal options are available?

Subject to some restrictions, a case may be argued in three stages, the court of first instance, the appeals court, and the Supreme Court.

An appeal requires that the value of the claim is at least NOK 125,000, but the appeal court may consent to hear the case even though the claim is of a lesser value. The court may reject the appeal if it considers that the appeal is clearly unsustainable.

An appeal to the Supreme Court may not be pursued without the consent of an appeals committee. Consent depends on whether the case is of general importance. Statistically, about 20% of the cases will be heard.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The court may appoint experts if it is requested by one of the parties, or on its own volition if it is necessary to obtain an adequate factual basis on which to base the decision. The parties may also present experts as witnesses. As a main rule, the court is free to assess the weight of the evidence.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

As a main rule, witnesses give oral statements during the main hearing and are not required to do so prior to trial. They may be required to present themselves for pretrial depositions if the court orders them to. The reports of expert witnesses may be exchanged prior to trial, but in any event the expert witnesses may be imposed to give oral statements during the main hearing.

Prior to trial, the parties must inform which evidence they will produce and what the evidence in question will seek to establish. A breach of this rule may lead to a dismissal of that evidence.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

In the pretrial procedures the parties must disclose the evidence that their claims are based on. Parties are also obliged to disclose any important evidence that they cannot presume that the other party has acquired knowledge of.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

In accordance with the CPA section 5-4 the parties are obliged to seek resolution of the matter outside the court system before they go to trial. Parties can also agree to solve the matter outside the court system and apply the procedural rules in the CPA. The court may also decide that the matter shall be subject to mediation by the court, *cf.* the CPA section 8-3. This can be decided at all the stages of the case.

The parties may also choose to refer the matter to arbitration.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, time limits do exist.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

As a main rule, there is a time-bar of 3 years for strict liability under

the PLA. A claim cannot be asserted more than 3 years after the day the claimant acquired or should have acquired the necessary knowledge of the damage, the "safety deficiency" and the identity of the "manufacturer". In any event, claims that are based on the PLA are time-barred 10 years after the product was made available for sale. However, liability claims relating to pharmaceutical products are time-barred 20 years from the day the product was made available for consumption.

As a main rule, fault based claims become time-barred 3 years after the claimant acquired or should have acquired knowledge of the damage and the party responsible. Regardless of the type of product or the claimant's knowledge, the time limit is 20 years. No time limits apply to fault based claims for personal injuries.

The condition or age of the claimant will not affect any time limit. The Court may not choose to disapply time-bars.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Concealment or fraud may affect the claimant's knowledge, and indirectly affect the aforementioned time-bars. There is no time-bar for a product liability claim if the "manufacturer", *cf.* the PLA section 1-3 (1), had or should have had knowledge of the "safety deficiency" and is found guilty of fraud or concealment in relation to this, and the liability claim is brought forward in a criminal case regarding product liability, *cf.* the PLA section 2-7 (3) and the Prescription of Claims Act (18/1979) section 11.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

Liability under the PLA is awarded as a monetary compensation, aimed to place the successful claimant in the position he was in prior to the damage.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Damage to the "safety deficient" product itself or damage to the product that the "safety deficiency" is part of is non-recoverable. Personal injury claims relating to bodily injuries and mental harms are recoverable under the PLA. Damage to property is also recoverable under the act, if the property is meant for private use or consumption, and was used by the defendant mainly for private purposes or consumption.

The TA may also provide compensation for pain and suffering, if the damage is caused intentionally or is the result of gross negligence, *cf.* section 3-5.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

No. As a main rule, the defendant must suffer an actual economic loss and is compensated for this. Damages for permanent injury and pain and suffering are exceptions, but are also meted out as monetary compensation as surrogates for the physical and/or mental damage suffered.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

No, but the compensation for pain and suffering has, to some extent, a punitive purpose.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

No such limitations apply.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

Certain conditions have to be met before the Court will hear group claims, *cf.* the answer to question 4.3 where some of the conditions are dealt with. Due to lack of legal capacity, the infant's legal guardian must act on behalf of the infant. In accordance with the TA section 3-2a compensation to persons under the age of 16 is standardised.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Any employment or welfare benefits paid by the state aimed towards placing the defendant in the position he was prior to the damage caused by the "safety deficiency" will be deducted from the claimant's full loss by the court directly.

In accordance with the TA section 3-7, government authorities may claim such benefits reimbursed, provided that the damage was caused intentionally.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Normally, the successful party will be reimbursed for all court fees and expenses that are related to the case from the losing party, provided that they are deemed reasonable by the court.

However, in some cases, typically where the legal issues of the case are complicated and the state of the law is uncertain, the court may decide to let each party bear its own costs. The court may also decide upon this if the successful party is to blame for the claim being brought to trial, for example when he refuses to accept a reasonable settlement, or the relative strength between the parties calls for it.

7.2 Is public funding e.g. legal aid, available?

Yes, in accordance with the terms in the Legal Aid Act (35/1980).

7.3 If so, are there any restrictions on the availability of public funding?

The conditions for obtaining legal aid are relatively strict. They will normally be fulfilled however, if the case is of sufficient significance and the applicant has a low annual income. The gross income must not exceed NOK 230,000 a year for a single person or NOK 345,000 for a couple sharing their income and expenses.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

No such arrangements are permitted under Norwegian law.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

There are no rules in Norwegian law prohibiting such funding.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Norway.

There have been no major new trends or developments in product liability law other than the rules allowing for group claims under the new CPA.

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Poland

Lovells

Ewa Rutkowska

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

Product liability claims in Poland may be made under any of the three concurrent legal regimes: strict product liability; fault-based tort liability; or the law of contract. Breach of statutory obligations can also give rise to liability if, as a result of the breach, a product causes injury or damage.

Strict liability

Strict product liability was introduced into Polish law in 2000 when new provisions implementing Directive 85/374/EEC were added to the Civil Code (articles 4491-11). These apply to damages caused by products put into circulation in Poland as of 1 July 2000. The Polish legislator decided to use the term "*liability for dangerous products*" instead of "*liability for defective products*" in order to avoid confusion with warranty claims under contracts of sale. However, the definition of a dangerous product in the Polish Civil Code is equivalent to that of a defective product in the Directive: any product which does not provide the safety one may expect taking into account the normal use of the product. Circumstances existing at the time when the product was put into circulation, in particular concerning its presentation and the information provided to consumers on its properties, shall be used to decide whether the product is dangerous.

Under the strict liability regime, anybody who produces a dangerous product in the course of his business shall be liable for any damage caused by that product to anybody else. The scope of recovery for damage to property under this legal regime is limited (see question 6.1).

Tort

Before the provisions on strict liability were introduced in the Polish legal system, product liability claims could (and indeed still can) be based on the traditional law of tort. Polish law has a very broad notion of tort: "*everybody who by his fault caused a damage to another person is obliged to redress it*". The Supreme Court has developed a concept whereby the marketing of a dangerous product constitutes a tort. Causing damage to human health or property is an unlawful act, and lack of due diligence amounts to negligence. The jurisprudence has drawn distinctions between design, production, information and monitoring defects.

Although product liability under the law of tort is generally fault-based, the Supreme Court has significantly eased the rules concerning proof of fault. The Court has accepted that putting a dangerous product on the market constitutes negligent behaviour. Moreover, a concept of an anonymous, organisational fault (rather than the personal fault of a defined individual) with objective elements has been applied in product liability cases. Consequently, this system has in practice been very similar to the strict liability regime provided for in the Directive.

Contract

If there is a contractual relationship between the injured person and the person providing the product, product liability claims may be based on the law of contract. Delivery of a dangerous product amounts to non-fulfilment or improper fulfilment of contractual obligations. A defective product is one which is not in conformity with a contract and therefore warranty claims can play an important role in product liability cases.

1.2 Does the state operate any schemes of compensation for particular products?

No, the state does not operate any such schemes.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Under the strict liability regime, responsibility for a dangerous product rests on:

- the producer, i.e. any person who produces the product in the course of his business;
- the producer of material, raw material or a component part of a product (unless the exclusive cause of the damage was defective construction or instructions given by the producer);
- the own brander (any person who presents himself as the producer by placing his business name, trade mark or another distinguishing designation on the product); or
- the importer (any person who, in the course of his business, introduces into domestic trading a product originating from a foreign country).

The liability of the abovementioned persons is joint and several.

If the producer, the own brander or the importer are not known to the injured party, any person who sells a dangerous product in the course of his business shall be liable for damages caused by that product unless he informs the injured party of the name and address of any of those persons or of his own supplier. The time limit for providing this information is one month from notification of the damage.

In product liability claims brought under the law of tort, it is usually the producer who is held liable for damage caused by a product. In the case of imported goods, importers have also been held liable. There have also been cases in which liability was found to rest with the seller alone or jointly with the producer.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

A producer's obligations do not end once the product is on the market. Producers are obliged to monitor their products and to take appropriate measures if they receive information concerning risks associated with a product which is already on the market. Producers have a duty to warn of these risks and, if a mere warning is inadequate, even to withdraw or recall the product from the market. A product recall obligation follows from the General Product Safety Act (which implements Directive 2001/95/EC). It can also be ordered by a competent authority, for example the President of the Office for Competition and Consumer Protection.

Claims for failure to issue warnings or to recall products may be made under the law of tort. It is also possible to bring a preventative action in which the court can order that the producer prevents anticipated damage by for example, recalling the dangerous product. However, such actions are not common in practice.

1.5 Do criminal sanctions apply to the supply of defective products?

Supply of certain defective products may fall under article 165 of the Criminal Code, which imposes criminal sanctions for certain defined actions that cause risk of substantial harm to the life or health of many persons, or to substantial property. One such defined action is the production of or putting into circulation substances, food products or other commonly used products, as well as medicinal products that do not fulfil the binding quality standards (article 165, section 1, point 2). The meaning of commonly used products is broad and comprises, for example, cosmetics, toys and even press.

The sanctions under article 165 of the Criminal Code depend upon the type of the act (whether it was intentional or unintentional) and its effects. As a rule, for intentional acts the perpetrator is liable to imprisonment for a term of between six months and eight years or, where the intentional act causes death, or severe damage to the health of many people, for a term of between two years and 12 years' imprisonment. If the criminal act was unintentional, then the perpetrator will usually be liable to a maximum term of three years imprisonment or, where the unintentional act causes death, or severe damage to health of many people, for a term of between six months' and eight years' imprisonment.

Under the General Product Safety Act, administrative fines of up to PLN 100,000 (approx. €22,000) may be imposed by the President of the Office for Competition and Consumer Protection on producers or/and distributors for non-fulfilment of certain obligations arising out of that Act. In particular, producers may be fined for placing products on the market that do not meet safety requirements. The same fine can be imposed on distributors for supplying products which they know or ought to know, on the basis of information in their possession and their professional experience, do not meet safety requirements.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

Under the strict liability regime, the claimant must prove the damage, the defect in (or dangerous feature of) the product, and the causal link between the damage and the defect. Some commentators have expressed the opinion that the claimant does not need to prove the defect as the occurrence of damage itself indicates that the product was defective. There is a statutory assumption that the producer both produced the product and put it into circulation in the course of his business, which is one of the prerequisites of liability.

Under the law of tort, the claimant must prove an unlawful act by the defendant, fault on the part of the defendant, the damage and the causal link between the damage and the defendant's act. However, in product liability cases the requirements on claimants to prove all the elements of the tort have been eased (see question 1.1). It is assumed that there was negligence on the part of the producer if he put a dangerous product on the market. It will usually be sufficient for the claimant to prove that the product was defective.

Under the general law of contract, the claimant must prove the non-fulfilment or improper fulfilment of contractual obligations, the damage and the causal link between the two. For warranty claims under the law of consumer sales, the claimant must prove that the goods were not in conformity with the contract.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

Under Polish law, the causal link must be adequate. It means that a person liable to redress the damage is liable only for normal effects of the action or omission which caused the damage. In product liability cases under the traditional law of tort, the Supreme Court accepted that it is sufficient for the claimant to show a high degree of probability that the causal link exists.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

If several persons caused the damage, their liability is joint and several. This means that the claimant may claim full compensation from any one (or some, or all) of them and full compensation by one of them sets the others free from those claims. The degree to which each of them contributed to the emergence of the damage is relevant only for the purpose of mutual settlements amongst them. The person who paid the damages may demand from the remaining persons a refund of an appropriate part according to the circumstances of the case, usually according to the fault of a given person and the degree to which he contributed to the damage.

There is no concept of market share liability under Polish law.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Product information and warnings are relevant considerations when evaluating whether the product was dangerous at the time it was introduced to the market. Such information determines the expectations of the consumer as to the safety of the product. If a risk caused by the product could have been reduced by appropriate warnings, the lack of warnings makes the product dangerous. This triggers the strict product liability when the product has caused damage. It is worth noting that before the strict liability regime was introduced, Polish courts accepted that a failure to sufficiently warn of risks, which subsequently caused damage, constitutes a tort.

The content of necessary product information and warnings depends on the ultimate product user. Different information standards apply to products addressed to professionals and to consumers. Polish law does not recognise the principle of "learned intermediary". However, some legal commentators express the opinion that if a product can be obtained only through a professional intermediary, the requirements to warn the ultimate consumer should be less stringent.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under the strict liability regime, the defences are as follows:

- the producer did not put the product into circulation;
- the product was put into circulation other than in the course of business of the producer;
- the dangerous properties of the product occurred after it had been put into circulation, unless they resulted from a cause inherent to the product;
- the dangerous properties of the product could not be foreseen on the basis of the state of scientific and technical knowledge at the time the product was put into circulation;
- the dangerous properties of the product are due to compliance with the provisions of law; or
- in case of the manufacturer of a component, the damage was caused solely by the defective construction or instructions given by the producer.

Under the law of tort, due to the specific shift in the burden of proof developed by the jurisprudence in product liability cases, the defendant may prove that there was no fault on his part.

Under the law of contract, the defendant may prove that the non-fulfilment or improper fulfilment of the contract was due to reasons that were not attributable to him.

In any case, the defendant may prove that the injured person has contributed to a certain extent to the emergence or increase of the damage. Under the general rule of Polish civil law, this will have an influence on the amount of compensation, which shall be correspondingly reduced in such a case. If the only cause of the damage was an act of the injured party or a third party or a *force majeure*, the defendant may argue that there is no causal link between the defect in the product and the damage.

The lapse of the limitation period is also a defence which can be used under each liability regime (see question 5.1).

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

A state of the art defence is available under the strict product liability regime. It is for the producer to prove that the dangerous properties of the product could not have been discovered, taking into account the state of scientific and technical knowledge at the time the product was put into circulation. It is an objective test; the actual knowledge of the producer should be of no importance.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

The fact that the manufacturer complied with regulatory and/or statutory requirements does not as such amount to a defence. It is only when the dangerous feature of the product is due to the application of provisions of law that the manufacturer can avoid liability.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Under Polish law, any judgment has the effect of *res iudicata* as between the parties to the proceedings with regard to the subject matter of the court's decision and the underlying facts. A claimant is prevented from claiming the same damage again unless some new facts have come to light which did not constitute a basis for the original judgment (in particular, facts which occurred after the date of the judgment).

As the judgment is *res iudicata* only between the parties to the original proceedings, a different claimant can litigate issues of fault, defect or causation in separate proceedings against the same defendant based on the same facts and issues which were decided by the court in an earlier case. Issue estoppel does not apply in respect of third parties. However, in practice, judges often consider what has been decided in earlier, similar cases if they have been heard by higher courts. Although they are not binding for third parties, Supreme Court judgments are as a rule followed by lower courts.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

The defendant cannot escape liability by claiming that the defect was due to the actions of a third party (for example, defective design by its sub-contractors or delivery of inappropriate materials). The defendant cannot seek a contribution or indemnity towards any damages from such a third party in the same proceedings, but it can do so in separate proceedings.

If the actions of a third party caused the defect, then the defendant in the original proceedings may, if it was required to pay damages to the injured party, demand appropriate compensation from the third party. The time limit for commencing such proceedings depends on the kind of action of the third party that caused the defect and the kind of legal relationship that exists between the third party and the defendant in the original proceedings.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Yes. Although such a contention is not directly regulated under the specific provisions on product liability (unlike article 8 section 2 of Directive 85/374/EEC), it may be based on general provisions of the Civil Code.

Pursuant to article 362 of the Civil Code, if the injured person contributed to the occurrence or increase of the damage, the defendant's duty to redress it shall be correspondingly reduced according to the circumstances, and in particular the degree of the fault of both parties.

If the claimant's actions were the exclusive cause of the damage, then there is no causal link between the damage and the defect of the product. Consequently, the producer or distributor (as the case may be) shall not be liable for the damage. If, however, the claimant's actions only contributed towards the damage, then liability will be determined on a case by case basis on the ground of the causal link between the damage and the defect in the product, and the claimant's actions.

The burden of proving that the claimant's actions caused or contributed to the damage rests on the party making the assertion.

4 Procedure

4.1 In the case of court proceedings Is the trial by a judge or a jury?

The first instance trial is by one or, in exceptional cases, three professional judges.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

No. The judge assesses all of the evidence himself. The court cannot call anyone to sit with the judge (or judges) and decide the case. When consideration of an issue requires special expertise, the court can appoint experts who will present a written and/or oral opinion (see also question 4.8). This expert opinion is a piece of evidence which is assessed by the court like any other evidence.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

Polish civil procedure does not provide a class actions procedure as in the US. A multiple claim procedure is available whereby several claimants may bring their claims in a single action when the claims are of the same kind and are based on the same factual and legal issues. The court has to be jurisdictionally competent to try each individual claim and all the claims together. However, even in this sort of multi-party litigation the court still determines each claim individually.

Since 2007 the Civil Law Codification Commission at the Ministry of Justice has been working on the introduction of a class action procedure into Polish law (the Law on pursuing claims in group proceedings). The draft law has been recently approved by the Council of Ministers and submitted to parliamentary works. According to the draft law, the class action procedure will be restricted to claims of the same kind based on the same factual or legal grounds filed by a group of at least ten parties acting on the plaintiff's side if the relevant factual grounds are common for all the parties. The claim is brought by a representative of the group being either its member or a regional consumer ombudsman. The group must be represented by a professional counsel in the court proceedings. The draft law provides for an "opt-in" procedure which foresees that the claim embraces only claims of the parties who have expressly consented thereto.

In face of an expanding amount of damage claims, regarding especially product liability claims, the amendment seems likely to encounter a considerable appreciation, both from the consumers and the courts.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Regional consumer ombudsmen and non-governmental organisations listed in a regulation of the Minister of Justice can bring claims in favour of citizens in matters of consumer protection. The issue of whether their authorisation to act for a consumer also encompasses product liability claims has not yet been resolved. So far, the prevailing opinion in the literature and in the jurisprudence is that these entities can only pursue claims arising out of contracts between a consumer and a professional. Hence, claims based on tort law or the strict liability regime would not be covered by their competence if there is no contractual link between the injured party and the defendant.

4.5 How long does it normally take to get to trial?

The length of time between filing a statement of claim and the first hearing depends on the workload of the relevant court and the complexity of the case. Usually it can take three to six months, and sometimes even longer, from the commencement of the proceedings until the date of the first hearing.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

The court may issue a preliminary judgment in which it decides

whether a claim is grounded in principle (based on issues of law and fact). The decision with respect to the actual amount of the claim will be taken at a later stage. The court is obliged to wait until the preliminary judgment becomes final before it can issue a judgment on the amount of the claim.

4.7 What appeal options are available?

All first instance judgments can be appealed and no permission of any court is required at this stage. The court of second instance decides issues of law and fact. It has a right to rehear the case and to make its own findings on the basis of evidence collected at both instances. However, in practice the review is usually limited to the question of whether the decision of the court of first instance was correct. The court of second instance may affirm, repeal or vary the first instance judgment.

The possibility of filing a cassation at the Supreme Court from a judgment of the court of second instance is limited. The Supreme Court reviews only issues of law. It accepts to hear a case if the matter contains an important issue of law or raises serious doubts, or if inconsistencies in jurisprudence, or if the underlying proceedings were invalid for procedural reasons, or if it finds the cassation to be manifestly founded. There is also a minimum value limit for disputes which can be subject to cassation (PLN 50,000 (approx. €11,000), or PLN 75,000 (approx. €17,000) in cases between businesses). If the matter is not capable of being challenged by a cassation, there is a possibility to apply for declaring a final judgment inconsistent with the law. Such a declaration enables the plaintiff to claim compensation from the State if a damage was caused to him/her by that defective judgment.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

If a matter requires special (e.g. technical or scientific) knowledge, the court appoints experts to present a written or oral opinion. Even if a judge has special knowledge on a given subject himself, he is obliged to appoint an expert. This is because a judge cannot replace an expert in civil proceedings, and because parties have a right to ask questions and challenge the results of an expert opinion.

Private expert opinions may also be presented by the parties. However, they have the same value as private documents, i.e. they are only evidence that a given person made a statement contained in the document, and as such they do not present a source of special knowledge for a judge.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/ expert reports exchanged prior to trial?

There are no requirements regarding the pre-trial stage under Polish law (except for cases between businesses) and it is not common for parties to exchange witness statements or private expert opinions before trial.

4.10 What obligations to disclose documentary evidence arise either before proceedings are commenced or as part of the pre-trial procedures?

Upon an order of the court (which may be issued during the proceedings), any party may be obliged to present a document which is in his possession and which constitutes evidence in respect of any issue relevant to deciding the case. The court usually orders such discovery at the request of an opposing party. Before the commencement of proceedings, submission of certain documents can be ordered by way of securing the evidence where there is a risk that it will be impossible or very difficult to obtain such evidence in the future. The Supreme Court has stated that the purpose of securing the evidence is not to allow a potential claimant to evaluate the prospects of his claim. The claimant does not have any claim for disclosure as such, and there is no general pre-trial discovery procedure.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Yes, alternative methods of dispute resolution are available in Poland. The Polish Code of Civil Procedure provides for mediation and arbitration.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, time limits do exist.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

The limitation period for claims under the fault-based law of tort is three years from the day when the injured party learned about the damage and the identity of the person liable for it. The general rule (subject to exceptions presented below) is that a claim in tort becomes time-barred after ten years from the event that caused the damage.

Where damage is caused by a criminal act, the limitation period is twenty years from the date when the crime was committed, regardless of when the injured party learned of the damage and the identity of the person liable for it. In personal injury cases, the limitation period cannot lapse earlier than three years from the day when the injured party learned about the damage and the identity of the person liable for it. The limitation period for minors bringing personal injury claims does not end earlier than two years from these persons becoming major.

Under the strict product liability provisions, the limitation period is three years from the day when the injured party learned or, acting with due diligence could have learned, about the damage and the identity of the person liable for it. In any case, claims become time-barred after ten years from the date when the product was first put into circulation.

Warranty claims under consumer sales contracts can be made when the lack of conformity becomes apparent within two years from the delivery of the good. A consumer's claim is time-barred after the later of the two-year period since delivery of the goods and the one-year period since he or she discovered the non-conformity in the goods. Furthermore, the claim will expire if the consumer has not notified the seller of the non-conformity within two months of having discovered it.

In warranty claims under non-consumer sale contracts, the claim will expire if the buyer has not notified the seller of the defect

within one month of the date when he or she has discovered the defect or, acting with due diligence could have discovered it. As for sale contracts between businesses, a warranty claim will expire if the goods have not been examined within the customary period of time after delivery and the buyer has not notified the seller of the defect without undue delay.

If claims are made under the general law of contract, the limitation period is ten years (but three years for businesses) from the moment when the claim has become due.

Special rules regarding the lapse of a limitation period apply to minors. In relation to such persons the limitation period cannot end earlier than two years after the person attained full age. The same applies to persons with mental disability who are eligible for full incapacitation.

The lapse of a limitation period is a defence which may be invoked by the defendant. The court considers the lapse of the limitation period only if it is expressly invoked by the defendant, and will not consider it *ex officio*. The court generally has no discretion in this respect. However, in exceptional cases, the court may rule a limitation defence inadmissible based on the general clause of article 5 of the Civil Code, according to which one cannot make use of one's right if it would be contrary to the socioeconomic aim of that right or to good custom.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

In cases of concealment or fraud, the limitation defence would be ruled inadmissible on the basis of article 5 of the Civil Code (see question 5.2).

Claims under consumer sales contracts can be made despite the lapse of the time limits described above if the seller knew about the non-conformity of the product and did not draw the consumer's attention to this fact.

The lapse of the time limits described above will also be of no relevance for warranty claims under a non-consumer sale contract if the seller maliciously concealed the defect or represented and guaranteed that the defect does not exist.

6 Damages

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

Under Polish law in case of a tort/product liability case one may seek: (a) an injunction (if due to the lack of the injunction the enforcement of the judgment shall be prevented or seriously impeded or the aim of the proceedings may not be reached); (b) compensation and other monetary remedies (see question 6.2 below); and (c) declaration that the defendant will be liable for the damage which will occur in future as a result of the event at issue (e.g. loss of health in future).

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Under Polish law, compensation always includes monetary damage, while non-monetary damage can be recovered only in instances where express provision has been made for it. Monetary damage includes both actual damage (*damnum emergens*) and lost profits (*lucrum cessans*).

