The International Comparative Legal Guide to:

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Recent Developments in European Product Liability

Arnold & Porter (UK) LLP

Introduction

The Product Liability Directive, 85/374/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.

In the last few years the European Court of Justice (“CJEU”) has ruled on several important issues regarding the scope of the Directive, including the meaning of “defect”, the application of special rules on liability and the rules governing jurisdiction in product liability claims. In this article we discuss those cases and also address the proposed Consumer Product Safety and Market Surveillance Regulations and proposals regarding collective consumer redress that could significantly change the legal environment for bringing product liability claims in the EU.

When is a Product Defective?

More than 20 years after the Directive was enacted, the CJEU has provided its first guidance on the circumstances in which a product may be treated as defective. In Joined Cases C-503/13 and C-504/13, Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt - and Others, the CJEU was asked to determine if a product is defective if it forms part of a product group which has a significantly increased risk of failure, but where a defect has not been detected in each specific product.

The Court considered two related cases concerning implanted medical devices, a pacemaker and a cardioverter defibrillator, which were both manufactured by Boston Scientific. In relation to the pacemaker, Boston Scientific’s quality control system established that a component used hermetically to seal the pacemaker could degrade over time causing premature and sudden loss of battery power. The risk of failure was between 0.3% and 0.9%. Boston Scientific wrote to physicians recommending that they consider replacing the pacemakers in affected patients, and agreed to provide the new devices free of charge and to pay for the explantation operation.

With regard to the cardioverter defibrillator, the manufacturer identified that, in certain circumstances, a magnetic switch in the defibrillator could remain stuck in the closed position, inhibiting the treatment of ventricular and atrial arrhythmias. Boston Scientific advised that the magnetic switch should be deactivated. In four cases out of 46,000, the devices were found to have a fault, and in those cases the patients became aware of the problem by audible beeping warning tones and the device was replaced.

The proceedings related to a claim by the patients’ health insurers who sought reimbursement of the costs of replacing the devices. In both cases, the affected devices were destroyed after removal, so there was no evidence that the relevant device had actually malfunctioned.

In deciding this question, the CJEU has provided some helpful guidance on the meaning of ‘defect’ for the purposes of the Directive. Defect is defined in the Directive; Article 6 provides that a product is defective when it does not provide the safety which a person is entitled to expect, taking into account all the circumstances, including the product’s presentation, the use to which it could reasonably be expected to be put and the time when the product was put into circulation (this is termed the ‘consumer expectations test’). In construing this provision, the Court made reference to the sixth recital to the Directive, and stated that the effect of that recital was that the “assessment must be carried out having regard to the reasonable expectations of the public at large”. Taking these factors into account, the Court concluded that the consumer expectations test must be assessed by taking into account various factors, including the intended purpose of the product, its objective characteristics and properties, and the specific requirements of the group of users for whom the product is intended. Although the test is, therefore, expressed as taking account of the expectations of the public at large, in practice, the test compasses the specific requirements and expectations of the group of users for whom the product is intended.

The CJEU concluded that, where products belonging to the same production series have a potential defect, it was possible to classify all products in that production series as defective without the need to establish that any specific product was, in fact, defective. In reaching its conclusion, the CJEU noted that, on the facts of the case, the affected patients were entitled to expect particularly high safety standards given that the devices were implanted and there was, therefore, a risk of death or cardiac failure if the product malfunctioned. Taking account of these factors, the Court concluded that its interpretation was consistent with the objectives of the Directive as indicated by, in particular, the second and seventh recitals to the Directive, which make it apparent that the legislation was intended to ensure a fair apportionment of risks between the injured person and the producer of the product.

Although the Court appeared to take account of the specific risks arising from implantable medical devices in reaching its decision, this conclusion is broadly framed. It refers to the position where a group or series of products “such as pacemakers or cardioverter defibrillators” have a potential defect, and treats it as relevant that...
the products had an “abnormal potential for damage”. However, the Court does not expressly limit the decision to the facts of those cases. It remains to be seen how national courts will interpret the CJEU’s decision. It is clear that the Court is saying that, in certain circumstances, it may be possible to prove the legal concept of defect for the purposes of establishing liability under the Directive without showing an actual material defect in the individual product. As the Court has not formulated any very clear principles, it is not apparent in what circumstances, apart from a case of implanted medical devices, defect may be established in this way.

