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Recent Developments in European Product Liability

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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 considered several important issues regarding the scope of the Directive, including the meaning of "defect", the approach to causation, 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 European Commission's consultation on the Directive, which will consider whether any changes should be made to its scope.

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 arythmias. 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 original implantation (in case of the pacemakers) or the costs of replacing the devices (in the case of the defibrillators). 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 guidance on the meaning of 'defect' for the purposes of the Directive. Defect is defined in Article 6 of the Directive, which 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, said to take into account the expectations of the public at large, in practice, the test encompasses 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 fair 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 cases before it, the affected patients were entitled to expect a particularly high safety level given that the devices were implanted and there was a risk of very serious damage if the product malfunctioned, i.e. a risk of death or cardiac failure. 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, its 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. The question of whether the design could, in practice, be safer, or the relevance of warnings was not discussed. 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. The precise scope of the *Boston Scientific* decision remains to be explored, Claimants may argue that, in the light of the wider definition of 'damage' adopted by the CJEU and the broad definition of defect applied (which includes the situation where the product forms part of a production series and there is an increased risk of failure), such costs should be recoverable.

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 actually to be defective, as opposed merely to be at increased risk of becoming defective.

Causation

In a pending reference, the French *Cour de Cassation* has asked the CJEU to provide guidance on the evidential requirements to prove causation for the purposes of the Directive. Case C-621/15, *W X Y v Sanofi Pasteur MSD SNC and Others*, concerns a claim for damages brought against Sanofi Pasteur in respect of Mr W's condition of multiple sclerosis which, it is alleged, was caused by his vaccination against Hepatitis C with a vaccine manufactured by Sanofi Pasteur. The Paris *Cour d'appel* reviewed the scientific evidence supporting the claim for causation and concluded that there was no scientific consensus to support the existence of a causal relationship in these circumstances. However, under French law, a causal association may be presumed where a disease manifests itself shortly after administration of an allegedly defective product in circumstances where there are no personal or family antecedents related to the disease, even if existing medical research does not generally confirm the existence of such an association. Against this background, the *Cour de Cassation* has asked the CJEU to provide guidance on the Claimant's obligation under Article 4 of the Directive to prove the "causal relationship between damage and defect" and whether the presumption of causation permitted under French law is consistent with that burden of proof.

Advocate General (AG) Bobek delivered his Opinion on the reference on 7 March 2017. He concluded that the standard of proof and what evidence is required to meet that standard are not harmonised by the Directive and are, therefore, matters of national law, subject to the overarching requirement that those national laws must respect the principles of equivalence and effectiveness. A factual presumption could, in principle, be relied on to establish causation provided that the national Court was convinced it was based on relevant evidence and was sufficiently rigorous such that it did not, in practice, amount to a reversal of the burden of proof.

In particular, he clarified that the method of proof may only involve presumptions that are rebuttable by appropriate evidence and rely on evidence which is both relevant and sufficiently rigorous to sustain the inferences drawn. In this context, he clarified that if there was no evidential basis for the presumption of causation, or if it was based on wholly irrelevant evidence, that would amount to an impermissible reversal of the burden of proof. However, the AG declined to rule on whether relevant but 'weak' evidence, such as the temporal link between the Claimant's vaccination and the manifestation of multiple sclerosis were sufficient. He stated that such matters should be determined by the national court, but indicated that as a matter of principle other EU laws (such as in the competition field) recognise presumptions based on limited factual evidence.

He also concluded that the rules of evidence implementing Article 4 of the Directive should allow judges the freedom to assess all of the evidence presented to them, including scientific research, but noted that there was nothing wrong with national laws attributing particular weight to specific pieces of evidence. Accordingly, there was no obligation under Article 4 to prove causation based on medical research. In reaching this decision, the AG noted that Article 4 only imposes on the Claimant the burden of proving that

the particular defective product caused the alleged harm (known as 'individual causation'); there was no requirement to establish that scientific research had proved the harmfulness of the product more generally ('general causation'). Furthermore, such a rule would make it impossible to establish causation in cases where medical research evidence was lacking, irrespective of the quality of the other evidence available and could impermissibly extend the 'defences' to liability under the Directive laid down in Article 7. However, he indicated that such evidence should be taken into account; laws which explicitly prohibited judges from taking potentially relevant evidence into account would, likely, be contrary to the principle of effectiveness.

The AG made a number of other interesting observations in reaching his Opinion. In particular, he disagreed with submissions made by Sanofi Pasteur that the Claimant was impermissibly inferring that the vaccine was defective from the existence of a causal link. While noting that was not how the French referring court had framed the reference, he concluded that even if Sanofi Pasteur were correct, such an inference was not problematic as the evidence being used to establish causation was serving indirectly to establish defect. In the same way that a presumption could be used to establish causation, it could also establish defect. Proof of defect was a matter for the national court. However, the AG also commented that the definition of defect in Article 6 of the Directive, while ambiguously worded, in his opinion referred to the baseline expectation of the product under normal conditions of use. He disagreed with Sanofi Pasteur's submissions that establishing a causal link alone was insufficient to prove defect, and that more was required, including an assessment of the cost/benefits of the product.

The AG's opinion that the determination of causation is essentially a matter of national law is unsurprising, as it respects the EU principle that procedural laws are a matter for Member States. Similarly, his suggestion that evidential rules that effectively result in a reversal of the burden of proof are not permitted is consistent with the clear wording of Article 4, which imposes the burden of proof on the Claimant. However, his comments about the interaction between causation and defect are more controversial, and contradict the case law in some Member States (such as the UK). The Directive provides that "all circumstances" may be taken into account in assessing defect, so it is unclear why, in appropriate cases, considerations of costs and benefits may not be taken into account. The AG's implicit suggestion that individual causation (i.e. that the product caused the individual Claimant's injuries) can be established without proving generic causation (i.e. that the product is capable of causing the type of injury alleged) is also novel to common law practitioners. It remains to be seen whether the CJEU will follow the AG's Opinion; even if it does its Judgments are usually more narrowly focused, simply addressing the questions referred.

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 lipoatrophy (loss of subcutaneous fat tissue). She brought proceedings in Germany 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 44/2001 (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 led to the damage to 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 Mineralenfabriek NV/SA*).

European Commission Consultation

Alongside its regular five yearly review of the operation of the Directive, the European Commission has announced a formal evaluation and 'fitness check', which will assess the functioning and performance of the Directive, and will look, in particular, at

how the Directive is applied to new technologies, such as software, the Cloud, the Internet of Things, advanced robots and automated systems. The Commission wants to assess how Member States are applying the Directive to these type of matters, including how to allocate liability to participants in the Internet of Things and whether the Directive covers liability caused by malfunctioning apps and non-embedded software. The evaluation will also look at whether the Directive continues to meet its objectives of guaranteeing at EU level the strict liability of the producer for damage caused by a defective product, while also ensuring free movement of goods and offering a high level of protection to EU consumers. The evaluation is scheduled to take place during 2017. A public consultation has been launched with separate questionnaires available to producers, members of the public and public authorities/law firms, which will close on 26 April 2017. In addition, the Commission intends to gather information through interviews with stakeholders.

Conclusion

More than 30 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 where the consequence of failure in terms of injury is serious, 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 it is realistic to provide a totally safe and reliable product or the costs of so doing and whether the 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, may be taken into account.

It is hoped that the European Court will, in future, be invited to provide guidance in these areas. The pending reference in the *Sanofi Pasteur* case may provide clarity on the scope of the Claimant's obligation to prove causation. It is too early to say whether the Commission's evaluation of the Directive will result in proposals to change its scope. However, it is encouraging that the Commission is reviewing its application to new technologies, to address any inconsistencies in application at an early stage in the development of those technologies.

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Arnold & Porter Kaye Scholer is an international law firm with over 1,000 attorneys in 13 offices in the US, London, Frankfurt, Shanghai and Brussels. With 40 partners and counsel specialising in product liability matters, the firm 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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Update on U.S. Product Liability Law

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Introduction

Personal jurisdiction continued to be a hotly contested issue in product liability law during the past year. Since the Supreme Court's decisions in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014) and *Walden v. Fiore*, 134 S. Ct. 1115 (2014), both state and federal courts have dismissed claims brought by plaintiffs in jurisdictions in which they do not live, did not purchase or use a product, and did not suffer any injury, even where a non-resident plaintiff's claims were joined with a resident plaintiff's claims. However, the Supreme Court of California took a different position in *Bristol-Myers Squibb Co. v. Super. Ct. of Calif.*, 206 Cal. Rptr. 3d 636 (2016) (*cert. granted* Jan. 19, 2017), holding that, in light of the defendant's extensive contacts in California, the defendant could be subject to specific personal jurisdiction over the nonresident plaintiffs' claims which arose from the same course of conduct that gave rise to the California plaintiffs' claims. The Supreme Court of the United States recently granted certiorari in this case, and the decision will likely have a significant impact on product liability litigation.

This past year has also seen its share of other important decisions, most notably in the areas of federal preemption, class actions, and multidistrict litigation. In addition, challenging expert testimony on causation has remained a powerful tool for managing mass tort litigation. Finally, the recent amendments to the Federal Rules of Civil Procedure have controlled the scope of discovery in product liability and other fact-intensive cases.

This chapter provides updates on each of the following topics:

- Personal Jurisdiction;
- Federal Preemption;
- Class Actions;
- Multidistrict Litigation (MDL) Trends;
- Admissibility of Expert Causation Testimony;
- Limiting the Use of Adverse Event Reports in Litigation; and
- Federal Rules Update.

Personal Jurisdiction

In the United States, the requirement of personal jurisdiction, which is grounded in the U.S. Constitution, protects defendants from being sued in jurisdictions in which they do not have certain minimum contacts. Personal jurisdiction can be general or specific, but a court must have one of these two forms of jurisdiction over a plaintiff's claims. If the court lacks personal jurisdiction, it must dismiss the case. General jurisdiction exists when a defendant has such a substantial connection to a jurisdiction that it may be sued in the jurisdiction based on any conduct, regardless of whether that conduct occurred in the jurisdiction or whether the lawsuit relates to the conduct that occurred in the jurisdiction. Specific jurisdiction exists when a defendant who is not subject to the general jurisdiction of a state has engaged in certain minimum contacts in the state relating to the lawsuit that allows a court to adjudicate the claims without offending "traditional notions of fair play and substantial justice". *Int'l Shoe Co. v. State of Wash., Office of Unemployment Comp. & Placement*, 326 U.S. 310, 316 (1945). In 2014, the Supreme Court's decisions in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014) and *Walden v. Fiore*, 134 S. Ct. 1115 (2014) altered the personal jurisdiction landscape for corporations who conduct routine nationwide business, and in particular, corporations who sell products in numerous states. Over the past two years, the lower courts have grappled with personal jurisdiction issues arising out of these decisions. As discussed in detail below, the U.S. Supreme Court recently granted certiorari in the matter of *Bristol-Myers Squibb Co. v. Super. Ct. of Calif.* and will consider whether specific jurisdiction can be found when there is no link between the defendant's forum contacts and the plaintiff's claims. As a result, significant personal jurisdiction decisions are anticipated in 2017.

General Jurisdiction. In *Daimler*, the Court held that a corporation is not subject to general jurisdiction in a state simply because it distributes or sells goods there. 134 S. Ct. at 761. Rather, the corporation must have "affiliations with the State [that] are so continuous and systematic as to render it essentially at home in the forum State". *Id.* (quotation omitted). Typically, a corporation is subject to general jurisdiction only in its "place of incorporation and principal place of business". *Id.* at 760. Since *Daimler*, two influential state courts have held that registering to do business in a state and maintaining an agent for service of process in a state alone does not establish general jurisdiction over a corporation. S*ee, e.g., Bristol-Myers Squibb Co. v. Super. Ct. of Calif.*, 206 Cal. Rptr. 3d 636, 648 (2016) (no general jurisdiction over foreign corporation who had registered to do business in California and maintained an agent for service of process in compliance with California law); *Genuine Parts Co. v. Cepec*, 137 A.3d 123, 148 (Del. 2016) (no general jurisdiction over Georgia corporation that registered to do business in compliance with a Delaware registration statute; compliance with the statute did not constitute "consent" to the general jurisdiction of the Delaware courts).

Specific Jurisdiction. In *Walden*, the Court further defined the minimum contacts required for the exercise of specific jurisdiction over a defendant: "the defendant's suit-related conduct must create a substantial connection with the forum State." 134 S. Ct. at 1121. *Walden* makes clear that the jurisdictional inquiry should be focused on the defendant's own specific contacts with the jurisdiction as they

relate to the litigation and not the connection between plaintiff and/or a third party and the jurisdiction. This is a particularly powerful tool for defendants in product liability and mass tort cases in which the claims of numerous plaintiffs from various states are often joined together and filed in a forum thought to be most favourable to plaintiffs (sometimes referred to as "forum shopping"). Dismissal on personal jurisdiction grounds is an effective way for defendants to prevent plaintiffs from engaging in such forum shopping. For example, in *In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, 164 F. Supp. 3d 1040, 1049 (N.D. Ill. 2016), *adhered to in part on reconsideration*, 2016 WL 861213 (N.D. Ill. Mar. 7, 2016), plaintiffs from Missouri and other states filed claims in Missouri state court against a manufacturer of a medical product marketed to treat hypogonadism. The case was subsequently removed to federal court where defendants challenged the court's exercise of specific personal jurisdiction over the claims of non-Missouri plaintiffs. *Id*. at 1047. The court evaluated whether specific jurisdiction existed based on whether defendants had the requisite minimum contacts with Missouri, the state in which the case was originally filed. Defendants argued that the non-Missouri plaintiffs' claims had no connection to defendants' conduct in Missouri and thus there was no basis for the exercise of specific jurisdiction because plaintiffs did not allege that the non-Missouri plaintiffs encountered any advertising for the defendants' product in Missouri, that they purchased or used the product in Missouri, that they suffered any injury in Missouri, or that the defendants engaged in any conduct in Missouri related to their claims. *Id.* Plaintiffs argued that jurisdiction existed over the non-Missouri plaintiffs' claims because they were joined to the Missouri plaintiffs' claims. *Id.* The court held that jurisdiction must exist over each plaintiff's claim independent of whether they were joined to Missouri plaintiffs' claims and that the court lacked specific jurisdiction over the non-Missouri plaintiffs' claims because "all of the factual allegations necessary to establish [the non-Missouri plaintiffs'] claims are based on defendants' conduct outside Missouri". *Id.* at 1048. In other words, because the non-Missouri plaintiffs' claims were based on conduct that occurred entirely outside of Missouri, the defendants did not have the requisite minimum contact with Missouri to allow the court to exercise jurisdiction over the non-Missouri plaintiffs' claims against them.

Courts across the country have similarly dismissed claims brought by plaintiffs in jurisdictions in which they do not live, did not purchase or use a product, and did not suffer any injury, even where the non-resident plaintiffs' claims were joined with a resident plaintiff's claims. *See, e.g., Addelson v. Sanofi S.A.*, No. 16-cv-01277, 2016 WL 6216124, at *4 (E.D. Mo. Oct. 25, 2016) ("simply marketing, promoting, and selling a pharmaceutical drug in [the forum state] does not establish specific jurisdiction"); *In re Zofran (Ondansetron) Prods. Liab. Litig.*, No. 15-md-2657, 2016 WL 2349105, at *5 (D. Mass. May 4, 2016) (dismissing claims brought by nonresident plaintiffs against nonresident defendant who had no forum contacts related to the nonresident plaintiffs' claims).

However, the Supreme Court of California took a different position in *Bristol-Myers Squibb Co. v. Super. Ct. of Calif.*, 206 Cal. Rptr. 3d 636 (2016) (*cert. granted* Jan. 19, 2017). There, hundreds of plaintiffs from many different states sued Bristol-Myers Squibb ("BMS") in California state court over the marketing and sale of a prescription drug, Plavix. Despite the fact that the non-resident plaintiffs purchased and used Plavix in their home states and BMS was not subject to general jurisdiction in California, the court held that "plaintiffs' claims concerning the allegedly defective design and marketing of Plavix bear a substantial nexus with or connection to BMS's extensive contacts with California as part of Plavix's nationwide marketing, its sales of Plavix in this state, and its maintenance of research and development facilities here so as to permit specific jurisdiction". *Id.* at 656. The court cited contacts including five offices in California employing over 400 people, research and laboratory facilities in California, the use of a registered agent in California, maintenance of an office in Sacramento to lobby on BMS's behalf, and sales of Plavix approaching nearly a billion dollars in California. *Id*. at 642, 647. It is unclear how far California courts will extend this decision, which the court noted was based on "this specific set of circumstances". *Id*. at 656.

The U.S. Supreme Court granted a petition for writ of certiorari on January 19, 2017 on the question of whether a plaintiff's claims arise out of or relate to a defendant's forum activities when there is no causal link between the defendant's forum contacts and the plaintiff's claims. *See Bristol-Myers Squibb v. Sup. Ct. of California*, No. 16-466, 2017 WL 215687, at *1 (U.S. Jan. 19, 2017). *BMS* and its prodigy will be carefully watched by plaintiff and defence lawyers in 2017.

Federal Preemption

Where state law conflicts with federal law, state law is preempted under the Supremacy Clause of the U.S. Constitution. U.S. Const. art. VI, cl. 2. In deciding whether a claim is preempted, courts determine whether Congress intended the federal law at issue to supplant state law. *See, e.g., Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992). Preemption may be expressed in an explicit provision of federal law or implied in the structure and scope of the federal regulatory scheme. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Over the last decade, preemption with respect to pharmaceutical products and medical devices approved by the U.S. Food and Drug Administration ("FDA") has continued to receive considerable attention from federal courts.

Pharmaceutical Preemption

In a case with far-reaching implications for pharmaceutical preemption, the U.S. Supreme Court held that certain product liability claims brought against generic drug makers are impliedly preempted. *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). In *Mensing*, plaintiffs alleged that the manufacturers of a generic drug failed to adequately warn of the risk of a severe neurological disorder. *Id*. at 610. The manufacturers argued that the claims were preempted because federal law requires generic medications to carry warnings identical to their brand-name equivalents, making compliance with both federal law and the alleged duty under state law impossible (a recognised ground for implied preemption). *Id*.

Plaintiffs asserted three bases on which the manufacturers could have independently modified the warnings: (1) by using FDA's changes-being-effected ("CBE") process; (2) by sending Dear Doctor letters to physicians; or (3) by proposing stronger warnings to the FDA. *Id*. at 614-16. The Court rejected the first two bases, noting FDA's position that a generic drug maker – unlike a brand name manufacturer – could not unilaterally strengthen its labeling by using the CBE process or disseminating a Dear Doctor letter. *Id*. at 615. As to the third basis, the FDA, writing as *amicus curiae*, urged the Supreme Court to hold that there was no true "impossibility" of complying with federal and state law, because it was undisputed that the manufacturers could ask the FDA to strengthen the warnings but had never done so; absent such a request, plaintiffs and the FDA contended, the manufacturers' preemption defence should fail. *Id*. at 620. The Court rejected this argument, because even if the generic manufacturer had proposed different labeling from the FDA, it was not clear that the agency, in exercise of its public health

judgment, would have agreed and permitted the new warning. *Id.* at 619-20. "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id*. at 623-24.

Two years later, the Supreme Court again found state tort claims brought against the manufacturer of a generic drug impliedly preempted. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013). In *Bartlett*, as in *Mensing*, a defendant generic drug manufacturer argued that it was impossible to comply with both its alleged state law duty to strengthen the warnings for its drug, and its federal law duty not to alter its approved labeling. After the First Circuit held that the plaintiff's claims were not preempted because the manufacturer could simply stop manufacturing the drug entirely and thus comply with both state and federal law, *id*., the Supreme Court reversed, explaining that its preemption cases "presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability". *Id.* at 2477. If the option of ceasing to act defeated a claim of impossibility, impossibility preemption "would be all but meaningless" because any conflict could be avoided if the regulated actor simply ceased acting. *Id*. (internal quotations omitted).