Under the law of tort, compensation is recoverable for damage to property and personal injury. Compensation for personal injury includes both monetary damage (all expenses related to the injury, e.g. costs of medical treatment and maintenance, as well as lost income, annuity or a single indemnity, and the cost of training for a new occupation) and non-monetary damages specified in the Civil Code. Compensation for non-monetary damage in form of pain and suffering is not obligatory. It is in the discretion of the court whether to grant it or not. Refusal to grant compensation must, however, be objectively justified. There are also certain types of damages which can be recovered in case of death of an injured party. Persons to whom the deceased either owed a statutory duty of maintenance or voluntarily and permanently provided maintenance can claim annuity. The court may also award appropriate compensation to the closest family members of the deceased if their standard of living has considerably deteriorated as a result of the death. Under the provisions of a recent amendment to the Civil Code a person whose closest family member died as a result of a tort will be entitled to seek compensation for the non-monetary damages, such as traumatic experience of losing a close family member, he/she suffered.

Under the strict product liability regime, the scope of damages recoverable for personal injury is the same as under the law of tort. There are some differences as far as recovery for damage to property is concerned. Strict liability covers only damage to items which are ordinarily intended for personal use and which the injured party has used mainly for such purpose. Compensation cannot be recovered for damage to the product itself or for profits which the injured person could have derived from the use of the product. Damage to property is recoverable only if the value of the claim exceeds the minimum threshold of €500. If it does, the full amount of damage can be recovered.

Under the law of contract, only monetary damage can be recovered. This includes damage to property and to the product itself.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

There have not been any cases regarding medical monitoring in Poland. Under the existing liability regimes, actual damage must occur in order for compensation to be recovered. In preventative litigation, the court can order that certain steps be taken in order to prevent the occurrence of threatened damage or that security be given by way of depositing a certain amount of money with the court. This, however, would not include the recovery of costs of medical monitoring before any damage had occurred.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

There are no punitive damages in Polish law.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no maximum limit on recoverable damages in Polish law.

It is worth noting that the amounts of compensation awarded by Polish courts are much lower than in the US or Western Europe due to a lower cost of living.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

A settlement may be concluded before or after filing the statement of claim. A settlement concluded before filling the statement of claim does not require any court approval. A settlement concluded after filing the statement of claim may be concluded either outside the court proceedings or as a court settlement (a settlement recorded in the protocol of the hearing which has the same legal force as a court judgment). A settlement concluded outside the court proceedings will usually result in the withdrawal of the case from the court by the plaintiff. Additionally, the settlement may be connected with the renouncement of the claim which is the most advantageous solution for the defendant. In case of a settlement concluded after filing the statement of claim the court decide that the withdrawal of the case or the renouncement of the claim is unacceptable if these actions are unlawful, contradict to the principles of community life or designed to circumvent statutory law.

If the parties decide to choose mediation they may conclude a settlement in the course of the mediation proceedings. If such a settlement has been reached the mediator records it in the mediation protocol or attaches the settlement to the mediation protocol. Then he/she forwards the mediation protocol together with the settlement to the court for the approval. The court may refuse to approve the settlement if it is unlawful, contradicts to the principles of community life or is designed to circumvent the statutory law. Additionally, the settlement may not be approved if it is incomprehensible or contradict within its terms.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

The Act of 27 August 2004 on healthcare services financed from public means provides that the entity obliged to finance healthcare services from public means (i.e. the National Health Fund) may claim the repayment of the incurred costs of healthcare services from the person who intentionally committed a criminal offence, ascertained by a final judgment, if this offence made those healthcare services necessary.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

As a rule, the losing party will be ordered to cover all necessary costs of the successful party. This includes court fees, other justified expenses and legal costs. The legal costs are limited to the fees of one attorney which are calculated on the basis of the value of the claim according to the scale provided for in the law. The statutorily recoverable legal costs usually do not cover the full amount of actual expenditure on legal services.

7.2 Is public funding e.g. legal aid, available?

Yes, public funding is available.

7.3 If so, are there any restrictions on the availability of public funding?

Legal aid is available to claimants who cannot afford to finance the costs of proceedings. A claimant has to file a statement of his family relations, property and income in order to obtain a waiver of court fees. Claimants who have been exempted from court fees (in whole or in part) can also be granted representation by an attorney paid by the State. Accepting such an appointment is a duty of every attorney. The quality of such legal representation, however, may not be sufficient to handle complex cases which usually require special expertise.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

According to their code of ethics, Polish attorneys should not work on a "no win, no fee" basis exclusively. The draft law on class action procedure (see question 4.3) provides for a possibility to agree on a percentage of the amount of damages awarded by the court to be the attorney's fee.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

A third party funding of claims is permitted under Polish law but, with some rare exceptions, such activities are not undertaken in practice.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Poland.

Over the last year, we have experienced some increase in the number of product liability cases in Poland. In particular, the pharmaceutical industry remains subject to high-profile cases. However, product liability litigation is still not as popular as it is in Western Europe.

The draft law on class action procedure undergoes further works and has not yet entered into force.

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Romania

Charles Vernon

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

Currently, there are three theories by which a product liability claim may be brought in Romania: (i) strict liability; (ii) tort liability; and (iii) contractual liability. There are three important laws regulating product liability matters in Romania. Law No. 240/2004 is in relation to the producer's liability for damages caused by defective products and implements European Directive 85/374/EEC regarding producers' liability ("Law 240"). Government Ordinance No. 21/1992 covers consumer protection issues ("GO 21") and Law No. 245/2004 ("Law 245") sets out the rules for product safety. In addition, the Romanian Civil Code (the "Civil Code") regulates the general law and rules applicable to tort and contractual liabilities.

Law 240 sets out the standards for strict liability in relation to products. Under Article 3 of this law, "the producer shall be liable for the actual and future damages incurred by the defects of such producer's products". According to the provisions of the law, a product is "defective" when the product:

> [...] does not offer the safety which a person is entitled to expect, taking all circumstances into account, including:

1. the presentation of the product;
2. the use to which it could reasonably be expected that the product would be put; and
3. the time when the product was put into circulation.

We should note that the stated standard set out above is very similar to that set out in Article 6 of European Directive 85/374/EEC.

Tort liability follows the general principles in the Civil Code, which states that an individual who negligently or willfully causes another person "damage", may be held liable to "repair" or remedy such damage. In order to recover, the claimant must prove the damage, the negligence and the causal nexus between the two.

The Civil Code also sets out the general principles in relation to contractual liabilities. These may only arise in cases when a contract has been formed between the respective parties and one of the parties does not fulfil or improperly fulfils (either through action or inaction) its obligations under the respective contract.

1.2 Does the state operate any schemes of compensation for particular products?

We are not aware of such schemes operating in Romania.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Under the provisions of Law 240, the "producer" bears responsibility for a defective product. However, please note that the law broadly defines the term "producer" as follows:

1. the entities who manufacture a final product, raw materials or parts of a product;
2. any person that presents itself as a producer and attaches to products its name, its brand name or other distinctive characteristics; and
3. any person importing a product in Romania with the intention to re-sell, lease, buy or commercially transfer the product ownership in any manner.

Moreover, in case the actual producer of a product cannot be identified, each supplier of the product will be construed to be the producer, provided that the respective supplier does not inform the injured person, within a reasonable period of time, of the identification of the actual producer or the person who supplied him the product.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Law 245 regarding the general safety of products (implementing European Directive No. 2001/95 CE) sets out guidelines for producers to ensure a product is safe before entering the marketing as well as after the product is on the market.

Producers are required to continuously monitor or otherwise keep themselves informed about their products for possible "risks" presented by such products. Producers must be "prepared" to take all "adequate" measures to avoid such risks, including issuing warnings and recalling a product from the market. The obligation to recall a product arises whenever a producer's monitoring or an investigation conducted by the relevant Romanian authority (for instance, the National Authority for Consumer Protection) concludes that the risks of the product cannot be otherwise avoided unless the product is recalled.

Failure to recall the product, when required, may result in a fine ranging from RON 700 (approximately Euro 170) to RON 7,000

(approximately Euro 1,700). However, Law 245 expressly provides that parties that breach its provisions may be subject to additional civil, administrative and criminal penalties (as provided by the general provisions of Romanian law).

1.5 Do criminal sanctions apply to the supply of defective products?

There are no specific criminal sanctions in relation to defective products. However, certain general provisions of the criminal law may be applicable, depending on the degree of harm and facts of a particular case. For instance, a producer could be charged with involuntary destruction of goods (for cases when a defective product causes the destruction of a good or renders a good unusable). In addition, depending on the facts, charges of involuntary bodily injury or involuntary manslaughter may also be levied. The penalties for such criminal offences may vary from penal fines to imprisonment (which is replaced by a penal fine in case of companies), in accordance with the gravity of the harm and the particular crime.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

As a general rule, the claimant has the burden of proof in relation to both fault/defect and damage.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

Romanian doctrine and jurisprudence have provided for numerous theories in relation to causation. However, in practice, the courts apply (by majority view) a test consisting of two interlinked factors, which establish the causal link with an action and the subsequent liability. The first factor is the actual cause of the event producing the damage, known as the "necessary cause" which consists of the action (or inaction), in the absence of which the relevant damage would have not occurred. The other factor consists of all other conditions favouring the occurrence of the relevant harm but which are not the immediate cause of the damage. Both factors are weighed by the court and used to determine if a causal link exists between the event and/or conditions and the harm.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

Please note that the concept of "market-share liability" is not regulated in Romania. However, under general civil liability principles applicable in Romania, when more than one person causes damage to a consumer, all such persons shall be held jointly and severally liable. This principle is also articulated under the provisions regulating strict liability; specifically article 5 of Law 240 states: "in case several persons are responsible for the damage, such persons shall be held jointly and severally liable".

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

As already stated, Law 245 requires a producer to only introduce safe products into the market. One factor to consider when determining if a product is safe is articulated by both GO 21 and Law 245 which states that a producer must provide consumers with adequate and proper information in relation to the respective product and the producer itself. If consumers are given inadequate or improper information, the producer may be subject to product liability.

According to article 20 of GO 21 "the producer has to inform the consumers of the name of the product, the name and/or the trademark of the producer, the address of the producers and importers from states that are not EU Member States, as well as for the producers, packagers or distributors from EU Member States". The same government ordinance states that the following information should also be displayed on the product label:

- the quantity; and when applicable, the following information;
- the warranty term, availability term or minimal durability date;
- the product's main technical and qualitative characteristics;
- the product's composition and used additives;
- potential risks which may be foreseen;
- product utilisation, handling, transportation, storing and preservation manner; and
- contra indications.

In addition, the nutritional value of a product may also be required to be on the label of food products if certain criteria are met.

The concept of a "learned intermediary" is also available under Romanian legislation. The producer bears the responsibility to give product information and warnings to the final consumer. However, in the classic case where a doctor (the "learned intermediary") prescribes a drug (defective or not), such doctor may be liable towards the patient for not knowing the actual effects of the respective medication. That is to say, there is a related or "chained" causation that may have lead to the actual damage.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under the provisions regulating strict liability, there are some circumstances when producers acting as defendants in court disputes may not be liable. Under article 7 of Law 240, a producer may avoid or limit liability if such producer can prove that:

- it did not release the defective product into the market;
- the defect which caused the damage did not exist at the moment the product was released into the market or the

defect occurred afterwards due to causes for which the respective producer does not bear responsibility or bears no responsibility;

- the defective product has not been manufactured for the purpose of sale or commercialisation or any other form of distribution and the defective product was not manufactured or distributed under the producer's usual business activity;
- the defect resulted from the producer's compliance with mandatory conditions imposed by regulations of the relevant authorities;
- the degree of scientific and technical knowledge at the moment the product was released into the market did not permit the detection of the relevant defect;
- the defect resulted from non observance by the consumer of the instructions provided by the producer as part of the technical information documentation delivered together with the product, proved by an expert's assessment; and
- a component's producer may be exonerated by liability in a case where the producer proves that the defect resulted from faulty design of the product and the components were integrated into that design or the wrong instructions where provided by the producer of the product that the component was incorporated.

Moreover, article 8 of Law 240 provides that a competent court of law may limit or exonerate liability in cases where the damage was caused by both a defective product and by the fault of the injured person (or the person suffering the damage).

Regarding liability from contractual obligations, please note that during the performance of a contract, the producer may be released from liability for non-performance (but not "improper" performance) of its obligations under the contract in case of a *force majeure* event.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

As stated under question 3.1 above, a producer may be exonerated of liability when the degree of scientific and technical knowledge at the moment the product was released on the market did not permit the producer to detect the relevant defect. As a general principle of law, the burden of proof falls on the invoking party.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

The fact that a producer proves that it complied with all regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of a product it is not regarded as a defence. According to Law 245, producers must release only safe products onto the market.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

In Romania, the legal system applies the principle of *res judicata*. Consequently, a matter that has already been decided upon by a court of law cannot be re-litigated between the same parties and containing the same object and cause.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

The producer may not claim in a case brought by a consumer that the fault/defect of the product was due to actions of a third party. Thus, the producer is fully liable for the defective products and may not invoke that the defect resulted from, for example, the fault of a sub-contractor or a supplier of raw materials. However, according to the provisions of the Romanian Civil Procedure Code, the producer may make a request to the judge(s) to summon the relevant third party into the same proceedings, thus becoming active part of the court trial. As a matter of practice, this is often made by a defendant seeking contribution or indemnity towards damages payable to the claimant. In addition, the producer may choose to file a recourse action against the relevant third party in separate proceedings. Generally, the time limit on commencing such proceedings is three years from the date of the judge's decision for the producer to pay damages to the original claimant when the judgment is final and irrevocable.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

As already stated under question 3.1 above, a defendant may be exonerated of liability in cases where a defendant proves that the defect resulted from the claimant's failure to observe the instructions provided by the producer as part of the technical information delivered together with the product. However, in case it is proven that the damage occurred as a result of both an existing defect of the product and a misuse by the claimant, the judge(s) may decide to reduce the extent of payable damages to the claimant.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

As a general comment, Romania does not apply the "jury" system. A judge or a panel of judges preside over all trials in Romania and only the judge(s) may decide on a matter brought in front of a Romanian court of law.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Judges may appoint experts, whether upon the expressed request of the parties or at the court's own initiative, if it considers it necessary to better assess the case. However their advice is only consultative and does not have any binding power on the court's final decision.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

Under Romanian law and practice the concept of a class action lawsuit does not exist. However, according to the provisions of the Romanian Civil Procedure Code, several claimants may file a common claim against a defendant provided that the object of the claim arises from the same right or obligation. In this case, the decision of the court is binding on all the parties. No individual that was part to such trial may initiate again a different action in court against the producer if the claim would have the same object, parties and cause (please also see question 3.4 above). On the other hand, if only part of the aggrieved parties initiate an action in court, the decision ruled in such case would not be binding on the non participating aggrieved parties. Consequently, such individuals could decide to initiate a separate action.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Under the provisions of article 30 of GO 21, consumers may organise under non-governmental associations whose sole purpose is to protect its members and consumers. Usually in Romania, the only who can file a court claim is the injured party; however, under the aforementioned ordinance consumer associations may file collective suits in order to protect consumers.

4.5 How long does it normally take to get to trial?

In Romania, trials regarding product liability are civil proceedings. Consequently, there is not a pre-trial stage and litigation starts immediately after filing a claim. However, for trials arising out of a contractual relation between two or more commercial professionals (e.g. producers, suppliers, merchandisers etc.), the Civil Procedure Code requires direct conciliation before appearing in a court of law.

The length of a trial may vary between a few months and a few years, depending on the difficulty of the matter.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Although a pre-trial stage does not exist, once a claim has been filed and proceedings have begun, a preliminary stage is part of the actual trial. At the preliminary stage, the issues raised usually relate to matters of law (such as exceptions regarding competence of the respective court, time limits, capacity and authority of the parties involved). Please also see our answer under question 4.1 above.

4.7 What appeal options are available?

In general, under Romanian procedural law a trial may have two successive common appeals, each of the appeals being judged by the relevant higher court (depending on the value, certain commercial cases can only have the second appeal). The first appeal usually deals with the facts of the trial as well as with the first court's interpretation of the law. The second appeal is more restrictive in terms of requirements for filing and usually only refers to the actual decision of the inferior court on a specific point. In any of the appeals the courts may rule upon the cassation of the inferior court(s) decision(s) and send it back for retrial. The highest court for appeals is the High Court of Cassation and Justice of Romania depending on where the main claim is first ruled upon.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

As mentioned under question 4.2, if it considers necessary, the court could summon a scientific/technical expert. The expert provides the court with a written report that will help the judge make a ruling at the respective trial. However, as said before, the judge is not bound by such expert's report. Moreover, the parties involved may challenge the results of the expert's report by requesting the opinion of different experts appointed at the request of the relevant party.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

As already mentioned, under Romanian law there is not a pre-trial stage; therefore, neither factual nor expert witnesses are required to take depositions. Please also see answer to question 4.10.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

In accordance with the provisions of article 172 in the Civil Procedure Code, whenever one of the parties to a trial reveals that the opposing party is holding a document relevant to the matter at hand, the court is compelled to request the respective party to disclose the relevant document. However, certain professionals are limited to disclosing information regarded as confidential under specific statutes or regulations.

The Civil Procedure Code provides an exception which states that any interested party in the litigation may ask the court to order the submission of a document or a deposition, in order to secure evidence prior to the trial, provided that the document or deposition would be difficult or impossible to obtain during the actual trial.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Yes. Parties may opt to resolve a product liability claim as an alternative to a court trial by using mediation and/or arbitration in accordance with the parties' legal status. Disputes between companies may be settled by any of the two alternative dispute resolution methods. Disputes between individuals, or individuals and businesses, may be settled through mediation even if a trial was already initiated.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, Romanian legislation provides time limits on brining or issuing proceedings.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

The time limits for bringing or issuing proceedings depends on whether the liability is tort, strict or contractual based. For tort liability, Romanian law provides a three-year time limit from the date the damage occurred for a claim to be filed.

Under strict liability, article 11 of Law 240 provides that a product liability claim is subject to a three-year statute of limitations from the date the claimant knew or should have known about the existence of the damage, the defect and the identity of the producer. However, a claim may not be filed within more than ten years after the respective product was introduced on the market.

For liability arising from contractual obligations, Law No. 449/2003 regarding product warranty, states a claim must be filed within two years of the delivery date of the noncompliant product. Moreover, the consumer must notify the producer with respect to the noncompliant product within two months from the discovery of the defect.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Under the provisions of Law 240 there is not a difference between defects hidden by negligence and defects hidden intentionally. Under the general provisions of the Civil Code regarding contractual liability, in cases regarding the sale of assets, the buyer may file a claim against the relevant seller within six months from the discovery of a defect of the acquired asset. However, if the relevant defect proves to be intentionally concealed, the statute of limitations is extended from six months to three years from the discovery of the concealed defect which cannot occur later than one year from the acquisition of the relevant asset. If the concealment is proved to have been done by fraud then the provisions of the Criminal Code could become applicable, in which case the term of such limitations might change.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

The Civil Code generally provides for monetary compensation.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

The general principles of tort liability grant the claimant the right to recover monetary and non-monetary damages (including bodily injury, mental damage and damage to property).

Strict liability regimes follow the same principles as tort liability; however, there are small differences. Law 240 provides that the term "damage" may represent a bodily injury, illness or death of a person. In addition, damage may mean the destruction of a good, other than the defective product, provided that the respective good is normally and privately used by the respective consumer and has a value of more than RON 200.00 (approximately EUR 48.00). Please note that the aforementioned law does not provide for compensation for the loss of the defective product or for loss of profits. However, Law 240 states that pecuniary damage does not exclude compensation for non-monetary damage.

In addition, if the destroyed good or the injured or deceased person was insured, insurance companies have the right to an action in recourse against the faulty producer.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

As stated under question 2.2 above, in order to recover damages, a claimant must prove "damage" (the existence of the damage). Consequently, a claimant cannot recover for medical monitoring prior to the occurrence of the damage.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Romanian legislation does not provide for punitive damages.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

Romanian law does not have a maximum limit on the amount of recoverable damages; therefore, the relevant producer will be fully liable for the entire amount of damages.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

Under Romanian law, parties may settle a claim before the claim is filed with the competent court, after the trial has started or as an alternative to court litigation (please also see question 4.11 above). When a claim is settled prior to any court hearings, the court does not need to approve the settlement.

If a claim is settled after the court hearing has started, the parties may opt to settle the claim, either outside the court proceedings followed by a withdrawal of the claim, or inside court proceedings, where the court will acknowledge the settlement within the judge's decision.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Although it is not a common practice, under the general principles governing tort liability, concerned authorities may step into court proceedings relating to tort liability as civil parties. Moreover, according to article 313 in Law No. 95/2006 regarding healthcare reform, "any person who by its own deeds brings damage to another person's health shall be fully liable and bound to repay damages towards the medical services supplier representing the expenses supported by such medical services supplier with the victim of such deeds". (Please note that in Romania medical services are free

because of the state health care system which is funded by a portion of fiscal residents' income.)

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

As a matter of law and practice, the successful party is entitled to recover from the losing party all expenses related to the respective trial, including fees paid for legal assistance, experts, expenses related to witnesses and all other incidental provable expenses.

7.2 Is public funding e.g. legal aid, available?

Yes, legal aid is available and permitted under the provisions of Government Emergency Ordinance no. 51/2008, concerning the public legal aid in civil disputes, in all stages of the trial. However the person requesting legal aid must meet certain minimum income requirements in order to benefit from such aid.

7.3 If so, are there any restrictions on the availability of public funding?

Government Emergency Ordinance no. 51/2008 provides under article 6 that any person who meets the requirements referred to under question 7.2 above, may benefit from free legal services and/or discounted or rescheduled payments of the legal taxes and duties. All expenses shall be borne by the state budget. However, the aid may not be sufficient in cases where additional expenses are incurred, such as experts. As a separate matter, the "loser pays" principle is applicable.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Under the provisions of the Lawyers Statute, Romanian lawyers are not allowed to establish their fees entirely based on the outcome of a trial or as a percentage of the trial's value. However, besides the flat fee agreed upon, prior to any legal assistance, a lawyer may receive a success fee.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Third party funding of claims is not regulated under the Romanian law.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Romania.

Following Romania's accession to the European Union on 1 January 2007, the country's economic growth has continued to be significant. Although the internal legislation related to product liability was harmonised with European directives in 2004, it was only recently that the legislative framework as begun to be fully developed. The regulation of strict liability deriving from defects or non-compliance of products has brought a new wave of practice and legal disputes among Romanian scholars and courts of law.

The most visible effect of such regulations was the increase in care producers use to manufacture better products and deliver better services for the general benefit of consumers. However, few notable cases related to this issue have appeared in front of the Romanian courts of law and therefore a clear practice has not yet developed. Nor is there a "litigation culture" in Romania. However, product liability issues are no longer a simple or isolated matter. It is becoming a minefield of complex law, litigation procedure and sophisticated tactics and we anticipate that the number and difficulty of such cases will only increase in the foreseeable future.

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Vernon | David is a Bucharest-based law firm providing full-service legal advice to a wide array of domestic and international clients, ranging from start-ups to large multinational companies and foreign governments. We pride ourselves on providing practical commercial solutions, enabling our clients to meet their goals and objectives. We accomplish this through our deep knowledge of the local business and legal environment, our people's dedication and enthusiasm and the way in which we equate our success to our clients' success.

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

The law relating to product liability in the Russian Federation is primarily regulated by certain provisions of the Civil Code (the "Civil Code") and federal Law No. 2300-1 "On Consumer Rights Protection" of February 7, 1992 (the "Consumer Protection Law").

According to the Consumer Protection Law the following categories of product liability exist:

(a) liability of a manufacturer or seller for inadequate information on goods and services;

(b) liability of a manufacturer, seller or importer for violation of a consumer's rights;

(c) liability for damage resulting from the supply of defective goods or services; and

(d) compensation for 'moral harm' (suffering) caused by the defective product.

Both strict liability and fault-based liability exist. According to Article 1095 of the Civil Code and Article 14 of the Consumer Protection Law, strict liability arises regardless of fault if goods or services obtained by a consumer or on its behalf have caused damage to health, life or property as a result of a defective design or manufacture, etc. or unreliable or inadequate information. In this case a claim may be brought, at the option of the consumer, against the manufacturer, seller or importer irrespective of whether or not the consumer had a contract with such party.

In order for fault-based liability to apply, according to Article 1064 of the Civil Code, the following four elements should be present, the burden of proof for the first three being on the claimant: (a) breach of a duty by the defendant; (b) damage, including physical/emotional harm, suffered by the plaintiff; (c) causation, i.e. that the damage was caused directly by the illegal act or omission; and (d) the fault of the defendant.

1.2 Does the state operate any schemes of compensation for particular products?

No, the state does not operate any compensation schemes.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

The claimant has the right to bring an action against any of these parties.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

If it is found that even though the consumer has followed the rules for the usage, storage or transportation of the goods, such goods or services caused death, injury or property damage to the consumer, the manufacturer should suspend the production or sale of such goods or provision of such services and where applicable recall items already sold.

Failure to do so allows the Federal Service for Protection of Consumer Rights and Human Welfare to issue an obligatory injunction recalling such goods or services from the market. If such injunction is not complied with, the Federal Service for Protection of Consumer Rights and Human Welfare may apply to court for its enforcement.

1.5 Do criminal sanctions apply to the supply of defective products?

Criminal sanctions do apply to the supply of defective products. Legal entities are not subject to criminal liability, but the individual directors may be prosecuted.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

There is a general rule that a party in a dispute should prove the circumstances for its claim or defence, unless the law provides otherwise. With respect to fault based liability under Article 1064 of the Civil Code, however, if a claimant proves breach, damage and causation, the fault of the wrongdoer is presumed, meaning that the burden of proof falls on the defendant, who should prove lack of fault.