The CJEU was also asked to provide guidance on the damages recoverable in such circumstances and, in particular, whether the costs of an operation to remove and replace the defective medical device constituted losses caused by personal injury which are recoverable under the Directive. Again, the CJEU adopted a broad approach to the meaning of ‘damage’. It held that since, under the Directive, it is necessary to prove that there is a causal relationship between the defect and the damage suffered, compensation for damage relates to any damage or losses that are necessary “to eliminate harmful consequences and to restore the level of safety which a person is entitled to expect”. As a result, in the case of the defective pacemaker, compensation for damage covered the replacement of the defective product, and included the costs of the surgical operations. In the case of the cardioverter defibrillators, the national referring Court was asked to determine whether deactivation of the magnetic switch was sufficient to remedy the defect in that product, bearing in mind the particularly vulnerable situation of patients using that implanted device and the high risk of damage if a defect arose.

The CJEU’s broad approach to the meaning of ‘damage’ appears to conflict with Article 9 of the Directive, which expressly provides that ‘damage’ does not include the costs of replacement of the defective product. It also potentially cuts across national case law on this issue, which can limit the damages recoverable in specific circumstances of this type. Claimant lawyers are likely to rely on the decision to argue that all losses and expenses potentially related to the use of a defective product are recoverable, however remote the loss.

One potential application is in relation to claims for the recovery of the cost of medical monitoring. Many US Courts have permitted the recovery of damages in respect of the cost of so-called ‘medical monitoring’ where a product has not yet caused injury, but may do so in the future, including the costs of regular investigations and appointments with a medical practitioner to determine if a condition or complication potentially caused by the product has in fact arisen. Claims have been brought in situations like the Boston Scientific case, where an implanted device has not in fact malfunctioned and the medical advice to the patient is to carry out regular checks to determine the continued safe operation of the device, rather than running the risk of operating to remove the device. There have also been cases involving medicinal products where medicinal monitoring may be approved to look for, for example, a rare adverse effect which may only become manifest some years after the product was taken. The approach to recovery of these types of damages differs throughout the EU. However, large-scale medical monitoring claims of the type pursued in the US have not been a feature of European litigation. Although the precise scope of the Boston Scientific decision remains to be explored, the wider definition of ‘damage’ applied by the CJEU could be used by Claimants to argue that such costs are properly recoverable where a product is deemed defective by applying the CJEU’s broad definition of defect, which includes the situation where the product forms part of a production series where there is an increased risk of failure.

In conclusion, depending on how the Boston Scientific decision is construed, it has the potential to expand the scope of liability under the Directive beyond what was previously understood, and more generally with respect to the range of damage recoverable where a product is found to be defective. Most legal commentators had previously assumed that, because under the Directive the claimant has the burden of proving that the product is defective, liability would only arise if a product was shown to actually be defective, rather than if there was merely an increased risk of it becoming defective.

Special Liability Systems

Article 13 of the Directive provides that special liability systems which existed at the time the Directive was first notified are not affected by its enactment. Germany has such a special liability system, the Arzneimittelgesetz of 24 August 1976 (the “AMG”), which provides for special compensation arrangements where a person is injured as a result of taking a medicinal product. In 2002, the AMG was amended to give the injured party the right to information about the medicine’s adverse effects from the pharmaceutical manufacturer.

In Case C-310/13, Novo Nordisk Pharma GmbH v S, the Claimant, who suffers from diabetes, was prescribed a medicine which she claimed caused her to suffer lipodystrophy (loss of subcutaneous fat tissue). She brought proceedings against the manufacturer, Novo Nordisk, seeking disclosure of information regarding the medicine’s adverse effects, relying on the amended AMG. Novo Nordisk objected to disclosure on the ground that the amendment to the AMG, which was made after the Directive entered into force, was contrary to the Directive. The CJEU was asked to determine whether, where a special liability system exists, it is possible for the national court to develop that liability system, and if so, whether the amendment to the AMG infringed the Directive. Consistent with existing case law, the Court found that while the Directive is a maximal harmonisation measure, it does not seek to harmonise liability for defective products beyond matters regulated by it. The CJEU held that as the amended AMG did not reverse the burden of proof laid down in the Directive, but was concerned only with the disclosure of information, the amendment which gave injured persons the right to request information fell outside the scope of the Directive and was, therefore, permissible. The case confirms existing CJEU case law regarding the scope of the Directive.