Since *Mensing* and *Bartlett*, manufacturers of generic and brand name pharmaceuticals have succeeded in arguing that state law tort claims are likewise subject to "impossibility preemption". S*ee, e.g., Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 298-300 (6th Cir. 2015) (holding claims preempted because "once a drug, whether generic or brand-name, is approved [by the FDA], the manufacturer is prohibited [by federal law] from making any major changes to the qualitative or quantitative formulation of the drug product...", and the plaintiff's additional argument that the defendant could have utilised a different design "in the first instance" *before* obtaining FDA approval was "too attenuated"); *Houston v. U.S.*, 638 F. App'x 508, 513 (7th Cir. 2016) (rejecting failure to warn, design defect, negligence, and other product liability claims because "[f]ederal law imposes on [a generic drug manufacturer] an 'ongoing duty of sameness to ensure that [a drug's] chemical design and labeling are the same as its brand-name counterpart", and "[t]he duty preempts a state-law claim against a generic manufacturer if, as here, that claim would require the manufacturer to redesign its drug, change its labeling, or exit the market in order to avoid liability"); *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d 34, 43 (1st Cir. 2015) (rejecting class action claims that drug manufacturer's labeling was misleading, where the FDA had already considered the clinical studies that allegedly rendered the labeling misleading, because under such circumstances the defendant "could not independently change its label to read as plaintiffs say it should have read in order to comply with California law"); *Seufert v. Merck Sharp & Dohme Corp.*, 187 F. Supp. 3d 1163, 1165 (S.D. Cal. 2016) (granting summary judgment in favour of drug manufacturers, because "clear evidence exists that the FDA would have rejected a reference to pancreatic cancer in [the drugs'] labeling. Thus, it would have been impossible for Defendants to provide the warning Plaintiffs seek, and Plaintiffs claims are preempted"); *Tsavaris v. Pfizer, Inc.*, 154 F. Supp. 3d 1327,1336-39 (S.D. Fla. 2016) (relying on *Barlett* and *Mensing* in dismissing design defect and other tort claims, "[b]ecause it would be a violation of federal law for [defendant], as a generic manufacturer, to change the composition of its drug to be safer"). *But see, e.g., Guidry v. Janssen Pharms., Inc.*, No. 15-4591, 2016 WL 4508342, at *14-16 (E.D. La. Aug. 29, 2016) (holding that "[a]ny state requirement that a brand name drug manufacturer should have adopted an alternative design to a prescription drug *after* it was approved by the FDA is preempted", but rejecting "the Sixth Circuit's reasoning in *Yates* concerning preemption in the *pre*-FDA approval context", and holding that "[f]ederal law does not prevent a drug manufacturer from complying with this state-imposed duty [to consider feasible, alternative designs] before seeking FDA approval") (emphasis added); *Brazil v. Janssen Research & Dev. LLC*, No. 15-CV-0204, 2016 WL 4844442, at *16-17 (N.D. Ga. Mar. 24, 2016) (rejecting *Yates*, and holding that design defect claims were not preempted because "a brand name drug manufacturer [unlike the generic drug manufacturer in *Bartlett*] may use the FDA's CBE regulation to unilaterally change its labeling without prior FDA approval. In doing so, a brand name drug manufacturer may comply with both state and federal law").

However, the FDA has proposed a rule that would permit generic drug manufacturers to unilaterally change their product labels through the CBE process, which, as discussed in *Mensing*, is currently only available to brand-name manufacturers. The rule, originally introduced in 2013, is currently scheduled to be finalised in April 2017. *See* Federal Register, "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products," available at www.federalregister.gov/documents/2013/11/13/2013-26799/supplemental-applications-proposing-labeling-changes-for-approved-drugs-and-biological-products (last visited Jan. 25, 2017); Office of Information and Regulatory Affairs, "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products," available at www.reginfo.gov/public/do/eAgendaViewRule?pubId=201604&RIN=0910-AG94 (last visited Jan. 25, 2017). If implemented, the rule change could significantly curtail preemption of failure to warn claims brought against generic manufacturers, who could no longer argue the inability to independently supplement product warnings.

Buckman Preemption

In *Buckman Co. v. Plaintiffs' Legal Comm.*, the U.S. Supreme Court addressed claims that plaintiffs suffered injuries from the use of orthopedic bone screws, and that the manufacturer of the device and its consultant "made fraudulent representations to the [FDA] in the course of obtaining approval to market the screws". 531 U.S. 341, 343 (2001). The Court held that "plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law. The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law". *Id*. at 348. More than 15 years later, courts continue to disagree regarding the application of the *Buckman* Court's "fraud on the FDA" holding.

For instance, in 2013, the Ninth Circuit held that federal law did not impliedly preempt Arizona state law failure-to-warn claims predicated on a medical device manufacturer's alleged failure to "report to the FDA any complaints about the product's performance", about which the product's labeling did not otherwise warn. *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1232 (9th Cir. 2013) (*en banc*). The court distinguished *Buckman* on the grounds that the plaintiff's "claim specifically alleges, as a violation of Arizona law, a failure to warn the FDA", *id.* at 1233 (emphasis added), whereas "the plaintiffs in Buckman alleged no state-law claim and were concerned exclusively with alleged fraud on the FDA that had occurred as part of that approval process". *Id*. at 1230. In other words, unlike in *Buckman*, the plaintiff in *Stengel* asserted "a state-law duty that paralleled a federal-law duty...", *Id*. at 1232. *See*

also McClellan v. I-Flow Corp., 776 F.3d 1035, 1040 (9th Cir. 2015) (negligent failure to warn and strict liability claims based on inadequate warnings were not preempted under *Buckman*, because the plaintiff's claims were not for "fraud-on-the-agency", but rather were "parallel" to federal law).

The Ninth Circuit's decisions depart from the holding of some other courts that allegations that a manufacturer "failed to provide the FDA with sufficient information and did not timely file adverse event reports, as required by federal regulations" are "foreclosed by [the FDCA] as construed in *Buckman*". *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205-06 (8th Cir. 2010). *See also, e.g., Aaron v. Medtronic, Inc.*, No. 1:13-cv-301, 2016 WL 5242957, at *12 (S.D. Ohio Sept. 22, 2016) (failure to warn, negligence, and product liability claims were impliedly preempted, because "[a]ny tort claim based on an alleged failure to submit adverse-event reports to the FDA would not be relying on traditional state tort law which had predated the FDCA") (internal quotation omitted); *Pearsall v. Medtronics, Inc.*, 147 F. Supp. 3d 188, 202 (E.D.N.Y. 2015) (declining to follow *Stengel*, because the "Plaintiff's failure to warn claim is predicated on Defendant's alleged failure to provide the required reports to the FDA", and "authority to enforce that claim rests with the FDA").

Express Preemption of Claims Against Manufacturers of Certain Medical Devices

The express preemption of claims against medical device manufacturers has also received considerable attention in federal courts in recent years. In 2008, the U.S. Supreme Court held that claims against manufacturers of Class III pre-market approved ("PMA") devices are expressly preempted to the extent they would impose requirements "different from, or in addition to the requirements imposed by federal law". *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (internal quotation omitted). This ruling shields manufacturers from tort liability for most claims related to PMA devices, which are subject to the most rigorous FDA review. *Id.* at 318-20. *Riegel* left open, however, the possibility that plaintiffs could plead a viable "parallel" state law claim, where a PMA-approved medical device deviated from a federally-imposed, device-specific requirement, in violation of both federal and state law. *Id.* at 330.

Numerous federal courts of appeals have continued to reject plaintiffs' attempts to circumvent *Riegel*. *See, e.g., Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1340-42 (10th Cir. 2015) (rejecting the plaintiff's design defect, breach of warranty, failure to warn, negligence, and negligent misrepresentation claims, because the plaintiff failed to offer a "parallel" federal requirement that had been violated); *Otis-Wisher v. Medtronic, Inc.*, 616 F. App'x 433, 434 (2d Cir. 2015) (affirming dismissal of design defect and failure to warn claims, because the plaintiff sought "to impose safety-related requirements on the device or its labeling beyond those imposed by the FDA").

Other courts, however, have diverged from these analyses and rejected arguments that claims regarding Class III PMA devices are expressly preempted under *Riegel*. *See, e.g., Cline v. Advanced Neuromodulation Sys., Inc.*, 17 F. Supp. 3d 1275, 1285 (N.D. Ga. 2014) (declining to reject negligence claim as expressly preempted, even though plaintiff only alleged violations of clinical good manufacturing practices ("CGMPs") generally applicable to medical devices, rather than device-specific PMA requirements); *Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170, 181 (N.D.N.Y. 2014) ("[T]he Court finds that at the pleading stage, where a plaintiff has limited access to the PMA *at the time she files her complaint*, allegations that the defendant violated either the PMA [requirements] or CGMPs, so long as they are supported by sufficient factual evidence of the violation and demonstrate a causal connection to the alleged injuries, are all that is required to. . .avoid preemption under. . . *Riegel*) (emphasis in original).

Class Actions

"The class action is an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 349 (2011) (quotation omitted). Federal Rule of Civil Procedure 23 sets out the requirements which must be met before a plaintiff can proceed with claims on behalf of similarly situated individuals. A plaintiff must demonstrate numerosity, commonality, typicality, and adequacy of representation, as set forth in Rule 23(a), and meet at least one of the criteria in Rule 23(b). Plaintiffs frequently seek class certification in a wide variety of cases, ranging from financial securities to construction products. One particularly common area of class litigation involves consumer fraud, pursuant to which plaintiffs seek damages for economic losses based on a manufacturer's alleged misrepresentations about a product.

A court's decision on whether to certify a class is a pivotal point in a putative class action. Oftentimes, recoveries for individual putative class members are small, especially in cases of consumer fraud. On their own, many have a difficult time justifying the legal costs required to obtain recovery; however, once certification has been granted the overall recovery and attorneys' fees available in these cases can be significant. *See, e.g., Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 617 (1997) ("The policy at the very core of the class action mechanism is to overcome the problem that small recoveries do not provide the incentive for any individual to bring a solo action prosecuting his or her rights. A class action solves this problem by aggregating the relatively paltry potential recoveries into something worth someone's (usually an attorney's) labor") (citation omitted). For this reason, class certification motions are often hotly contested, and a court's order granting or denying class certification is central to the overall outcome of the case.

The U.S. Supreme Court Considers Procedure for Class Certification Appeals

An order granting or denying class certification is a discretionary appeal. *See* Fed. R. Civ. P. 23(f) ("[a] court of appeals may permit an appeal from an order granting or denying class-action certification under this rule"). Appellate courts consider a number of guiding principles in deciding whether to accept the case; it is not a "bright-line" approach. *Blair v. Equifax Check Servs., Inc*, 181 F.3d 832, 834 (7th Cir. 1999) ("Likewise it would be a mistake for us to draw up a list that determines how the power under Rule 23(f) will be exercised. Neither a bright-line approach or a cataloug of factors would serve well"). *See also In re Lorazepam & Clorazepate Antitrust Litig.*, 289 F.3d 98, 106 (D.C. Cir. 2002) ("At the same time, there necessarily should be some hesitancy in creating a rigid test for the exercise of an appellate court's discretion to grant a Rule 23(f) petition for review"). While the particular considerations vary among the courts, they can generally be summarised into three main categories: (1) the decision regarding class certification sounds the "death knell" for either plaintiff or defendant; (2) the decision presents an unsettled issue of law; and (3) the district court's decision contains a substantive weakness. *See, e.g., Chamberlan v. Ford Motor Co.*, 402 F.3d 952, 957 (9th Cir. 2005) (outlining the considerations); *In re Delta Air Lines*, 310 F.3d 953, 957–59 (6th Cir. 2002) (providing an overview of case law among the courts of appeal).

In *Microsoft Corp. v. Baker*, which is currently pending before the U.S. Supreme Court, plaintiffs seek to circumvent the Rule 23(f) framework for appealing class certification decisions by creating appellate jurisdiction under 28 U.S.C. 1291. 136 S. Ct. 890 (2016) (*cert. granted*). In 2007, a number of plaintiffs individually sued Microsoft over alleged defects with the company's Xbox videogame console. The cases were consolidated, and at the conclusion of discovery plaintiffs moved to certify a class of similarly situated individuals. *See In re Microsoft Xbox 360 Scratched Disc Litig.*, No. C07-1121, 2009 WL 10219350, at *1–2 (W.D. Wash. Oct. 5, 2009) The record suggested that the alleged defect occurred in only one percent of cases, therefore the judge denied class certification on the grounds that individual issues of fact predominate over common issues of fact. *Id*. at *7–8. Two years later, the same lawyers filed a new lawsuit arguing that changes to the law in the Ninth Circuit would allow for certification, but the district court again denied class certification. *See Baker v. Microsoft Corp.*, 851 F. Supp. 2d 1274, 1280 (W.D. Wash. 2012). Plaintiffs sought an appeal under Rule 23(f), but their petition was denied. Rather than settle, plaintiffs then voluntarily dismissed their claims with prejudice. Upon entry of the order granting the dismissal by the District Court, plaintiffs appealed to the Ninth Circuit, asserting that the order of dismissal was an appealable final decision under 28 U.S.C. §1291, which grants an appeal as of right from a final decision issued by a U.S. District Court. The Ninth Circuit allowed the strategy, ruling that voluntary dismissal was "a sufficiently adverse—and thus appealable—final decision [under 28 U.S.C. §1291]". *Baker v. Microsoft Corp*., 797 F.3d 607, 612 (9th Cir. 2015). Microsoft sought appeal to the United States Supreme Court on the issue of "[w]hether a federal court of appeals has jurisdiction under both Article III and 28 U. S. C. §1291 to review an order denying class certification after the named plaintiffs voluntarily dismiss their individual claims with prejudice". *Microsoft Corp. v. Baker*, No. 15-457 (U.S. Sup. Ct.) (Mar. 11, 2016) (brief of petitioner).

If the court upholds the Ninth Circuit decision, it would have a tremendous effect upon class action litigation in the United States. Since defendants do not have the opportunity to dismiss cases filed against them, plaintiffs would be able to enjoy a one-sided, second chance at class certification. In an environment which already exposes defendants to substantial legal costs pre-certification, the pressure upon defendants to settle cases would rise.

The Ascertainability Requirement

Courts have recognised an implicit "ascertainability" requirement for class certification. This element stands in addition to the explicit requirements of Federal Rule 23. A plaintiff must demonstrate that class members are identifiable through objective criteria without resort to extensive and individualised inquiries. The ascertainability requirement eliminates "serious administrative burdens that are incongruous with the efficiencies expected in a class action", protects absent class members by facilitating the "best notice practicable" in a Rule 23(b)(3) action, and protects defendants by ensuring that those who will be bound by the final judgment are identifiable. *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 593 (3d Cir. 2012) (citations omitted). The scope of the requirement, however, varies among the courts of appeal. In particular, the Third Circuit has imposed a heightened ascertainability requirement which requires plaintiffs to demonstrate an "administratively feasible mechanism" for ascertaining putative class members. *See Byrd v. Aaron's Inc.*, 784 F.3d 154, 169–70 (3d Cir. 2015) (noting that the ascertainability inquiry requires both that the class be defined with reference to objective criteria and that the method of identifying class members be administratively feasible). However, in the past year, a number of other appellate courts have rejected this "heightened" ascertainability standard. Specifically, the Sixth, Eighth, and, most recently, the Ninth Circuits have ruled that plaintiffs do not have to meet the "administratively feasible" standard. *Rikos v. Procter & Gamble Co*., 799 F.3d 497, 525 (6th Cir. 2015); *Sandusky Wellness Ctr., LLC v. Medtox Sci., Inc.*, 821 F.3d 992, 995–96 (8th Cir. 2016); *Briseno v. ConAgra Foods, Inc.*, 844 F.3d 1121, 1125-26 (9th Cir. 2017).

In the most recent of these cases, *Briseno v. ConAgra Foods*, the Ninth Circuit has further widened the split between federal courts regarding the "administratively feasible" requirement. The court upheld the district court's ruling that plaintiffs need only define a class by an objective criterion. *Briseno*, 821 F.3d at 1132-33. Central to the court's ruling was that the words "administrative feasibility" did not appear in the text of Rule 23. "Traditional canons of statutory construction suggest that this omission was meaningful. Because the drafters specifically enumerated '[p]requesites,' we may conclude that Rule 23(a) constitutes an exhaustive list." *Id*. at 1125. First, the court rejected the argument that the administrative feasibility requirement was necessary to "mitigate the administrative burdens of trying a Rule 23(b)(3) class action". *Id*. at 1127. Instead, the court found that the requirements of Rule 23 already had an enumerated mechanism to achieve that goal. Second, the court found that a heightened pleading was not necessary to protect absent class members from fraudulent claims. *Id.*, at 1128-29. Third, because defendants already have existing opportunities to challenge class certification and the substantive merits of the plaintiffs' case, the court found that the administrative feasibility requirement was not necessary to protect the defendants' rights.

With the circuit split continuing to grow, the issue may be primed for review by the U.S. Supreme Court. The heightened standard would present another means for defendants to prevent dubious class action claims from moving forward, especially in cases where it is difficult—if not impossible—to determine who is a legitimate class member.

Multidistrict Litigation (MDL) Trends

The nature of product liability litigation leads to plaintiffs filing a large volume of claims in different courts. This can become an unwieldy and expensive process for plaintiffs and defendants alike. As a result, at times, one or both sides may be motivated to support the centralisation or coordination of litigation to avoid the additional work of litigating cases in different jurisdictions with different judges, trial schedules and local counsel and facilitate settlement. 28 U.S.C. § 1407 allows lawsuits "involving one or more common questions of fact" to be coordinated or consolidated in one federal district court for pre-trial proceedings, called a Multidistrict Litigation or "MDL".

To form an MDL, one of the parties petitions the Judicial Panel on Multidistrict Litigation or "JPML", which comprises seven sitting federal judges tasked with making determinations on MDL centralisation and location. If the JPML grants the petition, the related federal cases are transferred to the MDL court chosen by the JPML for pretrial proceedings, which includes fact and expert discovery. *See* 28 U.S.C. § 1407.

Factors in JPML Decisions

As of January 2017, there were 241 active MDLs, of which 69 were product liability actions. *See* http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_Type-January-17-2017.pdf (last visited Jan. 25, 2017). While these numbers are significant, there

has been a trend over the last several years against centralisation. For example, in 2009, the JPML granted over 80 percent of MDL petitions. But in 2016, the panel granted fewer than 50 percent of the petitions before it (26 of 55). Alan Rothman, "*And Now a Word from the Panel: A Year of Vanishing MDLs*", Law360, Jan. 24, 2017. Despite the overall downward trend against centralisation, the JPML continues to create more product liability MDLs than any other type (eight product liability and seven sales and marketing MDLs in 2016). *See id*. The panel often considers the following factors in rejecting or granting an MDL petition:

Number of actions. The JPML considers the number of actions filed or with the potential to be filed when deciding whether to certify an MDL. In cases where there are a small number of filed actions, the petitioner "bears a heavier burden to demonstrate that centralization is appropriate". *In re Nutek Baby Wipes Prods. Liab. Litig.*, 96 F. Supp. 3d 1373 (JPML 2015) (MDL certification denied); *In re California Wine Inorganic Arsenic Levels Prods. Liab. Litig.*, 109 F. Supp. 3d 1362, 1363 (JPML 2015). Even where there are common factual issues, a small number of cases and the potential for informal coordination between the parties often weigh against centralisation. *See id.* At times the JPML will contemplate the number of unfiled cases, but that is not always sufficient to sway the panel. *See In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.* ("*In re Mirena IUS*"), 38 F. Supp. 3d 1380, 1381 (JPML 2014) ("Although plaintiffs assert that the number of actions is likely to expand substantially, the mere possibility of additional actions does not convince us that centralization is warranted"); *but see In re AndroGel Prods. Liab. Litig.*, 24 F. Supp. 3d 1378, 1379 (JPML 2014) (MDL certification granted where "related cases will number in the thousands").

Number of counsel and informal coordination. In cases where many of the plaintiffs are represented by the same counsel and there are a limited number of defence counsel, the JPML will promote voluntary coordination as "a preferable alternative to centralization". *In re Spray Polyurethane Foam Insulation Prods. Liab. Litig.*, 949 F. Supp. 2d 1364, 1364-65 (JPML 2013); *In re Mirena IUS*, 38 F. Supp. 3d at 1381.