As for the strict liability, it is not necessary to prove that the existence of fault and liability is attached to breach of a duty, damage and causation. In this case under Article 1095 of the Civil Code, a manufacturer or seller should prove that the damage or

injury was caused by a *force majeure* circumstance or by the consumer's failure to comply with the rules for the use or storage of the product.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

It is not obligatory to arrange for an expert examination to obtain proof of causation. A claimant may describe the connection between an injury and the specific product that caused it in the claim. Naturally, however, an expert opinion will give additional weight to a claim.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

The conception of "market-share liability" does not work in Russia. Theoretically, the claimant has the right to file a claim to several possible producers. However, it is most probable that a court would dismiss such an action as the defendant is not specified.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Under the Consumer Protection Law, failure to provide adequate warning about certain characteristics of goods or services will enable a consumer to claim compensation for injury or loss caused by such characteristics. All relevant information regarding a product should be provided to the consumer. In case of injury or loss a consumer has the right to claim compensation from a seller, manufacturer, or importer.

The principle of "learned intermediary" is not used in Russia.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Article 1097 of the Civil Code provides a limitation period, which is either the recommended lifetime or the shelf life of the product. If these times are not established, then the limitation period is ten years from the date of production of the product. It should be noted that the ten-year term may be used when the manufacturer or the seller is not required to specify the lifetime or shelf life of the product. If such time is not indicated, and is required by law, the consumer may make a claim for compensation for loss at any time.

Article 1083 of the Civil Code allows a court to reduce the amount of an award of damages depending on the degree of contributory negligence of the claimant, but the damages may not be reduced to zero if the consumer has been killed or suffered injury or damage to health by using the product in question. The same Article, however, prevents an injured party from claiming compensation for an injury incurred 'by his own deliberate actions'.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

There is no state of the art/development risk defence in Russia. In such a case a general rule applies: the claimant must prove that the injury actually resulted from the product in question, regardless of the state of scientific and/or technical knowledge at the time of supply, and the defendant must prove that the injury was the result of a breach of the manufacturer's instructions, for example.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

A manufacturer should ensure that its products comply with safety requirements relating to the protection of consumer's health and property and the environment. However, if a claimant proves that the product in question caused harm to him/her, and that he or she followed the manufacturer's instructions, the court may hold that the manufacturer produced a defective product even though safety requirements were complied with.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

The claimant can only re-litigate issues of fault, defect or the capability of a product in another action brought by that claimant.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

The defendant can file a recall action to a third party requesting indemnification of losses in subsequent proceedings. According to a general rule, such an action may be filed within three years.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Yes, the defendant may claim that the claimant contributed to the damage, and may submit an expert opinion to the court as evidence of this.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

The trial is by a judge.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Yes, the court has the right to appoint a technical specialist to assist during the hearing.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

The conception of "class action" used in Russia differs from the one used in countries with a common law system. Similar cases may be combined by the judge into one proceeding.

Under the Consumer Protection Law, the Federal Service for Protection of Consumer Rights and Human Welfare or public associations may file a claim on behalf of an indefinite number of consumers for a declaration that the actions of a manufacturer, a seller, or an importer are illegal and for a suspension of such actions. This is not a claim for compensation for losses, but if the court declares such activity illegal then an individual who has suffered loss may make a separate claim for compensation.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

See question 4.3 above.

4.5 How long does it normally take to get to trial?

Upon the receipt of all documents by the judge of a court of general jurisdiction, a trial should be set within seven days. In practice, however, the trial will normally be later than this.

Business (*arbitrazh*) courts usually schedule a pre-trial hearing within two months of the submission of the claim.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

According to Russian law, a final decision is not made during a pre-trial hearing. The purpose of the pre-trial hearing is to consider matters of fact, but the judge may request a clarification of matters of law as well and make other preparations for the actual hearing. The pre-trial hearing is scheduled by a court when all relevant case documents have been exchanged by the parties in the *arbitrazh* courts and the claimant has submitted all documents to the court of general jurisdiction. At the pre-trial stage a judge reviews all documents provided, interviews the parties and requests additional documents that may be important for the actual hearing. After that, the court schedules an actual hearing.

4.7 What appeal options are available?

If the claimant or defendant are not satisfied by the court's decision, they may appeal it in a court of higher instance.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Only experts appointed by the court are considered to have expert status. Experts usually provide a written report on an issue, this contains detailed research and their conclusions. The court lists the questions to be addressed in the research, and each party to the dispute may amend such list of questions.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

The court often does not request an expert to be present at the pre-trial hearing, and relies on a written report. Witness statements and expert reports may be exchanged prior to, or filed during, the trial.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

The rules for the disclosure of documentary evidence are not as strict in Russia as they are in the USA. The parties to a dispute may file relevant evidence at any time during the hearing prior to the pronouncement of the court's decision.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Alternative methods of dispute resolution are not applicable.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, the time limits are provided in the Civil Code.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

The following circumstances do not depend on whether the liability is fault-based or strict:

1. In the case of damage resulting from defects in goods during their stated life term, full compensation is payable for such damage.
2. If the lifetime of the goods is required to be specified but is not specified, or the consumer was not provided with full and true information on the product's life term or any information on action to be taken upon expiration of such period and the possible consequences of failing to take such actions, or if upon expiration of such periods the goods may be dangerous to the life or health, then compensation is payable for loss or

injury irrespective of the time when the injury occurred.

3. If an injury results from defects in goods, the stated life term for which was not determined, then compensation is payable in the full amount if the injury was incurred within 10 years from the transfer of goods to the consumer. If the transfer date is unknown, than the relevant term is 10 years from the manufacture of the goods.

The age and condition of the claimant do not affect the calculation of time limits. The court does not have the right to suspend time limits.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Concealment or fraud does not affect the running of time limits. The running begins from the moment the injured party knew or should have known on violation of its consumer protection rights.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

Monetary compensation, compensation of moral harm and injunctive relief are available remedies in consumer protection cases.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Damage to consumer's life, health, property and moral damage are recoverable under the Consumer Protection Law.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

The Consumer Protection Law does not apply to possible future malfunctions and potential injury.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

The concept of punitive damages does not exist in Russian law, and damages are limited to the loss actually incurred and lost profit.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

We are not aware of any such limits.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

There are no special rules for the settlement of claims. The settlement agreement should be registered by the court.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

The Federal Service for the Protection of Consumer Rights and Human Welfare and the Russian Federal Fund for Social Insurance are the government authorities concerned with health and social security matters. These authorities do not have powers to claim reimbursement of benefits paid by the state to the claimant from compensation payments made by the defendant.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

According to Article 90 of the Civil Procedure Code and Article 110 of the Arbitrazh Procedural Code, the costs of the winning party are payable by the losing party. Expenses associated with the dispute, i.e. experts and interpreters which are incurred by the party requesting such services may be compensated by the losing party. However, if a claim is satisfied only partially, the expenses will be paid *pro rata* to the portion of the claim satisfied.

7.2 Is public funding e.g. legal aid, available?

Legal aid is not widely available in Russia.

7.3 If so, are there any restrictions on the availability of public funding?

Only certain categories of Russian citizens whose average per capita income is lower than the minimum for subsistence may be provided with free legal assistance.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Russian law does not precisely prohibit contingency fees, but contingency fee arrangements have been held to be unenforceable by the Supreme Arbitrazh Court.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

A representative acting per proxy from a claimant has the right to pay a state duty for bringing a claim.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Russia.

The Russian product liability law was substantially amended in 2008. The following essential amendments came into effect:

Certain powers have been delegated to the federal executive bodies by the Government of the Russian Federation. These bodies are now responsible for matters such as the social protection of certain categories of individuals (including Chernobyl cleanup veterans, the unemployed, and police officers), public health protection, recording of mineral resources, atomic power, consumer protection, export and import of objects of cultural value, maintenance of the state cadastre of real estate, civil matters (issue of the rules required for the parties while entering and executing public contracts), formation of public associations and other questions. The federal law amending the regulations came into effect on January 1, 2009.

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

Liability for damages arising from the supply of products found to be defective or faulty arises in contract, common law and statute. There is some overlap. The principle statute is the Consumer Protection Act 1987.

Contract

The law of contract implies a term that goods and services sold are fit for their intended purpose and of satisfactory quality. The Sale of Goods Act 1979 Section 14(2)A states that goods are of satisfactory quality if they meet "*the standard that a reasonable person would regard as satisfactory, taking account of any description of the goods, the price (if relevant) and all other relevant circumstances*". "Safety" and "fitness for purpose" are the markers for quality under the act. The liability of the seller to the purchaser is strict and it does not matter whether or not the seller was at fault in causing injury to the consumer.

Contractual liability is restricted to those in the contractual relationship, i.e. the seller and the consumer in the context of the Sale of Goods Act provisions. It is therefore important for retailers to ensure that contracts with manufacturers include provisions to indemnify that retailer against claims made by consumers.

The Unfair Contract Terms Act 1977 provides that liability for death or personal injury resulting from negligence cannot be excluded or restricted. Other liability for negligence can only be excluded if the restriction is reasonable.

Negligence

The common law of negligence (*delict*) has developed to fill the gap created by the non availability of a claim under the law of contract for injury caused by defects in a product negligently manufactured in circumstances where there is no direct relationship between the manufacturer and the ultimate consumer. Liability of a manufacturer to the ultimate consumer in *delict* (in England, tort) was first enunciated by the House of Lords in the Scottish case of *Donaghue v Stevenson* 1932 SC (HL) 31. The Court concluded in the circumstances of that case that a duty of care may be owed by a manufacturer to a consumer despite there being no contractual relationship between the manufacturer and the consumer, there having been no opportunity for intermediate examination by the retailer or consumer. The retailer with whom the consumer had a contractual relationship had no liability because in the circumstances he was unable to inspect the contents of the opaque sealed bottle.

The basic duty of a manufacturer/supplier at common law is to do what is reasonable in the circumstances. By its nature, the duty will vary according to the situation involved. It may be reasonable in one case to provide a warning to consumers, but in another to recall a particular batch of products (see question 1.4). Other possible steps which may be reasonable could include using an alternative design where one is available or ceasing production temporarily or permanently. In assessing what is reasonable in any particular case relevant factors may include:

- the severity of the risk, including the type of injury;
- obviousness of the risk to the consumer;
- the utility of the product;
- cost and practicality of overcoming the risk; and
- the state of scientific and technical knowledge in relation to the risk.

There is generally no need to warn the public against known dangers/risks. Other issues, such as the need to keep abreast of scientific developments may be relevant. Given the obligation to act reasonably in all circumstances, the actions of other manufacturers in the same field may be relevant and manufacturers should keep appraised of these.

The law of negligence is based on common law and is constantly developing on a case by case basis; manufacturers should ensure they have ongoing access to legal advice.

Statute

The most significant legislation in this area is the Consumer Protection Act 1987 ("the Act") which imposes strict liability (subject to the availability of certain defences - see question 3.1) on producers for harm caused by defective products. "Producers" will be liable if they have supplied "defective products" in the course of business which caused death or injury to the consumer or damage to property.

In order for a "producer" to be held liable, it must be established that:

1. The producer supplied (which includes manufactured - see below) a product.
2. The product was defective.
3. The defect caused injuries.

As liability is strict, it is not necessary for the consumer to show that the producer was negligent (although a separate common law claim under the law of negligence may also exist).

The *producer* includes the manufacturers, processors, growers and miners. It also includes own-branders, where a person marks the

product in a way that holds himself out as the producer, and suppliers of a defective product can be found liable if they fail to name the producer, importer or own branders behind them after a request by the injured consumer. More than one of these businesses could find themselves defending a claim in relation to a defective product.

A seller, as such, is not liable unless he is reasonably required by the person suffering the damage to identify one or more of the producers and fails to do so.

"*Product*" covers almost all consumer goods, extending to unprocessed foods, electricity, liquid or gaseous substances. Ships, vehicles and aircraft are specifically mentioned as are their component parts. "Buildings" are not "products" but the constituents of them, such as the steel frame or cement used are. If there is a defect in a component, both the producer of the component and the producer of the finished product may be liable, although the law in this area has not been tested.

The "*defective product*" is one in which the safety of the product does not meet the standard which consumers are entitled to expect. "Safety" also includes the safety of materials and components comprised in the product. It also covers instructions and warnings and what might be the expected use of the product. This is an objective test and all circumstances are taken into account, including marketing, marking and the reasonable expected use of the product, together with the instructions and warnings supplied.

Claims may be brought for breach of statutory duty if the act confers civil liability, such as Part 1 of the Act. Otherwise, consumer fraud statutes do not confer civil liability.

1.2 Does the state operate any schemes of compensation for particular products?

Yes. The Vaccine Damage Payments Act 1979 provides for fixed compensation to be paid to persons suffering severe disablement as a result of certain vaccinations.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

At common law, liability in negligence will lie with any party who owed a duty of care to the consumer, and whose breach of that duty caused loss or damage. That could potentially involve anyone in the supply chain and is likely to vary according to the circumstances.

Contractual liability will depend on the contractual relationships in place in the supply chain.

The Act (in Section 2) principally imposes liability on the "producer", the own brander or the importer of the product into the EU. A supplier may be liable instead of the producer if he fails to identify the producer/importer/own brander, having been requested to do so by the consumer.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

At common law, the discharge of the duty of care owed by a producer/importer/own-brander may, depending on the circumstances, require recall or withdrawal of the product, and failure so to do may give rise to liability. Manufacturers may also owe a duty to keep their products under review and to warn of any risks that come to light after supply.

There are specific statutory obligations imposed by the General Product Safety Regulations 2005 made under the Act ("the Regulations"), which include the requirement that "producers" (which includes manufacturers, importers and own-branders) must only place safe products on the market.

An "enforcement authority" (see question 1.5) has the power to serve a recall notice if action undertaken by the producer/distributor is unsatisfactory or insufficient and certain other conditions are met (regulation 15(4)).

1.5 Do criminal sanctions apply to the supply of defective products?

Yes. Compliance with enforcement of both general and specific safety regulations is generally undertaken by Weights and Measures authorities, usually through Trading Standards or Consumer Protection Departments in local councils. In Scotland, prosecutions are brought by the Procurator Fiscal.

The Regulations impose criminal liability for breach. They set out a number of offences which are punishable by imprisonment and/or fines including: failing to meet the obligation to supply only safe products; failing to provide consumers with appropriate information; producers/distributors failing to put themselves in a position to identify risks; failing to notify and co-operate with enforcement authorities; and failing to comply with safety notices.

The penalties for breach of the Regulations are a fine of up to £20,000 and imprisonment for up to 12 months.

The Regulations apply to all products to the extent that these are not subject to other specific safety requirements law such as those relating to medical devices, food, toys, cosmetics, machinery and electrical equipment which impose their own criminal sanctions.

In addition, section 6 of the Health & Safety at Work etc. Act 1974 imposes a general duty on those who supply "articles for use at work" to ensure, so far is reasonably practicable, that the articles are designed and constructed so as to be safe and without risk to health if properly used. This obligation extends to manufacturers, designers, importers, equipment rental companies and those who install products in the work place. Breach of the duty is a criminal offence.

Other statutes also impose criminal liability for defective products, such as the Food Safety Act and regulations made thereunder. The Corporate Manslaughter and Homicide Act 2007 introduced the offence of "corporate homicide" in Scotland. Broadly, an organisation (which includes companies) will be guilty of the offence if the way its activities are managed or organised causes a person's death and amounts to a gross breach of a relevant duty of care. The Act applies primarily in the context of health and safety at work but may also apply in the circumstances of product liability if a defect in a product has caused a fatality.

It should also be borne in mind that enforcement authorities have a raft of powers, including inspection of goods and documents, search and seizure, prohibition notices, suspension notices, power to publish warnings about unsafe goods and to apply to the court for forfeiture of goods, in addition to the ability to recommend prosecution.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

At common law and in contractual claims the onus is on the Pursuer ("plaintiff") to prove his/her case on the balance of probabilities. In

relation to claims under the Act the Pursuer requires to prove that the producer supplied the product, that the product was defective and that the defect caused the injury or damage. The onus of proving a defence under the Act rests with the producer. The standard of proof is, again, the balance of probabilities.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

It is unlikely to be enough for the claimant to show that the defender wrongly exposed the claimant to an increased risk known to be associated with the product (particularly where general causation is in issue) and if the claimant cannot prove (on the balance of probabilities) that the injury would not have arisen without such exposure. For example, in *McTear v Imperial Tobacco Limited* (2005 2 SC 1), it was held that in order to establish that exposure to a substance can cause, or has caused, a condition it must be shown on the evidence that, on the balance of probabilities, the condition would not have occurred "but for" the exposure. This applies to exposure on a single occasion and cumulative exposure. In *McTear*, the Court was concerned with whether smoking could cause lung cancer and if it could, whether it caused Mr. McTear's lung cancer. (The claim failed and it was held that there was no liability on the defenders.) Evidence of exposure associated with an increased risk of injury complained of is unlikely to be enough to prove causation although that is likely to depend on the circumstances of the case including the nature and strength of the association.

The "but for" test had been affirmed by the House of Lords in *Fairchild v Glenhaven Funeral Services Ltd and Others* (2002) All ER 305. In that case, it was accepted that the plaintiffs would not have contracted mesothelioma but for exposure to asbestos: the problem was that it was not possible to say whether it was an accumulation of asbestos fibres or one individual fibre which had triggered the condition. It was not possible to determine if only one employer, or some employers, out of several who had been negligent in respect of exposure to asbestos, were responsible for the exposure which caused the condition. Since the exposure could have been on a single occasion, could liability nevertheless be established against each of the employers? The Court held that where an employee had been exposed by different defendants during different periods of employment, to inhalation of asbestos dust in breach of each defendant's duty to protect him from the risk of contracting mesothelioma and where that risk had eventuated but, in current medical knowledge, the onset of the disease could not be attributed to any particular or cumulative wrong, a modified approach to causation was sufficient. Accordingly, the claimant could, on a balance of probabilities, prove the necessary causal connection to establish the defendants' liability.

The decision means that individuals who have been exposed to asbestos while working for more than one employer are entitled to seek compensation, despite being unable to prove which employer exposed them to the asbestos which may have caused their illness, it being possible that mesothelioma could be caused by just one speck or fibre of asbestos dust. The decision is not easy to translate to other circumstances and it is important to note that there was no issue among the parties as to whether 1) asbestos could cause mesothelioma and 2) that it caused mesothelioma in the employee in question. Damages for claims for mesothelioma are now covered by section 3 of the Compensation Act 2006.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

No. If the pursuer cannot prove his case on the balance of probabilities against a specific producer the claim will fail. However, if several companies supply parts to a manufacturer who assembles "the product" it may be that all of those businesses could be liable. This has not been tested in the Scottish Courts.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Failure to warn may give rise to liability under the Act and in negligence. In terms of section 3(1) of the Act, there is a defect in a product if the safety of that product is not such as persons generally are entitled to expect. In determining what persons generally are entitled to expect a variety of factors will be considered, such as any instructions or warnings provided in relation to the product. In *Chadwick v Continental Tyre Group Ltd* [2008] CSOH 24, the court considered that "a reasonably foreseeable risk cannot amount to a defect in a product within the meaning of Section 3".

Producers/distributors are likely to owe a duty to take reasonable care to provide sufficient information and warnings with their products.

There are few Scottish reported cases on the Act and the Scottish Courts have not decided the relevance of warnings provided by intermediaries.

In *McTear v Imperial Tobacco Ltd* (2005 2 SC 1), the Court accepted the proposition that there is no duty to warn of risks of which the ordinary member of a relevant class of people may reasonably be assumed to be aware. The Court referred to the standard of the "normally intelligent person".

Whether 'learned intermediaries' warnings are likely to be sufficient to discharge the obligation on the manufacturer to provide appropriate product information to the ultimate consumer will depend on the relevant facts and circumstances.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Section 4(c) of the Act contains six defences. It is for the producer to prove these to the court's satisfaction:

(a) *The defect in the product arose through compliance with a requirement imposed by law or a European Community obligation.* This defence may be difficult to utilise successfully. Government guidance suggests that a producer

would have to show that the defect was caused "inevitably" because of compliance with a regulation. This is a high test which may be difficult and expensive to evidence.

(b) *The producer did not, at any time, supply the product to another*. This would relieve a producer of liability if his products had been stolen or counterfeited.

(c) *The only supply of the product was other than in the course of business*. This excludes liability for items that are donated, gifted or privately sold with no view to profiting.

(d) *The product was not defective at the time of supply*. In the case of a supplier who has become liable through his failure to identify the producer, the time of supply will be the time of the last supply to them by the producer. This defence may operate where a product has become unsafe due to an act of the retailer through incorrect installation, lack of maintenance or misuse.

(e) *The "state of the art" defence*. This is, arguably, the most significant defence for manufacturers, especially for those producing innovative products or where there are medical science advances on the understanding of the causation of disease. This defence is available if the producer can show that the stage of scientific and technical knowledge was not such as to allow discovery of the defect at the time of supply. It should be noted that not all European countries have allowed for this defence and manufacturers and exporters should be aware of this if they supply goods to other Member States. It is an objective standard of knowledge and therefore it is important for manufacturers to ensure they are constantly aware and as up to date on scientific and technical literature and studies regarding a product as quickly as possible. This is an ongoing task. The European Court of Justice has stated that the applicable standard is the most advanced state of knowledge accessible at the time of supply.

(f) *A defect in a component is a result of the design of the finished product or the specification given by the producer of the finished product*. This defence is potentially of wide use as many products are comprised of numerous components. It could provide relief to a great number of manufacturers, as long as the product is not defective in itself.

The Law Reform (Contributory Negligence) Act 1945, which allows for reduction in damages where the injured party is partly responsible for the damage, is applicable to claims under the Act.

It should be noted that producers cannot contract out of or limit liability under the Act.

A due diligence defence is available in a prosecution for breach of the Regulations (Regulation 29).

The issues addressed in the statutory defences referred to above will be relevant also to the assessment of whether there has been negligence or breach of duty in any common law claim.

At common law the Pursuer's actual awareness and knowledge of risk associated with a product may provide a defence to a failure to warn case. The Court in *McTear* stated "*there is no liability in negligence for the supply of a potentially harmful product if the consumer, in knowledge of its potential harm, nevertheless chooses to consume it*".

In negligence, it is also a defence if the producer can show that the Pursuer freely and voluntarily accepted the risk of injury in full knowledge of the nature and extent of the risk (*volenti non fit injuria*). Invocation of the maxim of volenti is predicated on the assumption that negligence has otherwise been established and that if the defender's plea fails the Pursuer must succeed. The burden of proving it is therefore on the defender.

The Pursuer will not succeed with his claim if he cannot establish the essential elements of his case i.e. that a duty of care was owed to him by the producer; the producer breached that duty; and the breach caused the loss or damage; or if the pursuer fails to establish breach of contract.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Yes. See paragraph (e) in question 3.1. In terms of the Act it is for the producer to prove that the fault/defect was not discoverable. At common law the "state of the art" analysis will form part of the overall consideration of whether the manufacturer was at fault.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

It may be - see paragraph (a) in question 3.1. Otherwise, evidence of compliance with regulatory and/or statutory requirements are likely to be useful in establishing that the manufacturer has, in a claim for negligence, exercised reasonable care.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

A final Decree (judgment) is conclusive as between the parties to an action and their successors. Generally, factual issues can be re-litigated in an action involving different parties. However, the Court may consider the findings in the earlier case to be persuasive (depending on circumstances and any distinguishing features). A decision on a point of law may be binding on an equivalent or inferior court.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

Yes. Claims for contribution/indemnity can be brought under the Law Reform (Miscellaneous Provisions) (Scotland) Act 1940 either in the same proceedings or in subsequent proceedings subject to the usual rules on prescription and limitation. (See question 5.2.)

Contractual indemnities may be provided in the supply chain and invoked in the same or separate proceedings.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Yes. Liability under the Act and in *delict* can be limited/restricted if the defender can prove that the pursuer's own fault and negligence caused or materially contributed to the damage.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

In the Court of Session (the Supreme Court in Scotland) an action of damages for personal injury must be sent to jury trial unless parties otherwise agree or special cause is shown not to do so. "Special cause" might involve issues such as the legal and factual complexities. In practice, parties generally agree the case should be heard by a judge alone. Cases in the Sheriff Court will always be heard by a Sheriff sitting alone.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The Court can appoint an "assessor", generally if there are technical matters to be decided requiring special knowledge. In practice, the court will tend to rely on the experts called by the parties.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

There is no class action procedure in Scotland. However, where a number of actions arise out of the same cause of action the Court may appoint a "leading" cause and "sist" (freeze) the other actions pending the determination of the leading cause.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

No, they cannot.

4.5 How long does it normally take to get to trial?

This will depend on a variety of factors such as the nature and complexity of the claim. An action raised in the Court of Session may take anywhere from 6 months to several years to reach proof (trial).

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Yes. The Court can consider preliminary issues of law and issues of fact. These are decided by the judge.

4.7 What appeal options are available?

Appeal of a decision disposing of the subject matter of the case does not require permission of the Court. Product liability actions are often raised in the Court of Session (although they can also be raised in the Sheriff Court). Appeal from the Outer House of the Court of Session is made to the Inner House and from there until 1 October 2009 to the House of Lords and thereafter to the UK Supreme Court.