Jurisdiction in Product Liability Claims

The CJEU has also recently considered the issues of jurisdiction under Council Regulation 4/2001 (the “Brussels Regulation”) in the context of product liability claims. In Case C-45/13, Andreas Kainz v Pantherwerke AG, the Court was asked to consider the question of jurisdiction in a product liability claim brought by an Austrian Claimant against the German manufacturer of a defective bicycle. Mr. Kainz purchased the bicycle from an Austrian supplier and sustained injuries while riding the bike in Germany. He commenced proceedings for damages in the Austrian Courts. The manufacturer of the bicycle, Pantherwerke AG, contested jurisdiction.

The Brussels Regulation provides a special regime for establishing jurisdiction in tort cases under Article 5(3), which provides that in such cases a person may be sued in the courts of the place where the harmful event occurred or may occur. Existing CJEU case law means this is interpreted as either the place of the event giving rise to the damage, or the place where the damage occurred. Where these
places are not identical the Defendant may be sued, at the option of the Claimant, in the Courts of either of those places. In the Kainz case, the CJEU was asked to clarify the meaning of the place of the event giving rise to the damage. The Court held that in product liability claims, the place of the event giving rise to the damage is the place where the event which damaged the product itself occurred. In principle, this is the place where the product was manufactured. Applying this test, the Austrian Courts did not have jurisdiction to hear Mr. Kainz’s claim, even though he had purchased the defective bicycle in Austria, as the harmful event (both the damage and the event giving rise to that damage) occurred in Germany. The case provides clear guidance on the application of the jurisdiction rules under the Brussels Regulation to product liability claims. If the place where the damage occurred as a result of the defective product is different from the country of manufacture, the Claimant may, of course, choose to bring proceedings in that country, in accordance with existing CJEU case law (see, for example, Case C189/08 Zuid-Chemie BV v Philippo’s Mineralfabriek NV/Sa).

**Proposed Regulations on Consumer Product Safety and Market Surveillance**

The European Commission has published two proposals for Regulations on Consumer Product Safety and Market Surveillance of Products which are likely to be enacted shortly. Although the legislative process is well advanced, progress stalled during 2015 as a result of disagreement over the proposed introduction in the Regulation on Market Surveillance of a new requirement to label products with their country of origin. It is hoped that this matter may be resolved in the light of the publication in March 2015 of a report on the implications of the proposal. The report concluded that there was limited evidence that the introduction of country of origin labelling would improve product safety. In assessing whether the benefits of providing more information to consumers balanced the costs of implementing the change, the report concluded that this depended on the product sector and the implications of the proposal across the product sectors reviewed were mixed. In light of this report, it remains to be seen whether the current proposal for country of origin labelling will be pursued.

The Regulation on Consumer Product Safety (“CPS”) will replace the current General Product Safety Directive, 87/357/EEC; the new product safety regime will, therefore, be directly effective in Member States. Regulations remove the need for national implementation and, therefore, are viewed as reducing the potential for inconsistent transposition into national law. The draft CPS Regulation follows the same basic framework as the Directive, but seeks to harmonise this with the approach adopted in sector specific legislation such as the Toy Safety Directive, where responsibilities are imposed on each party in the supply chain: manufacturers; importers; and distributors. It requires manufacturers to hold a technical file, including a safety assessment, for the products they market, and imposes new obligations on distributors and regarding the labelling and traceability of products. The proposed Market Surveillance Regulation seeks to bring together in a single unified system powers governing the market surveillance of both consumer and business products.

From a liability perspective, any failure to comply with the new regime under the CPS Regulation, once it comes into force, will potentially increase companies’ exposure to claims. In particular, any failure by manufacturers to comply with the new requirement to maintain a product technical file will likely be relied upon by Claimants as evidence of fault or defect in relation to the manufacture and supply of faulty or unsafe consumer products. Manufacturers will only be required to maintain such a technical file where it is proportionate to do so taking account of the product’s risks; but they will need good reasons for deciding not to do so. The likely inference if a product is found to be unsafe is that a technical file should have been maintained.