Pending 28 U.S.C. § 1404 requests for transfer. Under 28 U.S.C. § 1404, the parties can move to transfer a lawsuit to another district court. JPML courts strongly favour the transfer of cases to the same district court over centralising the cases in an MDL. *In re 3M Company Lava Ultimate Prods. Liab. Litig.*, MDL No. 2727, at 2 (JPML Aug. 5, 2016) ("transfer under Section 1404 is preferable to centralization").

Procedural posture of existing cases. The JPML has not been consistent on whether the maturity of a litigation weighs in favour of or against centralisation. See *In re Yellow Brass Plumbing Component Prods. Liab. Litig.*, 844 F. Supp. 2d 1377, 1379 (JPML 2012) (MDL certification denied; "relatively advanced progress" of one action would inconvenience parties); *see also In re Mirena IUS*, 38 F. Supp. 3d at 1381 (MDL certification denied in 2014 for Mirena IUS; cases that "are in their infancy" are less likely to be centralised and "are well-positioned for informal coordination"). The JPML recently decided not to certify an MDL of cases involving the drug Cymbalta, where the procedural posture of the 41 personal injury actions varied significantly. Some of the actions had already gone to trial with millions of pages in discovery produced, whereas others did not even have scheduling orders. *In re Cymbalta (Duloxetine) Prods. Liab. Litig. (No. II)*, 138 F. Supp. 3d 1375, 1376 (JPML 2015). But in the talcum powder cases, the advanced nature of the state court proceedings weighed in favour of creating an MDL because the MDL judge could use the prior state court discovery to work out discovery issues once in the federal actions. *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No. 2738, at 2 (JPML Oct. 4, 2016).

Need for individual fact determinations. If a party demonstrates that individualised factual issues will predominate in the litigation, the JPML is more likely to deny MDL centralisation. In *In re Spray Polyurethane Foam Insulation*, individualised facts about the differences in chemical composition between the spray foam products, training and practices of the installer, and circumstances of each installation predominated over the common factual issues, and MDL centralisation was denied. 949 F. Supp. 2d at 1364-65. In contrast, in an anti-diabetes drug litigation, the JPML found that although four different drugs were involved, the similarity of use of the drugs to manage insulin levels, the plaintiffs' allegations of pancreatic cancer, and the fact that several plaintiffs took more than one drug at issue generated sufficient efficiencies to warrant centralisation. *In re Incretin Mimetics Prods. Liab. Litig.*, 968 F. Supp. 2d 1345, 1346-47 (JPML 2013).

Applicability of laws from different states. In cases that involve more state-specific inquiries, such as fraud actions, concerns about the different discovery and pretrial practice resulting from the different state laws work against centralisation. *In re Narconon Drug Rehab. Mktg., Sales Practices and Prods. Liab. Litig.*, 84 F. Supp. 3d 1367, 1368 (JPML 2015) (MDL certification denied).

Industry/Class-Wide MDL Certification

Plaintiffs often bring class-wide or industry-wide product liability lawsuits alleging that a type of product sold by several different pharmaceutical manufacturers has caused similar injuries in hundreds or thousands of people. At first glance, these class-wide lawsuits appear to be prime candidates for an MDL. They typically involve a large number of plaintiffs and have a common set of factual issues because the drugs treat the same conditions in the same or similar patient populations and act in a similar way in the body.

However, these cases have their own unique set of challenges for the JPML when deciding whether to create a class/industry-wide MDL, an MDL for each product/manufacturer, or some other method of coordination. One of the concerns with class/industry-wide litigation is the need to protect trade secret and confidential information from disclosure among direct competitor manufacturers. For this reason, the JPML is "typically hesitant to centralize litigation against multiple, competing defendants which marketed, manufactured and sold similar products". *In re Yellow Brass*, 844 F. Supp. 2d at 1378; *In re Spray Polyurethane Foam Insulation Prods. Liab. Litig.*, 949 F. Supp. 2d at 1364; *In re AndroGel Prods. Liab. Litig.*, 24 F. Supp. 3d at 1378 (JPML 2014). Another question is how cases that involve a plaintiff who has taken more than one of the implicated drugs will impact the decision to centralise. In recent years, the JPML has both granted and denied centralisation of class/industry-wide MDLs that raise these concerns:

- In *In re Incretin Mimetics*, plaintiffs alleged that four anti-diabetic medications by different manufacturers caused pancreatic cancer. All defendants supported centralisation. Dismissing the typical hesitation to centralise litigation among competing defendants, the JPML focused on the similar factual allegations to support the creation of the MDL. Specifically, the JPML mentioned that several plaintiffs had taken more than one drug and that the discovery for those plaintiffs would have similar documents and witnesses. 968 F. Supp. 2d at 1346-47.
- In *In re Fluoroquinolone Prods. Liab. Litig.*, plaintiffs requested centralisation of cases against the manufacturers and distributors of fluoroquinolone antibiotics alleging peripheral neuropathy injuries. All defendants opposed centralisation. The JPML acknowledged, but dismissed, its hesitancy to centralise litigation on an industry-wide basis. Instead, the court relied on the virtually identical

class warnings required by the FDA and the resulting shared factual questions regarding general causation, science, and regulatory issues to create the MDL. MDL No. 2642, at 2 (JPML Aug. 17, 2015).

- In *In re AndroGel*, plaintiffs proposed centralisation of all cases involving injuries from the use of testosterone replacement therapy ("TRT"), regardless of manufacturer or drug form (gel, patch, or injection). The six main defendants took varying positions from supporting a class-wide MDL to supporting product-specific MDLs. The JPML agreed to centralise all TRT actions, finding that the actions involved common questions of fact, including the use of one or more TRT, shared questions of general causation and science of the role of testosterone, and common regulatory issues. The court mentioned hesitancy to centralise on an industry-wide basis, but then focused on the fact that many plaintiffs used multiple forms of TRT and its concern that a "*de facto* industry-wide centralization" would be created regardless because the multiple-use cases would be swept into the MDL. The JPML disregarded the concerns of the defendants with small numbers of lawsuits filed against them, suggesting that the MDL judge could establish separate discovery and motion tracks for each product. 24 F. Supp. 3d at 1378-79.
- In *In re Invokana (Canagliflozin) Prods. Liab. Litig.*, plaintiffs alleged that SGLT-2 inhibitors (class of anti-diabetes medication) caused injuries such as diabetic ketoacidosis and kidney damage. The SGLT-2 inhibitors were manufactured by several competing drug companies, but the majority of the lawsuits were filed against Janssen for Invokana/Invokamet. Plaintiffs proposed either an Invokana/Invokamet-only MDL or a class-wide MDL, and defendants opposed one or both proposals. The JPML created an Invokana/Invokamet-only MDL, and declined to include combination-use cases involving Invokana and another SGLT-2 inhibitor, citing concerns about protecting market competitors' trade secrets and confidential information and prolonging pretrial proceedings with the need for separate discovery tracks. The court also mentioned the "relatively small number" of cases involving the other non-Janssen drugs as grounds for excluding the other manufacturers from the MDL. MDL No. 2750 (JPML Dec. 7, 2016).

Multi-Plaintiff Trials after MDL Certification

After resolving pre-trial issues, an MDL judge usually selects a few cases to be tried, called "bellwethers". A bellwether is intended to be representative of the range of cases in the MDL. *See Manual for Complex Litigation, Fourth*, § 22.315. The hope is that the bellwether cases will help promote judicial efficiency by allowing the court and parties to determine the nature and strength of the claims and help provide ranges of values for settlement. *Id*. After the bellwethers are decided, the remaining cases are remanded for trial. *See* 28 U.S.C. § 1407 ("Each action so transferred shall be remanded by the panel at or before the conclusion of such pretrial proceedings to the district from which it was transferred").

Typically, MDL courts try individual cases as bellwethers, but a recent trend has developed of consolidating or "batching" cases for trial. FRCP 42(a) grants courts the broad discretion to consolidate cases for trial "[i]f actions before the court involve a common question of law or fact". MDL judges appear to be taking full advantage of this rule and trying several cases at the same time, although the methods they employ to identify "common issues of law or fact" to consolidate trials differ.

The judge in the *Depakote* MDL – which had over 129 cases filed and 698 plaintiffs – ordered the parties to depose the prescribing physicians for 132 plaintiffs. *In re Depakote: Alexander v. Abbott Labs., Inc.*, No. 12-cv-52, at 2 (S.D. Ill. Sept. 20, 2016) (ECF No. 560). The parties had to submit individual reports summarising each deposition and provide specific information related to all of the plaintiffs' claims to help determine which cases could be consolidated for trial. *Id*. The judge explained, "batching cases together along common issues of fact and law is the only way to effectively, efficiently, and justly move through the volume of cases before the Court". *Id*.

In the *Ethicon* MDL, the court batched all 39 of the West Virginia cases for trial citing the application of common laws and similar allegations. *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 12-md-02327 (S.D. W.Va. July 1, 2015) (ECF No. 1619). In the *DePuy* MDL, the judge simply borrowed the JPML's decision to establish the MDL as the basis for batching five cases for the bellwether trial. He reasoned that the MDL was established because all cases "share[d] factual questions" as to whether the device was defective and had adequate warnings. *In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.*, MDL Docket No. No. 11-md-02244, at 4 (N.D. Tex. Jan. 8, 2016) (ECF No. 606). The *DuPuy* judge has since tried another six-plaintiff consolidated bellwether trial. *See* Cara Salvatore, "Trial Bundling Comes Under Fire In Boston Scientific Appeal", Law360, Oct. 31, 2016.

Many of these consolidated trials have resulted in sizeable plaintiffs' verdicts, which defendants have appealed, arguing that grouping trials encourages unfair outcomes. Boston Scientific is appealing a $27 million verdict won by four plaintiffs in a pelvic floor repair kit suit. *See* Salvatore, Law360. Johnson & Johnson is appealing a $150 million verdict (reduced from $498 million jury verdict) awarded to five plaintiffs in the *DePuy* multi-plaintiff bellwether trial and a $493 million dollar verdict (reduced from $1 billion jury verdict) awarded to six plaintiffs in another multi-plaintiff trial. *See id*.; Shayna Posses, "J&J Can't Speed Up Appeal in Hip MDL, Patients Tell 5th Circ.", Law360, July 26, 2016. The trend of multi-plaintiff trials presents obvious concerns for defendants about confusing and potentially prejudicing the jury with facts from different plaintiffs, particularly in light of these recent super-sized plaintiffs' verdicts in consolidated bellwether trials. It remains to be seen whether appellate courts will criticise or affirm the use of consolidated bellwether trials.

Admissibility of Expert Causation Testimony

As reflected in several important *Daubert* rulings in 2016, challenging expert testimony on causation remains a powerful tool for managing mass tort litigation. Expert testimony may be admitted in federal courts "if . . . scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue". Fed. R. Evid. 702. A witness qualified as an expert by "knowledge, skill, experience, training, or education, may testify in the form of an opinion or otherwise, if . . . (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the witness has reliably applied the principles and methods to the facts of the case". *Id*.

In Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993), the U.S. Supreme Court directed federal district courts to serve as gatekeepers, ensuring that all proffered scientific expert testimony is both relevant and reliable. In most jurisdictions, 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 tort 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, e.g., Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005). A *Daubert* ruling excluding expert testimony on causation can a have significant and dispositive impact on product liability litigation, including the dismissal of multiple cases or resolution of entire MDLs, as the following notable cases of 2016 reflect:

In re Mirena IUD Products Liability Litigation. Women claiming secondary uterine perforation following insertion of an intrauterine device (IUD) asserted product liability claims against the device manufacturer. In 2013, the cases were consolidated and transferred to an MDL in the U.S. District Court for the Southern District of New York. To meet their burden on causation, plaintiffs offered the opinions of four experts, all of which were excluded for failing to meet the *Daubert* standard of reliability. 169 F. Supp. 3d 396 (S.D.N.Y. 2016). First, an OB/GYN from the University of Tennessee "reverse-engineer[ed]" a theory of general causation for perforation. The expert hypothesised as to a mechanism by which perforation could occur but did not subject his hypothesis to testing or scientific validation, nor demonstrate that it had received "general acceptance" within the scientific community. *Id*. at 429-32. The court found that the expert's opinion was "at most, scientifically-grounded speculation: an untested and potentially untestable hypothesis", which was not sufficient to pass *Daubert* muster. *Id*. at 430-31. "Indeed, 'the courtroom is not the place for scientific guesswork, even of the most inspired sort. Law lags science; it does not lead it'". *Id*. at 431 (citing *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996)).

The second expert, a physiology professor, also offered an opinion on the mechanism of perforation based upon her purported expertise and review of the scientific literature. The court similarly excluded this opinion as unreliable speculation under *Daubert*, in part because the expert's mechanism involved an "immense analytical leap, without adequately explaining the reasoning or methodology behind it", relied on a handful of case reports, and ignored contrary scientific literature. *Id.* at 449-55.

Plaintiffs' third general causation expert, a biomedical engineer, was deemed unqualified to opine on the effects of levonorgesterel (the active pharmaceutical agent in the IUD) on the uterus because he was not a medical doctor and lacked relevant experience or expertise in hormonal contraception. *Id*. at 439. Further, his opinion that the IUD had "sharp edges" was excluded because it was based primarily on tactile feel and "devoid of objective standards that [could] be tested by others". *Id*. at 440. Finally, the court excluded the opinion of plaintiffs' specific causation expert because without a valid general causation opinion, the expert's specific causation opinion lacked a necessary foundational predicate. *Id*. at 457. The court instructed that "in the absence of evidence of general causation, evidence of specific causation is 'irrelevant'". *Id*. (citation omitted).

Following this *Daubert* ruling, the court granted an MDL-wide summary judgment motion because plaintiffs could not prove that secondary perforation could occur with Mirena. *In re Mirena IUD Prods. Liab. Litig.*, Nos. 13-MD-2434, 13-MC-2434, 2016 U.S. Dist. LEXIS 99221 (S.D.N.Y. July 28, 2016). Plaintiffs tried to salvage their cases by arguing that a series of purported admissions by defendants could substitute for expert evidence of causation. After a close review of the cited legal authority, the court concluded that "no court has held that admissions can substitute for required expert testimony, and this Court will not be the first". *Id*. at *44. While the court did not rule out that in certain, rare circumstances an admission could conceivably suffice, it indicated that "those admissions would have to be clear, unambiguous, and concrete, rather than an invitation to the jury to speculate as to their meaning". *Id*. at *30, *44. The admissions that plaintiffs relied on did not meet this standard. The court commented that it reached "this conclusion reluctantly, knowing that it [would] doom hundreds of cases, but in the Court's view it is compelled by the law". *Id*. at *67-68.

In re Lipitor Marketing, Sales Practices and Products Liability Litigation. Plaintiffs in this product liability MDL alleged that use of the cholesterol-lowering drug Lipitor caused Type 2 diabetes. Plaintiffs put forth four general causation experts to support the proposition that Lipitor was capable of causing diabetes. The court found that with respect to lower dosages of Lipitor (which is what the majority of plaintiffs had taken), there was no scientific support for the experts' general causation theories and excluded those opinions. 174 F. Supp. 3d 911 (D.S.C. 2016). Specifically, the court determined that plaintiffs' epidemiologist could not reliably apply the Bradford Hill criteria to determine causation because no statistically significant association between the drug and the disease was established in the scientific literature. *Id*. at 926. Plaintiffs' other experts were excluded for failing to base their opinions on a reliable literature review, cherry-picking data, and lack of meaningful and reasonable analysis. *Id*. at 929-36. As a result of this ruling, the court recently granted defendants' omnibus summary judgment motion, dismissing all but a few cases, for plaintiffs' failure to meet their burden on causation. *In re Lipitor Mktg. Sales Practices and Prods. Liab. Litig.* (No. II) MDL 2502, No. 2:14-mm-02602 (D. S.C. Jan. 3, 2017) (ECF No. 37). As in Mirena, plaintiffs tried to rely on admissions of the defendant *in lieu* of expert causation testimony to defeat summary judgment, and once again, this approach failed. Id. at 41-44. According to the court, "the effects of drugs on the human body and the causation of a complicated, progressive disease[ ]like diabetes do require expert testimony"; this is not a situation where a "lay juror can infer causation from common knowledge and lay experience." *Id*. at 38-39.

In re Zoloft Products Liability Litigation. Similarly, the U.S. District Court for the Eastern District of Pennsylvania recently granted summary judgment for defendants and dismissed cases in the Zoloft MDL following the December 2015 *Daubert* decision excluding the plaintiffs' general causation expert. 176 F. Supp. 3d 483 (E.D. Pa. 2016). The plaintiff's expert opined that maternal use of the prescription antidepressant, Zoloft, during early pregnancy was "capable of causing, or contributing to cause, cardiovascular birth defects". No. 12-md-2342, 2015 WL 7776911, at *1 (E.D. Pa. Dec. 2, 2015). The court found that although the expert, a biostatistician, was qualified to opine on the relationship between embryological developments and antidepressant medications, *id*. at *14-16, the expert "failed to consistently apply the scientific methods he articulate[d], has deviated from or downplayed certain well-established principles of his field, and has inconsistently applied methods and standards to the data so as to support his *a priori* opinion". *Id*. at *16. In granting summary judgment in favour of defendants, the court concluded that "Plaintiffs have failed to raise a jury question on the necessary predicate to success in any case: that Zoloft was capable of causing their injuries". 176 F. Supp. 3d at 501.

State Court Talcum Powder Litigation. Finally, in the state court context, the Superior Court of New Jersey granted defendants' motions for summary judgment because plaintiffs lacked expert testimony that talcum-based powder products cause ovarian cancer. *Carl v. Johnson & Johnson*, 2016 WL 4580145, No. ATL-L-6546(N.J. Super. Ct. Law Div. Sept. 2, 2016). After hearing testimony pursuant to the standards in *Kemp v. State of New Jersey*, 174 N.J. 412 (N.J. 2002) ("Kemp Hearing"), the court rejected the testimony of plaintiffs' experts, holding that they failed to show that their opinions were based on reliable data. Despite describing one of plaintiffs' general causation experts as "a brilliant scientist and a dazzling witness", the court excluded his opinions because the scientific literature on which he relied did not support his conclusion

that talc can travel to the ovaries and cause an inflammatory response which leads to ovarian cancer. *Id*. at 15-16. The court characterised these opinions as *ipse dixit* with "all the earmarks of a made-for-litigation presentation". *Id*. at 18. In sharp contrast, the court described the testimony of defendants' expert (Dr. Chodosh), who challenged the basis for plaintiffs' causation opinion, as "akin [to] turning on the lights in a dark room":

> The failure of Plaintiffs' experts to articulate a plausible hypothesis for the biological mechanism by which talc purportedly causes ovarian cancer is a serious deficiency. After hearing Dr. Chodosh's testimony, it is apparent to the court that there was no articulation of a plausible hypothesis because it is unlikely that one can be made. Dr. Chodosh's testimony illustrates the huge hole in Plaintiffs' scientific methodology, namely, the failure to consider the biology of cancer. Dr. Chodosh's testimony and the scientific studies . . . upon which he relies in formulating his opinions appear to support a reasonable hypothesis that talc does not cause cancer because it cannot cause cancer.

Id. at 13. With respect to the plaintiffs' specific causation expert, the court based its decision on the expert's failure to account for or eliminate plaintiffs' significant risk factors for ovarian cancer. *Id.* at 20. "His opinions rely upon an incomplete/irregular methodology unlike anything upon which his peers would rely, and appear to be grounded only in his instincts and personal predilections. In short, the mingling of various risk factors and the purported 'synergy' between talc and other health conditions is highly speculative and does not conform to any methodology utilised in the scientific community." *Id*.

Limiting the Use of Adverse Event Reports in Litigation

Adverse event reports (AERs) are one common type of "evidence" plaintiffs use to support product liability claims against pharmaceutical and medical device manufacturers. Plaintiffs use AERs at every stage in litigation – from initial pleadings to expert reports to trial – for three main reasons: (1) to support a failure to warn claim by persuading a jury that liability is warranted because the defendant was aware of a specific risk; (2) to relieve or reduce the burden of causation at trial; and (3) to seek expansive discovery not just for AERs, but for all internal communications related to adverse events and consumer complaints.