The Appeal Court may affirm, vary or set aside any order or judgment made in the lower court but is unlikely to disturb findings of fact made by a trial judge who had the benefit of hearing witness and expert evidence.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Experts generally will be appointed by the parties rather than the Court. The nature and extent of the expert evidence will depend on the type and value of the claim. Experts are likely to prepare a written report. They may meet to explore areas of agreement and narrow the areas in dispute.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

Witnesses are not required to give depositions. Usually, expert reports will be exchanged in advance of the proof. However, that is not technically necessary if the expert does not seek to rely on a written report (which would be unusual). Parties will exchange details of the identities of their witnesses in advance of proof but are unlikely to exchange statements. The Court can vary this procedure and seek exchange of witness summaries (or more unusually, witness statements).

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

Parties exchange any documents on which they intend to rely in advance of the proof generally by four weeks in advance of proof. There is no general obligation of disclosure. In the course of case progress and proof preparation either party can seek court orders for recovery of documents, in relation to which detailed rules apply. There is no right to "fish" for information through orders for general disclosure.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Yes. Parties may elect to seek alternative methods of dispute resolution such as mediation; however, a party is under no obligation to do so.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, see the answer to question 5.2.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

Under the Prescription and Limitation (Scotland) Act 1973, and

subject to various exceptions, contractual and delictual obligations prescribe after a period of five years from the date the obligation became enforceable. Generally all claims will prescribe after a long-stop period of 20 years.

A time limit of 3 years applies to personal injury actions. The period of limitation runs from either: a) the date of injury (or death), or where injuries were attributable to a continuing act or omission, that date or the date on which the act or omission ceased; or, if later, b) from the date which the pursuer could reasonable have become aware: i) that his injuries were sufficiently serious; ii) that his injuries were attributable in whole or in part to an act or omission; and iii) of the identity of the defender.

Specific periods apply in respect of product liability claims under the Act. Claims for damages caused in whole or in part for a defective product will prescribe after a period of 10 years. A limitation period of 3 years also applies from the date the pursuer should reasonably have become aware that: a) a product was defective; b) the damage was caused by the defect; c) the damage was sufficiently serious; and d) that the defender was liable therefor.

The court has an equitable power to allow an action to be brought out with the limitation periods for personal injury and product liability noted above in certain circumstances.

In calculating both prescriptive and limitation periods, periods during which the person seeking to bring the action was under a legal disability by reason of nonage or unsoundness of mind are disregarded.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Periods during which a relevant claim, which would postpone the operation of prescription, was not made by reason of fraud on the part of the defender (or any person acting on his behalf), or error induced by words or conduct of the defender or any person acting on his behalf, are excluded from the reckoning of the prescriptive period.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

The principle remedy is monetary compensation. However, the remedies of declarator and interdict are available if appropriate in the circumstances of the case.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Damages for death or bodily injury (including mental damage) are recoverable under the Act together with damages for loss of or damage to property for private use and consumption - subject to a minimum threshold of £275. (Section 5(4)). Damages are not recoverable in respect of damages to the defective product itself.

In negligence damages are intended to put the pursuer in the position he would have been in but for the breach. Damages to the product may be recoverable through a claim for pure economic loss.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

This is unlikely to comprise a relevant claim for damages unless there is a primary liability in terms of the product in question. If a product liability claim does arise the cost of monitoring might be a relevant head in relation to damages arising from that liability.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

No. In Scotland, damages are assessed by reference to the loss and injury sustained.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

No, there is not.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

No, they do not.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Yes. Depending on the circumstances, the defender may require to repay certain benefits received by the claimant under the Social Security (Recovery of Benefits) Act 1997.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The award of expenses is a discretionary matter for the court. In the normal course of events the losing party will pay the successful party's expenses, this includes both legal fees and court expenses. They are generally assessed at a judicial rate for both legal fees and expenses. This is unlikely to cover all fess and outlays incurred. The successful party will submit an account of expenses and if this is disputed, a Taxation before a Court Auditor will be required.

7.2 Is public funding e.g. legal aid, available?

Civil legal aid is available in Scotland depending on the circumstances of the case.

7.3 If so, are there any restrictions on the availability of public funding?

There are three criteria against which availability of civil legal aid is determined in Scotland.

(a) Probable cause

This is a relatively low threshold to cover, for example, jurisdiction, title to sue and a legal basis for action. It is not an assessment of likely success.

(b) Reasonableness

This involves a cost-benefit analysis and an assessment of prospect of success and recovery. The test also involves assessing whether private client of moderate but not abundant means would pay to raise or defend proceedings.

(c) Financial eligibility

Both income and capital are assessed. Income in the previous 12 months is taken into account as well as the capital that the applicant has at the present date. Depending on these matters, the applicant may be refused or asked to contribute to the legal aid.

Successful cases that recover money or property can be subject to 'clawback'. This would mean that any shortfall between the expenses awarded and any contribution made by the claimant compared with the solicitors' fees paid by the legal aid board could be recovered by the board from the profits of a successful case.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Yes. There are no Conditional Fee Arrangements in Scotland but a "no win, no fee" arrangement may be available.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Yes. Insurance may be available.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Scotland.

There have been few developments in Scotland over the last year. The Scottish government demonstrated its intention to differentiate itself in certain fields such as pleural plaques legislation. The Damages (Asbestos-related Conditions) (Scotland) Bill was passed by Scottish Parliament in March 2009 and its expected to received Royal Assent in April/May. It provides that asbestos-related pleural plaques constitute "actionable harm" for the purposes of an action for damages for personal injury (thus over-turning the decision of the House of Lords in *Grieves v FT Everard & Sons Ltd* [2007] UK HL 39).

The results of the Civil Courts Review are expected in mid 2009 and may affect dispute resolution methods (such as mediation) and the introduction of class actions. Law Applicable to Non-Contractual obligations (Sc) Regulations 2008 are now in force importing jurisdiction in product liability cases.

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

Traditionally, the Slovak legal system has distinguished liability for damage and liability for defects of products, performances and services. The liability for defects is contractual; the liability for damage is liability in tort. They can be claimed concurrently and independently from each other. Both liabilities are basically treated in the Civil Code (Act No. 40/1964 Coll.); particularities for business to business relations are specified in the Commercial Code. Due to implementation of the *acquis communautaire*, the liability for damage caused by defective products was introduced by Act No. 294/1999 Coll. transposing Product Liability Directive 85/374/EEC.

The liability for defects applies to any contractual relation, where one hands over an asset (e.g. a product) to another against payment. The handing over guarantees that the asset has the attributes set forth in the contract or that is usual, that it can be used according to its nature and the purpose of the contract or in a way agreed upon and that it is free of legal defects at the moment of the hand over. It is strict and it cannot be excluded or limited neither by an agreement nor a unilateral legal act.

The liability for damage is generally fault-based. The Civil Code provides: "*Everyone is liable for damage, which he caused by violating a legal duty. A person who proves not to have caused the damage by the fault shall relieve himself of the liability for them.*" (Sec. 420). However, the liability for damage caused by a defective product is one of the special cases where liability for the damage is strict. This liability applies only to relations to consumers. It cannot be limited or excluded in advance. Any agreement to such effect is null and void.

The liability related to a product can arise also from violation of statutory or regulatory obligations such as the prohibition to market dangerous products set out by Act No. 250/2007 Coll. on Consumer Protection (Consumer Protection Act).

1.2 Does the state operate any schemes of compensation for particular products?

There is no scheme of special compensation operated by the state in the Slovak Republic.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Under the contractual liability for defects any person who is obliged to provide a thing (goods) or service to another bears responsibility for defects thereof.

Under the liability for damage caused by a defective product, responsibility rests on the producer. Liability extends to importers of the product into the Internal Market and those who present themselves as producers. Also distributors or other suppliers can be liable. Act No. 294/1999 Coll. on Liability for damage caused by defective products (Product Liability Act) makes responsible the following persons:

- a person, who manufactured a product or abstracted it;
- a person who presents himself as producer by putting his name, trade mark or any other distinguishing feature on the product;
- a person importing a product from outside of the EU for the purpose of sale, hire or any other form of use in the course of his business; this is without prejudice to the liability of above mentioned producers; and
- any person, who supplies the product unless he informs the person who suffered a damage of the producer's identity or of the identity of person who supplied him with the product; this applies also to the imported product, if the importer of the product is unknown even if the foreign producer is known.

If there are more persons liable concurrently their responsibility is joint and several.

Within the statutory liability for general product safety, set out by the Consumer Protection Act, responsible persons are:

- a producer/manufacturer, as the professional whose activities may affect the safety of the product; and
- the importer and distributor (seller, supplier), as the persons placing products on the market not affecting the safety of the product.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

In the field of general safety of products, the market surveillance authority (the Slovak Trade Inspection, the State Institute for Drug Control) is authorised to order the producer, distributor, importer and, if necessary, any other person, to withdraw immediately the product or series of products from the market or to recall it from consumers, if it has been proven that it is not safe. Where

necessary, also the liquidation of a product can be ordered. The market surveillance authority can take these measures directly itself. The recall of a product can be imposed only if the risk of damage to consumers persists despite timely and appropriate notification to persons in jeopardy.

Under the requirements of general safety of products, the producer, importer, distributor and supplier are obliged to place on the market only safe products, monitor products they market and, when they become aware of any threat originating from their product, to inform consumers involved and to withdraw it from the market and, if necessary, to recall the products. Failure to do so entails the liability in administrative *delict* sanctioned by a penalty.

Every consumer has the right to submit motions and complaints concerning a product's safety. The above measures can be ordered upon a consumer's motion or complaint or as a result of inspection by the market surveillance authority performed *ex officio*. The market surveillance authority also deals with the related administrative delicts.

1.5 Do criminal sanctions apply to the supply of defective products?

The marketing of defective product can be subject to criminal sanctions. Pursuant to the new Criminal Code (Act No. 300/2005 Coll.), section 269, whoever wilfully harms a consumer by placing on the market products or services and concealing essential defects thereof and thereby causes him at least small damage, shall be punishable with imprisonment for 6 months up to 3 years. The imprisonment can be substituted for or combined with a house arrest, prohibition to undertake an activity or a pecuniary punishment. In case of qualified facts of the crime such as gaining a profit or causing damage to more persons, imprisonment for up to 12 years can be imposed.

Small damage means damage in the amount of EUR 266 up to EUR 2,665. If the damage caused is lower, the act is deemed to be an offence (administrative *delict*) punishable by a fine.

The key aspect of this criminal act is fraud that consists in concealment of essential defects of the product.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

In case of a claim under the contractual liability for defect, the aggrieved party bears the burden of proving all preconditions of the liability, i.e. with the existence of a contractual obligation, the breach of the obligation to deliver a product free of defects, damage and causality.

In case of a claim based on liability for damage caused by a defective product, the burden of proof is laid as follows: the consumer who suffered damage shall prove existence of defect, damage and causal connection between the two. The producer can be relieved from liability for damage, if he furnishes proof of one of the exonerating circumstances (see question 3.1 below).

Because both liabilities are strict, the proof of fault is inapplicable.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

There has been no test established for assessment of causation. A court assesses each case individually taking into consideration all circumstances. Generally, the causal relation needs to be direct. The probability that damage would have arisen anyway can be considered as failure to bear the burden of proving the causation. However, it depends on overall assessment of a case by a court.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

There are two situations of concurrency of several producers treated in the Product Liability Act. One situation is concurrency of a component producer and a whole product producer. If the producer of a component of the product proves that the defect of the product is attributable to the design of the whole product, in which the component was fitted or if the damage was due to the user's manual for the entire product, the producer of the component frees himself from liability.

The other situation is when several producers are liable, i.e. none of them proved he had not produced it or distributed it. Then their liability is joint and several; each of them is responsible for full damage. If there are several possible producers and no clear evidence of infliction of any of them, it can result in failure to prove causation.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

The providing of information is one of the basic methods of the consumer protection. The general information obligation is set out in section 11 of the Consumer Protection Act. A seller (distributor) is obliged to inform a consumer about the characteristics of a product, on the method of use and maintenance of the product, on the risks associated with its incorrect use or maintenance and on storage conditions. If necessary in view of the nature of the product and in view of the method and time of its use, the seller is obliged to ensure that the information also is intelligibly provided in an appended written manual.

If the producer (or importer) does not enter into a direct contract with the seller, they are obliged to provide truthful and complete information about the product's characteristics to the supplier. The supplier is obliged to provide truthful and complete information about the product's characteristics to the seller.

Each member of the supply chain has the information duty towards the following one, but the key responsibility towards a consumer rests on the seller. He may not free himself of the information duty by stating that the producer, importer or supplier failed to provide him with the necessary or correct information; this does not apply to instances when such facts are commonly known.

The principle of "learned intermediary" has not yet been generally accepted under the Slovak law. The fact that the intermediary owes a separate obligation to assess the suitability of the product for the particular consumer may be taken into account as a limit to a producer's liability for damage due to failure to perform information obligation, but it would not exempt the producer from liability for defective product and damage caused by it. Providing information does not exonerate the producer from liability for a defective product.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The producer can defend himself against a product liability claim by providing the proof that:

a) he did not put the product into circulation;

b) the defect of the product, which caused the damage, did not exist at the time when the product was put into circulation or that this defect came into being afterwards, taking all the circumstances preceding the damage into account;

c) the product was neither manufactured by him for sale or any other form of use for economic purpose, nor was it distributed in the course of his business;

d) the defect of the product is due to the product's compliance with a statutory/regulatory requirements; and

e) the state of scientific and technical knowledge at the time when the model was put into circulation was not such as to enable the existence of defect to be discovered.

The producer of a component of the product can defend himself by proving that the defect of the product is attributable to the design of the whole product, in which the component was fitted or if the damage was due to the user's manual for the entire product.

Further, the producer is entitled to seek limitation of his liability by proving that the claimant's acts contributed to the rise of damage.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

The development risk defences are available under the subsection 5(1)(e) of the Product Liability Act. The burden of proving that defect was not discoverable at the time of putting the product into circulation rests on the defendant (producer/manufacturer).

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

This ground of defence is available under the subsection 5(1)(d) of the Product Liability Act. The producer relieved himself by proving that the defect is due to compliance with statutory/regulatory requirements.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

The claimant can re-litigate the issue provided that an estoppel by judgment does not impede it, i.e. neither the parties nor facts are the same. However, there is a threshold set for the total compensation of damage resulting from personal injury or death and caused by identical products with the same defect, in amount of SKK 3,500 million (app. EUR 116,178,716).

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

The defendant has the right of recourse against the third party who caused the damage by intention or negligence. He can claim this right in subsequent proceedings, which shall be brought within the general time limit of three years from the moment when the defendant has fulfilled his obligation to compensate the claimant (aggrieved person).

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

The defendant can make the counterclaim that the claimant contributed to damage and reach appropriate limitation of the liability. If the defendant proves that the damage is caused exclusively due to a claimant's act, he can relieve himself of liability completely on the ground that the causation on his part is disproved.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

In the Slovak legal system, the trial by a jury does not exist. Product liability cases are heard by a judge at a general court.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

If the decision depends on consideration of facts requiring professional knowledge, the court can appoint an expert. The expert does not sit with the judge and does not assess evidence. He shall provide the court with explanations of technical questions. The court examines the expert and usually orders him to make the written report on technical questions posed by the court. The expert can be appointed upon proposal of any party or without a proposal. Where more experts have been appointed, they may elaborate a common report or one can provide the cross-report to the report of another. The assessment of evidence is always matter of the judge.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

In general, for reasons of economy of proceedings, the court may join cases commenced therewith and related to one another on a factual basis or concerning the same participants and may hear them in joint proceedings. If there are several persons who suffered damage caused by the same producer, upon proposal the court will likely join the proceedings.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

This is a special option for consumer protection proceedings available. An association established for the purpose of consumer rights protection may bring an action before the court or may be a party to such proceedings instead of individual consumers. The precondition is that the association has been included on the list of qualified entities maintained by the European Commission.

4.5 How long does it normally take to get to trial?

The right to a fair trial within a reasonable time is guaranteed. However, there are no fixed procedural time limits. The actual practice of courts is that the first hearing is ordered in about 6 months from receiving of the statement of claims.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

If it is useful, the court may first issue a judgment dealing only with a part of the case or with the base thereof - interlocutory judgment. The issues decided preliminary can be issues of fact as well as of law. In practice, the court decides first on the ground of the claim (issue of law) and then, if it is relevant, on the extent of damage and on compensation.

4.7 What appeal options are available?

Generally any judgment issued in the first instance can be contested by appeal. The appeal may be filed within fifteen days after the delivery of a written execution of the judgment. The appeal may be based only on the grounds listed in the Civil Procedure Code (e.g. the conditions of the proceedings were not met, the factual basis was ascertained incompletely, the decision is based on an incorrect legal consideration, etc.).

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The court can appoint experts upon its own initiative or upon proposal of a party. See the answer to question 4.2 above.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

There is no pre-trial phase in the civil proceedings in Slovakia where witnesses or experts would be required to present themselves, nor any witness statement or expert reports are exchanged. All pieces of evidence are presented and carried out at trial, not prior to it.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

There is no evidence disclosure obligation prior to a commencement of proceedings.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Yes, according to the Slovak law disputes can be settled in mediation as well as in arbitration. An arbitration jurisdiction needs to be established by a written agreement or arbitration clause.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, the right to compensation of damage is subject to the statute of limitation.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

Pursuant to section 9 of the Product Liability Act, the right to compensation is limited to three years since the day when the aggrieved party became aware or could have become aware of the damage caused by the defective product and the identity of the producer.

If the right to compensation is not claimed within ten years of the day when the defective product, which caused the damage, was put into circulation, the right to compensation comes under the statute of limitation. After this period the court cannot grant compensation if the defendant has pleaded limitation.

The time limits are invariable. However, in case of a person who is not capable of legal acts (temporarily or permanently) (such as a minor or person of unsound mind), the period does not start until a legal representative (guardian) to him or her is appointed. An already running limitation period continues, but it shall not end within one year after the legal representative is appointed or after this impediment expires.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

The concealment or fraud can be relevant for the running of the time limit in the respect that the period would not start unless the claimant became aware or could have become aware of the identity of the producer.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

The damaged party may seek that the breaching party refrain from unlawful conduct and that it removes the unlawful state of affairs. Further, it may seek adequate financial compensation of damage or, if the damaged party requires so and it is possible and purposeful, restitution in integrum instead.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Pursuant to the Product Liability Act recoverable is damage to life or health and damage to property designed for personal use or consumption and which the damaged party used for this purpose, other than the defective product itself. In case of damage to property, damage is only recoverable is when the damage exceeds SKK 20,000 (EUR 663.90).

For compensation of damage to property, real damages and loss of profit are recoverable. For compensation for death or personal injury, compensation for pain and aggravation of an individual's social assertion is recoverable, and loss of earnings, loss of pension allowance and treatment costs are reimbursed. In case of death, the maintenance to survivors and reimbursement of burial expenses can be awarded.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

If the product has not yet caused injury, there is no actual damage that could be claimed and compensated according to the Slovak law.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are not recognised in the Slovak legal system.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

Yes, see question 3.4 above.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

There are no special rules concerning the settlement of claims.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

The Social Insurance Agency (institution providing social security) can claim damages towards a party who caused the payment of social security benefits in consequence of a breach of law by intention or negligence. The payment of social security benefits to an injured party as a result of a breach of law by this party is not deemed to be damage that shall be subject to the right to recourse. The party who was held liable for damage to health or life is responsible for repayment of the sum.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The successful party is entitled to recovery of costs necessary to a useful exercise or defence of a right against the losing party. Costs of proceedings such as court fees, costs of evidence, expenses and remuneration of experts, as well as costs of legal representation of the party are recoverable.

7.2 Is public funding e.g. legal aid, available?

There is a scheme of legal aid operated by the Ministry of Justice in Slovakia pursuant to Act No. 327/2005 Coll. on Provision of Legal Aid for People in Material Need. The free legal aid by the Centres of Legal Aid can be provided *inter alia* in civil law matters, product liability issues included. A person in material need can be also freed from payment of court fees.

7.3 If so, are there any restrictions on the availability of public funding?

The preconditions of granting free legal aid are the material need of a person (financial criteria), the prospect of success and the value in litigation.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

According to the law, an attorney's tariff contingency fee is allowed up to 20% of the value of case. The attorney is entitled to remuneration on condition that the client had success in the case.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

There is no regulation of third party funding in Slovakia.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Slovakia.

Product liability litigation is rare. Till now, no finished cases brought under the national legislation implementing the Product Liability Directive in the Slovak Republic have been reported. The cases concerning product liability are usually based on contractual liability for defective products according to the Civil Code and the Commercial Code.

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South Africa

Cliffe Dekker Hofmeyr Inc.

Pieter Conradie

1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

The Consumer Protection Bill of 2007, which will change the Common Law principles regarding product liability, was expected to be promulgated some time ago, but the Bill has not yet been signed by the President of the Republic of South Africa. All expectations are that this will occur at some time during 2009. The Common Law principle, that negligence must be proved for a manufacturer to be held liable for a defective product, will change when the Consumer Protection Bill has been promulgated.

At present, the Common Law still applies and product liability will arise whenever a product supplied by a distributor or manufacturer contains a defect which causes damage either to a person or property.

The manufacturer or designer of a product can be held liable for loss or damage caused as a result of the use of his product, either on the basis of contract or on the basis of *delict* (unlawful conduct).

At present, the liability is fault based, but with the introduction of the Consumer Protection Bill, this will change. Section 61 of the Consumer Protection Bill will introduce a concept of strict liability in our law.

Failure to comply with a statutory obligation does not impose a civil liability and compliance with statutory obligations does not automatically bar a civil claim for damages. Mere compliance with a statutory obligation may assist a defendant to plead such complaince as one of its defences, but may not be successful as its sole defence.

1.2 Does the state operate any schemes of compensation for particular products?

No, the state does not operate any such schemes.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

The manufacturer may be held liable based on the doctrine of liability for negligence regardless of contractual privity. In *Cooper and Nephews vs Visser 1920 AD*, the Appeal Court accepted that if the manufacturer's negligence had caused the loss, it could be sued despite the absence of privity between it and the purchaser.

The distributor will not be held liable in terms of product liability principles.

The retail supplier may be held liable contractually although there will often be no privity of contract between the seller and the ultimate consumer who suffers damage or loss as a result of a defect in the product sold. Such consumer may be left remediless, unless the consumer can prove a breach of warranty of some kind.

The same principles apply for the importer, whether in the capacity of a manufacturer or retail supplier.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

In terms of the Consumer Protection Bill, the manufacturer, importer and producer will have the obligation to recall products, but the commission established in terms of the Consumer Protection Bill will also be entitled to recall products if it has reasonable grounds to believe that any goods may be unsafe.

Until the Consumer Protection Bill has been promulgated the situation is that certain safety requirements or minimum standards may have been prescribed in regard to certain products by law often through standards authorities such as the South African Bureau of Standards (SABS) and other regulatory products. It is important for products to comply with such standards and in the event of failure or non-compliance, an obligation could exist to recall such products. A claim for failure to recall will be based on *delict* and liability follows only if the *omissio* was in fact wrongful; and this will be the case only if in the particular circumstances a legal duty rested on the manufacturer to act positively to prevent harm from occurring and he failed to comply fully with such duty. The causing of damage by means of conduct in breach of a statutory duty is *prima facie* wrongful.

1.5 Do criminal sanctions apply to the supply of defective products?

In terms of the Consumer Protection Bill a person may be convicted of an offence in terms of the Bill for, for example, hindering the administration of the Bill, but there is at present no specific criminal sanction which applies with regard to the selling of defective products. However, the South African general principles of criminal law can be utilised by the prosecuting authority to formulate charges.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The claimant must prove that the product is defective or faulty and, as a result thereof, caused the damage.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

South African Delictual Law distinguishes between factual and legal causation. According to the Appellate Division, the "*but for*" test applies with regard to factual causation. Different from factual causation is legal causation, which deals with the remoteness of damages and therefore no liability.

A claimant will therefore have to prove that the increased risk to which he/she was exposed to, without any warning about the existence of the risk, caused the harm. The increased risk must be causally connected with the injury suffered. Without proof of such nexus, the claimant will be unsuccessful.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

It should be ruled by the court that the claimant did not prove his case and the claim should be dismissed. The doctrine of contributory negligence applies in South Africa and may play a role to distribute liability between various parties.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Failure to warn about inherent or hidden dangers in a product does give rise to liability for the manufacturer. Warnings on a label or instructions in a brochure will be necessary in certain circumstances where the possibility of damage is foreseeable. The manufacturer should know the product it manufactured and must therefore be able to foresee the likelihood of certain events which may cause damage, as long as such events are not too remote.

The manufacturer should inform and warn the ultimate consumer in the event of the product manufactured reaching the consumer in its final form. In such event it should not be necessary for the intermediary to warn further. One would expect the manufacturer not to supply information to an intermediary which is of a warning nature and not also to warn the end user of such possible danger, especially if the product is in its final format and already packed and sealed to be sold on to a customer. In the event of an intermediary receiving information from a manufacturer and the intermediary is of the view that the consumer should be warned about an additional danger contained in the information received from the manufacturer, then the intermediary should either not supply the product further on in the chain or it should ensure somehow that the consumer becomes aware of such information about the product. The intermediary cannot just ignore information at its disposal which should be made available to the next entity in the chain of supply.

3 Defences and Estoppel

3.1 What defences, if any, are available?

In terms of Section 61 of the Consumer Protection Bill, only certain defences will be available to the producer, importer, distributor or retailer. The defences will be:

- That the unsafe product characteristic, failure, defect, or hazard that resulted in the harm, is only attributable to compliance with any public regulation.
- That the alleged unsafe product characteristic, failure, defect or hazard did not exist in the goods at the time that he was supplied.
- That it is unreasonable to expect the distributor or retailer to have discovered the unsafe product characteristic, failure, defect or hazard.
- That the claim for damages is brought more than three years after the damage occurred.