**Other European Developments – Collective Redress**

Possible changes to the procedural rules affecting many product liability claims may have a significant impact on the overall legal environment and increase the number of such claims brought in the EU.

Discussions regarding the effectiveness and efficiency of existing EU collective redress mechanisms have been ongoing for many years. A series of reports have been produced looking at the problems faced by consumers in obtaining collective redress for infringements of consumer protection legislation, but proposals to introduce legislation in this area have proved controversial and faced political deadlock.

These reports found that many Member States have no collective redress mechanism, and in those countries where there was a mechanism in place 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. Indeed, in its Green Paper on Consumer Collective Redress published in November 2008, the Commission concluded that because of these differences “a significant proportion of consumers who have suffered damage do not obtain redress”.

**Commission Recommendation 2013/396/ EU on Common Principles for Collective Redress Mechanisms**

Apparently, in an attempt to break the political impasse, the Commission has introduced a Recommendation on Collective Redress, 2013/396/EU, which sets out a number of common principles to be applied by Member States in their national collective redress systems. The principles are intended to apply horizontally in all areas where collective claims are made, but in its accompanying Communication the Commission singles out, in particular, the areas of consumer protection, competition, environment protection, protection of personal data, financial services and investor protection.

Member States were asked to implement the principles set out in the Recommendation by 26 July 2015. However, the Recommendation is not binding and it, therefore, remains to be seen whether any changes to existing national laws will be made. Within two years following implementation, by 26 July 2017, the Commission will assess the practical impact of the Recommendation and will determine whether further measures should be proposed to consolidate and strengthen EU laws on collective redress. This timetable is extremely challenging, given that for those Member States who act upon the Recommendation it may require changes to Members States’ legal systems and procedural frameworks, and this has led some commentators to suggest that the Commission’s initiative is bound to fail.
One area that will remain under review is whether there is a need for specific rules on jurisdiction and choice of law in collective redress actions: the Commission rejected this proposal in its Communication, but said that it will review experience of these issues in cross-border cases. As matters currently stand, there is considerable uncertainty as to whether any strengthened measures will be introduced in future. According to the Commission’s Communication, Member States that responded to the consultation expressed divergent views on whether binding rules on collective redress should be introduced, ranging from support to “strong scepticism”. Some Member States supported the idea of binding rules only in certain legal areas such as competition law (Sweden and the UK) or for cross-border claims only (Denmark).

The overall aim of the Recommendation is to facilitate access to justice by ensuring that collective redress mechanisms are available to assist in the resolution of large numbers of similar claims, while at the same time ensuring that appropriate procedural safeguards are put in place to avoid abusive litigation. Put simply, the Commission’s aim is to make redress more widely available to consumers who suffer damage, if necessary by facilitating litigation. The Commission Communication rejects ‘US style’ class actions which it describes as vulnerable to abusive litigation and highlights the fact that such class action procedures, and in particular the availability of punitive damages, funding of cases by means of contingency fees, extensive discovery of documents and ‘opt-out’ class action procedures, have encouraged defendants to settle claims that may not be well-founded. The Recommendation seeks to balance these different considerations, proposing that all Member States should have collective redress mechanisms in place, while at the same time introducing ‘safeguards’ in terms of the format of that procedure. The few Member States which do not presently have any collective redress mechanisms are, therefore, encouraged to introduce these.

To balance this, the Commission proposes a range of safeguards, including recommending that Member States’ collective redress procedures are ‘opt-in’, no punitive damages should be available, there should be restrictions on the availability of funding by means of contingency fees and through third party funders and the ‘loser pays’ rule should apply to the payment of costs.

The Common Principles

The Recommendation contains a set of principles which would apply to all collective redress mechanisms, whether their purpose is to provide injunctive relief to stop illegal practices, or to provide compensation to injured parties in mass harm situations. These are:

1. **Standing to bring a Representative Action** – Member States should designate representative entities to bring representative actions on the basis of defined conditions of eligibility. In particular, the Commission suggests that the representative entity should be non-profit making, have a direct relationship with, or interest in, the subject matter of the collective proceedings and act in the best interests of the group represented. Alternatively, Member States should be permitted to empower public authorities to bring representative actions on behalf of claimants seeking compensation.