In a significant ruling last year in the *AndroGel* litigation, an MDL with over 6,000 pending lawsuits, Judge Matthew F. Kennelly of the Northern District of Illinois entered an order granting plaintiffs' motion to compel the full drug and safety investigation files for adverse events reported to the FDA. *In Re Testosterone Replacement Therapy Prods Liab. Lit.*, 14-cv-1748, MDL No. 2545, (N.D. Ill. June 22, 2016) (ECF No. 1363). Plaintiffs in the litigation alleged that testosterone replacement therapy drugs could cause heart attacks and strokes, and that the defendants failed to warn doctors and patients about those risks. The court noted that "[t]hese back-up materials for defendant's reports to the FDA are relevant regarding, if nothing else, what defendants knew about adverse effects potentially associated with their products and when they knew it". *Id*. Judge Kennelly noted in his opinion that "[t]here is, to be sure, burden associated with production of these materials, including the need to redact patient-identifying and some other information, but defendants have not shown that the burden is undue given the relevance of the information and the overall scope of this litigation". *Id*. The judge further noted that the question of whether the relevant files will be admissible evidence at trial is a separate matter that will be considered by the court in the future. *Id*.

The court has scheduled six *AndroGel* bellwether trials starting in June 2017. Although it remains to be decided whether these documents will be admitted into evidence, some courts have indicated that AERs may be used to show the defendant's knowledge of the alleged defect. *See, e.g., In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prod. Liab. Litig.*, 181 F. Supp. 3d 278, 286-87 (E.D. Pa. 2016) (AERs admissible to show notice provided that AERs were limited to those involving similar circumstances as the injury at issue); *In re Fosamax Prods. Liab. Litig.*, No. 06 MD 1789, 2013 WL 174416, at *4 (S.D.N.Y. Jan. 15, 2013) ("Adverse event reports . . . are admissible if used as evidence that [defendant] was on notice of potentially serious jaw injuries"). However, other courts have excluded or limited this type of evidence for three main reasons: (1) AERs are inherently unreliable; (2) AERs are irrelevant and prejudicial; and (3) AERs are inadmissible hearsay.

Inherently Unreliable

In the U.S., AERs are voluntarily reported by healthcare professionals and consumers to FDA or the manufacturer, and an AER does not mean that the event was actually caused by the product at issue. In fact, FDA does not require that a causal relationship between a product and an adverse event be established to be reported. *See* 21 C.F.R. § 314.80(l) (stating that submitting an AER is not an admission that the drug caused or contributed to the adverse event). And pharmaceutical manufacturers are obligated to report to the FDA adverse events or side effects occurring in patients taking their medications of which they become aware "*whether or not considered drug related*". 21 CFR § 314.80(a) (emphasis added). This means the company reports information that comes "from any source", and the information is often anecdotal and incomplete. For example, the company may not know the patient outcome, or may not know the complete medical history of the patient. And there is no guarantee that a reported event actually happened, or that the event was actually caused by the product or device.

In *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005), users of an herbal weight-loss supplement containing ephedrine and caffeine sued the manufacturer alleging that the drug was unreasonably dangerous because it resulted in ischemic strokes and heart attacks. The plaintiff proffered expert testimony that relied upon adverse event reports and other consumer complaints in reaching the conclusion that the supplement caused vasospasms and vasculitis, which in turn caused heart attacks and strokes. *Id*. at 1239-41. The court concluded that reliance on AER data "lacks the indicia of scientific reliability" and that information contained in AERs "offers one of the least reliable sources to justify opinions about both general and individual causation". *Id*. at 1250. In reaching this conclusion, the court emphasised that the FDA reports reflect complaints called in by product consumers without any medical controls or scientific assessment – they simply believe they are experiencing a medical problem from taking a product. *Id*.

Other courts have similarly concluded that AERs and case reports are not reliable evidence of causation. *See, e.g. In re Mirena IUD Prod. Liab. Litig.*, No. 13-MC-2434, 2016 WL 4059224, at *16 (S.D.N.Y. July 28, 2016) ("Case reports are not reliable evidence of causation"); *Chapman v. Procter & Gamble Distributing, LLC*, 766 F.3d 1296, 1308 (11th Cir. 2014) (Fixodent) (affirming exclusion of causation testimony because reliance on "generalized case reports, hypotheses, and animal studies are insufficient proof of general causation"); *Berman v. Stryker Corp.*, No. 11 C 1309, 2013 WL 5348324, at *5 (N.D. Ill. Sept. 24, 2013) (prosthetic knee) (reliance on Manufacturer and User Facility Device Experience ("MAUDE") medical device adverse event reports alone was inappropriate basis to infer causation are because "such reports can contain inaccurate and non-validated

data"); *Trainer v. Sec'y of Health & Human Servs.*, No. 10–865V, 2013 WL 4505803 (Fed. Cl. July 24, 2013) (hepatitis A vaccine) (finding no "causal link" between the product and the alleged harm where the claimant attempted to rely on case reports and anecdotal evidence because "[t]here are too many unknown variables that make such raw information inherently unreliable"). *But see In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prod. Liab. Litig.*, 181 F. Supp. 3d at 287 ("Though AERs [adverse-event reports] do not have the same controls as other sources of data, courts have found that they can be relied upon by experts, along with other data or research, in forming opinions about causation").

Irrelevant and Prejudicial

Even if a judge is inclined to allow expert testimony based on AERs, some courts have been willing to exclude this type of evidence as irrelevant (Rule 401) or prejudicial (Rule 403) under the Federal Rules of Evidence. Some courts have concluded that events described in AERs are irrelevant if they are not substantially similar to the allegations at issue. *See, e.g., Hershberger v. Ethicon Endo-Surgery, Inc.*, No. 10-cv-837, 2012 WL 1113955, at *2 (S.D. W. Va. Mar. 30, 2012); *Brooks v. Chrysler Corp.*, 786 F.2d 1191, 1195 (D.C. Cir. 1986) ("Evidence of prior instances is admissible on the issues of the existence of a design defect and a defendant's knowledge of that defect only if a plaintiff shows that the incidents occurred under circumstances substantially similar to those at issue in the case at bar") (quotation omitted).

Similarity is often very difficult to establish because most AERs (per FDA requirements) do not contain sufficient information to draw a comparison with a plaintiff's injury. For example, in *Hershberger*, the defendant moved to exclude other incident reports involving Ethicon staplers and evidence relating to AER reporting forms on the grounds that the information was irrelevant under the Federal Rules and the substantial similarity test. The investigative files were maintained and produced by the defendants during discovery, but the court noted that each of the reports were compiled based upon third party information. Moreover, while the complaints involved similar devices and allegations of similar defects, nowhere in the AER files was there any indication that "reasonable secondary explanations" were eliminated. 2012 WL 1113955, at *2. Put simply, the incidents were not clearly the result of a faulty device and thus not substantially similar so as to permit admission. *Id*.

And even if AERs are found to be "substantially similar", they can prejudice the jury. AERs can confuse juries because it is difficult to instruct juries on the differences between direct and associational proof of causation. Juries might also attribute too much weight to official-sounding FDA reports. AERs also help plaintiffs' counsel construct a "bad company" narrative: the manufacturer knew and did nothing, when in fact, the AERs are required even when there is no evidence of causation. In *In re Norplant Contraceptive Prods. Liab. Litig.*, No. MDL 1038, 1997 WL 80527, at *1 (E.D. Tex. Feb. 19, 1997), the court excluded AERs on the grounds that the probative value would be outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury. *Id*. at *1. There, the court emphasised that the introduction of the reports may confuse the jury because the jury already had the responsibility of considering the medical histories of the individual plaintiffs, and would also waste time because the defendant would then need to rebut the significance of the adverse event reports. *Id.*

Inadmissible Hearsay

Finally, AERs consist of multiple levels of hearsay – *e.g.*, something a patient told a doctor, who told a nurse, who reported it to the manufacturer, who filed the AER – and therefore may be excluded as unreliable hearsay if offered for its inherent truth. *See, e.g., Klein v. TAP Pharm. Prods., Inc.*, 518 F. App'x 583, 584 (9th Cir. 2013) (Lupron) (affirming exclusion of adverse event reports, as they "were hearsay reports of uncertain reliability, lacking information relevant to causation"); *Goldstein v. Centocor*, No. 05-21515 CIV, 2007 WL 7428597, at *1-3 (S.D. Fla. May 14, 2007), (Remicade) (excluding AERs as hearsay and rejecting plaintiff's argument that AERs are admissible under the business records exception). *But see In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prod. Liab. Litig.*, 181 F. Supp. 3d at 285 (noting that an AER is not hearsay if offered for knowledge or state of mind, and not for its inherent truth). Thus, AERs may be inadmissible under federal and state law if offered for the truth of the matter asserted. *See* Fed. R. Evid. 802.

Federal Rules Update

The December 1, 2015 amendments to the Federal Rules of Civil Procedure were designed to "improv[e] the disposition of civil cases by reducing the costs and delays in civil litigation" and "secure the just, speedy, and inexpensive determination of every action and proceeding". Rep. of the Judicial Conf. Comm. On Rules of Prac. & Proc., September 2014 ("Comm. Rep."), at 13. Many of the amended rules were a significant overhaul of the discovery process, and case law to date suggests that the courts will enforce the goals behind the amendments.

Proportionality

Fed. R. Civ. P. 26(b)(1), which defines the scope of permissible discovery in civil litigation, was amended to explicitly provide that information sought must be "proportional to the needs of the case" to be discoverable:

> Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense *and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable*. Fed. R. Civ. Proc. 26(b)(1) (new language in italics).

Under the amended rule, discovery is permissible if the information sought is "relevant to any party's claim or defense", and "proportional to the needs of the case". Fed. R. Civ. Proc. 26(b)(1).

Although the amendments did not change the "existing responsibilities of the court and the parties to consider proportionality", Comm. Notes on Rule 26(b)(1), the amendments made the proportionality factors more prominent in litigation, and recent cases demonstrate that it provides courts with a basis to limit the scope of discovery. *See, e.g., United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 839 F.3d 242, 259 (3d Cir. 2016) (noting that the district court, in conjunction with counsel and their clients, must limit the expense and burden of discovery while still providing enough information to allow plaintiff to test its claims); *In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-02641, 2016 U.S. Dist. Lexis 126448, at *122-123, n.1 (D. Ariz. Sept. 16, 2016) (the court did not allow broad discovery of communications with foreign regulators, because it was not proportional considering the extensive discovery already conducted); *Rickaby v. Hartford Life & Accident Ins. Co.*, No. 15-cv-00813, 2016 WL 1597589, at *4

(D. Colo. Apr. 21, 2016) (conducting Rule 26(b) proportionality analysis and holding that additional discovery sought in ERISA case was "extensive and unnecessary").

Enforcing Specificity in Objections

Amended Rule 34 sharpened the requirements for responding to discovery requests. As amended, Fed. R. Civ. P. 34(b)(2) requires that parties "state with specificity the grounds for objecting" to a discovery request, as well as indicate "whether any responsive materials are being withheld". According to the Advisory Committee, this amendment was intended to curb the use of boilerplate objections in an attempt to avoid costly and lengthy disputes stemming from hollow discovery responses. Comm. Notes on Rule 34.

In cases decided since the amendments, courts have been quick to enforce this Rule and require parties to specifically state the grounds and reasons for objecting to discovery requests, as opposed to providing standard and generic objections. *See, e.g., Gondola v. USMD PPM, LLC*, No. 3:15-cv-411, 2016 WL 3031852, at *2-4 (N.D. Tex. May 27, 2016) ("a party seeking to resist discovery . . . still bears the burden of making a specific objection"); *Moser v. Holland*, No. 2:14-CV-02188, 2016 WL 426670, at *1, 3 (E.D. Cal. Feb. 4, 2016) ("[g]eneral boilerplate objections are inappropriate and unpersuasive"); *Spencer v. City of Orlando*, No. 6:15-cv-345, 2016 WL 397935, at *2 (M.D. Fla. Feb. 2, 2016) (stating that "vague, overly broad and unduly burdensome" objections are "meaningless standing alone") (quotations omitted).

Electronically Stored Information (ESI) Procedures

Finally, amended Rule 37 allowed courts broad discretion to cure prejudice caused by the loss of ESI, and further provided standards for when courts could impose sanctions for the failure to preserve ESI. Fed. R. Civ. P. 37(e) now states, "[i]f [ESI] that should have been preserved in the anticipation or conduct of litigation is lost because a party failed to take reasonable steps to preserve it, and it cannot be restored or replaced through additional discovery, the court: (1) upon finding prejudice to another party from loss of the information, may order measures no greater than necessary to cure the prejudice; or (2) only upon finding that the party acted with the intent to deprive another party of the information's use in the litigation may: (A) presume that the lost information was unfavorable to the party; (B) instruct the jury that it may or must presume the information was unfavorable to the party; or (C) dismiss the action or enter a default judgment". This amended rule now establishes a uniform approach to handling ESI preservation issues and imposing spoliation sanctions and curative measures.

Recent decisions regarding amended Rule 37(e) start to give shape to how this amended rule will be implemented by courts going forward. Ultimately, it provides a greater protection to parties who unintentionally fail to preserve ESI and standardises the judicial approach to sanctions. *See Global Material Techs., Inc. v. Dazheng Metal Fibre Co.*, No. 12 CV 1851, 2016 WL 4765689, at *3 (N.D. Ill. Sept. 13, 2016) (negligent or grossly negligent conduct was insufficient to warrant severe sanctions); *Akinbo JS Hashim v. Ericksen*, No. 14-cv-1265, 2016 WL 6208532, at *5(E.D. Wis. Oct. 22, 2016) ("Here, there is no evidence that any defendant intentionally destroyed the evidence in bad faith. Accordingly, the court will deny plaintiff's motion for sanctions"); *Martinez v. City of Chicago*, No. 14-cv-369, 2016 WL 3538823, at *24 n.11 (N.D. Ill. June 29, 2016) (adverse inferences are "severe measures" not to be used when a party only acted with negligence or gross negligence).

Ultimately, the 2015 amendments to the Federal Rules of Civil Procedure were a significant shift towards pursuing enhanced cooperation in the early stages of case management, and courts have paid close attention. In addition, amendments to the Federal Rules of Civil and Appellate Procedure went into effect on December 1, 2016 which impact the calculation of deadlines for filings in civil cases and service of foreign entities. While these changes are technical, they are significant and worth note.

Electronic Service of Documents

Electronic service of documents no longer entitles parties to an additional three days of response time, as amended, Fed. R. Civ. P. 6(d) and Fed. R. App. P. 26(c) eliminates the three additional day rule to deadlines triggered by electronic service. These amendments align the Federal Rules with current technology, treating documents served electronically as though they were delivered immediately, as opposed to constructing the former "mailbox rule" through additional response time. According to the Advisory Committee, the three additional days of response time – adopted in 2001 – is no longer necessary in light of "advances in technology and widespread skills in using electronic transmissions". Fed. R. Civ. P. 6 advisory committee's note to 2015 amendment.

Impact of Post-Judgment Motions on Appeals

The previous Fed. R. App. P. 4(a)(4) provided that "[i]f a party timely files in the district court" certain post-judgment motions, then "the time to file an appeal runs for all parties from the entry of the order disposing of the last such remaining motion". Significant splits among judicial interpretation of the meaning of "timely" led to the amended Rule 4(a)(4) which states, "[i]f a party files in the district court any of the following motions under the Federal Rules of Civil Procedure – and does so within the time allowed by those rules – the time to file an appeal runs for all parties from the entry of the order disposing of the last such remaining motion". Thus, a post-judgment motion must be filed within the time period allowed by the Federal Rules of Civil Procedure in order to toll the appeal period. A post-judgment motion filed with an extension granted by the district court does not suffice.

Service in a Foreign Country

Lastly, Fed. R. Civ. P. 4(m) was amended to resolve any ambiguities regarding service in a foreign country. Because service in a foreign country often takes longer than the time allotted in Rule 4(m), the rule now explicitly states that foreign service on corporations, partnerships, or other unincorporated associations is exempt from the 90-day service rule in Rule 4(m).

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Criminal Liability for Defective Products

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Introduction

When a business discovers that one of its products may be unsafe, its first concerns will often be the negative publicity that will follow a recall and the potential civil claims from end-users and/or other companies in the supply chain.

However, the possibility of criminal prosecution should also be given close attention from the outset. The reputational damage from having been prosecuted for a criminal offence can be a significant concern in itself, and for the most serious offences (i.e. corporate manslaughter and breaches of health and safety law), companies can face very significant fines under new sentencing guidelines that have been in force since February 2016. In addition, individual directors/employees can in some cases face fines and/or imprisonment.

This article discusses the various criminal offences which arise in the context of defective products. We consider in turn offences under the General Product Safety Regulations 2005, the Consumer Protection Act 1987, the Health and Safety at Work etc. Act 1974 and the Corporate Manslaughter and Corporate Homicide Act 2007.

The General Product Safety Regulations 2005

The main regulatory regime that imposes criminal liability on producers and distributors of unsafe products in the UK is set out in the General Product Safety Regulations 2005 ("GPSR"). The GPSR give effect to the European General Product Safety Directive (2001/95/EC) and apply to all products except to the extent that they are subject to sector-specific regulations (e.g. food and drink, toys and cosmetics). The Regulations impose broad safety requirements backed up by criminal sanctions.

Changes to EU law / impact of Brexit

The GPSR is part of UK law albeit its purpose is to implement EU law. It should therefore be covered by the Government's proposed Great Repeal Act (i.e. the saving legislation under which all current UK laws that are derived from EU law will remain in force after the UK leaves the EU unless and until they are specifically repealed and replaced with new national law).

In 2013, the European Commission published a new draft Regulation on Consumer Safety which, when enacted, will repeal the General Product Safety Directive 2001 (i.e. the EU law which is implemented in the UK by the GPSR). If enacted in its current form, the new Regulation will maintain the most important features of the existing regime but there will be some additional requirements including clearer rules for marking products to assist in any recall. Unlike the General Product Safety Directive 2001, the new Regulation on Consumer Safety will have direct effect in all Member States. If the new Regulation is passed by the European Parliament before the UK formally leaves the EU, it will take effect in the UK and will, presumably, then be preserved via the Great Repeal Act. If, on the other hand, it is not passed by the European Parliament before Brexit, it will not become law in the UK.

General safety requirement

Producers

The core requirement under the GPSR is that producers must not place any product on the market unless it is a safe product (Regulation 5). A safe product is defined broadly in Regulation 2 as one which, under normal or reasonably foreseeable conditions of use, does not present any risk or only the minimum risk compatible with the product's use.

There is a presumption that the general safety requirement is met where the product conforms to either: (i) any applicable specific health and safety requirements laid down by UK law; or (ii) a voluntary national standard which gives effect to a European standard (reference to which has been published in the Official Journal of the European Union). For certain types of products (e.g. refrigerators, freezers, hot water boilers etc.), the producer is required to certify conformance with the relevant EU level safety standards by displaying the 'CE mark' on the product (or, if that is not practical, on its packaging). We are not aware of any discussion as to whether or not these provisions of the GPSR (which incorporate EU safety standards) will be amended when the UK leaves the EU.

Under the GPSR, the very fact of placing an unsafe product on the market is itself a criminal offence. It is an offence of strict liability subject only to the defence of due diligence, which is discussed below. The maximum penalty is a fine not exceeding £20,000 or imprisonment for a term not exceeding 12 months, or both.

In many cases it will be clear that a product is unsafe but, in others, the complicated definition provided by Regulation 2 might allow room for uncertainty. Difficult questions could arise from the range of factors to be considered in determining whether a product is unsafe, including:

- the characteristics of the product including its composition, packaging and instructions;
- the presentation of the product, its labelling, any warnings and instructions for use;

- the effect of the product on other products; and
- whether vulnerable consumers, such as children and the elderly, are at risk.

In addition, Regulation 6(3) provides that one factor in assessing whether or not a product is safe is "*reasonable consumer expectations concerning safety*". This underlines the point that different levels of risk will be acceptable in respect of different types of product.