Prior to the promulgation of the Consumer Protection Bill, the position is:

- The product is not defective and was not used as intended or recommended or prescribed.
- Conclusive state of the art prior tests were done.
- Absence of negligence.
- Contributory negligence.
- Consumer contracted out of the right to sue.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

The Consumer Protection Bill introduces the state of the art defence. At present the position is that if the defendant pleads that the defect in the product was not discoverable given the state of scientific and technical knowledge, then the defendant will bear the onus to prove such allegation. The plaintiff will merely have to prove that the product is defective.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

The Consumer Protection Bill introduces this defence. However, at present such defence does not exist. It will only be a defence in criminal proceedings. In civil proceedings compliance with

legislation will not be a defence to prevent damages being awarded against a party.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

Any claimant may, within the law of prescription, claim damages independent of other similar claims lodged. Each case will be treated separately. Different claimants could have suffered different hardships and the facts of each case may also be different.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

Yes, defendants can join other defendants to a civil action in the same proceedings and seek a contribution to the award being made or claim that such joined defendant is solely liable. The running of prescription will be interrupted when papers are served on the defendant to be joined. Therefore, it would be more practical to join the defendant as soon as possible in the same proceedings because the running of prescription will then be interrupted. To join a defendant instead of bringing a separate action against such defendant will also save legal costs. There may also be some other advantages to join a defendant as a party to the action.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Yes, a defendant can plead that the plaintiff's actions caused the loss or contributed to the damages suffered. The court can make findings about the manner in which the plaintiff was negligent and the degree of such negligence. This will have an effect on the award made, if any, regarding the amount of damages suffered by the plaintiff.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

High Court trials are heard by a judge and Magistrate Court trials by magistrates.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

No, courts in South Africa do not have that power.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

In terms of our High Court Rules and our Constitution, actions can be instituted by groups of people with the same interest in South Africa, but these are not class actions as known in the USA.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

No. Only if the claimants ceded their right, title and interest to such body.

4.5 How long does it normally take to get to trial?

It depends in which legal jurisdiction the action was brought. On average it takes approximately one to one and a half years for a matter to be brought to trial.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

A court will hear points *in limine* and special pleas, for example, prescription of a claim first before it entertains the merits of the matter. Parties may also agree to split the merits of the case and quantum of damages of the claim and hear the merits of the case first, thus resulting in the saving of legal costs if the claimant does not succeed in proving the merits of its case.

4.7 What appeal options are available?

An automatic appeal from the lower court (Magistrates Court) to the Supreme Court is available.

From the judgment of a single judge an appeal to an appeal tribunal of three judges sitting in the Supreme Court is available. However, leave to appeal is required from the single judge. If leave to appeal is not granted, a petition to the Chief Justice will have to be made to obtain leave to appeal.

A further appeal from the three judges is available to the Appeal Court.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

A court will not appoint experts of its own accord. The parties to the action are entitled to present expert evidence. The nature and extent of the expert evidence are not restricted but a summary of such evidence must be made available to the counter party before the trial commences.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

South Africa does not have the deposition procedure.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

In terms of our discovery procedure, a party is obliged to make full

disclosure of all documents, tape recordings and correspondence relevant to the case and make copies of same available to the other side. The discovery procedure is usually completed by the time the first pre-trial meeting is held a few weeks before the trial commences.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Yes, but only if the relevant parties agreed to alternative dispute resolution mechanisms to resolve a dispute. Mediation and arbitration are well-known dispute resolution mechanisms in South Africa.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes, certain time limits do exist.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

A debt arising from *delict* or contract prescribes three years after it originated and therefore action must be instituted within such three-year period. Prescription shall commence to run as soon as the debt is due. A debt shall not be deemed to be due until the creditors have knowledge (or ought reasonably to know) of the identity of the debtor and of the facts from which the debt arises. The completion of prescription will be postponed in the event that the person against whom the prescription is running is a minor, or is insane, or is a person under curatorship. It is not within the discretion of the court to apply time limits. In terms of certain Acts of Parliament, periods of notice have been prescribed, and limits of time have been fixed within which actions must be brought.

In terms of the Consumer Protection Bill, the defence of prescription may also be raised.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Prescription will not commence to run in the event of the concealment of facts or a fraudulent act, preventing a claimant from having full knowledge of the facts on which its claim arises.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

All these remedies are available in South Africa.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

In terms of the Consumer Protection Bill, harm for which a person may be held liable includes:

- the death of, or injury to, any natural person;
- an illness of any natural person;
- any loss of, or physical damage to, any property irrespective of whether it is moveable or immovable; and
- any economic loss that results from the harm.

Prior to the promulgation of the Consumer Protection Bill, the following types of damages are recoverable: damages for breach of contract; damages for pain and suffering; patrimonial damages such as loss of income; medical expenses; and damage to property.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

No, they cannot.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

No, South African Law does not recognise punitive damages.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no maximum limit on the amount of damages recoverable provided that the damages claimed from the respective parties are proven by the claimant.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

Court approval is not a prerequisite for a settlement to be entered into. However, to ensure that the settlement agreement is enforceable, it should be made an order of court and in this process, the court is not entitled to interfere with the terms of the settlement, unless the court is of the view that the terms of the settlement is not in the public interest. Regarding claims on behalf of infants, such claims must be instituted by the guardian of the infant. The High Court, being the upper-guardian of all minors, will have to sanction the settlement agreement to ensure that the infant's interests are protected.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

No they cannot.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Yes, court fees are recoverable on a party to party scale which provides that the successful party is entitled to recover the court fees in terms of the High Court Rules as per a taxed bill of costs, subject to the discretion of a Taxing Master.

In the event that an order as to attorney and client costs is granted by the court, the successful party will be entitled to recover their own legal costs according to the Court Rules from the losing party as per the taxed bill of costs, subject to the discretion of a Taxing Master. In the event that an order as to attorney and own client is granted, the successful party will be entitled to recover all legal costs including the costs of their attorney.

7.2 Is public funding e.g. legal aid, available?

Yes, public funding is provided by institutions such as the Legal Aid Board, the Legal Resource Centre and certain Legal Aid Clinics.

7.3 If so, are there any restrictions on the availability of public funding?

Yes. A means test exists for the purpose of determining the indigence of an applicant for aid. In civil matters the income and assets of the applicant and/or his/her spouse are both taken into account to qualify for aid. However, certain restrictions exist regarding the types of claims and financial assistance is often not provided for monetary claims for damages based on contract and *delict*.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Contingency fees are allowed in South Africa. However, the "success fee" may not exceed the normal fee by more than 100%, provided that, in the case of claims sounding in money, the total of any such success fee payable by the client to the legal practitioner, may not exceed 25% of the total amount awarded or any amount obtained by the client in consequence of the proceeding concerned, which amount may not for purposes of calculating excess, include any costs.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

In terms of a judgment in the South African Court of Appeal delivered in 2004, an agreement in terms of which a person provides a litigant with funds to prosecute an action in return for a share of the proceeds of the action was not contrary to public policy or void. Third party funding is therefore permitted. Funding may be provided by way of any legitimate means.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in South Africa.

The common law principle, that negligence must be proved for a manufacturer to be held liable for a defective product, will change when the Consumer Protection Bill of 2007 has been promulgated. Manufacturers and retailers will be held strictly liable with the promulgation of the Bill. The third draft of the Bill was approved by the Cabinet on 5 December 2007 and it is anticipated that the Bill will become law during 2009. The Bill will introduce liability for damages caused by goods and will therefore change the Common Law with regard to liability in South Africa. The Bill will furthermore promote a fair, assessable and sustainable market place for consumer products and services and for that purpose, to establish national norms and standards relating to consumer protection, provide for improved standards of consumer information, to prohibit certain unfair marketing and business practises, to promote responsible consumer behaviour, to provide for harmonisation of laws relating to the protection of consumers, to promote a constant enforcement framework relating to consumer transactions and agreements. Furthermore, the Bill makes provision for a notification process in the event of a product being defective.

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Pieter has been the attorney for various large corporations in South Africa representing them in the United States of America, Britain and Europe.
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Involved in actions in New York in both Federal and State Courts on behalf of defendant corporations, where jurisdiction and forum non conveniens points were successfully taken. In view of various matters being dealt with in New York, Pieter has gained extensive knowledge about the New York legal system, which includes knowledge about class actions, punitive damages and jury trials.
Involved in the first HIV+ related case in South Africa and has been the attorney of record in various cases reported in South Africa.
Involved in an international court case involving the sale of a 1962 Ferrari GTO, which was the most expensive car deal in the world. The car was sold for £8m to a Japanese billionaire. The matter was heard in the courts of the United States of America and in Britain.

Spain

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

The Spanish legal system provides for the two general systems of contract and tort liability, in addition to a specific system of strict product liability which was introduced via the implementation to Spanish law of the 1985 EC Directive 85/374 on liability for defective products. Pursuant to Article 13 of this Directive, this strict liability system should not affect any rights an injured person might have under "the rules of the law of contractual or non-contractual liability" or "a special liability system". Accordingly, Article 128 of the Spanish Royal Legislative Decree 1/2007 Consumer's Act ("**Consumer's Act**") provides that the strict product liability system shall exist alongside the contractual or tort liability systems.

This specific system of product liability is based on **strict liability** (Articles 128 to 149 of the Consumer's Act). It enables an injured party to bring an action without having to prove any breach of contract, fault or negligence on the part of the producer, the cornerstone of this system being the notion of "defect". The defective product is defined by Article 137 of the Consumer's Act as "a product which does not provide the safety which a person is entitled to expect", taking all circumstances into account.

The producer owes the same duty towards any injured party, whether a contracting party or a third party. For strict product liability to apply, the claimant must prove that the product was defective, the existence of a damage (bodily injury or damage caused to property, under certain restrictions, see question 6.2 below) and the causal link between the defect and such damage.

Contractual liability arises in cases of damages to the product itself. The 1999 EC Directive 1999/44/EC on certain aspects of the sale of consumer goods and associated guarantees has been implemented into Spanish Law and is contemplated in Articles 114 *et seq*. of the Consumer's Act. Accordingly, consumers can use the remedies in force within the time limits foreseen in the Act when the product itself suffers the damage.

The injured party may also rely on the guarantee against hidden defects (Articles 1484 *et seq*. of the Spanish Civil Code). Under these provisions, the seller may be held liable where a defect, which is not apparent, renders the product sold unfit for the use for which it is intended, or diminishes the usefulness of the product to such a point that the injured party would not have acquired it or would not have paid the agreed-upon purchase price, had he or she known of the defect. The fact that the seller was unaware of the existence of such a defect is not a valid defence.

Tort liability constitutes an appropriate remedy when a party is seeking damages for an injury which does not result from the breach of a contractual obligation by the co-contracting party. Liability for fault is based upon Article 1902 of the Spanish Civil Code. In order for a claim in tort to be successful, the claimant must prove:

1. that the defendant has been negligent, i.e., failed to behave like a "reasonable man", or breached any obligation imposed by a statute or regulation;
2. that he has suffered a loss; and
3. a causal link between the two.

A breach of statutory obligations will usually give rise to an administrative sanction and to the obligation to compensate the damages caused.

1.2 Does the state operate any schemes of compensation for particular products?

Where there are multiple victims of the same harmful product, these victims should be properly compensated. The State has budgeted for various funds created by the legislator (e.g., *Real Decreto-Ley* 9/1993, dated 28 May for the victims of HIV contaminations caused by transfusions). The aim of such public compensation schemes is to give victims full and fast compensation, instead of having to go through long and expensive court proceedings. However, all these provisions subject the benefits of the scheme to the prior renouncement of actions against the public administration and civil servants.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Under strict product liability the producer (defined by Article 138 of the Consumer's Act as the manufacturer of a finished product, producer of raw material, or the manufacturer of a component) or the importer to the EU will be held liable of the damages caused by the defective product.

The distributor or retail supplier will be held liable under the same conditions as the producer if he is supplying a product which he knows is defective.

The distributor or the retail supplier may be held liable when the producer or the importer to the EU are unknown (Article 138.2 of

the Consumer's Act). He may, however, escape liability by designating, within three months from the time he is notified of the victim's claim, his own supplier or the manufacturer.

The distributor or retail supplier who compensated the consumer can still sue the producer, under the same rules as if he had been the victim, if he commences this action within one year of having paid the damages to the injured party.

Under contractual liability, because there are implied guarantees and obligations which bind the distributor and/or the retail supplier, these parties may often be held liable for the defect of a product (e.g., on the grounds of the guarantees against hidden defects, see question 1.1 above).

Under Article 1902 of the Spanish Civil Code, any party in the distribution chain may potentially be held liable if he has incurred in wilful misconduct or negligence.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Directive 2001/95/EC of 3 December 2001 on General Product Safety (hereinafter "**GPSD**"), which is aimed at protecting consumers from products that would not meet safety standards, was implemented into Spanish law by Royal Decree 1801/2003 dated 26 December 2003 ("**RD 1801/2003**"). In order to ensure this protection, national authorities have been granted additional powers and further obligations have been imposed on the manufacturers and distributors.

- Follow-up and recall obligations

Under the general principle of consumer safety all products sold in Spain must, when used under normal conditions or under abnormal conditions which are reasonably foreseeable by a professional, present the level of safety which one may legitimately expect and not endanger the health of persons.

The person responsible for putting a product on the market has a duty to take the necessary measures to be kept informed of any risk that his or her product may create and, where necessary, to withdraw and recall any product that may endanger the consumers (Article 4 of the RD 1801/2003).

Given that producers and distributors are under an obligation to act diligently and may not supply products which they as professionals knew (or should have known) did not meet the required standards, a failure to recall a defective product constitutes a fault, which may give rise to an action for compensation, should the other conditions of liability be fulfilled.

- Notification obligation

Producers and distributors are obliged to immediately notify the competent authorities of the *Comunidades Autónomas* if they discover that their product is dangerous (Article 6 of the RD 1801/2003). The failure to notify the authorities will not give rise *per se* to a sanction, but it will be taken into account in any civil, administrative or criminal proceedings concerning the product.

Due to the existence of the EU Rapid Information System ("**RAPEX**"), the notification to one Member State of a defect or danger automatically leads to the notification of all Member States if the product has been marketed in other EU Member States.

1.5 Do criminal sanctions apply to the supply of defective products?

The harmful effects of a product may constitute grounds for criminal sanctions. The action may be brought by the public prosecutor on his own initiative or following from a complaint filed by a victim. The prosecutions in matters of product liability may be based upon the alleged criminal conduct of the manufacturer, distributor and/or seller (for example, in the manufacturer knew that the product was potentially harmful but nevertheless decided to market it). In addition to the criminal conviction of the guilty party, the victim may obtain civil damages from such party before the criminal court.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The burden of the proof generally falls on the claimant (Article 217 of the Spanish Code of Civil Procedure). Pursuant to this principle, an injured party must prove that the supplier of a product is at fault, that he has suffered a legally recognised injury and that there is a causal link between the fault of the supplier and the damage suffered.

In strict liability cases, the injured party will have to prove the defect, the damage and the causal link between the defect and the damage suffered.

However, Article 217.6 of the Spanish Civil Procedure introduces the principle that the burden of proof must take into account the proving availability and easiness. Therefore, if the defect and the damage are proved, courts will tend to establish the presumption that the defect existed. As a consequence, the defendant will have to prove wrong the presumption. It is therefore advisable for manufacturers to carry on tests (e.g. expert's reports) that are not usually in the consumer's reach.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

The same principle relating to the existence of a causal link applies in the different liability systems. As a general rule, the damage must be the immediate and direct result of the supplier's breach. Whether there is a direct causal relationship will be determined on a case-by-case basis by the trial courts based on two principal theories of causation. The first, called the theory of "equivalent conditions", provides that an act or omission will be deemed to be the proximate cause of the damage, if such damage would not have occurred in its absence. The second theory, known as the theory of "adequate causality", provides that an act or omission will be deemed to be the proximate cause of the damage if, "given the normal course of events", this act or omission made it probable that the damage would occur.

Spanish courts have generally rejected the risk theory; however, in cases where the claimant has proved the defect and the damage they have accepted as a presumption that a causal link exists, thus inverting the burden of proof to the defendant, who will have to prove that it does not exist.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

In principle, there is no market-share liability in Spain.

Under the strict product liability system, if the producer or importer to the EU of the product cannot be identified, the supplier will be held liable provided that he does not inform the victim of the identity of the producer or the importer to the EU within three months of being notified of the claim of the injured person (Article 138 of the Consumer's Act).

In addition it should be noted that possible producers responsible for the damage will be held jointly and severally liable before the injured party. The producer who indemnifies the injured party will have a right of redress against the other parties who participated in the causation of the damage.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Under the strict product liability system, according to Article 137 of the Consumer's Act, the safety that one is entitled to expect must be assessed taking into account the "presentation of the product". As a result, any absence of sufficient warning of the potential dangerous effects of a product, in the notice of information, may be regarded as a defect. This was the case in the Ruling of the Appeal Court of Barcelona dated 18 April 2008 regarding the absence of warnings in the directions for use of the medicine.

The fact that the consumer received the product from a "learned intermediary" (e.g., a doctor prescribing to the patient the use of the product) does not exonerate the manufacturer from being held liable, as the fact that the intermediary did not inform the consumer as to the potential harmful effects of the product does not prevent the product itself from being classified as defective under Article 137 of the Consumer's Act. In the above-mentioned ruling, the Court understood that even though the doctors should have been aware of the possible risks, this does exempt the manufacturer from including the warning in the directions for use of the medicine, as these are part of the presentation of the product and the consumer is entitled to receive complete information.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Where all the conditions for civil liability are fulfilled, the producer may however be totally or partially exonerated from his liability:

Strict product liability: the producer may be completely exonerated from his liability pursuant to one of the five defences set out by Article 140 of the Consumer's Act. In particular, the producer may prove (i) that he did not place the product on the market, (ii) that the product was not intended to be sold or distributed by any means, (iii) that the defect did not exist when the product was placed on the market, (iv) that the product was manufactured complying with mandatory requirements, or (v) that the "state of scientific and technical knowledge" at the time when the product was placed on the market, was not such as to permit the discovery of the defect.

In addition, the producer may also be totally or partially exonerated from his liability if attending to the circumstances of the case the damage is due to a defect of the product as well as the fault of the victim or the act of a third party for which the victim is responsible.

Article 140.2 of the Consumer's Act provides that the manufacturer of a component of the finished product will not be held liable if he proves that the defect is due to the design of the product to which it has been incorporated or due to the instructions given by the producer.

Force majeure: the effect of which is to totally exonerate the producer from his liability. It is traditionally defined as an event which is unavoidable, unforeseeable and outside the control of the defendant. *Force majeure* can result from the fault of the victim or the act of a third party, as long as they present the above-mentioned characteristics. The supplier may invoke *force majeure* regardless of the type of claim brought against him. As regards contractual liability, parties may in their contract exclude some events from being considered as *force majeure* (e.g., strikes).

Contractual liability: in addition to *force majeure*, a producer or retailer of a product may limit or eliminate the risk of a product liability claim being made against him based on contractual law by including a clause to that effect in the contract. However, such a clause will be ineffective if the injury caused to the user resulted from an intentional act or omission (wilful misconduct - *dolo*) or to gross negligence of the supplier. These clauses are always ineffective in contracts entered into between a professional and a consumer.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Article 140.1.e) of the Consumer's Act does provide for a development risk defence. The producer will be exonerated from his liability, if he proves that the "state of scientific and technical knowledge" at the time when the product was placed on the market, was not such as to permit the discovery of the defect. However, this cause of exoneration may not be raised in relation to medicines or food.

The defendant will have the burden to prove that the "state of scientific and technical knowledge" at the time when the product was placed on the market, was not such as to permit the discovery of the defect.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Under the strict product liability regime the producer may be held liable even though he complied with professional rules or applicable standards, or if the product he manufactured is covered by a marketing authorisation.

However, Article 140.1.d) of the Consumer's Act does provide for a defence resulting from the compliance with specific regulatory or statutory requirements. In order to avoid liability, the producer will have to demonstrate that the defect of the product results from his compliance with requirements imposed by imperative statutes or regulations.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

The principal effect of a judgment rendered by Spanish courts is to bar the suit from being brought again by the same parties on the same event when it has already been the subject of a previous legal cause of action that has already been finally decided between the parties (*res iudicata*), avoiding multiple judgments being handed down between the same parties based on the same grounds. In civil law systems, *res iudicata* does not preclude the possibility of other plaintiffs of bringing an action on similar factual issues and legal causes of action, against the same defendant. However, the subsequent proceedings can be suspended (*litispendens*) until a ruling is rendered in the first proceedings.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

The act of a third party does not exonerate the liable party from his or her liability towards the victim, but only allows him or her to recover from this third party the amount of damages which corresponds to this third party's direct contribution to the damage. A third party may therefore be forced to intervene in the same proceedings. The liable party sentenced for the whole damage may also later, by way of a subrogation action, obtain payment from the third party. In such a case, the party who brings a claim against the third party after he has been declared liable has to do so no later than twelve months counting from the date on which he paid the indemnity (Article 143 Consumer's Act).

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

The fault of the victim or of a person for whom he is responsible can constitute contributory negligence, when it has directly caused the injury, even partially. Such a fault may partially or totally exonerate the defendant and thus lead to a shared liability between the defendant and the claimant (Article 145 Consumer's Act). The extent of the damage for which the defendant will be liable will depend to what extent the victim was himself at fault for causing the damage.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

Spanish civil proceedings are always conducted by a judge.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Under Spanish law, there are no expert assessors who assist the judges and sit with them in court.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

Article 11 of the Spanish Civil Procedure recognises legal standing to certain groups of consumers and consumer associations to defend the interests of its associates and of the association, distinguishing two different scenarios:

(a) When a group of affected consumers is determined or easily determinable, Spanish law recognises legal standing to consumer associations, legal entities incorporated to defend consumer's interests and to the groups of affected consumer. This action is called collective action.

(b) When the persons affected by the damage are undetermined or not easily determinable, Spanish law recognises legal standing exclusively to consumers associations. This action is called undetermined action (*acción de intereses difusos*)

Any consumer who has legitimate interest may intervene in the proceedings initiated by consumer associations.

Once class actions have been admitted by the court, the proceedings will be made public through the media in order to enable affected consumers to join the proceedings. In the case of collective actions, the initiation of proceedings must have been announced to the affected consumers prior to the filing of the claim. The consumer will be able to intervene at any moment but will only be allowed to participate in those procedural steps that have not yet taken place.

When the action is undetermined, the announcement through the media of the proceedings will suspend them during two months. After this suspension, consumers will no longer be able to intervene in the proceedings. However, a decision favourable to the consumers in an undetermined action will also be enforceable by consumers who did not take part in the proceedings but fulfil the requirements set out by the decision.

The Spanish class actions regime provides therefore for an opt-in procedure.

In addition, the exercise of a class action does not prevent an individual from initiating a claim on his own, though the subsequent proceedings may be suspended if the parties request so, until a decision is rendered in the first proceedings.

Class actions are not frequently brought in Spain.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Yes, claims can be brought by consumer associations, legal entities whose purpose is to defend consumer's interests, or groups of affected consumers (Article 11 Spanish Civil Procedure).

4.5 How long does it normally take to get to trial?

The length of the proceedings will vary from case to case. Generally the trial takes place after 6 to 14 months following the filing of the claim.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Ordinary civil proceedings provide for the celebration of two

hearings. In the first hearing (*audiencia previa*) the court will decide upon any procedural issues that may impede the continuation of the proceedings or determine their ending. These issues are, among others, lack of capacity or representation, absence of joinder, *res iudicata*, *litispendens*, or inadequate procedure.

Issues of fact cannot be decided in the preliminary stages.

4.7 What appeal options are available?

The main appeal options foreseen under Spanish law are:

(a) **Ordinary appeal:** This appeal is filed against the final decisions and judgments rendered by the First Instance Courts (*recurso de apelación*). The appeal is decided by the Court of Appeal who can review the facts as well as the application of the law.

(b) **Extraordinary appeals:** These appeals are filed against the judgments issued by the Court of Appeal and it is decided by the Spanish Supreme Court. In order to file a cassation appeal (*recurso de casación*) the case must meet one of the following requirements: (i) affect the protection of fundamental rights; (ii) the amount involved exceed 150,000 Euros; or (iii) cassational interest of the decision of the Court of Appeals. In order to file an procedural infringement appeal (*recurso extraordinario por infracción procesal*) the case must meet one of the following requirements: (i) infringe laws regarding jurisdiction and competence; (ii) infringe law regarding the ruling; (iii) infringe laws regarding the equitable treatment of the parties; or (iv) infringement of fundamental rights recognised in Article 24 of the Spanish Constitution.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Parties are entitled to file expert witness reports together with their claim or answer to the claim. Parties can also ask the court to appoint an expert witness.

There are no restrictions on the nature or extent of the expert evidence.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

In civil proceedings there is generally no pre-trial deposition. It will only be possible to practice evidence prior to the commencement of proceedings in exceptional circumstances: when the claimant foresees and proves that due to the nature of the evidence it might turn impossible to practice it at a later moment. The claimant may also seek measures to secure evidence. Provided these exceptional circumstances are met, factual or expert witnesses may be required to present themselves for pre-trial deposition.

Expert reports are filed together with the parties' pleadings. The reports requested by the parties must be filed in any event prior to the preliminary hearing (*audiencia previa*), and the claimant is entitled to request an extension of his expert report if the report filed by the defendant raises issues not dealt with in the claimant's expert's report.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

There are no proceedings for discovery or disclosure of documents under Spanish civil procedure. Indeed, as a general principle, the parties freely decide what factual evidence they want to file in support of their claims. However, Article 328 of the Spanish Code of Civil Procedure allows a party to request from the other parties the disclosure of a document that the party does not have. The documents to be disclosed must be correct and precisely identified.

