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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 recent European caselaw, the draft 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 Reports on the Application of the Directive

The European Commission reports on the practical implementation of the Directive every 5 years and it is presently seeking the views of interested parties with the aim of publishing its next report later this year. This will consider how the Directive is operating in practice, whether it strikes an appropriate balance between consumer protection and the interests of producers, whether there is a need for guidance on the interpretation of its provisions and whether any changes should be made to its terms.

The most recent "Third Report" which was published in September 2006 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 address 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 Ten-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 ten years after the product has been put into circulation, and proceedings alleging strict liability under the Directive must therefore be commenced within ten 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 was 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 later 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. 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, 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 begin to run until the reconstitution because the test only applies to a product "in the form that it reaches the public". It is very questionable that a court would be persuaded by this argument, but more generally 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 and a further preliminary reference to the ECJ was made seeking clarification of the extent of any discretion of national courts to allow substitution of parties after the expiry of the ten-year longstop. The ECJ's judgment in Case C-358/08, *O'Byrne v Aventis Pasteur SA* was delivered in December 2009. It ruled that the expiry of the ten-year longstop period under Article 11 of the Directive was an absolute bar; all rights against the producer expired at that time unless proceedings had been commenced against it properly prior to the expiry of the longstop period. As the Directive was intended to provide a system of complete harmonisation of the laws of Member States, national laws governing procedural matters, such as the substitution of one defendant for another, could not be applied in such a way as to permit such substitution where the effect was to allow a producer to be sued after the expiry of the longstop period.

The court reaffirmed that national courts had no discretion to extend or disapply the longstop period. In particular, it made clear that subjective elements, such as the fact that the claimant made a mistake in identifying the producer, could not justify a relaxation of the requirements of Article 11 so as to permit such substitution. Any other conclusion would be inconsistent with the rationale of the Directive, which was to harmonise the laws of Member States, balancing the greater burden of no-fault liability imposed on producers under the Directive by restricting their liability under that regime to a reasonable length of time.

The ECJ went on to provide guidance on the application of this principle in circumstances where a consumer takes steps to seek to identify the producer. Under Article 3(3) of the Directive, a supplier of a product is to be treated as the producer unless he informs the injured person "within a reasonable time of the identity of the producer or the person who supplied him with the product". There has for many years been debate about the application of this provision, and whether it was sufficient for a supplier simply to deny that it was the producer, without specifying who the producer was. The ECJ made clear that this is insufficient; any such denial must be coupled with information about the identity of the producer or the company's own supplier. The court has also clarified what is a 'reasonable time' for the purposes of such notification. This requires that the supplier must provide the information "on its own initiative and promptly". What amounts to 'promptly' will be a matter for the national court, but it is clear that the supplier cannot simply await a request from the injured person before providing such information.

Other European Developments - Proposed Consumer Rights Directive

A new Directive is likely to be approved later this year, which will clarify and strengthen the laws relating to consumer rights and update the existing legal framework in line with advances in modern technology and the increasing use of the internet. The most recent proposal, approved by a plenary vote of the European Parliament, seeks to harmonise existing laws which are contained in two Directives governing distance contracts and contracts negotiated away from business premises (Directive 97/7/EC and Directive 85/577/EEC), setting down maximum standards from which Member States cannot derogate, while also laying down minimum standards in respect of certain other contractual rights, consolidating the Directives which govern unfair contract terms (Directive 93/13/EEC) and consumer sales and guarantees (Directive 1999/44/EC).

This combination of full harmonisation of the laws relating to distance and doorstep selling with minimum harmonisation of other measures reflects a political compromise. Concerns were raised

during the legislative process that full harmonisation of all provisions would lead to an unacceptable levelling down of certain consumer rights; for example, in the UK the right to reject faulty goods would have been lost. The current proposal therefore makes clear that while the provisions governing distance contracts and doorstep contracts are fully harmonised, Member States may put in place laws which provide a higher level of consumer protection in respect of certain other matters such as implied terms as to quality and description, delivery of the goods, transfer of risk, guarantees and unfair contract terms.