There is a distinction in the GPSR between unsafe products that pose a "*serious risk…requiring rapid intervention*" and those that do not. Severity of risk is determined through a structured risk assessment (discussed in more detail below). This distinction is primarily relevant to the Government rather than the producer since the Government is required to share information on products posing serious risks via the European RAPEX system but the distinction is also relevant to producers (and distributors) because it affects the speed with which they are expected to notify the authorities. RAPEX is a system which facilitates rapid exchange of information concerning dangerous products between governments of Member States and the European Commission. It remains to be seen whether the UK will continue to participate in RAPEX under the post-Brexit settlement.

The relevant prosecuting authority will always have a discretion whether or not to prosecute. Our experience is that the authority will normally choose not to prosecute where the producer is a reputable business and is seen to be taking responsible measures to address the risk created by the product. However, the fact that an offence will often already have been committed by the time the defect is discovered provides the authority with a helpful enforcement tool should the producer not take what the authority considers to be the required remedial action, or fail to do so in the way the authority wishes it to, or within its desired timetable.

Distributors

The equivalent obligation placed upon a distributor is not to supply (or possess for supply or offer or agree to supply) a product that he knows (or should have presumed on the basis of the information in his possession and as a professional) is a dangerous product.

In practice, it is more difficult for a prosecutor to establish that a distributor has committed an offence than it would be in respect of a producer. This is because it is necessary to prove knowledge or implied knowledge on the part of the distributor that the product was unsafe (whereas, for a producer, there is no such requirement). The maximum penalty is the same as for a producer: a fine not exceeding £20,000 or imprisonment for a term not exceeding 12 months or both.

Duty to notify

One of the most difficult judgments to make in practice is when to notify the enforcement authority that a product is (or may be) unsafe. After a producer (or distributor) first becomes aware of a potential issue it will want to carry out tests, which can be time-consuming, to understand the nature and extent of the problem before deciding on a course of action. There may be some uncertainty as to whether or not the product is unsafe and, even if it clearly is, a producer will usually want to establish the risk it poses and, crucially, how many units of the product have been supplied, where and to whom. The most effective recalls in our experience are those in which the producer is able to supply the enforcement authorities with this relevant information and explain what steps it is taking.

Regulation 9, however, requires that once the producer or distributor knows that the product is unsafe (i.e. that it poses risks to the consumer that are incompatible with the general safety requirement) they must notify the enforcement authority "*forthwith*". European Commission Guidelines to producers and distributors interpret this to mean that notification should be made as soon as relevant information has become available and, in any event, (i) within 10 days, or (ii) immediately and not later than three calendar days where a serious risk is identified. The Guidelines are not strictly binding but are likely to receive judicial notice (this may well be the case even after the UK leaves the EU given that: (i) the wording of the GPSR will remain unchanged and the guidance is therefore still likely to be seen as relevant; and (ii) producing new guidance is unlikely to be a priority for the UK Government).

Failure to notify in accordance with Regulation 9 is a criminal offence and it is committed by a producer or distributor where it is proved that he ought to have known that the product posed risks to consumers that are incompatible with the general safety requirement and failed to notify "*forthwith*". In our experience, some latitude is given and the enforcement authorities tend to focus on ensuring proper steps are taken to counter the risk rather than on prosecuting companies for technical breaches. However, the position might be different if a consumer has been injured before the authorities are notified. In such circumstances, the risk is that the matter will be viewed with the benefit of hindsight and it will be more difficult for the producer/distributor to show that they ought not to have known the product posed a risk. There is, therefore, always some risk in delaying notification.

As noted above, because of the different expectations regarding speed of notification, a company that has determined that a product is unsafe will need to undertake a further assessment to determine whether or not the risk is "*serious*". The European Commission Guidelines for producers and distributors (referred to above) set out a risk assessment methodology. This requires producers to determine:

- The severity of injury that could be caused by the product (slight, serious or very serious).
- The probability of an injury occurring. This will depend on (i) the proportion of products likely to exhibit the defect, and (ii) the likelihood of the defect leading to harm. For example, if the defect affects at least 10% of the products and the consequential hazard is likely to occur during normal use, the overall probability of injury is high. If, alternatively, 1% or less of the products are affected and the hazard is less likely to occur, the overall probability of injury is low.
- Whether or not the hazard is likely to affect particularly vulnerable people.
- Whether the danger is obvious or addressed by adequate warnings/safeguards.

Combining the outcomes of these different elements will lead to a classification of low, moderate or serious risk.

Separate Commission Guidelines aimed at Member State governments (which are required to determine whether or not a risk is serious for the purposes of RAPEX notification) provide a more sophisticated risk assessment methodology. For example: (i) they provide far greater detail on the classification of different types of injury; and (ii) they require the user to consider the factual scenario that could lead to an injury and to assess separately the probability of each step in that story in order to come to an overall probability of injury. Although 'Member State Guidelines' are not directly applicable to them, producers would be well advised to consider these since they are used by the enforcement authorities. Again, it remains to be seen whether or not the UK will continue to participate in the RAPEX system after it leaves the EU and, if it is does not, what relevance, if any, these Guidelines will have.

Other obligations of producers

Criminal sanctions can also follow non-compliance with the following obligations placed upon producers under Regulation 7:

- the obligation to provide consumers with the relevant information to enable them to assess the risks inherent in a product and to take precautions against those risks where such risks are not immediately obvious; and
- the requirement to adopt measures to enable a producer to be informed of the risks which a product might pose. For example, by (i) marking the product or its packaging with the name and address of the producer and the product reference, and (ii) investigating and, if necessary, keeping a register of complaints concerning the safety of the product.

Other obligations of distributors

Distributors are required under Regulation 8, within the limits of their activities, to participate in the monitoring of product safety by:

- passing on information on the risks posed by a product;
- keeping documentation necessary for tracing the origin of a product and producing it when required; and/or
- co-operating with the enforcement authority and/or the producer to avoid the risk posed by an unsafe product.

Again, these obligations are reinforced by criminal sanctions.

A successful prosecution under Regulations 7 or 8 will result in a fine or imprisonment for a term not exceeding three months or both.

Safety notices

An enforcement authority has the power under the GPSR to serve upon a producer or distributor a variety of safety notices, including:

- Suspension notices (Regulation 11), which prevent the producer/distributor, for the period of the notice, from placing the product on the market or supplying it. This type of notice is appropriate where the authority needs time to organise its own safety evaluation of the product.
- Requirements to mark or warn (Regulations 12 and 13). These notices are appropriate where the authority considers the product could pose risks in certain circumstances. The notices ensure the producer/distributor either marks on the product or provides warnings with the product.
- Withdrawal notice (Regulation 14) – which prohibits the producer/distributor from placing the product on the market or supplying it. This is an extreme step and will be taken only if an enforcement authority considers (i) that the product poses a serious risk (requiring urgent action), or (ii) that the action being taken by the producer/distributor to remedy the problem is insufficient.
- Recall notices (Regulation 15) enable the enforcement authority to require a producer/distributor to recall a product. It is a power of last resort and may only be used where other action provided for under the Regulations would be insufficient. Unless the product poses a serious risk (requiring urgent action), a recall notice can only be issued if the action taken by the producer/distributor is unsatisfactory or insufficient and the authority has given not less than 10 days' notice of the recall. It is very rare indeed for a recall notice to be imposed on a reputable business since they almost invariably recall dangerous products voluntarily at an early stage.

Contravention of any of these notices is a criminal offence with maximum penalties of a fine not exceeding £20,000 or imprisonment for a term not exceeding 12 months or both.

Defence of due diligence

In relation to each of the offences referred to above, it is a defence for the producer/distributor to show (on the balance of probabilities) that it took all reasonable steps and exercised all due diligence to avoid committing the offence.

Although the burden of proof is only to the civil standard of the balance of probabilities, in practice it is a difficult defence to establish because it requires the corporate entity not only to prove the existence of suitable systems and procedures but, in addition, that the corporate entity sought to ensure that the system was in practice followed correctly. Thus, though the existence of a rigorous regime of safety testing, quality control and inspection might indicate a company has taken reasonable steps – at a structural level – to avoid marketing an unsafe product, demonstration that these rules have been consistently complied with – at a practical level – is also required.

The prosecution of individuals

Regulation 31(2) provides that where a corporate entity is guilty of an offence under the Regulations then, in respect of any act or default which is shown to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of any director, manager, secretary or other similar officer, that individual, as well as the corporate entity, shall be guilty of that offence and shall be liable to prosecution.

Although the wording of the section would appear to potentially include any number of people within a corporate entity holding different positions of seniority, case law has clarified that in most instances the prosecution against individuals will be limited to directors. In the case of *R v Boal* [1992] 2 WLR 890, the Court of Appeal held, in relation to a similar provision in the Health and Safety at Work etc. Act 1974, that the section was only aimed at those who are in "*a position of real authority, the decision makers within the company who have both power and responsibility to decide corporate policy and strategy*".

Consent will be established where a director, knowing of the material facts by which the corporate entity committed the offence, agrees to conduct the business on the basis of those facts. The prosecution must therefore prove both that the director was aware of the state of affairs and that he agreed to it.

Connivance arises where a director is equally well aware of what is going on but his agreement is tacit. He does not actively encourage what happens, but lets the state of affairs continue. Connivance, therefore, requires the prosecution to prove awareness on the part of the individual, although this can be established by inference.

In contrast, neglect will be established where the director ought to have known about a particular practice given his specific role and position within the company. Neglect, therefore, presupposes the existence of a particular duty on the part of the person charged with the offence. The question will be whether, in any given factual scenario, the director had failed to take some step and whether the taking of that step either expressly fell within the scope of his particular responsibilities or should have done so.

Powers of enforcement authority

The enforcement authority is usually the trading standards office of the local authority in the area where the defective product is first discovered. Trading Standards Officers are given wide powers under the GPSR to conduct investigations, including the power to

enter premises and inspect any record or product or any procedure connected with the production of a product, provided it is not covered by legal privilege. In addition, they have the power to seize or detain samples of the product.

It is an offence to intentionally obstruct an officer in carrying out his duties and this is punishable with a fine.

The Consumer Protection Act 1987

The Consumer Protection Act 1987 ("CPA") gives effect to the European Product Liability Directive (1983/374/EEC) and acts as an umbrella under which detailed regulations applying to some specific types of products (e.g. toys and cosmetics) are promulgated. Other products, such as food and drink, have their own sector-specific regimes out with the CPA. As explained above, where a class of products is subject to a sector-specific regime, the provisions of the GPSR will still apply to the extent that the specific regime does not include an equivalent provision (i.e. the GPSR fills any gaps in the specific regimes).

Part II of the CPA applies to all consumer goods which are ordinarily intended for private use and consumption, save for certain specified exceptions which include food, controlled drugs and licensed medicinal products which (as noted above) are subject to their own sector-specific regimes. Generally, the CPA is narrower in application than the GPSR, since it applies only to (i) the producer of the product, (ii) someone who holds himself out as a producer of the product (for example, by applying his own brand mark on a product manufactured by someone else), or (iii) the importer of the product into the EU.

The CPA provides the Secretary of State with the power to make safety regulations and it is under this umbrella that numerous regulations have been made which seek to ensure the safety of goods. Regulations made under the CPA include such diverse matters as the composition, design, construction, finishing or packaging of goods as well as regulations which specify the required approval and testing regimes for specific goods and identify what markings, warnings and instructions should be provided.

The CPA grants the enforcement authority the power to impose suspension notices which are similar to the provision under the GPSR but which may be used where the enforcement authority has reasonable grounds for suspecting that any safety provision has been contravened. The CPA also provides the enforcement authority with similar powers of entry and search to those provided under the GPSR.

The sector-specific regulations made under the CPA are similar in structure to the general regime set out under the GPSR in that they provide a specific safety standard and a means of demonstrating compliance. The specific regulations then refer back to the CPA which contains provisions relating to the defence of due diligence and the liability of individuals, identical to those in the GPSR.

Breaches of Regulations made under the CPA are punishable by an unlimited fine or imprisonment for a term not exceeding six months or both.

The Health and Safety at Work etc. Act

Under the Health and Safety at Work etc. Act 1974, specific duties are placed upon manufacturers and others in relation to articles and substances for use at work.

Under section 6 of the Act, it is the duty of any person who designs, manufactures, imports or supplies any article for use at work, so far as is reasonably practicable:

- to ensure that the article is so designed and constructed that it will be safe and without risks to health at all times it is being set up, used, cleaned or maintained by a person at work;
- to carry out or arrange suitable testing to ensure the safety of persons whilst the article is being used at work;
- to take necessary steps to ensure the persons who are supplied with the article are provided with adequate information about its use to ensure that it will be safe and without risks to health at all times when it is being set up, used, cleaned or maintained by someone at work; and
- to ensure that revisions of information are provided.

The duty owed in each case is a qualified one namely to take steps so far as is reasonably practicable. The Act makes it clear that the duty is imposed only so far as the matter is within the control of the employer.

The maximum penalty for breach of duties under the Health and Safety at Work etc. Act 1974 is an unlimited fine or imprisonment for up to two years or both.

Corporate Manslaughter

Where a defect in a product causes death, the Corporate Manslaughter and Corporate Homicide Act 2007 may be engaged. This statutory offence applies only to organisations (individuals can be prosecuted for the common law offence of gross negligence manslaughter) and is designed to punish failures in the way in which an organisation manages or organises its activities which are considered by a jury to be sufficiently serious to amount to gross breach of the duty of care owed to the deceased.

Although the Act has now been in force for almost nine years, we are not aware of a prosecution involving a defective product having been brought. However, the wording of the Act makes clear that it does apply in respect of duties of care owed by organisations involved in "*the supply…of goods or services (whether for consideration or not)*".

The offence is only committed where there is a gross breach of a relevant duty of care owed by the corporate entity under the law of negligence. The Act sets out relevant duty of care situations which, as noted above, expressly include duties owed by an organisation supplying products.

Importantly, the offence is only made out where it can be established that a senior manager, or managers, played a substantial role in the organisation's failure. This means that an organisation will not be guilty of manslaughter where the failure of junior employees causes death and that failure cannot be attributed to a failure by a senior manager or managers.

Management or organisational failure

The central question will be whether the death was attributable to a management or organisational failure. In this context, evidence of a failure by a senior manager or managers to follow expected systems and practices to properly identify or rectify a defect in a product which subsequently causes death will be relevant.

During the consultation process, the Government explained that its intention was that:

> "*The prosecution shall be based not only on the immediate events that led to the death but on the wider context in which those events were able to take place. The wider context could include concepts of corporate culture if appropriate. It could also include a failure to have systems in place or to control risks for the carrying out of particular activities or failure*

to enforce systems; inappropriate delegation of health and safety responsibilities or inadequate supervision of delegated responsibilities."

The Act itself ensures that broad concepts of corporate culture will be considered by specifically providing that the jury may consider the extent to which the evidence shows there were attitudes, policies, systems or accepted practices within the organisation that were likely to have encouraged any failure. It is likely that the Judge in his summing up will specifically direct the jury to have regard to these matters.

A gross breach of a duty of care

A gross breach is defined in the Act as "*conduct falling far below what can reasonably be expected of the organisation in the circumstances*". It is a matter for the jury to decide what standard the organisation should have met and whether the organisation fell far below that standard.

Senior managers

A senior manager is defined as someone who plays a significant role in the making of decisions about how the whole, or a substantial part, of the organisation's activities are to be managed or organised, or is someone who is actually managing or organising the whole or a substantial part of the activities.

Whether or not an individual is a senior manager is a question of fact which will be decided by considering all the circumstances. In any prosecution there is likely to be a substantial amount of argument over the identity of the senior managers.

Sentencing

New sentencing guidelines have been in force since February 2016 covering corporate manslaughter and offences under the Health and Safety at Work etc. Act. The guidelines do not apply to offences under the GPSR or CPA (although they do apply to offences relating to the safety of food products which, as noted above, are subject to a separate regime which is outside the scope of this article).

The guidelines, therefore, apply to unsafe products only where there is a prosecution for corporate manslaughter (where a dangerous product has caused death) or under the Health and Safety at Work etc. Act (in the context of a workplace accident involving an unsafe product). We are not aware of any plan to introduce similar guidelines in relation to product safety offences under the GPSR and CPA. However, it may well be that the imposition of higher (and more carefully assessed) fines for corporate manslaughter, health and safety and food safety offences indicates a direction of travel.

The guidelines represent a much more mathematical and structured approach to sentencing corporate manslaughter and health and safety offences than existed previously. The guidelines are based upon the following public policy objectives:

- Sentences (for all offences and all categories of offender) should be proportionate to the offence. A fine must therefore reflect the seriousness of the offence and take into account the financial circumstances of the offender.
- Sentences should punish and deter wrongdoing. Fines must therefore "*be sufficiently substantial to have a real economic impact which will bring home to both management and shareholders the need to comply with legislation*".

The guidelines aim to meet these objectives via a multi-stage approach to sentencing:

- First, a Judge must categorise the offence by reference to the level of the company's culpability and the risk of harm it created. In the case of corporate manslaughter, there may be relatively little to distinguish between different offenders (since the harm will always be of the most serious kind and the level of culpability must be high for the offence to have been committed). However, the guidance does recognise that some cases will be worse than others (e.g. where there are multiple fatalities and/or other injuries the offence will be seen as more serious than if there was only one fatality and where there may have been additional causes other than the offender's conduct).
- The Judge must then consider the size and financial means of the company. The guidelines classify corporate entities by reference to turnover: "*micro*" up to £2 million turnover; "*small*" £2 million–£10 million; "*medium*" £10 million–£50 million; and "*large*" more than £50 million. The guidelines also envisage that higher fines may be appropriate for "*very large organisations*" being "*those whose turnover very greatly exceeds [£50 million]*". Although there is no clarity on what is meant by "*very greatly exceeds*", examples given in the guidance suggest that a turnover of £300 million would not necessarily make a business "*very large*" but a turnover of £900 million might well.
- For a large company (i.e. more than £50 million turnover), the range of fines available on conviction for corporate manslaughter is £3 million to £20 million. What fine might be imposed within this range would depend primarily on the category of offence (i.e. the level of culpability and the severity of harm). For a 'very large company' an even higher fine might be possible.
- This contrasts strongly with the current position. Existing guidance states that an appropriate fine will seldom be less than £500,000 and may be measured in millions of pounds but, in reality, most fines following successful prosecutions have been less than £500,000.
- Finally, the court will, if necessary, adjust the fine to take account of any aggravating or mitigating factors and to ensure that it meets the public policy objectives set out above.

The new sentencing guidelines have led to a number of very significant fines since February 2016, although to date none of these has arisen from prosecution for breach of section 6 of the HSWA or for statutory corporate manslaughter relating to a dangerous product.

Finally, the Corporate Manslaughter and Corporate Homicide Act empowers the Courts to make Publicity Orders. These require companies to publicise the fact of their conviction, details of the offence and the amount of the fine. The Guidelines indicate that these should normally be imposed as part of the sentence. The Order will specify the place where the public announcement should be made and this should ensure the conviction becomes known to shareholders.

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The Practicalities of Managing a Global Recall

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Introduction

Recent years have seen a continued growth around the globe in the frequency and scale of product recalls across various sectors. This includes a substantial growth in recalls initiated without associated safety incidents. More intense scrutiny from regulators and the press, growing consumer awareness of compliance issues and increasingly complex regulatory frameworks have combined to make the management of product recalls an ever more critical issue for businesses large and small. It has never been more important to properly plan for, and effectively manage, product recalls. Before considering the practicalities of product recall, it is worth reflecting on some key changes in the political and regulatory landscape which impact upon this area:

One clear trend in recent years, driven by increasing concerns over the risk of adverse publicity, as well as growing regulatory pressure, has been an increased focus by businesses on ensuring strict compliance with regulations, even in the absence of evidence of a specific safety risk. Even if a product has been marketed for years without any complaints, and bears the requisite conformance markings, questions can still be raised over the safety of the product, for example, where no one can produce the conformity assessment documentation or if there is a suggestion that the testing performed did not completely reflect the latest regulatory standards. The onus is increasingly shifted onto manufacturers to demonstrate that all of the components are harmless. Equally, commercial concerns, and in particular the need to protect the reputation of a business for quality, can be a powerful factor.