In specific circumstances and at the discretion of the judge, a third party can be requested to file or disclose a specific document which is in its possession if the court considers it is essential for the case.

Before proceedings are commenced, a party may also request from a judge to seek elements of proof on which the solution of the dispute may depend (e.g., request the defendant to disclose a document that is in his possession; request the defendant to disclose his insurance contract; in collective actions, take the necessary measures to identify the affected consumers when they are easily determinable).

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Arbitration is an available alternative method of dispute resolution. Parties may choose to resort to arbitration either in their initial contracts (in an arbitration clause) or after a dispute has arisen.

Arbitration clauses between suppliers and consumers will only be valid if they refer the dispute to the consumer arbitration system. Within the consumer arbitration proceedings, the parties will be first encouraged to settle the dispute through mediation.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes there are time limits, which vary depending on the action to be brought.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

Time limits are set out by law and are compulsory for the judge, as the latter has no discretionary power to alter or ignore them.

Under the **strict product liability** regime, the producer may be found liable for ten years after the product was put on the market, provided that no judicial claim has been initiated previously (Article 144 of the Consumer's Act). Within such a period of time, the victim's claim must be filed no later than three years after it suffered the harm provided that the person responsible for the damage is known (Article 143 of the Consumer's Act). If the plaintiff is a supplier who has not manufactured the product but is sued by the injured party, he may bring an action against the manufacturer under the same rules applicable to the injured party, no later than one year after he paid the indemnity to the injured party (Article 143 of the Consumer's Act). After ten years from the date on which the product was put on the market, a claim can still

be filed on classic grounds of contract or tort liability provided the time limitation for such actions has not expired.

Actions brought under **contractual liability** are barred after fifteen years (Article 1964 of the Spanish Civil Code).

Actions in **tort liability** are barred after a one-year period which runs from the moment when the victim had knowledge of the injury (Article 1968 of the Spanish Civil Code).

The age or condition of a party, do no affect the calculation of any time limit.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Concealment and fraud may affect the running of time limits if they hinder the claimant from knowing who the party responsible for the damage is.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

Monetary compensation as well as injunctions to do, injunctions to cease to do and injunctions to pay are available remedies. Bearing in mind the nature of the actions that might be brought in product liability cases, monetary compensation will be the most commonly used remedy.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Under the strict product liability system, pursuant to Article 129 of the Consumer's Act, the recoverable damages are the damages caused by the defective product to the victim itself (i.e., death or personal injury) and to goods (other than the defective product itself) provided that the said goods are aimed for private use and the victim has used them principally for that purpose.

Damages to the product itself are not covered under the strict product liability regime (Article 142 of the Consumer's Act).

In line with the 1985 EC Directive as regards the ceiling on the producer's liability for death or bodily damage caused by identical products with the same defect, the maximum amount of liability arises to 63,106,270.96 Euros (Article 141 Consumer's Act).

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Only the loss directly caused by the product and which the injured party has actually suffered in the past or which the victim is certain to suffer in the future may give rise to liability for damages. Therefore, the possible future damage may not be compensated.

As for medical monitoring expenses incurred in order to control the evolution of the risks of illness or injury associated with the defective product, or as regards the costs of a surgical operation preventing the risk created by the defective product, they are generally not recoverable.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

In the Spanish system of civil liability, the damages granted to the injured party are supposed to compensate the injury, not to punish the liable party. Their amount must correspond to the exact extent of injury. Therefore, there are no punitive damages under Spanish civil law.

In a contract, the parties may stipulate a liquidated damages clause which may provide for an amount of damages which exceeds or limits the amount of damages resulting from the sole breach of a contractual duty. The judge has a discretionary power to reduce or increase the amount fixed by such clauses, if the main obligation has been partially or irregularly fulfilled by the debtor (Article 1154 of the Spanish Civil Code).

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

The only limit applies to the producer's liability for death or bodily damage caused by identical products with the same defect. The maximum amount of liability in those cases arises to 63,106,270.96 Euros (Article 141 Consumer's Act).

There are no maximum limits for the total amount that a liable party may be required to pay to injured parties regarding damages to property caused by the defective product.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

Court approval is not required for the settlement to be applied by the parties, which will be governed by general contract law. Nevertheless, once the judicial proceedings have been initiated the parties may request the court to ratify their settlement agreement. If the settlement is ratified by the court, in the event it is not fulfilled, the parties may request its judicial enforcement.

There are no special rules for the settlement of groups/class actions.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Government authorities concerned with health and social security matters are entitled to claim against the party responsible for the damage the reimbursement of treatment costs, unemployment benefits or other costs paid in respect of the injury allegedly caused by the product.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

One must here distinguish between the court fees, the other

incidental expenses, i.e. the procedural costs which are strictly necessary pursuing the suit, and the other expenses incurred by a party in respect to the dispute.

(a) Pursuant to Article 394 of the Spanish Code of Civil Procedure, the successful party may be able to recover the procedural costs from the losing party if (i) all claims made by the successful party are accepted, (ii) all claims brought by the losing party are rejected, and (iii) provided that the court does not find that the case raised serious factual or legal doubts. The recoverable incidental expenses can be, e.g., the translation costs, the experts' fees, the witnesses' expenses, the counsels' fees and proctor's fees.

The only legal limit to these expenses is where there are several successful parties. In such case, the losing party will only have to pay for these concepts up to one third of the amount in dispute to each of the successful parties. This limit will not apply if the court finds that the losing party behaved in a reckless manner.

(b) Any other legal costs incurred by a party, such as the legal fees when they are freely determined between the lawyer and his or her client, are generally not recoverable. The lawyers' fees are usually determined in accordance with the criteria established by the bar associations.

(c) Court fees are not recoverable.

7.2 Is public funding e.g. legal aid, available?

Legal aid is available in Spain and consists in a financial aid (total or partial) in proceedings before State courts (direct payment by the State to the appointed counsel).

7.3 If so, are there any restrictions on the availability of public funding?

Jurisdictional aid is granted to individuals who can prove that their income is too low to afford access to justice.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Contingency fee arrangements ("*quota litis*") have been forbidden in Spain until very recently. The Spanish Supreme Court rendered a decision on 4 November 2008, which recognised the validity of strict contingency fee arrangements.

Nevertheless, until now it was possible to enter into a fee agreement with the client stipulating an increase of fees in the event of a particularly positive result and the calculation of which is set out in advance.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Spanish law does not establish any provisions that forbid third parties to fund the victim's claims.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Spain.

It is worth highlighting the recent decision from the Spanish Supreme Court admitting the validity of contingency fee arrangements where the lawyer's fees will exclusively depend on the result of the case ("*quota litis*") since these kind of fee arrangements were previously forbidden.

This possibility might entail an increase of class actions proceedings regarding product liability issues.

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With over three and a half thousand people operating from 27 offices in Europe, Asia, the Middle East and the USA, Lovells is one of a small number of truly international law firms.

Lovells has an outstanding product liability practice covering all aspects of product liability including risk prevention and management, compliance with product safety regulations, product recalls and personal injury claims, with particular emphasis on multi-party and cross-border litigation. The practice operates in all key jurisdictions with over 90 highly experienced practitioners globally.

Our lawyers have been closely involved in many of the major product liability issues over the last decade, having advised on a wide range of products including pharmaceuticals, food and drink, motor vehicles, tobacco, mobile phones, aircraft, trains, vaccines, cosmetics, blood products, medical devices and asbestos.

Lovells' product liability lawyers are supported by dedicated Science and Project Management Units.

To find out how Lovells can help you around the world, please contact:

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

Product liability is primarily regulated by the Product Liability Act (PLA) based on the EC directive 85/374/EEC. The PLA provides for strict liability for personal injuries incurred as a result of a defect in a product. Liability is also strict for damage caused by a defective product to property (other than the defective product itself) of a type ordinarily intended for private use or consumption which, at the time of the damage, was used by the injured person for his own private use or consumption. Agreement clauses contravening the PLA, e.g. by limiting compensation for personal injury, are invalid.

In addition, a number of specific acts stipulate strict liability for certain causes of injury or damage, *i.a.* electricity, inflammable or explosive goods, nuclear activities and activities harmful to the environment.

An injured party may also base a product liability claim on the general rules of the Tort Liability Act (TLA). Liability for personal injury or property damage under the TLA is based on negligence (or intent). The wider scope of the TLA makes it necessary *i.a.* for claims for damage to property not intended or used for private use or consumption, e.g. in business and industry. The TLA does not apply when liability is covered by an agreement (unless there is gross negligence or intent).

Contractual liability therefore often plays a role for product liability between businesses, but also for damage caused to the product itself as this is neither covered by the PLA nor the TLA. Contractual liability can follow from an express or implied warranty or from the Sale of Goods Act. The Consumer Sales Act and the Consumer Services Act provide further liability for damage to consumers' property in contractual relationships between consumers and businesses.

1.2 Does the state operate any schemes of compensation for particular products?

There are a number of insurance schemes that provide for strict liability for particular products and situations. The state manages an insurance and compensation scheme for work-related injuries. There are also mandatory insurance requirements for injuries and damage due to motor vehicle traffic and personal injuries due to medical treatment. In addition, there is an industry-wide private insurance scheme for damage caused by pharmaceutical products.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

According to the PLA, anyone who has produced (i.e. manufactured, extracted or grown) a product or imported the product into the European Economic Area for the purpose of putting it into circulation, has a primary liability for the defects of that product. If the defective product was a component of another product, both the producer of the component and the producer of the finished product are liable. In addition, anyone who has marketed the product under his own name or trade mark is liable. As a secondary responsibility, any distributor or "retail" supplier of the product is liable unless he can identify the producer or importer of the product. In case there are multiple liable parties, they are considered jointly and severally liable.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

The Product Safety Act, based on the EC directive 2002/95/EEC, stipulates that a producer that has put a dangerous product into circulation shall, without delay, recall the product from any distributor that holds it, if this is necessary to prevent injury. Should this measure not be sufficient to prevent injury, the producer shall, without delay, recall the product from any consumer that holds it. A product is considered dangerous if it, during normal or reasonably foreseeable use and life span, presents more than low risks for injury and or if the risks are not compatible with the product's intended use.

A failure to recall a dangerous product does not affect liability under the PLA, but may constitute negligence in liability under the TLA.

Further, a business may be ordered by the appropriate authority to issue a recall under penalty of a fine and may be fined for failing to issue a recall.

1.5 Do criminal sanctions apply to the supply of defective products?

Not generally. However, responsibility according to the Criminal Code for the crimes of carelessly causing injury or death to other persons or carelessly exposing them to grave danger may

theoretically be applicable. Also, for some specific products, e.g. medical technical products, there are criminal sanctions for supplying defective products.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

A person claiming compensation according to the PLA has the burden of proving (i) that he has incurred injury or property damage, (ii) the existence of a defect in a product, and (iii) that the injury or property damage was caused by that defect.

A person claiming compensation according to the TLA must prove (i)-(iii) above and also (iv) that the defect was caused by the defendant's negligence.

A product is considered defective when it is less safe than a person is entitled to expect. So-called systemic defects, i.e. the known and accepted risks or effects of certain products, e.g. known side effects of pharmaceutical products or the effects of alcohol or tobacco, do not fall within the scope of the PLA.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

There is no established standard of proof of causation for product liability. It would however not be enough to show an increased risk of injury. Rather, the claimant must prove that the injury was caused by the defect in the product. In cases where causality can be unclear or complex, e.g. environmental or medical injuries, the courts have been known to apply somewhat lower standards of proof for causation.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

There is no market-share liability. However, any producer that cannot show that he was not responsible for putting the defective product into circulation is liable. If more than one producer is thus considered responsible, they are jointly and severally liable.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

The Product Safety Act stipulates that a producer that has put a dangerous product into circulation must warn of the risks for damage and injury and inform consumers of how it can be avoided. While failure to warn does not directly give rise to liability, insufficient information and documentation about a product may be considered a defect in the product according to the PLA and may therefore, provided that it can be established that this defect caused a damage or injury, be grounds for a claim under the PLA.

There is no principle of learned intermediary in Swedish law.

3 Defences and Estoppel

3.1 What defences, if any, are available?

A number of defences can be made against a claim under the PLA. If the defendant proves (i) that he did not put the product into circulation, (ii) that it is probable that the defect did not exist at the time he put the product into circulation, (iii) that the defect was caused by compliance with mandatory regulations by a public authority, (iv) that the product was not produced by him for sale or for any form of distribution for economic purpose nor produced by him in the course of his business, or (v) that the defect, given the scientific and technical knowledge at the time the product was put into circulation, was not discoverable, he is not liable under the PLA.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Yes, see question 3.1 above. The producer has the burden of proof regarding discoverability. There is unfortunately no Swedish case law regarding the standard of proof for such a defence.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Yes, but only if the defect causing damage was due to such compliance and only if the requirements were mandatory.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

There is no issue estoppel preventing different claimants from litigating the same issues of fault, defect or damage in separate trials. Between two parties, the same issues may not be re-litigated if already tried in earlier proceedings.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

Defendants can seek contribution from a third party, however only

in subsequent proceedings against such third party.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Yes, defendants can allege that the claimant's actions caused or contributed towards the property damage or personal injury and argue that the compensation therefore shall be reduced. Compensation for personal injury may only be reduced if the injured party's contribution was grossly negligent or intentional if the claim was brought under the TLA. Negligence is sufficient for reducing a claim under the PLA.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

Most civil cases (including all product liability cases) are tried by a panel of three judges. Cases regarding lesser amounts, or when the parties consent thereto, may be tried by a sole judge.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

Yes, in theory the court could appoint technical or other experts to sit with the judge, although this is very rare. The court may also appoint experts to give expert testimony (see question 4.8 below).

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

The Group Action Act sets out the procedure for dealing with multiple claims. A group action may be initiated by (i) a natural or legal person with a claim covered by the group action, (ii) a non-profit organisation representing consumer or employee interests, or (iii) a suitable public authority (e.g. the Consumer Ombudsman). The group action has legal effect on all members of the group, even if they are not parties to the case.

A group action may be initiated if (i) it is based on the same or similar circumstances for the group members' claims, (ii) the grounds for such claims are not manifestly different, and (iii) if the court finds that the claims, the group and the representative are appropriate for a group action.

The procedure is 'opt-in', meaning that potential group members who, after being informed of the group action by the court, wish to be included in the group must notify the court else be deemed to have left the group.

Unless initiated by an authority, a group action must have a member of the bar as counsel (which is not a requirement for any other procedures in Sweden).

Group actions are very rare in Sweden.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Yes, see question 4.3 above.

4.5 How long does it normally take to get to trial?

The time to trial varies greatly on the circumstances of the particular case and between the different district courts. As a general rule, it takes between one and three years to get to trial.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Yes, when appropriate, the court may decide preliminary issues through a separate judgment on one of several issues that are each individually of immediate importance to the outcome of the case. The matters thus tried may relate to issues of law, to issues of law and fact, but not to factual issues only. There is no trial by jury and these issues are decided by the judge or panel of judges.

4.7 What appeal options are available?

A judgment by the district court may be appealed to the court of appeal, which will normally grant leave to appeal unless the issue is completely clear. A judgment by the court of appeal may be appealed to the Supreme Court. The Supreme Court will generally only grant leave to appeal if a case is assumed to be of value as a precedent.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The court may appoint an expert to assist it. The parties may also present expert evidence. There are very few restrictions on presenting evidence and evidence will only be dismissed if the court deems it manifestly unnecessary.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

There are no pre-trial depositions in the Swedish procedure, nor are statements from factual witnesses used. Witness statements/expert reports by expert witnesses are generally required prior to trial.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

There is no pre-trial discovery in the Swedish procedure. A party may request the other party, or any third party in possession of certain documents, to disclose documentary evidence at any time during the procedure. Such a request must however be specific and refer to a certain identified document or set of identified documents assumed to have value as evidence and may be denied if disclosure of the document(s) would reveal business secrets.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

In principle, a product liability claim could be settled through arbitration if the parties so agree. In practice, it is rare in product liability cases as an arbitration agreement involving a consumer or

other natural person would likely be set aside by a court as unreasonable.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

Yes there are.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

The time limits vary depending on what the claim is based on and the court may not choose to disapply them. They must, however, be invoked in order to be applicable.

A claim under the PLA must be brought within three years from the time when the claimant discovered, or ought to have discovered, the defect. In no event may an action be brought later than ten years after the defective product was put into circulation.

A claim under the TLA must be brought within ten years from the time of the act (or omission) that caused the damage. A claim for damage in a contractual relationship regarding the purchase of goods must be brought within two years from the time the contract was entered into, if the parties have not agreed otherwise. The time limit under the Consumer Sales Act and the Consumer Services Act is three years, unless the vendor has offered a longer warranty.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Concealment or fraud does not directly affect time limits. Concealment or fraud may however indirectly affect the time limit according to the PLA as it may determine the time when the claimant discovered or ought to have discovered the defect.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

The primary remedy in Sweden is monetary compensation, but injunctive or declaratory relief is available under certain circumstances. A request for a declaratory relief in a product liability case may e.g. be granted if the damage is difficult to assess and the time limit for bringing a claim is approaching.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Damage to the product itself is not covered under the PLA or the TLA. If there is an agreement between the parties, such damage may be compensated through the agreement or the general rules of the Sale of Goods Act.

Bodily injury and mental damage is recoverable under the PLA and TLA and compensation for such damage covers (i) reasonable medical costs and other associated costs, (ii) compensation for present and future loss of income, (iii) certain compensation for disability, disfigurement and scars, and (iv) certain compensation for pain and suffering.

Damage to property of a type ordinarily intended for private use or consumption which, at the time of the damage, was used by the injured person for his own private use or consumption is recoverable under the PLA less a deduction of SEK 3,500. There is no corresponding deduction under the TLA. Compensation for property damage covers repair or replacement costs up to the market value of the damaged property.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

No, unless a defective product has already caused damage or injury, damages cannot be recovered.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages in product liability cases do not exist under Swedish Law.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no stipulated limit on damages recoverable. A court may however reduce the amount of compensation for a claim or series of claims if considered unreasonably burdensome for the defendant.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

All settlements of group actions must be approved by the court. There are no special requirements for settlements in other product liability cases.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

No, not in general.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The general rule in Sweden is that the successful party can recover every cost deemed necessary for its pleading of the case, including court fees, expenses, legal costs and counsel fees, from the losing party.

7.2 Is public funding e.g. legal aid, available?

Yes. In addition, most natural persons in Sweden have insurance that covers legal expenses up to a limited amount.

7.3 If so, are there any restrictions on the availability of public funding?

Public funding is only available for persons with limited resources that do not have requisite insurances and only covers 100 hours of legal work.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Contingency fees are generally not allowed by the Swedish Bar Association (however a form of contingency fee is allowed in group actions). For non-lawyer counsel, there is no such restriction. Contingency fees are rare in Sweden.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Third party funding of claims is permitted without restrictions.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Sweden.

The Supreme Court (NJA 2008 p.100) has confirmed that a government authority does not, in the absence of explicit support in law, have a right of recourse against a manufacturer of a defective product for costs or compensation disbursed to users of the defective product. In order to contain a salmonella outbreak related to the feed, a number of pig farmers were forced to slaughter their pigs. The farmers were compensated for part of their losses by the Swedish Board of Agriculture, but the Supreme Court found that the Swedish Board of Agriculture did not have a right to claim compensation from the feed producer for its disbursements to the farmers.

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

In Switzerland, product liability may be based on the Product Liability Act ("PLA") (see (a) below), tort (see (b) below) and contract law (see (c) below). A product liability claim may furthermore be based on statutes regulating specific kinds of products, industries or activities which contain product liability related provisions (see (d) below). Since the PLA provides only for a supplemental cause of action it does not affect any rights which a claimant may have based on other legal grounds. Thus, an injured person may base a claim on the PLA or alternatively on tort, contract or public law (Article 11 (1) PLA).

a) The PLA provides for a strict liability of manufacturers, importers and suppliers for personal injuries and damages to items of property in private use caused by defective products. A product is defective pursuant to the PLA if it does not provide the safety which a person is entitled to expect. The provisions of the PLA resemble to a large extent the EEC Directive 85/374 on product liability.

b) General tort law provides for a fault-based liability of any person who unlawfully causes damage to another (Article 41 *et seq*. of the Swiss Code of Obligations ("CO")). However, liability based on tort law is predominantly derived from the liability of the principal (Article 55 CO). Pursuant to this provision, a principal, e.g. a company, is liable for damages caused by its employees or other auxiliary persons in the course of their employment or business. With regard to this liability of the principal the law provides for a reversal of the burden of proof: it is not the claimant who has to prove the fault of the principal but the principal has to prove that he has taken all precautions appropriate under the circumstances in order to prevent damage of that kind. Due to the tough conditions as to such precautions set by the Federal Supreme Court, the fault-based liability of the principal comes in effect close to a strict liability. Since tort law provides a basis to recover a wider scope of damages compared to the PLA, it remains an important cause of action for product liability claims in Switzerland. Although the following comments mainly refer to product liability based on the PLA, references will therefore also be made to relevant aspects of other causes of actions, in particular tort.

c) Under contract law damages may be recovered based on general contractual liability (Article 97 *et seq*. CO) or based on special contractual provisions, e.g. sales warranty (Article 197 *et seq*. CO) or the liability of the contractor (Art. 368 *et seq*. CO). While contractual liability is generally fault-based, Article 208 (2) CO exceptionally provides for the strict liability of the seller for direct damages. Damages can, however, in principle only be recovered based on contract law if the injured person and the defendant have a contractual relationship. Hence, contractual liability plays only a subordinate role in product liability litigation.

d) Finally, product liability related damages can be recovered based on liability provisions of public law regulating specific kinds of products, industries or activities, e.g. Article 27 of the Explosives Act.

The civil procedure in cantonal courts is governed by cantonal codes of procedure (which differ to quite some extent, depending on the canton and the issue). In general, the following comments only refer to civil proceedings in the Canton of Zurich.

1.2 Does the state operate any schemes of compensation for particular products?

Switzerland does not operate any schemes of compensation for particular products.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

Within the scope of the application of the PLA the "producer" is strictly liable for injuries and damages caused by a defective product. The statute provides for a broad definition of the term "producer" which includes (pursuant to Article 2 (1) PLA):

- the manufacturer of a finished product, the manufacturer of a component part as well as the producer of any raw material (lit a);
- any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer (lit b); and
- any person importing a product for sale, hire, leasing or any from of distribution in the course of his business into Switzerland (lit c).

Each supplier of a product is subsidiarily liable if he does not disclose the identity of the producer or the person who supplied him with the product and, if applicable, the importer upon request of the injured person within a reasonable period of time.

The claimant is burdened to prove that the defendant is a producer within the definition of Article 2 PLA.

In general, tort and contract law provide for a fault based liability of manufacturers and/or suppliers.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

The PLA does not contain any provisions on the recall of defective products. However, such duty arises pursuant to legal doctrine under tort law (Article 41 and 55 CO). In Swiss law, legal doctrine - being defined as legal treatises written by scholars, university professors, lawyers etc. - has, in principle, the same relevance as case law (*cf.* Article 1 (3) Swiss Civil Code).

Pursuant to such doctrine, a producer has a duty to monitor its products after sale in order to take the appropriate measures if hitherto unknown sources of danger give rise to risk of damages. If a producer realises that his product might lead to damages, he has to take all appropriate measures to prevent potential future damages. This includes the obligation to, if possible, immediately change the design of the product or otherwise halt production and/or to change the relevant documentations and instructions. It furthermore obliges the producer to take all appropriate measures to prevent damages resulting from products already put into circulation, be it through the publication of new instructions and warnings or via a recall of the respective products.

Furthermore, statutes regulating specific kinds of products, industries or activities, contain duties to monitor, recall or warn if product defects are discovered, e.g. Art. 59 of the Pharmaceutical and Medicinal Products Act.

1.5 Do criminal sanctions apply to the supply of defective products?

The PLA does not provide for criminal sanctions. However, criminal liability might arise under the Swiss Penal Code (SPC). In product liability cases criminal liability will usually arise from negligent bodily injury (Article 125 SPC) and involuntary manslaughter (Article 117 SPC).

Pursuant to Article 102 SPC, not only individuals, but also a company can be liable under the Penal Code if the responsible individual cannot be identified within the organisation and the criminal act occurred within the company's course of business.

Additionally, certain statutes governing special products, industries or activities provide for criminal sanctions (e.g., Article 13 of the Federal Act on the Safety of Technical Installations and Appliances).

However, the conditions for criminal sanctions differ from those of the PLA, tort and contract law. A liability arising under the latter therefore does not lead automatically to criminal sanctions.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

In order to establish a claim under the PLA, it is for the claimant to prove that the product did not provide the safety that one is entitled to expect as well as the damage. The claimant furthermore has to show that the defendant is a producer within the definition of Article 2 PLA.

While in tort the burden to prove fault is usually on the claimant (Art. 41 *et seq.* CO), this rule is significantly modified in product liability cases since these are predominantly based on the liability of the principal. For the latter cause of action the law provides for a reversal of the burden of proof of fault: it is not the claimant that has to prove the fault of the principal but the principal has to prove that he has taken all precautions appropriate under the circumstances in order to prevent damage of that kind.

For claims based on breach of contract (Art. 97 *et seq.* CO) the defendant is generally burdened to prove the absence of fault.