2. **Admissibility** – the Recommendation appears to support a process of approval or certification of all collective actions by the courts to ensure that manifestly unfounded cases are not pursued.

3. **Provision of Information** – the representative body must be able to publicise the proposed proceedings.

4. **Costs** – the Commission proposes that the ‘loser pays’ principle should apply and that the party that loses a collective redress action should reimburse the legal costs of the winning party.

5. **Funding** – claimants should be required to provide details of their source of funding for the litigation at the outset of the case. Although the Recommendation accepts the funding of collective proceedings by third party funders, this would only be permitted in restricted circumstances.

6. **Cross-Border Cases** – Member States should ensure that claims can be brought in their jurisdiction by foreign groups of claimants or representative entities from other countries. In particular, any representative entity that has been officially designated by another Member State as having standing to bring proceedings in that country should be permitted to bring a claim in another Member State which has jurisdiction to hear the collective proceedings.

The Regulation also lays down a number of specific principles relating to injunctive collective redress. These are very generally worded and suggest that Member States must provide expedient procedures so that any injunctive orders can be made promptly to prevent any continuing harm, and should provide for sanctions, such as daily fixed-fee penalty payments, to ensure that any injunctive orders are complied with.

With regard to compensatory collective redress, the Commission makes detailed recommendations governing the basis of the proceedings. These include:

1. **“Opt-in” Collective Redress Mechanism** – the Commission considers that claims should generally be pursued on an “opt-in” basis because this respects the right of individuals to decide whether they want to litigate. However, exceptions to this principle may be permitted if they are justified by reason of “sound administration of justice”. Member States such as the Netherlands, Portugal, Bulgaria and Denmark which already have “opt-out” collective redress mechanisms may, therefore, be able to justify their continued operation on the grounds of appropriate national administration of justice. A similar justification could be made by Belgium and the UK which have recently introduced new collective redress procedures that can be pursued on either an “opt-in” or an “opt-out” basis.

2. **ADR and Settlement** – parties to any collective proceeding should be encouraged to settle the dispute both pre-trial and during the proceedings. Where a collective settlement is agreed, the Commission also proposes that this should be approved or verified by the Courts.

3. **Contingency Fees** – in general, Member States should not permit contingency fees as these risk creating an incentive to conduct litigation which might result in spurious claims being brought. However, Member States can exceptionally allow for contingency fees provided these are appropriately regulated, taking into account the right to full compensation of the individual claimants.

4. **Punitive Damages** – these should not be permitted. In its Communication the Commission makes clear that the aim of collective redress procedures should be to facilitate compensation.

5. **Collective Follow-on Actions** – the Commission generally favours so called “follow-on” actions and considers that proceedings should generally only be brought after any regulatory action has been concluded, so as to avoid the risk of conflicting decisions.

Since the Recommendation was published, Belgium, France and the UK (in respect of claims for damages relating to breaches of competition law only) have introduced new collective redress procedures. In view of the limited implementation steps which have been taken to date by other Member States, it remains to be seen whether the Recommendation will have a significant impact in practice.
Conclusion

More than 20 years after the Directive was enacted, the CJEU has finally provided guidance on some of the difficult issues of interpretation raised by the Directive. While the clarification provided by the Boston Scientific decision is welcomed, there remain questions regarding how that decision should be interpreted. It remains to be seen whether national courts will apply the decision by inferring the existence of defect only in the case of high risk products groups, such as implanted medical devices, or whether it will be applied more broadly whenever a product is part of a group or series of products that has a potential defect.

In addition, there remain other areas of uncertainty regarding the interpretation of the Directive, for example:

■ the scope of the development risks defence; and
■ what information may be taken into account in assessing whether a product is defective – for example, 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 European Court will, in future, be invited to provide guidance in these areas.

A number of new legislative initiatives are being pursued in parallel by the European Commission, particularly in relation to mechanisms for collective redress that may in future enhance consumer rights in respect of defective products and make it easier to pursue claims for compensation. It remains to be seen whether the Commission’s Recommendation on Collective Redress will be implemented in Member States: the timetable to do so is very short. However, if no steps are taken this may provide a platform for the Commission to propose legislation in future. What seems clear is that further developments are likely over the coming years in relation to EU mechanisms for collective redress.
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