Increasingly onerous regulatory requirements and more detailed monitoring by authorities further raises the pressure on businesses. European market surveillance authorities must now not only provide a monitoring system for the safety of consumer products, but also, according to Art. 19(1) of Regulation 765/2008/EC, perform appropriate checks on the characteristics of products. This is carried out both by means of checking documentation and, where appropriate, physical and laboratory testing. Sample testing is no longer largely a theoretical requirement. It has become reality. German law now requires that regulators use one sample per 2,000 inhabitants each year as an indicative target for each Federal State (s.26(1) of the German Product Safety Act). The cost and resources necessary to meet this target are to be met by the German Federal States.

In Europe, the prospects of more fundamental change to the regulatory framework may have diminished, at least for the time being. Efforts within the European Union to agree a new Regulation of the Parliament and the Council on consumer product safety and repeal Council Directive 87/357/EEC and Directive 2001/95/EC have stagnated in the wake of controversy over its contents, and, given the recent political turmoil in Europe, it remains unclear when or in what form a new product safety regime might now emerge. The intention was to pass the legislation as a Regulation, meaning that it would be directly binding in the EU Member States (in contrast to the present General Product Safety Directive which required national implementation). The EU Parliament's objective was to tighten up product safety requirements and market surveillance rules so as to strengthen consumer protection in the EU. Further, the Parliament wanted tougher penalties for firms selling non-compliant or potentially dangerous products. The proposals also included a black list for firms found to have repeatedly and intentionally infringed EU product safety rules, and an option for EU manufacturers to put 'made in EU' or the name of their country on the label (in cases where the product was produced in more than one case, the country referred to would be the location of the last substantial, economically justified processing resulting in a new product or representing an important stage of manufacture). However, in May 2015, the European Council failed to reach an agreement on the proposals regarding the mandatory 'made in' marking, and at the time of going to press it remains unclear when, or in what form, the proposed Regulation will become law.

Those businesses based in, or trading with, the UK also face the uncertainty of not knowing how post-Brexit Britain will organise its own product safety regime and whether, for example, it will look to align more closely to the US frameworks or seek to maintain a system which reflects the EU approach. At the same time, the impact of a change in political regime in the US on trade and product regulation creates further uncertainty.

Whatever form the new generation of product safety regulation takes, there can be no doubt that the expectations placed by lawmakers, regulators and consumers on businesses in product supply chains will continue to increase.

The prospect of further change on the horizon means that adopting a co-ordinated, proactive and consistent approach to a product issue across all the affected regions of the world before a crisis gathers its own momentum is ever more critical. In the remainder of this chapter, we examine some of the practical issues to be considered when formulating and implementing a multi-jurisdictional product recall.

Investigation and Risk Assessment

When a company receives reports of problems with a product, it should:

- Assemble a team to investigate the facts – including details

of any reported incidents or complaints – as thoroughly, yet rapidly, as possible. The team will need to be small so that it can act quickly and decisively and should typically include representatives from the technical, purchasing, sales, marketing, finance and legal functions within the company. The team should be led by a senior officer who has authority on behalf of the company, ideally has had crisis management training and will take responsibility for making difficult business decisions often based on incomplete and uncertain information.

- Commission a detailed technical analysis into the possible safety or quality issues using internal resources or an independent expert. The choice may depend upon the nature of the potential defect, the complexity of the investigation, the extent of relevant internal expertise and the time available. The importance of ensuring that the facts are properly evaluated and the truth determined mean that there is often a strong case for bringing in independent investigators, where circumstances allow.
- Seek to understand the scope of the problem, for example, whether it is limited to particular models or batches of products, the output of specific manufacturing sites and the affected date range, to establish how many units are affected, how many have already been sold and what proportion remains in the company's control or in the distribution network. The investigation will need to ascertain the key dates and key documents and determine how the issue has developed so that an effective risk assessment can be undertaken and appropriate actions agreed.
- Once the nature of the issue is identified, there is a need to undertake an assessment of the risk that the product may present a danger to users and the likely consequences if it does. There are a number of different risk assessment methodologies – but essentially most involve identifying the hazard and its cause, estimating how many products are affected, which users of the product are at risk and whether this includes particularly vulnerable sections of the population such as children or the elderly. The overall risk can then be estimated based upon the severity and likelihood of injury. Consideration should also be given as to how obvious the potential hazard is and whether there is any warning on the product or in user instructions to alert users of the hazard. The European Commission has prepared detailed guidelines for undertaking a risk assessment and determining whether notification of regulators is required in EU Member States where the product is sold (see http://webcache.googleusercontent.com/search?q=cache:GaEWkFek_a0J:ec.europa.eu/DocsRoom/documents/15261/attachments/1/translations/en/renditions/native+&cd=1&hl=en&ct=clnk&gl=uk).
- Consider options for responding to the incident and formulate an appropriate strategy for minimising the risk presented by the defective products. There are many actions short of a full consumer recall which might be appropriate in different circumstances depending on the risk assessment, the traceability of the affected products and the sales channels, including:
  - ceasing future sales until the product is re-designed or the stock in the supply chain is rectified;
  - issuing safety warnings or more detailed instructions to users which, if followed, minimise the risk;
  - withdrawing the product from sale by retailers (often referred to as a trade withdrawal); and
  - a modification or retro-fit of products in consumers' premises or elsewhere in the field.
- One of the first things any business faced with a product crisis will need is an effective communication plan. This will need to cover communications with: (i) regulators and other government agencies; (ii) business partners (including customers and others in the supply chain); (iii) the public; (iv) known consumers/users; and (v) the media. The plan should be updated regularly as information is uncovered. We discuss aspects of this further under 'Communications', below.

The appropriate response to any safety issue should reflect the legal obligations in respect of product safety in the relevant jurisdictions and the commercial imperative of acting (and being seen to act) in the best interests of consumers. Often a company will take a combination of corrective measures in parallel as part of a co-ordinated response. The proposed strategy should be limited as far as practicable to the affected products with a view to completing the exercise as quickly and cost effectively as possible.

One of the major issues to consider in any product recall strategy is how to notify the risk associated with the product to the end users who bought the product before the problem was identified. The investigation team will need to understand the extent of traceability through to end users. Direct communication with end users – whether by way of letters, email, or through social media, is usually more effective than indirect measures such as "point of sale" notices in stores, warnings posted on company websites or newspaper advertisements. Point of sale notices are increasingly seen as out-of-touch with consumer purchasing behaviour and are correspondingly used less frequently. Manufacturers may need to liaise with distributors and retailers for documentation which will contain end user names and details.

The company has a clear interest in contacting as many end users as possible and alerting them to the risk. Claims by customers or end users will directly impact the company financially, but often the greatest impact will be on a company's brand or reputation. A company should not be seen as balancing the risk of injury to end users, and associated claims against the costs of taking steps to minimise the risks. This approach significantly increases the likelihood of criminal proceedings or other enforcement action against the company and adverse media comment.

It is rare that national legislation will dictate the detail of the corrective measures which are required. A product recall or other corrective action will need to be tailored to the individual facts. In many cases, the company will need to satisfy regulators that the proposed measures are sufficient. A company needs to ensure that the solution which it is proposing is both practical and effective. For example, a solution which involves the insertion of an additional fuse in an electrical appliance to avoid the risk of fire where there is an electrical surge is not a practical solution if the fuse blows every few days and the appliance cannot be used. This may well create an even greater PR crisis for the company. Sufficient testing should be undertaken to ensure that the modifications made to a product design address the prior safety issue, and to avoid, as far as is possible, a situation where the same product is subject to multiple recalls in quick succession (an experience faced by many Toyota owners in 2009–2011).

Different standards and regulations will often apply as regards product safety in different countries and the regulators in some jurisdictions are more interventionist than in others. However, in a world where information and opinion travels freely across the internet, businesses should be cautious before adopting inconsistent approaches in different countries or regions, unless these differences can be clearly justified. Maclaren attracted some negative publicity in November 2009 when it failed to offer a free safety kit to European owners of a baby stroller in the same way as it had in the United States.

One of the first steps which an economic operator should take when it receives information that one of its products may be unsafe is to investigate whether it has insurance which may respond. Product liability insurance cover will typically protect a company against its

liability for personal injury or damage to property other than to the defective product or component supplied. A business may also have specific product recall cover (either as a "stand alone" policy or an extension to a product liability/public liability policy), although this is less common. A product recall policy may indemnify a company in respect of the costs of undertaking a product recall or other remedial action, as well as the company's liability for financial losses suffered by customers or end users. If there is any potential for a policy to respond to meet future liabilities or costs associated with a potentially defective product, notification should be made to insurers as early as is practicable. A company needs to comply with all conditions under the relevant policy. In practice, it should keep insurers informed of the steps which it proposes to take to minimise the risk of injury from use of the defective product, the details of any threatened or actual claims which are received and any other material developments.

Where the product in question has been manufactured by a third party or if the defect in the product arises from the supply of a defective component or raw material, it may be sensible to notify the supplier that it is held responsible for all associated costs. The extent to which the supplier is liable will typically depend on a company showing that there has been a breach of the express or implied terms of the contract between them. In many cases, however, a company may want to work with the supplier to make necessary changes to rectify the defect or change the design of the product going forwards. In practice, this can be more difficult when there is a dispute with the supplier as to who should bear ultimate liability for the recall costs.

Dealing with Multiple Regulators

Where a manufacturer of a consumer product has reason to believe that the product is unsafe, it is typically obliged to notify the national regulators in countries where the product is sold. In the United States, there is a strict duty to notify the Consumer Product Safety Commission (CPSC) where there is:

- non-compliance with a safety rule or voluntary standard;
- a defect creating a substantial product hazard; or
- an unreasonable risk of serious injury or death.

A company must report to the CPSC within 24 hours of receiving information which reasonably supports the conclusion that the issue is notifiable. If the issue is not "clearly notifiable", the company must conduct a "reasonably expeditious" investigation to evaluate the information; such investigation should not take more than 10 days.

In the European Union, economic operators, i.e. producers, representatives, importers and distributors (as defined in Regulation 765/2008/EC on the requirements for accreditation and market surveillance relating to the marketing of products; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:EN:PDF), must notify the authorities in any Member State as soon as they know, or should know, that a consumer product poses an unacceptable risk. There is no centralised EU reporting authority. The notification should include details of the product involved, a full description of the risk which the product presents, information enabling the product to be traced and details of the corrective action taken or proposed to be taken. There is considerable subjectivity in the application of any risk assessment (notwithstanding the European Commission guidelines) and in reality regulators in different European countries take different views as to what level of risk they regard as acceptable. The European Commission's guidance on notification provides that the relevant national authority should be informed without delay when it has information indicating that a product is dangerous and in any case within 10 days of obtaining such information. In the case of serious risks, there is a three-day time limit for notification and in emergency situations, where immediate action is required, immediate notification should be made "by the fastest means".

Changes in EU law over recent years have further broadened the range of products for which a notification to the relevant regulator is required. As well as requiring immediate action to bring non-compliant product into conformity, the Low Voltage Directive (2014/35/EU) and Electromagnetic Compatibility Directive (2014/30/EU) require manufacturers to notify the authorities where a product presents a risk. In contrast to the position under the General Product Safety Directive, these obligations are not limited to consumer products. The decision to broaden the trigger for notification from 'dangerous' to 'non compliant' products is also novel, although it remains to be seen what impact this will have in practice on the approach of producers and regulators.

In practice, a company will not want to notify any regulator until it not only understands the nature and scope of the problem, but has also decided what corrective measures need to be undertaken. In many cases, there is a tension between the obligation to notify regulators within a short timescale and the desire to complete an investigation and decide on an appropriate corrective action before a notification is made. In Europe, there is little evidence of authorities contemplating action against companies for late notification under the General Product Safety Directive. The Market Surveillance Regulation (Regulation 765/2008/EC), which is directly enforceable in the Member States, provides for notified bodies to suspend, or to withdraw, conformity certificates if they detect issues, and to report concerns to the regulator. In practice, the company (supported by technical teams and lawyers) will want to be working as quickly as possible to have a clear strategy in place for dealing with the product risk before they go to the regulator.

In the United States, the risks and financial sanctions for not reporting, or delaying reporting, are significantly greater. For example, in 2010, Toyota agreed to pay a total of over $32 million in fines following allegations that it had failed to report a known safety defect relating to accelerator pedals within the required timeframe, and, in another incident, had failed to disclose information fully relating to steering control issues on certain models. Even these were later dwarfed by a settlement reached with the US Department of Justice in 2014 under which Toyota paid $1.2 billion following accusations that it had misled consumers over safety problems. Businesses operating in the US market should take careful note of the US Attorney General's comment that this settlement would "*serve as a model for how we treat cases with similarly situated companies*". In view of these trends, and, more fundamentally in order to protect consumer safety, companies should ensure that, if in doubt, they report the full facts in a timely fashion.

Where there are a number of countries involved, a company should choose where it wants to lead and co-ordinate the process of notifying regulators. This may be the country where the company maintains its corporate headquarters or the country where most affected products have been placed on the market. The company should take specialist advice as to whether particular authorities are likely to be satisfied with the corrective action which the company proposes. It should consider where it has the best relationships with regulators and enforcement authorities as if a company or its lawyers have a good working relationship with the relevant authorities, this can help in resolving the product issue in a professional and efficient manner. In the US, due to the importance and size of the market, and the stringent regulatory regime, backed by substantial sanctions, many international businesses let the CPSC take the lead in a global recall.

Across Europe, although there is essentially a harmonised regime by virtue of the General Product Safety Directive, there is considerable variation of approach between the regulations of Member States. Some authorities require more information than others; some will require meetings, whereas others are satisfied with a written notification; some authorities are more likely to question the adequacy of the investigation or the proposed corrective action; some are more proactive than others and require information to monitor the efficacy of a recall programme. Although the European Commission has powers in relation to product safety, for example, to initiate product recalls and to ban products, in practice it does not exercise these powers and rarely intervenes in the decisions of Member States, even where there is a dispute as to the extent of a risk which has pan-European implications.

A company will want to make a simultaneous notification of relevant regulators. This is due to the desire to control the PR message in a co-ordinated manner and a necessary consequence of communication between regulators. As a result of the General Product Safety Directive, there is a common obligation and timeframe for notification across Europe. In practice, we would recommend that one law firm take the lead in working with the company and seeking to ensure that the legal strategy is aligned with the objectives of the business. This will typically involve working closely with the company in investigating the cause of the problem, seeking to minimise product risk and thus the exposure to claims arising out of the incident, interviewing factual witnesses, engaging any relevant technical experts and developing defence theories. The lead law firm should co-ordinate the global notification of regulators.

Although formal notification should take place on the same day in all regions, the company and its lawyers may want (and are invited by the European Commission's guidance to seek) informal, earlier dialogue with certain authorities. This gives comfort that the proposed solution will be regarded as satisfactory by regulators. One country in Europe can be used to create the blue-print of the master notification pack, containing the completed notification form and additional documentation such as the risk assessment and proposed safety notice. The notification form sets out prescribed information such as details of the defect, the affected batches, the number of units affected, the countries in which the product has been marketed and the proposed remedial action. A company will want to decide, in conjunction with its lead lawyers, how much additional information is provided to regulators and how best to present the information such that national regulators do not need to ask questions or request further detail which causes unnecessary delay. To reduce the prospect of individual regulators intervening or questioning the adequacy of the proposed corrective action, a company will want to ensure that the regulator understands the international nature of the recall exercise and that their country is just one piece in a much larger jigsaw.

Following any informal meetings, the master notification pack can then be translated as necessary for submission to other regulators. In relation to serious risks which may have a significant impact on the company's business, local product liability lawyers should be retained in each of the affected countries to make any necessary amendments to the documentation to reflect the nuances of local regulations or practice. The company, or more often its lead lawyers, should carefully manage the costs of the notification exercise, agreeing a fixed fee in advance with the local lawyers for checking the documentation and attending to the notification procedure.

Practice varies across Europe concerning the approach to formal notification. Generally speaking, there are benefits in fixing a meeting with the regulator. It demonstrates the seriousness attached to the problem by the company and a willingness to discuss the issue. Ideally the company will already have a relationship with its regulators, but if not it will need to gain the trust of the regulator. In most situations, the company will not want to implement its proposed solution until it is satisfied that fundamental concerns will not be raised by the regulator. This is more likely to be achieved at an early stage through a meeting. Who attends a meeting will depend upon the circumstances and the normal practice in the country in question. In most cases, no more than two or three representatives should attend. It is more common for lawyers (whether external or in-house) to attend in continental Europe than in the UK. A person with a technical background should attend to be able to explain the cause of the problem and the proposed solution.

It is important to be honest and straight-forward with the regulator. If the information provided to the regulator appears inaccurate or inconsistent, it is more likely that the regulator will take a more aggressive and interventionist approach. Where the risk assessment and proposed solution have been worked through systematically and professionally, the regulator may have greater confidence that the company is adopting the right approach without extensive questioning or monitoring.

Regulators are increasingly encouraging companies to make a single notification across the affected countries within the European Economic Area, through use of the General Product Safety Directive "Business Application" online procedure. This procedure has been available since 1 May 2009. The notification form is transmitted electronically to the relevant authorities in the Member States which a company wants to notify. Relevant translations need to be attached to the form reflecting the countries to be notified. Initially, many companies preferred to co-ordinate the individual notification of European Union regulators, using meetings and a completed notification pack; they saw an advantage of direct contact to gauge the reaction of the regulator and to satisfy him or her as to how seriously the matter is being treated by the company and the adequacy of the proposed corrective action. However, many companies now prefer to combine the benefits of a single formal "Business Application" notification with informal meetings with regulators in key markets. This solution is often seen by companies as the most effective way of making the market aware of a potential safety issue, whilst at least partially enjoying savings on legal costs and management time.

A regulator in any European Union Member State is obliged to share information concerning "serious risks requiring intervention" with the European Commission using the Community Rapid Alert System for non-food consumer products (RAPEX). Where appropriate, and particularly where serious risks arise in relation to products in multiple jurisdictions, the Commission shares that information with other Member States and with regulators outside the European Union, in particular, the US and China (in respect of consumer products made in China). Each Friday, the Commission publishes a summary of the information notified to it by Member States on the DG SANCO website. The Commission does not disclose the whole notification to the public, especially not detailed risk descriptions, test reports or details of distribution channels which may be confidential. Whilst the overall number of notifications rose from 139 in 2003 to 2,123 in 2015, the approach of different countries as to whether to make a RAPEX notification varies considerably. Some countries apparently make a notification as a matter of course, whereas other countries rarely use the system. The 2015 RAPEX Annual Report showed that all 31 participating countries sent notifications through the RAPEX system, but five countries (Hungary, Germany, Spain, Bulgaria and the UK) accounted for nearly half of all notifications. Although it is principally a matter for the Member State in question as to whether it makes a notification, the Commission's notification guidelines provide the option for a company to notify in one Member State

and for that country's regulator to make a RAPEX notification to the other Member States, e.g. upon a company's request, even if there is no serious risk. Companies may be permitted to have sight of the proposed RAPEX notification form.

Proactive use of RAPEX may be one strategy in circumstances where the company would prefer not to incur the costs in making separate notifications in all Member States where the product was placed on the market. Companies should, however, recognise that they may well face questions from regulators in other Member States besides the one in which the original notification was made and there is an increased risk of authorities taking an interest in these circumstances. Regulators may well visit stores to see if the product is still being sold and may undertake random testing on such products or simply make contact with the local subsidiary and raise questions concerning the product. In serious cases, we advise companies to notify directly, at least in the key countries affected, as regulators are more likely to raise queries and objections if they first receive indication of a product problem from a regulator in another country, or even worse, through the media.