Under all product liability regimes it is for the claimant to prove his damage and a causal link between such damage and the defect or breach of duty.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

In order to establish liability, the claimant seeking relief has to prove a so-called "adequate causation" between the defect of the product and the injury or damage. A defect constitutes an adequate causation for an injury or damage if the defect is in accordance with everyday experience and the usual course of events suitable to cause the damage. The damage therefore has to be caused by the defect to a substantial degree, mere natural causation is not sufficient.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

A person can only be held liable if it can be proven that he is a producer within the definition of the PLA. However, each supplier of a product is subsidiarily liable if he does not disclose the identity of the producer or the person who supplied him with the product. Therefore, an injured person can recover the damages from the supplier if it cannot be established which of several possible producers manufactured the defective product.

If more than one producer contributed to the defect they are jointly and severally liable. The claimant does not need to establish which of these single contributions effected the damage.

There is no market-share liability in Switzerland.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

Pursuant to Article 4 (1) PLA, a product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account. One circumstance to be taken into account is, according to the exemplary enumeration of Article 4 (1) PLA, the presentation of the product. "Presentation" is widely interpreted and includes all kinds of information, advice and warnings issued by the producer.

In general, the producer of a product is obliged to instruct consumers and users on how to use the product safely and warn regarding potential dangers. A product which is otherwise free from defects can still be legally defective, if the producer failed to instruct the consumer properly. On the other hand, a product with an inevitable residual risk can be legally free from defect if the producer issues proper instructions and warnings. However, such instructions and warnings can not eliminate other defects, in particular design and manufacturing defects, of a product.

The PLA does not provide for the principle of "learned intermediary". In general, it is the responsibility of the producer to ensure that all necessary information and warnings reach the consumer. If a failure to instruct or warn is an adequate cause to effect the damage, the producer can be held liable.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Pursuant to Article 5 (1) PLA a producer is not liable if he proves:

- that he did not put the product into circulation (lit a);
- that, having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him (lit b); or
- that the defective product was neither manufactured for sale or any other form of distribution for economic purposes nor manufactured or distributed in the producers' course of business (lit c).

A producer of raw material or of a component is not liable, if he can show that the defect resulted from the design of the product in which the raw material or component was incorporated or that the defect resulted from the instructions given by the producer of the final product (Article 5 (1) PLA).

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

Pursuant to Article 5 (1) lit e PLA the producer is not liable if, based on the state of scientific and technical knowledge at that time the product was put into circulation, one was not in a position to discover the defect.

The producer bears the burden of proof that the defect was not discoverable at the time it was put into circulation.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Under the PLA a producer is not liable if he proves that the defect occurred due to compliance with mandatory regulations issued by the public authorities (Article 5 (1) lit d).

However, a producer is obliged to design and manufacture a product according to the latest state of scientific and technological knowledge. The compliance with existing voluntary standards does therefore not exempt from liability if they do not represent the latest state of scientific or technological knowledge.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

In general, judgments only have legal effect between the parties to the proceedings. Different claimants can therefore re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage in separate proceedings. However, although prior judgments have no legal effect on later proceedings, they can influence the decision of the court to a substantial degree.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

Article 7 PLA provides for a joint liability for all persons liable for damages resulting from a defective product, independent of the legal basis of such liability. Where a damage is caused by a defendant and a third party, the defendant and the third party are therefore jointly and severally liable, irrespective of their individual contribution to the damage. However, the defendant can seek recourse from a liable third party for the damages paid to the claimant. It is at the discretion of the court to determine whether and to what extent there is such a right of recourse against a third party.

In general, the recourse takes place by means of a subsequent separate proceeding. In the initial proceeding, the defendant may seek the assistance of a potential liable third party by issuing a third party notice. However, such a third party notice cannot lead to a liability of a third party in the first proceeding but only means that the primary judgment against the defendant will have legal relevance in the recourse proceedings against the third party.

The recourse is subject to the statute of limitation applying to the initial claim.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

Pursuant to Article 44 CO, the judge may reduce or completely deny any liability for damages if circumstances for which the damaged party is responsible have caused or aggravated the damage. These provisions of tort are pursuant to Article 11 (1) CO applicable on claims based on the PLA as well.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

There are no juries in civil matters in Switzerland. All cases are therefore tried before a judge.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

The court does not have the power to appoint technical specialists to sit with the judge. However, special courts, e.g. the Commercial

Court in Zurich, partly consist of lay judges experienced in the industry of the case at hand.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

Swiss procedure laws do not provide for class action mechanisms.

However, claimants may bring a claim against the same defendant together as a group of claimants if the cause of action is sufficiently similar or identical, the same court is competent for all claims and if the same procedure is applicable to all individual claims.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Claims cannot be brought by a representative body in product liability litigation.

4.5 How long does it normally take to get to trial?

Litigation is predominantly conducted in writing. In an "assertion phase" the parties present the facts of the case to the court by exchanging briefs and by submitting documentary evidence. In a subsequent "evidentiary proceeding" the court takes evidence (on relevant and disputed facts that cannot be proven sufficiently by documentary evidence) in a hearing. These hearings usually take hours rather than days.

After submission to the court, the statement of claim is usually served on the defendant within a short period. The court sets a time limit by which the defendant has to submit his statement of defence. The subsequent (second) submissions of the claimant and of the defendant are subject to the same procedure.

The hearing to take evidence usually takes hours rather than days.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

There are no preliminary trials in Switzerland.

4.7 What appeal options are available?

Generally, the cantons are divided into jurisdictional districts with District Courts operating as courts of first instance. Cantonal Superior Courts serve as appellate bodies for judgments rendered by these District Courts but also as courts of first instance for a limited amount of subject matters and claims. Some cantons - Zurich, Bern, St.Gall and Aargau - have established a specialised Commercial Court which has sole cantonal jurisdiction over commercial matters. Only in the Cantons of Zurich and St.Gall there is, additionally, a Court of Cassation which reviews judgments rendered by the Superior Court and the Commercial Court.

The Swiss Federal Supreme Court is Switzerland's highest court and the sole federal court in civil matters. Final cantonal decisions may be appealed to the Swiss Federal Supreme Court for violation of federal law if the amount of the judgment exceeds CHF 30,000.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

The court may appoint experts to assist it in considering technical issues. Such expert opinions are introduced to the proceedings as means of evidence. The court is free to determine the weight to be given to such expert opinion, as the court is free in weighing all presented evidence.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

There are no pre-trial depositions. Witness statements and expert reports are given in an evidentiary hearing (see question 4.5) and are not exchanged prior to such hearing.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

There are no pre-trial discovery procedures in Switzerland and there is, in general, no obligation to disclose documents and other evidence before the evidentiary proceedings (see question 4.5).

However, pursuant to the Code of Civil Procedure of the Canton of Zurich parties should file documentary evidence in their possession to their briefs and/or make reference to any evidence they wish to rely on.

On request of a party, the court may order a party to the proceedings as well as a third party to produce documents in its possession if the requesting party wishes to rely on these documents as evidence (and if the court regards the issue as relevant).

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

Alternative methods of dispute resolution, e.g. mediation or arbitration are available.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

The limitation periods differ between the various legal grounds of liability.

Claims for the recovery of damages brought under the PLA are subject to a relative statute of limitations of 3 years which period begins to run from the day the claimant became aware or reasonably should have become aware of the damage, the defect and the identity of the producer (Article 9 PLA). Additionally, Article 10 PLA provides for an absolute statute of limitations barring any claims that are brought later than 10 years after the defective product that caused the damage was put into circulation.

Claims based on tort law are subject to a relative statute of limitations of one year after the day the claimant was aware of the damage and the liable person (Article 60 para. 1 CO) and to an absolute statute of limitations of ten years after the tortuous act.

The general statute of limitations for contractual claims is ten years. However, a claim based on sales warranties is barred one year after

the delivery of the purchased product and furthermore requires an immediate notice of defects by the buyer.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

See question 5.1.

The age or condition of the claimant does not affect the calculation of any time limits. Statutes of limitations are regulated solely by federal law and courts have in general no discretion in applying these time limits.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Pursuant to Article 9 PLA the relative limitation period of three years begins to run from the day on which the claimant became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer. Therefore acts of concealment or fraud affect the commencement of the relative limitation period. However, such acts do not affect the absolute limitation period of 10 years (see question 5.1). If the tortuous act of the producer constitutes concurrently a criminal offence, the longer limitation period of the penal code is also applicable to civil claims based on PLA and tort law (Art. 60 (2) CO).

If the buyer is wilfully deceived by the seller, an omission of notification of defects by the buyer does not limit the sales warranty (see question 5.1).

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

In general, the PLA as well as tort and contract law provide for monetary compensation of damages caused by defective products.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

Pursuant to Article 1 (1) lit a PLA compensatory damages are available for all damages caused by death or personal injury. Furthermore, compensation for damage to, or for destruction of, any item of property other than the defective product itself, provided that the item of property is of a type ordinarily intended for private use or consumption and was used by the claimant mainly for his own private use or consumption is available based on the PLA (Article 1 (1) lit b). However, a producer is only liable for damages in excess of CHF 900 to such property (Article 6 (1) PLA).

Since the PLA provides only for a supplemental cause of action, damages that are not recoverable under the PLA may be claimed based on other legal grounds, in particular tort or contract law.

Based on tort liability all damages caused by death or personal injury as well as all damages to property other than the defective product itself, in particular damages to commercially used property, as well as other damages can be recovered. Furthermore, a judge may award, based on tort law, an adequate sum of money as reparations in case a person has been killed or has sustained bodily injury (Article 47 CO). The judge will base his decision regarding the award of reparations mainly on the degree of the injury and the degree of fault of the tortfeasor.

Damages to the defective product itself can only be recovered based on contract law (e.g., Article 97 *et seq.* and 197 *et seq*. CO).

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

There is neither case law nor doctrine establishing the recoverability of costs of medical monitoring in circumstances where the product has not yet malfunctioned and caused injury.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Punitive damages are not available in Switzerland and are considered incompatible with Swiss public policy. Pursuant to Article 135 (2) of the Federal Act on Private International Law ("PIL") a Swiss court may not award punitive damages even if the applicable foreign substantive law provides for such damages.

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is no maximum limit on the recoverable damages.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

The settlement of a claim is accomplished by means of a private contract. In order to have a procedural effect on ongoing court proceedings, i.e. the termination of the proceeding, the contract has to be filed with the court. In the canton of Zurich the court is obliged to examine the contract with regard to legal permissibility and clearness before it can approve the settlement and end the proceedings.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Pursuant to Article 72 *et seq*. of the Federal Act on the General Part of the Social Security Law, insurance carriers subject to this law (e.g. compulsory health insurance, unemployment insurance, accident insurance and disability insurance) can seek recourse for treatment costs, unemployment benefits or other costs from any person liable for these damages. The claim against such person is subrogated to the insurance carrier in the moment of the damaging event. The injured party is, therefore, not entitled to recover these damages from the liable person directly.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

The loser pays rule applies. The successful party can recover its legal costs (attorney fees and expenses) from the unsuccessful party. Whilst the unsuccessful party has to bear all court fees or other incidental expenses, the amount of legal costs (attorney fees and other expenses) to be compensated is governed by a statutory tariff schedule and mainly depends on the amount at stake.

7.2 Is public funding e.g. legal aid, available?

A party can be exempted from paying court costs if it can show that it is unable to pay these costs and that the case at hand is not without reasonable chance of success. If necessary for the protection of the rights of such a party, upon request, the court may appoint an attorney at no cost for such party.

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7.3 If so, are there any restrictions on the availability of public funding?

See question 7.2.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Contingency fee arrangements with attorneys are not permissible in Switzerland. However, attorneys may enter into an arrangement as to success fees, but only in addition to a non-conditional, basic remuneration (which must, however, cover at least the attorney's costs and expenses and also contain some profit element).

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Parties may fund litigation by third parties and may promise in return a share of the result to such third parties.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in Switzerland.

There are at present no new peculiar cases, trends or developments in Product Liability Law in Switzerland.

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1 Liability Systems

1.1 What systems of product liability are available (i.e. liability in respect of damage to persons or property resulting from the supply of products found to be defective or faulty)? Is liability fault based, or strict, or both? Does contractual liability play any role? Can liability be imposed for breach of statutory obligations e.g. consumer fraud statutes?

In the United States, product liability law is governed by the laws of each state. Product liability claims may be brought under theories of strict liability, negligence or breach of warranty. Generally, a plaintiff in a product liability lawsuit has the burden of proving that the product in question was defective due to an unreasonably dangerous condition or characteristic. There are three categories of product defect: (1) design defect; (2) manufacturing defect; and (3) warnings defect, i.e., failure to adequately warn of risks and dangers associated with product use. A product liability plaintiff may recover for injuries to the person, including death, and damage to property.

1.2 Does the state operate any schemes of compensation for particular products?

The federal government has established compensation systems under limited circumstances. For example, Congress passed the National Childhood Vaccine Injury Act of 1986 which created the National Vaccine Injury Compensation Programme ("VICP"). VICP is designed to compensate individuals or families of individuals who have been injured by childhood vaccines. The National Childhood Vaccine Injury Act provides an alternative to the tort system. To obtain compensation, a party must file a claim with the U.S. Court of Federal Claims. A physician then reviews the claim on behalf of the government to determine whether it meets the criteria for compensation. The initial decision regarding the amount of compensation is made by a "Special Master". A party may appeal the Special Master's decision to the Court of Federal Claims and then to the Federal Circuit Court of Appeals. A party may sue the manufacturer of a vaccine only if the vaccine is not covered by the National Vaccine Injury Compensation Programme or, for vaccines covered by the programme, only after the party has sought relief through the National Vaccine Injury Compensation Programme and been denied compensation or received an award the party rejects.

1.3 Who bears responsibility for the fault/defect? The manufacturer, the importer, the distributor, the "retail" supplier or all of these?

In most jurisdictions, product liability claims may be asserted against any entity involved in making a product available to the consumer, including manufacturers, wholesalers, distributors and retail suppliers of the product. Some jurisdictions have enacted so-called "innocent seller" statutes or case law that protect retailers from liability arising out of their sale of defective products provided certain conditions are met, such as jurisdiction over the manufacturer, adequate remedy against the manufacturer, lack of knowledge of the defect by the seller, and inability by the seller to discover product defect.

1.4 In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

A majority of jurisdictions have held that, in the absence of a statutory requirement or action by a governmental regulatory authority, a manufacturer has no duty to recall a product or take steps to remedy defects discovered after the product has already been sold. However, courts in a minority of jurisdictions have held that a manufacturer does have a post-sale duty to recall or repair a product.

1.5 Do criminal sanctions apply to the supply of defective products?

Criminal prosecution is possible in connection with product liability claims, particularly where there has been an alleged violation of federal or state laws regulating the product at issue.

2 Causation

2.1 Who has the burden of proving fault/defect and damage?

The plaintiff in most instances bears the burden of proving all elements of a product liability claim. Although the elements of a strict liability claim vary according to state law, a plaintiff typically must prove that the defendant's product was (1) defective and (2) the cause of the plaintiff's injury. Under a negligence theory, a plaintiff must also prove that the defendant knew or should have known of the alleged product defect.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure?

A plaintiff must prove both actual and proximate causation. Actual causation includes both general and specific causation. To establish general causation, the plaintiff must prove that the defendant's product is capable of causing the type of injuries alleged. To establish specific causation, the plaintiff must prove that the product caused the plaintiff's alleged injuries. Generally, to establish actual causation, the plaintiff must offer expert testimony that, to a reasonable degree of medical probability, the defective nature of the defendant's product caused or substantially contributed to cause the plaintiff's alleged injuries.

To establish proximate causation, a plaintiff must establish that the injury is the natural and probable consequence of the defendant's conduct. The concept of proximate causation acts as a limit on the extent of a defendant's liability. A defendant may not be held liable for every consequence that follows the defendant's action; rather, liability is limited to the natural and probable consequences of its action or inaction.

2.3 What is the legal position if it cannot be established which of several possible producers manufactured the defective product? Does any form of market-share liability apply?

In the majority of jurisdictions, the plaintiff bears the burden of proving that the defendant manufactured the product that caused the plaintiff's injury. However, a few jurisdictions have adopted market share liability. It was first adopted by the California Supreme Court in a 1980 case involving the synthetic estrogen drug diethylstilbestrol, also known as DES, which was manufactured by as many as 300 manufacturers between the 1940s and the 1970s. Market share liability has subsequently been adopted in a number of other jurisdictions in the United States, including Florida, New York, Hawaii, Washington and Wisconsin.

Under market share liability, the plaintiff may recover for injuries caused by a product identically manufactured by more than one manufacturer even though it is not possible to determine the identity of the manufacturer of the particular product that caused plaintiff's injury. The legal requirements for recovering under the market share theory of liability vary in each of these jurisdictions. For example, in California, a plaintiff must join a "substantial share" of manufacturers of the product in question and each defendant can be held liable for its share of the market, unless it proves it could not have manufactured the product that actually caused the plaintiff's injury. In New York, a plaintiff must also join a "substantial share" of manufacturers, and each defendant may be held liable for its share of the national market. However, because New York adopted market share liability as a method of apportioning defendants' liability according to their alleged collective culpability, defendant may not exculpate itself even if it can show that it did not manufacture the product that actually caused the injury. In Florida, plaintiff must show that she has made a genuine attempt to identify the manufacturer responsible for her injury, but has no burden to join a substantial share of manufacturers. Each manufacturer joined as a defendant in Florida is presumed to have an equal market share (as determined by the number of defendants in the case), unless it proves that its actual market share was less.

2.4 Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account: only information provided directly to the injured party, or also information supplied to an intermediary in the chain of supply between the manufacturer and consumer? Does it make any difference to the answer if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, e.g. a surgeon using a temporary or permanent medical device, a doctor prescribing a medicine or a pharmacist recommending a medicine? Is there any principle of "learned intermediary" under your law pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make available appropriate product information?

A product contains a warning defect when the foreseeable risks of the product could have been reduced or avoided by providing reasonable warnings or instructions, and, due to the absence of such information, the product is unreasonably dangerous. The plaintiff usually bears the burden of proving that adequate warnings or instructions were not provided. When determining the adequacy of a product's warning, the court must weigh a number of factors, including the targeted consumers. For example, a product intended for children may require more information than a product intended for adults. Furthermore, a product's warning need not provide information about every possible risk in order to be adequate. In fact, a warning with too much information often makes it difficult for the consumer to identify the most important warnings.

Where liability is premised on a defendant's failure to warn of risks or dangers associated with the use of a prescription drug, the learned intermediary doctrine provides that the defendant manufacturer discharges its duty by warning the prescribing physician of the dangers associated with use of the product. It is then the learned intermediary's responsibility to warn the user. The learned intermediary doctrine applies in cases involving prescription drugs because these products can only be obtained through a licensed physician, who is in a superior position to understand and evaluate the warnings in light of the patient's medical condition and background. Nearly all states, along with Puerto Rico and the District of Columbia, recognise the learned intermediary doctrine. Only one state has expressly rejected the learned intermediary doctrine. See *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899 (W.Va. 2007). However, the United States District Court for the District of New Mexico recently held that the New Mexico Supreme Court would not adopt the learned intermediary doctrine, despite the fact that there were three New Mexico Court of Appeals decisions adopting or applying the doctrine. See *Rimbert v. Eli Lilly and Co.*, No. Civ 06-0874, Memorandum and Order (D.N.M. August 22, 2008).

The learned intermediary doctrine has also been held to apply in cases beyond prescription medications. The learned intermediary doctrine has also been applied to medical devices and even heavy industrial equipment where an employer acts as the intermediary in instructing employees regarding safe use of the product.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Statutes of Limitation

A plaintiff's claim will be barred if it is not brought within a certain

specified period of time after the plaintiff is injured. Statutes of limitation vary according to the jurisdiction and the theory of liability, but can range in duration from one year to six years for personal injury claims. Many states apply a so-called "discovery rule", which provides that the statute of limitation will not begin to run until a plaintiff knows that he has a cause of action. A plaintiff typically has knowledge of a cause of action when he knows, or should know, that he has been injured and that the product at issue may have caused his injury. A minority of jurisdictions liberally interpret the "discovery rule" to prevent the running of the statute of limitation until the plaintiff knows, or should know, that he has been injured, that the product at issue caused the injury and that the defendant engaged in wrongful conduct.

Statutes of Repose

In contrast to statutes of limitation, statutes of repose provide that a claim will be barred if not brought within a specific number of years after the product was manufactured or sold, regardless of when the plaintiff's injury occurs. Time periods for statutes of repose are typically longer than statutes of limitation, but the "discovery rule" generally does not apply to statutes of repose. Thus, statutes of repose are viewed as an absolute time bar on a claim.

The Learned Intermediary Doctrine

See question 2.4 above.

Intervening and Superseding Cause

A defendant in a product liability action may assert as a defence that the plaintiff's injury was caused by the intervening conduct of a party other than the defendant. The intervening conduct may be that of another defendant, of a non-party or of the plaintiff himself (see Comparative Fault/Contributory Negligence below). However, intervening conduct is generally a defence to a product liability claim only if the conduct is also a "superseding cause". Most courts hold that intervening conduct is a superseding cause where the conduct is such that a manufacturer could not be expected to guard against such conduct in the design of the product. Examples of intervening, superseding causes include failure to properly maintain a product, negligent use of the product, use of a product for a purpose not intended or reasonably foreseen by the manufacturer, failure to inspect a product, failure to follow instructions regarding the installation of a safety device, failure to comply with a product recall, alteration of a product, or criminal action.

Comparative Fault/Contributory Negligence

Formerly, many jurisdictions completely barred recovery by a plaintiff where the plaintiff's own negligence caused, or contributed to cause, the plaintiff's injury. Most jurisdictions no longer bar recovery by a plaintiff who is contributorily negligent; rather, they apply comparative fault under which the plaintiff's recovery is reduced if the plaintiff's own conduct contributed to the injury. Some jurisdictions impose "pure" comparative fault to reduce a plaintiff's recovery by the percentage of fault attributed to the plaintiff's negligence. Other jurisdictions apply "modified" comparative fault, which reduces a plaintiff's recovery by the percentage of fault assigned to the plaintiff, but bars recovery if the percentage of fault assigned to the plaintiff reaches a certain level. For example, in some jurisdictions applying "modified" comparative fault, a plaintiff may recover provided her percentage of fault is less than the percentage of fault attributed to the defendant(s). Under this system, a plaintiff may not recover if her fault is equal to that of the defendant(s). In other jurisdictions applying "modified" comparative fault, a plaintiff may recover provided that the percentage of fault attributed to her does not exceed the percentage of fault attributed to the defendant(s). Thus, a plaintiff may still recover where the plaintiff's fault is equal to that of the defendant(s).

Assumption of the Risk

In many jurisdictions, it is a defence to a product liability claim if the plaintiff knew of a product defect, recognised the danger posed by the product, but nevertheless proceeded to use the product and was injured. This defence is different from contributory negligence in that it applies a subjective standard, i.e., what the plaintiff actually knew, rather than the objective standard applied to a contributory negligence determination, i.e., whether the plaintiff acted as a reasonable person under the circumstances.

Pre-emption

Where a governmental or regulatory body has promulgated rules and regulations regarding product safety, some courts hold that product liability claims that, if successful, would require additional conduct by the manufacturer, are pre-empted by the governmental or regulatory rules and regulations. The pre-emption doctrine is intended to prevent manufacturers from being subjected conflicting federal and state standards. See also question 8.1 below.

Compliance with Governmental Standards

See question 3.3 below.

State of the Art

See question 3.2 below.

3.2 Is there a state of the art/development risk defence? Is there a defence if the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply? If there is such a defence, is it for the claimant to prove that the fault/defect was discoverable or is it for the manufacturer to prove that it was not?

In negligence actions, the fact that a product was manufactured according to the state of the art, i.e., the level of scientific and technical achievement in the relevant field, is relevant evidence that the manufacturer exercised due care. Evidence that a manufacturer complied with the state of the art may also be relevant in strict liability cases, particularly in a design defect case, where such evidence may be relevant to determine the feasibility of an alternative design, consumer expectations or the standard for design defect. State of the art evidence is, however, inadmissible in some jurisdictions. Generally, in jurisdictions where evidence of the state of the art is admissible, the burden of proof is on the defendant to prove that it complied with the state of the art. However, in jurisdictions that require a plaintiff asserting a design defect theory to offer proof of a safer, feasible alternative design, the burden of demonstrating the relevant state of the art is on the plaintiff.

3.3 Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

In a majority of jurisdictions, a manufacturer's compliance with regulatory and statutory requirements is evidence of due care or lack of defect, but is not conclusive. In a small number of states, a manufacturer's compliance with regulatory and statutory requirements creates a rebuttable presumption that the product is not defective.

3.4 Can claimants re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, provided they arise in separate proceedings brought by a different claimant, or does some form of issue estoppel prevent this?

A plaintiff is not estopped from litigating issues of fault, defect or

the capability of a product to cause a certain type of damage where another plaintiff has unsuccessfully litigated the same issue(s). However, in some circumstances, where an issue is decided against a defendant in one proceeding, the defendant may be precluded from re-litigating the issue in future proceedings involving different plaintiffs.

3.5 Can defendants claim that the fault/defect was due to the actions of a third party and seek a contribution or indemnity towards any damages payable to the claimant, either in the same proceedings or in subsequent proceedings? If it is possible to bring subsequent proceedings is there a time limit on commencing such proceedings?

See question 3.1 above.

3.6 Can defendants allege that the claimant's actions caused or contributed towards the damage?

See question 3.1 above.