It remains to be seen whether the minimum harmonisation measures will be progressed; the version of the proposed Directive approved by the Council during earlier stages of the legislative process only included the distance and doorstep selling provisions. Further discussions will now take place between the European Parliament and the Council of Ministers with a view to agreeing the text. It is hoped that the Directive could be adopted after a final vote in the European Parliament later this year.

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.

Over recent years various EU institutions have progressed a series of initiatives which have reviewed the effectiveness and efficiency of existing EU collective redress mechanisms and 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 level 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 published a Green Paper on Consumer Collective Redress (COM (2008) 794 final) in November 2008, which concluded 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 a range of possible options (which could be combined or pursued independently) to address this issue.

A series of further EU initiatives have subsequently been progressed, including proposals for collective redress in the context of damages actions for breach of anti-trust rules and a Discussion Paper published in May 2009. Following on from these developments, in February 2011 the Commission published a further consultation paper "Towards a Coherent European Approach to Collective Redress" which seeks to identify common legal principles on collective redress which would guide any future EU initiatives in this area. Collective redress is defined broadly to include any mechanism that may result in the cessation or prevention of unlawful business practices which affect a multitude of claimants or the compensation for harm caused by such practices. It includes actions for compensation and for injunctive relief (to stop the continuation of illegal behaviour). The consultation appears to respond to criticisms that previous initiatives were inconsistent and were advanced on a piecemeal basis, with separate legislative proposals being progressed in the areas of consumer protection and competition law. The Commission is therefore consulting horizontally, across a broad range of industry sectors, with the aim of developing a coherent approach to legislation relating to collective redress.

While the main aim of the consultation is to ensure that adequate mechanisms are in place so that citizens and businesses are able to seek redress on a collective basis, the consultation document acknowledges that improved mechanisms for collective redress could also assist consumers and businesses in initiating private actions against unlawful practices, thereby supporting regulatory agencies by indirectly policing breaches of EU law. This aspect of the proposal has proved controversial, with some commentators suggesting that promoting law enforcement is a matter for the EU enforcement agencies.

The consultation seeks views on whether any changes should be made to existing laws; whether new mechanisms of collective redress would add value; how they would work and whether they should be introduced generally or in specific areas, such as competition law and consumer law. It also identifies certain general principles which could guide any future EU initiatives for collective redress, which are:

(1) the need for effectiveness and efficiency of redress;

(2) the importance of information and of the role of representative bodies;

(3) the need to take account of collective consensual resolution as a means of alternative dispute resolution;

(4) the need for strong safeguards to avoid abusive litigation;

(5) availability of appropriate financing mechanisms, notably for citizens and small and medium sized enterprises; and

(6) the importance of effective enforcement across the EU.

In relation to the proposed safeguards to avoid the risk of "abusive litigation", the European Commission has made clear that it does not support the combination of factors present in so-called "US style" class actions, including the availability of punitive damages, the absence of limitations regarding standing, the availability of contingency fees and the wide ranging discovery procedures for documentary evidence, which it considers potentially provide economic incentives to litigate unfounded claims. It seeks views on safeguards which could be introduced to prevent such "abusive litigation" while still preserving effective access to justice for EU citizens and businesses, including the introduction of the "loser pays" principle (which means that the losing party pays the court and lawyers fees of both parties) and restrictions on when proceedings can be commenced (for example, the need for court approval prior to the commencement of proceedings).

Conclusion

Although the Product Liability 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 decisions in *O'Byrne* provide helpful

clarification on the application of certain 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
- 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 in the medicines and medical devices field, 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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Mr. Dodds-Smith is a Fellow of the Royal Society of Medicine and is a member of the Defence Research Institute and the Federation of Insurance and Corporate Counsel. He has written widely on product liability issues including as co-author of the chapter on product liability for medicinal products in the Butterworths textbook on Medical Negligence.

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Ms Brown also provides advice on product safety and health and safety laws. She advises on all aspects of regulatory compliance, including the notification of product recalls to UK and EU authorities and enforcement actions/investigations by regulatory agencies. She also acts in litigation relating to the recovery of recall costs. She is a member of the British Institute of Comparative Law's product liability forum.

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Arnold & Porter is an international law firm with over 600 attorneys in nine offices in the U.S. and London and Brussels. With more than 100 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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