Frequently, companies are concerned that commercially sensitive information that they provide to regulators may enter the public domain or become accessible to their competitors. In the European Union, there is a presumption of public disclosure in respect of information regarding the risks to consumers, in particular, information concerning the identification of the affected products, the nature of the risk and the corrective measures taken. Information which "by its nature, is covered by professional secrecy in duly justified cases" is protected where its disclosure is not necessary to alert the public to the risk which the product presents. Guidance indicates that regulators in Member States and the European Commission should not make disclosure of information which undermines the protection of court proceedings or monitoring and investigation activities. In these circumstances, it may be possible to get assurance from the Commission that information will not be made available. It is significantly easier to get protection for confidential information from the CPSC in the US if the information is marked as confidential and its status is not challenged by the CPSC. Depending on the circumstances, it may also be possible to claim 'self critical analysis' privilege in the US in relation to communications with regulators and associated documentation.

Communications

As already noted, a co-ordinated and consistent approach to communications is a critical aspect of product recall planning. This must include a clear strategy for dealing with the media. Companies want to be seen as being as proactive and in control when dealing with a product crisis and not constantly one step behind developments or unable to give information expected by the media in a timely fashion.

This can be easier said than done when a story suddenly breaks and the company does not have all the information it needs to make informed decisions on its response. Speed is critical and it is often necessary to make decisions without all the information which a company would want to consider in a normal business context. We live in a 24-hour, multi-media age and the speed of decision-making needs to reflect this, in order to minimise damage to a company's reputation.

On occasions, a company may need to broaden the scope of a recall or take additional corrective measures. This might be where new information comes to light which indicates that additional product models or batches also present a safety risk or, for example, where new information (e.g. a serious injury) leads to a re-assessment of the potential risk. This is an inevitable consequence of the need to take decisive action without being able to wait for all the relevant information to become available. This can be extremely damaging from a PR perspective as a further announcement tends to create a further wave of publicity and the company risks losing public credibility. In this regard, lessons have been learned from Toyota's overlapping recalls in 2009–2011, and from the more recent Takata airbag recalls which grew exponentially between 2013 and 2016, ultimately affecting more than 70 million vehicles worldwide, with Takata agreeing to fines and compensation payments amounting to $1 billion following criminal charges brought by the US authorities.

The company should engage Public Relations professionals to work with its management and legal team. Where possible, there are benefits in having a single senior spokesperson to talk on behalf of the company and to explain the action it is taking and why it is taking this action across different regions. The spokesperson will benefit from media training as he or she becomes the face of the company which is in the spotlight. It is easier for a spokesperson with no direct personal background or prior involvement in the event leading to an incident to remain calm, to stick to the officially approved messages and to avoid being drawn into detail on the investigation. In different regions, the company may want to appoint additional points of contact for communications purposes. All enquiries should be channelled through these designated points of contact. These contacts need to be fully briefed on developments and the company needs to ensure that a clear and consistent message is delivered in all countries. It is necessary to take control of the situation at an early stage and explain the company's commitment to conduct a thorough investigation. The company should be available and co-operative with the media, ensuring that journalists are made aware of the contact points and the proposed timing of any press statements.

A company's reputation can be enhanced by effective management of a crisis. It wants to portray itself as forward-thinking and committed to safety, quality and customer service. How a company handles a crisis is often remembered long after the product issue is resolved. Thorough preparation ensures that key information concerning the nature and extent of the product issue is communicated effectively and the responses to questions demonstrate that the company is acting promptly and responsibly in light of the available information. The company needs to be seen as accountable for its product, to be sincere and genuine in its communications and show concern and sympathy for any injured persons. Public statements should be in plain language, avoiding technical jargon, and avoiding speculation if the cause of the problem is unknown. A press statement and accompanying pack can be useful for the initial briefing of the media and lists of questions and answers should be prepared for responding to consumer and press enquiries, including how to deal with difficult areas where the company may face criticism for its actions.

Companies need to take into account the legal consequences of any statements they make. In many circumstances, the company will not want to accept that its product is unsafe or that it is legally required to undertake a consumer recall. There may well be a potential dispute between a supplier and the company as to the cause of the problem. Where insurers are involved, it may be necessary to agree in advance the content of proposed communications. No admissions of liability or incriminating statements should be made without the insurer's consent and a proper understanding of the implications in terms of claims by or against the company. In most circumstances, it is not advisable to publically seek to pass blame onto third parties, such as a supplier, notified body, testing house or sub-contractor. This can suggest a lack of accountability and may fuel a public debate between the relevant businesses in the media. Whilst more than 15 years ago now, many still remember the very

public debate between Ford and Firestone/Bridgestone over the cause of road accidents involving Ford Explorers with Firestone tyres, which severely damaged the reputations of both companies.

Companies should, either themselves or through their PR advisers, monitor the publicity surrounding the product crisis. Often the press want to overstate the safety risks to increase a story's profile and the attention which it receives. Companies should be quick to correct any inaccuracies in reporting and ensure that the risk is fairly portrayed. Analogies can often be useful in putting a product risk in its appropriate context. A record should be maintained of the press releases and public statements made on behalf of the company, as well as any interviews which are conducted. Claimant lawyers are also increasingly on the look-out for recalls and product safety incidents in the press and then using these to attract clients keen to pursue a claim against the manufacturer in question, through press comments or on websites. Companies should, however, also in lower scale cases, monitor the situation so that they are aware of any future claims they may face. Taking a leaf from their American colleagues, claimant lawyers in Europe are increasingly seeking to use the press to their advantage.

The rise in social media in recent years and popularity of sites such as Facebook and Twitter has posed an additional challenge to companies who find themselves in a recall scenario. Product issues are often first reported online; consumers can use these forums to vocalise complaints and even call for boycotts of products or companies, and rumours quickly circulate around the world. This makes it essential for companies to understand and monitor social media in responding to any crisis.

However, it is not just a case of monitoring what is being said about the company or product. Case studies, particularly in the US, have shown how companies with an existing social media presence can use this to their advantage. It can be an effective way of quickly correcting inaccurate rumours that can rapidly spread across the Internet, and offers an opportunity to engage with and reassure customers, restoring consumer confidence in the brand. It is important that messages disseminated through social media are consistent with the company's PR strategy and with the line communicated down more traditional channels. On the other hand, however, where companies have an existing social media presence, but fail to engage with consumers in the face of a product incident, this can lead to frustration and huge consumer dissatisfaction.

Implementing a Recall

The appropriate response will depend upon:

- the technical investigation into the cause of the problem;
- whether it concerns all products within a certain date range or just certain batches or manufacturing facilities;
- the outcome of the risk assessment as to the likelihood of further incidents involving consumers;
- the severity of injuries that may occur; and
- any warnings which are included on the product or packaging.

A full consumer recall is generally a last resort if no other steps will effectively minimise the risk to consumers. There is no simple formula as to the number of incidents or what proportion of products need to be potentially unsafe before action is required. This needs to be considered as part of the risk assessment. The company may want to involve both lawyers and PR advisers in its deliberations. Many companies will have an incident management plan to use as a tool in formulating and implementing its proposed strategy. The solution should be acceptable to the public, to regulators and to the own staff in light of the nature and extent of the risk which the products present. The company will want to ensure that the proposed solution is effective, addresses the potential hazard and does not give rise to other safety or quality issues. The solution should be as convenient and easy as possible for consumers, to minimise the potential for further brand damage in its implementation.

The proposed corrective measures should reflect the nature of the product, where it is installed and how consumers use the product. The costs and practicalities need to be properly thought through. The proposed solution will want to ensure that only owners of affected products can take advantage of the recall and that the dangerous products are returned or destroyed (e.g. in exchange for a replacement or refund). In broad terms, it is easier to return smaller consumer goods for refund or replacement, than it is large items or products which are in constant use, where measures to repair the product *in situ* may present the best solution. Real difficulties can arise when there is a risk that a product may not be safe to use, but consumers may not regard any significant period whilst it cannot be used as acceptable (e.g. a car or refrigerator).

There may be a need to find a creative solution. For example, where there is a very large volume of product which needs to be modified in end users' homes, where the risk is relatively low, it might be possible to implement the corrective action in tranches (with the highest risk end users first) to avoid customer care issues caused by significant delays between notification letters to end users and the issue being resolved. With certain products, technology can provide a cheap and effective solution to identification and communication with end users (via text message or interactive websites). The rise in prominence of social media has provided an additional route to consumers with messages about recalls. The CPSC has issued a short "Social Media Guide for Recalling Companies" (http://www.cpsc.gov/en/Business--Manufacturing/Recall-Guidance/Social-Media-Guide-for-Recalling-Companies/), with guidance on what should be included in online recall notices to ensure they are picked up by search engines. The CPSC itself now publishes recall press releases through Twitter, and encourages companies to post their recall press releases and photographs on all social media outlets, including, but not limited to, Facebook, Pinterest, Google+ and Instagram. The proposed solution should also reflect consumers' rights. Legal advice may need to be taken in various countries as to whether consumers can insist on a refund or whether a company is entitled to repair a defective product.

In most circumstances, where regulators are satisfied with the company's proposed response to an incident, they will leave the company to deal with the matter on a voluntary basis, often requesting that they be kept informed of developments. However, most authorities (including those in Europe and the United States) have broad powers to order a recall to be undertaken or take other steps if they are not satisfied with the company's response. There is an obligation on EU Member States to notify the European Commission where the Member State in question takes any measure to restrict, withdraw or recall products from the market. This includes measures in response to non-serious product risks.

In many cases, where manufacturers, wholesalers or importers are implementing a product recall, they will chose to deal direct with end users, for example, arranging a direct product exchange rather than expecting consumers to go to return the defective product to a retail store for replacement. Retailers prefer not to be involved and their involvement will have a cost implication for the manufacturer. Dealing directly with consumers gives the manufacturer greater control over its brand and arguably will be perceived by consumers as showing greater accountability for its products. Some companies affected by a recall will outsource part (e.g. the call centre facility) or all of the exercise to a specialist service provider, which has experience and the resources to implement the solution.

Delivery addresses, completed guarantees, warranties or registration cards and details of bank debit and credit card purchases can all provide information to enable direct contact to be made with end users. Distributors and retailers are expected to co-operate with manufacturers in identifying end users where a product presents a safety risk. This is a typical exception to data protection restrictions on the release of personal end user information. Where information is available, direct contact should be made with end users – typically by letter or by email.

In many situations, a company will not have the names and addresses of purchasers of a significant proportion of the products. It is therefore faced with how best to bring the risk to unidentified purchasers' attention. Common steps include:

- Establishing a designated free telephone number (or series of freephone numbers in different countries) for consumers to call for more information and to register for a retro-fit or the supply of a replacement product. Sufficient additional personnel need to be briefed to answer telephone calls.
- Publishing a safety notice in national newspapers, specialist magazines or the trade press. Practice varies between countries concerning the size of the notice and the number of newspapers in which such notices are placed, but these details are typically at the discretion of the company. Occasionally, regulators stipulate certain requirements. As part of the planning process, space in the newspaper needs to be booked a few days in advance.
- Issuing a press release concerning the incident. Although this does not need to be in identical terms as a safety notice or the factual information on the company's website, care should be taken not to under-state the risks. This may provoke regulators to pay closer scrutiny to a company's response and may also potentially open the company up to a greater risk of regulatory claims, in particular if there are future incidents involving the product. Where a matter is newsworthy, a press release provides an opportunity for the company to get its message across and will also generate press coverage which will in turn alert further consumers to a recall programme.
- Details of the defect, potential hazard and the proposed corrective action should also be put on the company's website, as well as those of regulators and consumer associations. Social media is increasingly used to spread the message more widely, and to refer concerned consumers to the website. The company webpage might allow consumers to provide details of their model and product number to check whether it is included within the batches caught by the recall programme. The company can then make arrangements for supply of a replacement product or alternative corrective action. Companies frequently prefer to direct consumers to the website or encourage them to send emails as this makes it easier and cheaper to manage significant volumes of enquiries.
- In serious cases, where there is a risk of immediate harm, manufacturers may choose to alert end users through television and radio advertisements. This is rarely adopted by manufacturers due to the high costs and a concern that it may have a broader negative impact on their brand.

It is important for companies to maintain a record of the steps which they have taken to identify affected consumers and details of all communications with such consumers. If there was a subsequent incident arising from use of the product and enforcement action was being contemplated against the company, this information can be provided to a regulator to evidence the action taken by the company to minimise the risk. The company may be able to show that it contacted the affected end user. The company should monitor a product recall or rectification programme by tracking the rate of response (e.g. the proportion of affected products which have been exchanged or rectified). The response rate will inform the company and regulator's decision as to whether additional steps are needed, such as placing repeat or additional safety notices in newspapers if the initial response rate is disappointing or in extreme cases using television or radio announcements.

The public are becoming increasingly de-sensitised to product recalls and response rates are accordingly much lower than might be expected. In addition to traceability through to end users, the response rate will be affected by factors such as:

- the purchase price (the more expensive the product, the greater the likelihood of consumers going to the trouble of returning the product);
- the sales period the recall covers and the normal life of the product (the more disposable the product and the further in the past it was bought, the less likely it will be returned);
- the remedy which is available to consumers (more end users will respond if there is the option of a full refund rather than a repair or replacement); and
- the extent of the risk (the greater the risk of injury, the less likely that consumers will ignore the safety notice).

Where there is good traceability through to end users and a serious safety risk, a response rate of over 50% might be expected. Where there is poor traceability and a less serious risk of harm, the response rate might be below 25%. We typically see slightly higher response rates in the US as compared with the EU – perhaps reflecting a more developed consumer rights culture in North America.

In deciding on whether to take action, companies will want to comply with legislation and to minimise the risk to consumers. However, they will also be seeking to be seen to "do the right thing" for the purposes of brand protection and to minimise the prospect of future criminal or regulatory action against the company or its senior management by authorities. It can be argued that companies are increasingly taking action that is not strictly necessary from a legal perspective because of a more risk-averse approach to business.

As part of any recall or other corrective programme, a company should consider the lessons it learns. It should look to turn the negative situation into a positive opportunity. This might involve matters such as improved design standards or quality systems, increased vigilance in post-sale monitoring or keeping contingency plans up-to-date.

Managing Costs and Claims

Global recalls can be extremely expensive. In addition to lost sales and a diversion of senior staff away from core duties, companies face significant costs in implementing a recall (e.g. in manufacturing and supplying replacement products free of charge, setting up call centres, recruiting additional staff, logistics costs, advertisement costs, testing costs and professional fees). A detailed record of these costs should be kept with supporting evidence – particularly if there is any prospect of the costs being met by insurers or by a supplier. The greatest risk is the potential impact on the future sales of the manufacturer's products or on its brand.

Claims by end users who have suffered injuries or financial claims by customers can be very significant. Where a company receives notification of claims, it should bring these to the attention of its insurers. A manufacturer, importer or brand owner may face liability to consumers in negligence or under statute (e.g. strict liability principles), or contractual claims from its customers.

Companies whose products are the subject of a global recall may face parallel proceedings in different jurisdictions and also the risk of multi-party suits as well as class actions, especially in courts within the United States. A court's jurisdiction may be challenged

on the basis that a particular court does not have the legal authority to adjudicate a dispute. For instance companies that are foreign to the United States may be able to argue that the court lacks personal jurisdiction over the proposed defendant (following the United State Supreme Court's holdings in *International Shoe* and subsequent cases such as *Daimler AG v. Bauman*). As a result, companies who can appropriately avoid a legal forum in the United States would therefore not be exposed to a class action mechanism. In contrast, within Europe, injured parties often have a choice as to where they bring proceedings, and in most cases, it will be impossible to have claims dismissed on the basis that another forum is more appropriate.

Class actions are well established in the US and their ability to bring together thousands of claimants in a single lawsuit can present the threat of substantial exposure where product defects cause injury or loss. Many class actions are pursued under consumer protection laws which (unlike the usual position in US litigation) provide successful claimants with the right to recover their legal costs from the defendant. US businesses (and those based elsewhere whose products are sold to end users in the US) should ensure that their legal teams contemplate at an early stage what class actions might exist and how this should impact on their strategy. In recent years, more European countries have introduced legislation whereby individuals who have claims involving common issues of fact or law can join together in taking action. The procedures vary and may involve a representative or consumer association bringing an action on behalf of the individuals or some other form of collective action. The effect of these changes is to make it easier and cheaper for individuals to pursue compensation claims where they are affected by the same defective product from the same manufacturer or supplier. These developments significantly increase companies' potential exposure to product liability claims. Looking forward, the risks for businesses operating in Europe are likely to increase as consumers become more aware of their rights, there is greater use of social media to bring proposed compensation claims to the attention of injured parties and lawyers become more proactive in using the new procedures. Additional options for collective redress procedures on a pan-European level are still being considered.

Finally, the threats arising from product crises extend beyond court actions. Increasingly, company executives find themselves having to account for the actions of the business at legislative hearings such as Senate Committees in the US and Parliamentary Committees in Europe. This is not only embarrassing and difficult for the individuals involved (who face the threat of criminal charges if they are found to be untruthful in their account), but presents a real threat to the public image of the business, all the more so in an age of 24-hour news and Twitter trending.

In an international context, companies will benefit from experienced lead lawyers to advise them on a defence and settlement strategy and co-ordinate with local law firms in relevant jurisdictions to ensure that the company's case is consistently presented in any national courts, with regulators, to legislative bodies and in the media.

Document Management

The management of documents is a crucial aspect of risk management in a product crisis. A company will want to be able to produce contemporaneous records to show that it acted responsibly, having regard to the relevant legislation and the best interests of consumers and was justified in taking the decisions which it took. A record should be maintained throughout a crisis, documenting the information which was available at particular times, the investigation which was undertaken and the rationale underlying the decisions which were taken by the crisis committee based on such information and investigation. It is important to adopt and adhere to a document retention policy whereby documentation is available to assist in the defence of product liability claims in the future. Documents relating to product safety should not be destroyed.

Care should be taken in documenting the minutes of the crisis committee meetings on the basis that such record may be considered by regulators in the future in deciding whether to take enforcement action against the company or by a customer or group of injured parties who are pursuing a damages claim against the company.

At the outset of a product crisis, employees should be reminded about the potential harm that might be caused to the business by creating documents which are prejudicial to the company's interests. Particularly in emails, due to their conversational and informal nature, employees can frequently exaggerate or speculate about the cause of a problem. Emails are far more likely to be inaccurate as they are rarely checked. A company can improve its prospects of successfully defending civil claims or regulatory actions if it is sensible about the content and circulation of documents.

Lawyers can play an important role in relation to document management. In certain jurisdictions, it may be possible to gain the protection of legal privilege in respect of communications with lawyers and documents created for the purpose of taking legal advice or as part of the litigation process. Companies should not seek to use the doctrine of privilege inappropriately or to hide the true position from regulators or potential claimants. However, on occasions, the doctrine of privilege may enable frank exchanges of information between a company and its lawyers or allow technical experts to explore lines of enquiry or undertake additional testing (at the instruction of the lawyers advising the company on threatened or actual proceedings), without such underlying material having to be disclosed.

Since the rules of disclosure and privilege vary significantly, the creation and circulation of documents should be considered carefully with lawyers across the relevant jurisdictions. Care should be taken regarding the distribution of documents as this may cause privilege to be lost. In an international context, where documents are shared with another group company, they may become disclosable in proceedings against the recipient company in that jurisdiction.

Conclusion

Companies with international activities face a difficult set of challenges in their handling of product risk and compliance issues. No company is immune from a product crisis. Managing a global recall needs experienced product liability lawyers to advise companies not only on their legal obligations, but also on practical considerations, which can mean the difference between failure and success. Whilst there is no substitute for specialist legal advice tailored to the particular circumstances of a specific product incident, we hope that this chapter provides a useful reference point for companies preparing for, and managing, a serious incident with cross-border implications.

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Richard has advised many leading manufacturers, suppliers and retailers on product safety and product liability issues and acted on major commercial disputes following product failures. He has considerable experience in managing product recalls, crisis management and product liability claims.

High profile cases in which Richard has been involved include acting for two food businesses caught up in the horsemeat scandal, advising a leading automotive manufacturer on emissions issues, acting in a series of multi-million pound Court actions involving drinks manufacturers who recalled product following the discovery of trace levels of benzene in carbonated drinks, advising a business facing claims arising from the PIP breast implant litigation, acting in relation to various significant claims on behalf of food manufacturers arising out of the contamination of spices with Sudan 1 and Para Red and on substantial claims arising out of the discoloration of u-PvC window profiles. He has co-ordinated the recall of a number of business and consumer products, including global and pan-European recall and regulatory notification programmes.