4 Procedure

4.1 In the case of court proceedings is the trial by a judge or a jury?

In both federal and state court, either party may demand a trial by jury. Most federal juries are comprised of 6 persons and 2 alternates and verdicts must be unanimous. State court juries are commonly comprised of 12 persons, and the number of jurors to render a verdict varies. In some states, unanimity is required, while others require 9 of 12 or 10 of 12. In state courts using six-person juries, some require 5 of 6 jurors to render a verdict.

4.2 Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

A federal court may appoint a "Special Master" who may serve as a referee, auditor, examiner or assessor to assist the court with complicated issues. Rule 53(b) of the Federal Rules of Civil Procedure provides that, absent a statute otherwise, a special master should be appointed only to: (1) perform duties consented to by the parties; (2) hold trial proceedings and make findings of fact on specific issues to be decided without a jury; or (3) address pre-trial an post-trial matters that cannot be addressed by a judge or magistrate in a timely and effective manner.

4.3 Is there a specific group or class action procedure for multiple claims? If so, please outline this. Is the procedure 'opt-in' or 'opt-out'? Who can bring such claims e.g. individuals and/or groups? Are such claims commonly brought?

A federal court may "certify" or allow a class action to go forward if the requirements of Rule 23 of the Federal Rules of Civil Procedure are met. Rule 23(a) provides that four prerequisites must be satisfied for a suit to be certified as a class action. First, the class of parties must be so numerous that joinder of all members of the class is impracticable. Second, there must be questions of law or fact common to all members of the class. Third, the claims or defences of the parties who wish to bring the claim on behalf of the class must be typical of the claims or defences of the class. Finally, the parties who wish to bring the claim on behalf of the class must be capable of fairly and adequately protecting the interests of the class.

If the four prerequisites are satisfied, Rule 23(b) provides that an action may be allowed to proceed as a class action in one of the following three circumstances: (1) the prosecution of separate actions by individual members of the class would create a risk of inconsistent or varying adjudications with respect to individual members of the class which would establish incompatible standards of conduct for the defendant, or adjudications with respect to individual members of the class would be, as a practical matter, dispositive of the interests of other members of the class who are not parties to the action or would substantially impede or impair their ability to protect their interests; (2) the defendant has acted or refused to act on grounds generally applicable to the entire class; or (3) questions of fact or law common to the members of the class predominate over questions affecting only individual members and a class action is superior to other methods for the fair and efficient adjudication of the controversy.

Rule 23(b)(3), directs the court to consider the following factors in making a determination whether common questions of fact or law predominate over individual issues and whether a class action would be superior to other methods for adjudication of the controversy: (a) the interests of members of the class in individually controlling the prosecution of separate actions; (b) the extent and nature of any litigation concerning the controversy already commenced by members of the class; (c) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and (d) the difficulties likely to be encountered in the management of the class action.

If a court determines that the provisions of Rule 23 are satisfied, it may certify the proposed class and allow the representative plaintiffs to litigate the case as a class action. Typically, the representative plaintiffs must provide notice to potential members of the class that they may opt out of the class and pursue their claim individually. If a class member fails to "opt out" of the class, the class member becomes part of the class action and is bound by its result.

4.4 Can claims be brought by a representative body on behalf of a number of claimants e.g. by a consumer association?

Generally, a representative organisation, such as a consumer association, has no standing to file a product liability claim for injuries sustained by its members. However, some such organisations file petitions with governmental regulatory authorities requesting that the regulatory authority take action against manufacturers, such as requiring a recall of the product or imposing additional safety standards.

4.5 How long does it normally take to get to trial?

The length of time it takes for a case to get to trial varies by jurisdiction. In the federal courts, during the 12-month period ending September 30, 2008, the overall median time to trial was 32.9 months. See Statistical Tables for the Federal Judiciary, September 30, 2008 (http://www.uscourts.gov/judbus2008/appendices/C05Sep08.pdf). However, there is great variation within the federal courts during this period, ranging from only 10.1 months in the Eastern District of Virginia to 166.4 months in the Middle District of Louisiana. See *id.*

The length of time it takes to get to trial in state court varies by jurisdiction, but comprehensive statistics are unavailable.

4.6 Can the court try preliminary issues, the result of which determine whether the remainder of the trial should proceed? If it can, do such issues relate only to matters of law or can they relate to issues of fact as well, and if there is trial by jury, by whom are preliminary issues decided?

Judges in federal and state courts may use the summary judgment procedure to dispose of specific issues or an entire case prior to trial. Rule 56 of the Federal Rules of Civil Procedure and comparable rules in state courts allow a court to enter summary judgment as to specific issues or the entire case where no genuine issue of material fact exists and judgment may be entered as a matter of law. Courts may use summary judgment proceedings or other pre-trial hearings to make determinations regarding the admissibility of expert testimony. Where expert testimony is held inadmissible, these proceedings, referred to as "*Daubert* hearings" in federal court, may make trial unnecessary if a party is unable to meet their burden of proof without expert testimony.

In contrast to summary judgment, courts may also hold separate trial proceedings regarding preliminary issues, the result of which determine whether it is necessary to try remaining issues. Rule 42 of the Federal Rules of Civil Procedure and comparable rules in state courts allow a court, where convenient or to avoid prejudice, or where conducive to expedition and economy, to order the separate trial of any claim or any separate issue. In such proceedings, the court may go beyond matters of law and make findings of fact. Additionally, the constitutional right of the parties to trial by jury applies in the separate proceedings. Commonly known as "bifurcation", this procedure is frequently sought by defendants facing claims for punitive damages to prevent the jury from considering issues such as the defendant's wealth and other prejudicial evidence irrelevant to the determination of liability and actual damages. In such instances, defendants typically request that the court try issues related to liability and actual damages first and then, only if actual damages are awarded, to consider evidence relevant to punitive damages in a separate proceeding.

4.7 What appeal options are available?

Before appealing a judgment or order to an appellate court, a party may request, by motion, that the court that entered the order or judgment reconsider its order or judgment in limited circumstances, such as where new evidence has been discovered that could not have been previously discovered or where fraud has been committed upon the court.

Appeals may generally be taken only from a "final decision". See 28 U.S.C. §1291. A "final decision" is one that settles the rights of the parties and disposes of all issues in the case. There are, however, exceptions under which an "interlocutory appeal", which is an appeal from a decision that is not final, may be taken. Such instances include orders granting or denying injunctions, orders involving a controlling question of law if an immediate appeal will advance the ultimate termination of the litigation, orders constituting a clear abuse of discretion where the court's legal duty is plainly established, reference of an issue of state law to a state appellate court and other limited circumstances. See 28 U.S.C. §1292. Additionally, an order granting or denying certification of a class action, although not a final decision, may be appealed pursuant to Rule 23(f) of the Federal Rules of Civil Procedure.

4.8 Does the court appoint experts to assist it in considering technical issues and, if not, may the parties present expert evidence? Are there any restrictions on the nature or extent of that evidence?

Parties may present expert testimony in both federal and state courts where such testimony will be helpful to the judge or jury in evaluating the evidence. The admission of expert testimony in federal courts is governed by Rule 702 of the Federal Rules of Evidence. Rule 702 provides that an expert may testify if the expert is qualified by knowledge, skill, experience, training or education and if the expert's proposed testimony is based upon sufficient facts or data, is the product of reliable principles and methods and if the principles and methods have been reliably applied to the facts of the case. Additionally, in evaluating the qualifications of experts and the reliability of expert opinions, federal courts are guided by the U.S. Supreme Court's decision in *Daubert v. Merrell Dow Pharms.*, Inc., 509 U.S. 579 (1993). The *Daubert* decision sets forth several factors to guide courts in determining whether an expert's opinions are reliable, including whether the expert's method or theory has been tested, whether the method or theory has been subjected to peer review and publication, the rate of error of the technique or theory, the existence of standards and controls applicable to the method or theory, and whether the method or theory has been generally accepted in the scientific community.

State courts have rules similar to Rule 702 and many apply the *Daubert* decision. However, some state courts still apply the "general acceptance" standard set forth in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), which was rejected by the Supreme Court in *Daubert*. Under the *Frye* test, an expert's opinion is admissible if the technique employed by the expert is "generally accepted" as reliable in the relevant scientific community.

4.9 Are factual or expert witnesses required to present themselves for pre-trial deposition and are witness statements/expert reports exchanged prior to trial?

In both federal and state courts, parties may take pre-trial depositions (sworn testimony given before a court reporter) of fact and expert witnesses. Rule 30 of the Federal Rules of Civil Procedure limits the length of a deposition to one day of seven hours, unless otherwise agreed by the parties. State court rules regarding depositions vary by jurisdiction, but typically allow broad latitude for the deposition of both factual and expert witnesses.

Rule 26(a)(2) of the Federal Rules of Civil Procedure requires the parties to disclose the identity of all experts that may be used at trial, and to provide a written report containing a complete statement of all opinions to be expressed and the reasons and bases in support of the opinions, the data or other information considered by the expert in forming the opinions, exhibits to be used in support of the opinions, the qualifications of the expert, including a list of all publications authored by the expert within the preceding ten years, the compensation to be paid to the expert, and a list of all other cases in which the expert has given testimony at deposition or at trial in the previous four years. State court rules regarding the disclosure of expert reports vary by jurisdiction.

4.10 What obligations to disclose documentary evidence arise either before court proceedings are commenced or as part of the pre-trial procedures?

The Federal Rules of Civil Procedure and comparable rules in state courts are designed to prevent parties from "ambushing" adversaries at trial with unknown evidence. Accordingly, parties are required to disclose information to be used at trial, including documentary evidence, before trial begins. Rule 26(a)(1) requires all parties, at the outset of a case, without awaiting any discovery requests, to provide copies or a description by location and category of all documentary evidence the party may use to support its claims or defences. Moreover, the parties are under a continuing

obligation to supplement their disclosure of such information as it becomes known to them throughout the case.

While courts had applied Rule 26(a)(1) to require disclosure of information that is stored electronically, the Federal Rules of Civil Procedure were amended in 2006 to specifically include electronic information within the information that must be disclosed at the outset of a case. The changes to the rules were heavily influenced by the Sedona Conference, a research and educational institute dedicated to the advancement of law and policy related to complex litigation. The revised rules were also heavily influenced by the body of case law that had developed in recent years regarding discovery issues related to electronic information. Most notably, Judge Shira A. Scheindlin, a Judge of the United States District Court for the Southern District of New York, issued a series of opinions in *Zubulake v. USB Warburg LLC* regarding discovery of electronic information.

Rules 26 through 37 of the Federal Rules of Civil Procedure provide numerous discovery tools which a party may use to obtain relevant information from an adverse party. Parties may discover information relevant to the case by taking depositions of factual and expert witnesses, propounding written interrogatories, requests for production of documents and things, requests for admissions, and physical and mental examinations of a party.

Finally, federal courts and most state courts require the parties, in advance of trial, to exchange written witness and exhibit lists, as well as copies of all exhibits that may be used at trial.

4.11 Are alternative methods of dispute resolution available e.g. mediation, arbitration?

There are various methods of alternative dispute resolution available in product liability matters, including negotiation, mediation, and arbitration. Negotiation involves the parties voluntarily attempting to resolve the dispute without intervention by a third party. Mediation introduces a neutral third party - the mediator - into the process. A mediator assists the parties in attempting to negotiate a resolution. While mediation is non-binding, it has become one of the most common forms of alternative dispute resolution. In an arbitration, the parties select a neutral third party (sometimes a panel of three) to hear the dispute and render a final decision, which is usually binding. Binding arbitration requires the parties to agree to forego their right to litigate the matter. The structure of arbitration differs and can be tailored to the specific parties and dispute.

It has become common for both federal and state courts to require parties to engage in some form of alternative dispute resolution before trial.

5 Time Limits

5.1 Are there any time limits on bringing or issuing proceedings?

As discussed above in response to question 3.1, a plaintiff must file suit within the applicable statute of limitations, which vary by jurisdiction but generally range from one year to six years.

A suit is commenced when the plaintiff files the Complaint, also called a Petition in certain jurisdictions, which contains the relevant allegations and a request for relief. When the Complaint is filed, a summons is issued commanding the defendant to appear before the court to answer the complaint. Rule 4(m) of the Federal Rules of Civil Procedure provides that a complaint will be dismissed if the plaintiff does not serve the complaint and the summons on the defendant within 120 days of issuance of the summons. A defendant must answer the Complaint within 20 days of service of the summons and Complaint. State courts have similar rules and similar timeframes, although the time to answer is 30 days in many jurisdictions.

In federal court, plaintiffs may request that a defendant waive the requirement of formal service of the summons in order to avoid the costs associated with such service. If a defendant refuses to waive formal service and plaintiff subsequently serves the defendant with the Complaint and summons, the defendant must pay the expenses associated with formal service of the summons. Where a defendant agrees to waive service of the summons, the defendant has 60 days after signing the waiver of service to answer the Complaint, rather than the usual 20-day period in which to answer where formal service is made.

After the plaintiff files the Complaint and the defendant files its answer, federal courts and most state courts issue scheduling orders that govern pre-trial discovery and trial of the case.

5.2 If so, please explain what these are. Do they vary depending on whether the liability is fault based or strict? Does the age or condition of the claimant affect the calculation of any time limits and does the Court have a discretion to disapply time limits?

Statutes of limitation begin to run when a claim accrues. The time of accrual varies depending on the jurisdiction, but generally a claim accrues when a plaintiff has been injured and knows or should know the cause of his injury. Statutes of limitation are "tolled" or suspended where a plaintiff has not reached the age of majority, is mentally incapacitated or, in some jurisdictions, is imprisoned. The limitations period begins to run again when the plaintiff reaches the age of majority, when the mental incapacitation is lifted or when the period of imprisonment ends.

5.3 To what extent, if at all, do issues of concealment or fraud affect the running of any time limit?

Statutes of limitation are commonly tolled where a defendant commits an ongoing fraud that prevents the plaintiff from realising that he or she has been injured.

6 Remedies

6.1 What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

The primary remedy sought in product liability cases is monetary compensation. See question 6.2 below. Some courts have also ordered defendants to pay for medical monitoring of plaintiffs to detect the future development of latent injuries or diseases. See question 6.3 below.

6.2 What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

In a product liability claim, a plaintiff may recover for personal injury and wrongful death, including pain and suffering, medical expenses, loss of income, loss of financial support and loss of consortium. A product liability plaintiff may also recover for damage to property, including damage to the product itself and

damage to other property. Finally, a product liability plaintiff may recover punitive damages, which are discussed below.

6.3 Can damages be recovered in respect of the cost of medical monitoring (e.g. covering the cost of investigations or tests) in circumstances where the product has not yet malfunctioned and caused injury, but it may do so in future?

Since the late 1980s, some federal and state courts have ordered product liability defendants to pay for medical monitoring of plaintiffs to detect the future development of latent injuries or diseases. Courts have expressed divergent views about the circumstances under which medical monitoring claims are appropriate. Some courts have rejected medical monitoring claims absent manifest physical injury, while others recognise these claims as the only appropriate way to compensate parties for an increased risk of injury.

6.4 Are punitive damages recoverable? If so, are there any restrictions?

Most jurisdictions allow for the recovery of punitive damages in product liability actions. A plaintiff typically must prove, by clear and convincing evidence, that a defendant acted wilfully, wantonly or with malice in order to recover punitive damages. Many jurisdictions require that actual damages are awarded in order to award punitive damages.

The United States Supreme Court struck down a punitive damages award that was 145 times the amount of the compensatory damages award on the ground that such an award was an arbitrary deprivation of property in violation of the defendant's constitutional right to due process. See *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003). The Court noted that any award ten times the amount of compensatory damages or larger would likely be unconstitutional on due process grounds.

Since the Supreme Court's decision in *State Farm*, there have been hundreds of cases that reference the case, yet result in extremely varied interpretations of it's ratio guideline. See, e.g., *Adidas America, Inc. v. Payless Shoesource, Inc.* 2008 WL 4279812 at *16 (D. Or. Sept. 12, 2008) (reducing a punitive damages award to less than a 1:1 ratio); *Bunton v. Bentley*, 153 S.W.3d 50 (Tex. Dec. 19, 2004) (reducing a single-digit ratio award in light of State Farm); *Buhmeyer v. Case New Holland, Inc.* 446 F. Supp. 2d 1035 (S. D. Iowa 2006) (holding a punitive damages award of over twenty-seven times compensatory damages unconstitutionally high). Other courts find ways to circumvent the single-digit ratio guideline or interpret the ratio guideline as a suggestion rather than a requirement. See, e.g., *Mathias v. Accor Economy Lodging, Inc.*, 347 F.3d 672 (7th Cir. Oct. 21, 2003) (interpreting State Farm's ratio guideline as a suggestion rather than a rule); and *Santamaria v. Dallas Independent School District*, 2007 WL 1073850 (N.D. Tex. April 10, 2007) (upholding 100:1 ratio in a case involving nominal damages).

These varied interpretations of State Farm have resulted in extremely inconsistent punitive damages awards. In an effort to control the awarding of inconsistent punitive damages, 32 states have enacted punitive damage reform of some sort. See Tort Reform Record: December 2008 at www.atra.org. Also, the Supreme Court recently limited punitive damages in *Philip Morris USA v. Williams*, where it held that punitive damages are inappropriate for harm allegedly done to non-parties. See 127 S.Ct. 1057, 549 U.S. 346 (2007).

6.5 Is there a maximum limit on the damages recoverable from one manufacturer e.g. for a series of claims arising from one incident or accident?

There is not a limit on the amount of monetary damages recoverable from one manufacturer. However, some states limit the number of punitive damage awards, but not the amount, to one award that may be recovered from a single defendant for any act or omission, regardless of the number of claims that arise.

6.6 Do special rules apply to the settlement of claims/proceedings e.g. is court approval required for the settlement of group/class actions, or claims by infants, or otherwise?

Federal and state courts often require court approval for settlement of claims, including claims involving minors or those ruled incompetent. Also, Rule 23(e) of the Federal Rules of Civil Procedure requires federal court approval of the settlement of any certified class action.

6.7 Can Government authorities concerned with health and social security matters claim from any damages awarded or settlements paid to the Claimant without admission of liability reimbursement of treatment costs, unemployment benefits or other costs paid by the authorities to the Claimant in respect of the injury allegedly caused by the product. If so, who has responsibility for the repayment of such sums?

Liens may attach to a settlement or damage award from a product liability lawsuit if the plaintiff received governmental assistance through Medicare or Medicaid for the injury that gives rise to the lawsuit. These liens will usually require the repayment of any governmental assistance received. See 42 U.S.C. § 1396a. Such liens do not require prior notice and can attach to the total amount recovered, after attorney fees and expenses.

7 Costs / Funding

7.1 Can the successful party recover: (a) court fees or other incidental expenses; (b) their own legal costs of bringing the proceedings, from the losing party?

Rule 54 of the Federal Rules of Civil Procedure provides that a prevailing party may recover costs other than attorneys' fees as a matter of course unless the court directs otherwise. "Costs" are defined by 28 U.S.C. § 1920 to include fees of the court clerk, fees of transcripts necessarily obtained for the case, fees for printing, witness fees (limited under 28 U.S.C. § 1821 to $40 per day plus mileage and reasonable travel expenses), copying costs and fees of court-appointed experts and translators.

Attorneys' fees are generally recoverable only where specifically authorised by a statute creating a cause of action, such as claims of alleged civil rights violations. Attorneys' fees are typically not recoverable in product liability suits.

7.2 Is public funding e.g. legal aid, available?

While a criminal defendant is entitled, under the Fifth Amendment to the United States Constitution, to the effective assistance of legal counsel, which requires federal and state governments to pay the costs of securing such counsel for indigent defendants, there is no

corresponding right to counsel in civil cases. There are, however, a variety of sources of legal aid, both public and private to assist indigent litigants in prosecuting their cases. A major source of such legal aid comes from the various state bar organisations. Additionally, attorneys are generally encouraged and expected to provide a portion of their services *pro bono*, i.e., free of charge, to indigent clients.

7.3 If so, are there any restrictions on the availability of public funding?

Public funding is not available for civil litigation, but a number of sources of legal aid exist to assist indigent civil litigants. Due to the many varied sources of legal aid in the United States, it is not possible to provide a comprehensive overview of restrictions applicable to the provision of legal aid. Virtually all sources, however, have specific income thresholds beyond which legal aid will not be provided.

7.4 Is funding allowed through conditional or contingency fees and, if so, on what conditions?

Contingency fees are allowed in the United States. Various conditions and ethical considerations apply in each jurisdiction, but most jurisdictions allow contingency fees of up to 30-40% of the judgment awarded to a party, provided that the parties enter into a fee arrangement in advance.

7.5 Is third party funding of claims permitted and, if so, on what basis may funding be provided?

Expenses associated with bringing a lawsuit are often initially funded by plaintiffs' attorneys. If a recovery occurs, either through settlement or judgment, then the expenses are usually subtracted from the recovered amount. The exact details in which expenses associated with bringing a lawsuit are handled is often dictated by the parties' fee arrangement.

8 Updates

8.1 Please provide, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in the USA.

Federal pre-emption continues to be one of the primary developing issues in the context of prescription drug and medical device product liability litigation, since they are regulated by the FDA. Within the last two years, the U.S. Supreme Court decided three cases which address the issue of federal pre-emption. On February 20, 2008, the U.S. Supreme Court, in an 8-1 decision in *Riegel v. Medtronic, Inc.*, held that state law claims against medical devices requiring FDA pre-market approval are pre-empted. 128 S.Ct. 999 (2008). This decision hinted at the possibility that the Supreme Court might subsequently adopt federal pre-emption in a broader context.

Two weeks after the *Riegel* decision, the Supreme Court handed down a 4-4 split decision in *Warner-Lambert Co. v. Kent*, thereby upholding the Second Circuit ruling that allowed pharmaceutical cases to proceed under a Michigan statute requiring plaintiffs to prove the company misled the FDA. 128 S.Ct. 1168 (2008). Even though the split-decision has no precedential effect, it came as a surprise to some who thought that *Kent* would continue to broaden the scope of pre-emption demonstrated by *Riegel*.

The Supreme Court recently decided *Wyeth v. Levine*, which raised the issue of pre-emption as it relates to prescription drugs. On March 4, 2009, the Supreme Court, in a 6-3 decision, held that that federal law did not pre-empt plaintiff's state-law claims based on the facts of the case. 555 U.S. ___ (2009). The Court concluded that "it is not impossible for Wyeth to comply with its state and federal law obligations and that Levine's common-law claims do not stand as an obstacle to the accomplishment of Congress' purposes in the FDCA". *Id.*

Shortly after the Levine ruling, on March 9, 2009, the Supreme Court granted *certiorari* in two Third Circuit cases involving pre-emption, *Pa. Employees Benefit Trust Fund v. Zeneca, Inc.* and *Colacicco v. Apotex, Inc.* The Supreme Court vacated the judgments in both cases and remanded them for further consideration in light of the *Levine* ruling. In the months and years to come, the reach of the *Levine* decision will continue to be debated.

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John is an associate in the Pharmaceutical and Medical Device Litigation Division of Shook, Hardy & Bacon LLP. John's practice focuses of representing pharmaceutical and medical device manufacturers in complex products-liability litigation in federal and state courts throughout the United States. John's responsibilities have included a wide range of pre-trial and trial activities. He also has significant experience in discovery management for complex litigations. John graduated from the University of Kansas (B.A. 1999, with distinction) and from the University of Notre Dame Law School (J.D. 2003). During law school, he was Symposium Editor for the *Journal of Legislation*. John is admitted to practice before the state courts of Missouri and the U.S. District Court for the Western District of Missouri.

Shook, Hardy & Bacon L.L.P. (SHB) is an international law firm that was established in Kansas City, Mo., in 1889. Today, SHB has grown to nearly 1,800 employees worldwide, including more than 500 attorneys and 250 research analysts and paraprofessionals in nine offices: Geneva, Switzerland; Houston, Texas; Kansas City, Missouri; London, England; Miami, Florida; Orange County, California; San Francisco, California; Tampa, Florida; and Washington, D.C.

SHB is widely known for successful results in major litigation for public and private companies of all sizes. The firm has substantial litigation practices in the areas of: products liability; intellectual property; environmental and toxic tort litigation; employment litigation; commercial litigation; and corporate law.

SHB's vast litigation experience and ability to handle national and international litigation sets it apart from other firms. Several recent accolades attest to our standing as a premier litigation law firm in the United States and around the globe. In 2008, *The American Lawyer* named SHB the Product Liability Litigation Department of the Year and *Who's Who Legal: The International Who's Who of Business Lawyers* recognised the firm as Global Product Liability Firm of the Year for the fourth consecutive year. The firm also has been recognised on *The National Law Journal's* "Defense Hot List" for two consecutive years, and was named by the *Legal Media Group* as the World's Leading Product Liability Law Firm for 2009.

Additionally, many SHB attorneys have been recognised for their outstanding professional skills and abilities by: *Chambers USA: America's Leading Lawyers for Business; The Best Lawyers in America; The Legal 500 United States; Lawdragon: The 500 Leading Lawyers in America; Lawdragon: The 500 Leading Litigators in America; Who's Who Legal: The International Who's Who of Business Lawyers; and Who's Who Legal: The International Who's Who of Product Liability Lawyers*.

In addition to our work in the courtroom and boardroom, SHB has been singled out for its innovative diversity efforts. Clients, including The Coca-Cola Company and DuPont, and organisations such as the Minority Corporate Counsel Association have honoured SHB for our commitment to building an inclusive environment for attorneys and employees.

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