Richard has experience in the consumer products, automotive, food, pharmaceutical and medical devices and chemical sectors.

Richard specialises in defending companies who face multi-party and cross-border proceedings and devising and implementing strategies to minimise their exposure. Richard is recognised as a leading expert on the development of "class action" procedures in Europe, having presented widely on this subject. He was a member of a Task Force of the International Bar Association which considered guidelines for the international harmonisation of class action procedures.

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Fabian studied law at Eberhard-Karls-Universität in Tübingen and was admitted to the bar in 1997. He worked as a lawyer in an international law firm and specialised in product liability, product safety and insurance/reinsurance. In 2001, Fabian was seconded to the legal department of a major US electronics corporation. He joined Eversheds as a partner in 2007. Fabian regularly publishes articles and speaks at national and international conferences.

Fabian has been nominated as a leading lawyer for product liability in Germany by the Legal Media Group "Guide to the World's Leading Lawyers".

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Product Liability Horizons – Medical Devices Liability at the Cutting Edge of Technology, Robotics and AI

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Introduction

The World Economic Forum estimates the size of the global healthcare market to be between 5 to 6 trillion dollars. The demand for healthcare continues to grow year on year, with the world's major regions expected to see increases in healthcare spending ranging from 2.4%–7.5%. Such increases are driven by an ageing population, increased expectations from patients, and a move from a focus on treating communicable diseases to chronic diseases. As our general health improves, the ailments affecting us require more innovative and personalised approaches to address them.

With limited infrastructure and financial resources, healthcare providers are increasingly looking to find innovative, cost- and time-efficient methods of treatment in order to meet our growing expectations of service. The use of medical devices is one area of healthcare which is aiding this drive. Medical devices range from everyday items such as contact lenses and plasters, to smart pacemakers and artificial organs. This article looks at some of the latest innovations in the medical device sphere, and the possible product liability implications of bringing increasingly complex devices into the market.

Advances in Medical Devices Technology

Robotics

Earlier this year, an epilepsy sufferer became the first person in Wales to undergo pioneering robotic surgery to implant probes into her brain – an operation that, for this lady and many others, was previously impossible because of the complexity of the procedure.

Robots such as the "da Vinci Surgical System" (Da Vinci System) are now being used in hospitals all over the world to perform keyhole surgery which allow surgeons to perform complex procedures using only a small number of incisions. The advance of robotic surgery is rapidly revolutionising the medical industry because of the precision at which robots operate, as well as the impact it has on a patient's recovery time – with robotic surgery being far less invasive, minimising the time a patient has to spend recovering in hospital.

Issues are, however, beginning to arise in respect of who is liable when something goes wrong – where does role of the technology end and the skill of the surgeon begin? Who does the manufacturer need to warn and notify about the dangers of using the particular medical product? What training is required? Questions such as these are likely to become harder to answer with the advancement of robotic technology such as Verb Surgical, a product being developed by Google and Johnson & Johnson which is likely to compete with the Da Vinci System, and the Smart Tissue Autonomous Robot (STAR), which last year carried out the first autonomous soft tissue surgery on a pig's small intestines.

In the recent case of *Taylor v Intuitive Surgical, Inc.* [Feb 2017], the Washington State Supreme Court ruled that a manufacturer of a medical device has a duty to warn its customer (the hospital that owned and operated the equipment), about the dangers that are associated with the use of its product, not just the physicians using the product.

The case was brought against Intuitive Surgical, Inc. (Intuitive), the global manufacturer of the Da Vinci System. The claimant, Mr. Taylor, suffered complications following surgery for prostate cancer using the Da Vinci System in 2008. These complications, according to an expert, hastened his death four years later. Mr. Taylor's personal representative brought a claim against Intuitive for product defect, breach of warranty, breach of contract, violation of Washington's Consumer Protection Act, failure to warn and product liability under the Washington Product Liability Act (WPLA). Only the claim for Intuitive's failure to warn the hospital of the dangers of the Da Vinci System under the WPLA made it to trial.

At first instance, the court held that Intuitive was not negligent in providing warnings or instruction to the surgeon who operated the Da Vinci System and the Plaintiff appealed on the basis that the court had erred by declining to instruct the jury that Intuitive had a duty to warn the hospital. On appeal, the Court of Appeal upheld the original ruling and confirmed that Intuitive had fulfilled its duty to warn by warning the surgeon. The Plaintiff appealed to the Washington State Supreme Court on the ground that Intuitive had a duty to warn the hospital as the purchasing hospital of the Da Vinci System and the Washington State Supreme Court found in favour of the Plaintiff. Pursuant to the WPLA, warnings must be provided with products, and these must be provided to the purchaser of the product (in this case the hospital). The Washington State Supreme Court held that a manufacturer cannot discharge this duty by warning the physicians using the product because the purchaser (i.e. the hospital) needs to know about the dangers of its own products.

It would be interesting to see how an English court would have decided such a case. Would the manufacturer's duty of care to warn physicians of the dangers of using their product be sufficient? Would the manufacturer have to warn the ultimate purchaser, and not have to warn the physician? What duties would the physician have before using the products in question?

Bionic Implants and Robotic Prosthetics

Medical Bionic implants are the products produced through a combination of biology, electronics and engineering. Medical Bionics, as they are termed, are robotic versions of body parts inserted into the body in order to fulfil a certain role, in place of the original component or part of the body. Medical Bionics are distinct from artificial organs because, at times, they work better than the component of the body which they are replacing. Bionics are commonly made from biomaterial, a living or non-living biological substance introduced to the body as a portion of the artificial organ or bionic device to substitute an organ or functions associated with it. The use of such biomaterial reduces the risk of the body's immune system attacking and rejecting the new implant.

Heart bionics, such as pacemakers and artificial heart valves, have been used for years, and manufacturers continue to produce newer models of such bionics, to the benefit of patients. Orthopaedic bionics have more recently been revolutionised, with new technology enabling users to control robotic limbs using their brains. Recent innovations in the prosthetics limbs industry include the use of mind-controlled prosthetics which enable people who have lost their arms to be able to use their prosthetic arm like a normal arm, instantly reacting to brain signals to move and pick up objects. In November 2016, a paralysed man was reported to be able to "feel" using a robotic arm connected to microelectrodes in his brain. This was a major breakthrough for the industry as it was the first time a paralysed human had been able to regain the sensation of touch.

Looking to the future, scientists hope to create prosthetic limbs which will move and feel like any normal limb. Researchers are also looking into the possibility of reconnecting the brain with a paralysed individual's muscles to regain movement, a process known as neuro-prosthesis. A recent study funded by the US National Institutes of Health and the US Department of Veterans Affairs enabled a man who was paralysed from the shoulders down to be able to feed himself as a result of the technology.

With the increased insertion of artificial materials (metals, plastics, wires, etc.) into the bodies of patients, and the complexity of the medical devices involved, issues will inevitably arise in the event of a medical device malfunctioning, or breaking. Manufacturers of relatively non-sophisticated devices compared to bionic implants have faced lawsuits from patients who have had incurred injury through the use of products such as hip replacements.

In the UK, the Consumer Protection Act 1987 (the CPA), which implements EC Council Directive 85/374/EEC, provides the statutory product liability framework for England and Wales. Before the case of *Wilkes v DePuy International Limited* [2016], it had been over 15 years since the provisions of s.2 and s.3 of the CPA had been considered in detail by the courts in the case of a medical product.

In the *Wilkes* case, the patient Anthony Wilkes received a hip replacement in 2007, produced by DePuy International. The hip replacement consisted of a stainless steel femoral stem (known as a C-stem) which was connected to a large metal femoral head using a device called a taper sleeve adaptor. Three years after the implantation of the hip replacement, the C-stem fractured and Mr. Wilkes brought a claim against DePuy in negligence and under the CPA, arguing that he was entitled to expect that there would not be a risk of fatigue fracture of the C-stem. DePuy denied that the C-stem was defective, and argued that an express warning was given in instructions for use provided to surgeons with the stem. DePuy further argued that the medical device had been tested beyond the relevant British Standards, and had been approved both in the UK and Europe.

The preliminary issue of whether the stem was defective under the CPA was heard before Mr. Justice Higginbottom. Mr. Justice Burton, in his judgment in the case of *A v National Blood Authority* [2001], had said that under the CPA, the assessment of whether there was defect with a product should start with the identification of "the harmful characteristics which caused the injury". Higginbottom J departed from this view, and stated that the proper approach under the CPA should be to start by identifying whether the product suffered from a defect or not, and if so, what that defect might be.

Higginbottom J went onto reject the rigid distinction between "standard" and "non-standard" products, saying that such classifications distracted from the exercise that the court is required to undertake to consider the appropriate level of safety taking into account all relevant circumstances.

The judgment also clarified that issues of avoidability of a defect, the risk-benefit balance and cost are circumstances which could be taken into account when determining safety of a product, though the focus should be on the product itself, and not "unduly" upon the acts and/or omissions of the product designer or manufacturer.

Finally, Higginbottom J acknowledged that the grant of regulatory approval could be a relevant circumstance and may provide powerful evidence of the level of safety which persons generally were entitled to expect.

The judgment has been widely welcomed by those in the product liability arena, with there being greater certainty for manufacturers as to how the safety of their products will be a looked at by the UK courts in the future. This legal environment should further encourage the development of innovative products in the UK such as bionic implants and robotic prosthetics. A significant burden will, however, be placed on those bodies tasked with regulating these rapidly developing areas of medical technology.

While the lead will need to be taken by the regulators themselves, the day-to-day testing and assessment of medical devices falls to notified bodies. The European Court of Justice recently held that the purpose of a notified body is to protect the end users of medical devices.

In the case of *Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH*, the European Court of Justice made a preliminary ruling on the liability of a notified body under the Medical Devices Directive 93/42/EEC (Directive). The case was initially brought to the German courts by Mrs Schmitt who had been fitted with defective breast implants in Germany in 2008. The French manufacturer of the breast implants, Poly Implant Prothèse (PIP), had been using industrial grade silicon which did not comply with the quality standards under the Directive and following an investigation by the French authorities, PIP went into insolvency. Mrs Schmitt had the breast implants removed in 2012 and brought a claim against TÜV Rheinland LGA Products GmbH (TÜV), the German body who was responsible for auditing PIP's quality system for the purposes of certification under the Directive, for non-material damage and any future material damage. In support of Mrs Schmitt's case, she argued that an adequate inspection of the delivery notes and invoices by TÜV would have enabled TÜV to ascertain that the silicon was not an approved form in accordance with the Directive.

Mrs Schmitt brought an appeal to the highest court in Germany who referred three questions to the European Court of Justice:

1) Is it the purpose and intention of Directive 93/42/EEC that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product and surveillance acts in order to protect all potential patients and may therefore, in the event of a culpable infringement of an obligation, have direct and unlimited liability towards the patients concerned?

The Court held that the Directive imposes primary liability for a product's compliance on the manufacturer. The Directive is silent

as regards liability of notified bodies. The Advocate General was of the view however that the directive does not limit the obligation as to product safety to the manufacturer alone, but that it also imposes duties on Member States. It was up to Member States, through national legislation, to ensure that medical devices were placed on the market only if they complied with the requirements outlined in the Directive.

2) Does it follow from the aforementioned points of Annex II to Directive 93/42/EEC that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product and surveillance is subject to a general obligation to examine devices, or at least to examine them where there is due cause?

3) Does it follow from the aforementioned points of Annex II to Directive 93/42/EEC that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product and surveillance is subject to a general obligation to examine the manufacturer's business records and/or to carry out unannounced inspections, or at least to do so where there is due cause?

In relation to questions 2 and 3, the Court found that the primary role of notified bodies is a scientific one, and that they must satisfy the requirements both as to their independence and their expertise. The Court found that whilst a notified body is not under an obligation to carry out unannounced inspections, examine devices and/or examine the manufacturer's business records, on evidence that a medical device may not comply with the strict requirements of the Directive, the notified body must take all reasonable steps to ensure it fulfils its obligations under the Directive. The challenge of fulfilling those obligations is likely to increase in the future with the growing complexities involved with bionic implants and robotic prosthetics devices.

Combination Products

Combination products are those products which consist of two regulated components, a medical device, and an active pharmaceutical ingredient. The pharmaceutical drugs in the medical device are either impregnated or surface coated. Current examples include catheters with an antimicrobial coating, drug-coated stents and auto-injection devices.

Combination products, even more so than stand-alone medical devices in general, are highly regulated. In the EU, the main regulation covering medical devices is Council Directive 93/42/EEC of June 1993, as amended (known as the Medical Device Directive, MDD). Annexe 1 of the Directive provides the physio-chemical requirements of certain medical devices, which include:

i) ensuring "the compatibility between the materials used and the biological tissues, cells and body fluids, taking account of the intended purpose of the device…"; and

ii) "…if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned…".

Implanted medical devices have been shown to facilitate better treatment for patients. People with diabetes have especially benefitted from having auto-injection devices administering insulin as and when the device detects that the blood sugar level of the patient has altered. One of the main challenges which manufacturers of such implanted devices have faced has been the fact that the immune system of the body has caused a fibrotic cascade. Fibrosis is the thickening and scarring of connective tissue which prevents the implanted medical device from interacting with the surrounding environment. The device is then unable to sense glucose levels and effectively deliver insulin. So far, physicians have used strong immunosuppressant drugs in order to overcome the problem of fibrosis; however, this in itself results in further side effects. Researchers have recently targeted specific protein receptors in order to better understand the body's immune response to implanted medical devices, and early results from tests in rodents have shown positive results in reducing fibrosis once a medical device has been implanted. It is hoped that such research can be extended to humans, and implanted devices can be used more effectively in patients.

The US has recently signed into law legislation which in part makes it easier for combination products to gain FDA clearance. Previous legislation involved the FDA, through its Office of Combination Products, reviewing a pre-market combination product and determining the device's appropriate process for approval by determining the device's primary mode of action (PMOA). The 21st Century Cures Act signed into law in December 2016 provides that the FDA shall not determine the PMOA is a drug/biologic simply because the product has a chemical action on the human body. Sponsors of combination products will now also have the ability to register their disagreement and appeal decisions of the FDA, as well as request meetings. This legislation has been welcomed by the global medical device manufacturers, and will provide clarification on the regulatory process for combination products in the US.

The EU has also recognised that medical devices in general are important to the quality of life of patients, and have agreed two new Regulations on medical devices and in vitro diagnostic medical devices. The Regulations aim to provide greater protection of public health and patient safety by subjecting high-risk devices to stricter pre-market control. The Regulations also introduce a comprehensive EU database on medical devices (EUDAMED), which will contain a living picture of the lifecycle of all products available on the EU market, as well as unique device identifiers, implant cards for patients with implants, and financial mechanisms to ensure patients are compensated should they receive defective products.

Telemedicine and the Future of Hospitals

Telemedicine (the use of telecommunication and IT to provide healthcare remotely) is changing the way patients receive healthcare, with the global telemedicine market expected to grow to nearly US $60 billion in 2020.

The accessibility of telemedicine is one of its major benefits, particularly for those living in rural areas where access to a doctor or a hospital in an emergency is difficult. Whilst there are different technologies which make up "telemedicine", it generally involves the use of technology such as a mobile app used by patients to speak directly to a physician on web chat, video chat or by sending photos. This enables patients to be diagnosed quickly from the comfort of their own home. In less developed or war-torn countries such as South Sudan, doctors are able to refer difficult cases to a host of experts from around the world using telemedicine technology, helping to ensure patients receive the correct diagnosis.

In more developed countries, a key benefit is the convenience of the technology. The average waiting time for a doctor's appointment in the UK has increased to nearly two weeks and a high number of sick days taken by employees can cost economies millions. Telemedicine provides instant access to a doctor, 24 hours a day, meaning patients can be diagnosed much earlier and therefore recover much quicker. Patients with chronic conditions can also relay key medical data such as their blood pressure, heart rate and other vital signs of their conditions to their doctor through wearable monitors (such as smart

watches), and the doctors have the ability to monitor their patients remotely, reducing the requirements for routine check-ups and freeing up appointment times for other patients who need urgent physical care.

In Cleveland, USA, telemedicine is being used to create a new type of hospital, one which is run entirely remotely, with doctors and nurses caring for patients in clinics across the region using a camera at the foot of each patient's bed. This technology makes it easier for patients to receive quality round-the-clock care, particularly in clinics where there are no specialists to work the night shift. The remote doctors are able to zoom in on patients and track their condition or recovery. If a patient looks to be deteriorating, the doctors are able to quickly alert a nurse on the ground who can provide immediate treatment. Whilst the technology and model of healthcare is still in development, one can foresee questions of liability arising in scenarios where technology is responsible for being the primary carer of a patient, as opposed to physicians on the ground. Who would be liable if the connection to the patient was cut, and staff on the ground were not able to respond to a patient whose health was crashing? What safeguards would a hospital have to put in place to maintain live transmissions around the clock? Where malfunctions are detected, would it be the manufacturer of the devices, or on the ground technical support teams ultimately responsible for the repairs?

The hospital of the future could be unrecognisable from the hospitals of today, from mobile check-in, self-service kiosks for blood and urine tests and robots operating the majority of surgeries. Wearable devices will track a patient's condition and be able to send updates to doctors as well as to patients' and relatives' phones whilst the advancement of robots will mean surgeries will be less invasive and recovery times will be quicker. Hospitals may be operated using a "command centre" such as those being trialled in Cleveland, resulting in doctors closely monitoring patients from afar, and potential complications being picked up quicker than is possible using the traditional methods of ward rounds.

With the increased use of technology, be it remotely controlled combination products, wearable devices or hospital command centres, there comes hand in hand security concerns. The healthcare industry spends millions each year on stringent IT security measures to protect against the threat of cyber-attacks. Should a hacker gain access to a hospital's IT system, they potentially have the ability to obtain countless electronic patient records. With an increasing number of medical devices connected to the internet, there are more avenues which hackers could potentially use to gain access to a hospital's systems. Such a hack could have potentially catastrophic consequences for patients. For example, if hospitals in the future are run through a centralised command centre, as being trialled in Cleveland, a cyber-attack, even if it only lasted a short amount of time, could result in physicians being unable to monitor their patients and provide the care needed resulting in potentially tragic consequences and significant liabilities.

The resulting litigation could become an extremely complex dispute, with aspects of a product liability, data protection and IT dispute. Combination products and wearable monitors also have the ability to be hacked. In scenarios where a hacker gains access to a patient's digital insulin injector, and prevents insulin from being administered at the appropriate time, or is able to remotely shut down a patient's pacemaker, could the manufacturer be held liable for not providing sufficient security provisions? What would happen if the patient themselves had not changed the default password or failed to update the software regularly as advised making the device vulnerable to an attack? What if they had altered the device in some other way? In those circumstances, could the patient be held totally liable? As more and more devices are connected to the internet in the revolution known as the Internet of Things, these questions will increasingly need to be addressed by regulators, legislators and the manufacturers developing these products.

3D Printing

3D printing technology has been used in the healthcare industry for a number of years now, with a range of medical devices such as prosthetics, hearing aids, customised implants and surgical equipment all being able to be produced by 3D printing methods. A fall in the cost of the printers and advances in the materials used has, however, resulted in a vast increase in the availability and use of 3D printed products.

One of the main benefits of 3D printed products is the cost of the end products. Medical products produced using 3D printing are much cheaper than those produced using traditional methods. Such cost and efficiency savings are attractive to governments and result in the costs to patients being lower, potentially opening up healthcare access to a wider range of patients.

To date, 3D printing technology has been used to create artificial skin, kidney, liver, orthopaedic and dental implants. March 2016 saw the FDA approve the first 3D printed tablet (Spritam (Levetiracetam) from Aprecia Pharmaceuticals). Questions as to who will be liable when a 3D-printed medical device malfunctions will turn on the facts of the individual cases but who should the patient sue? The healthcare provider operating the 3D printer? The manufacturer of the 3D printer? The developer of the software that drives the 3D printer? The designer of the 3D printed item? In England & Wales, the CPA is designed to remove such decisions from a consumer – they can, within reason, sue the most visible party and then leave it to the parties in the manufacturing, distribution and supply chain to grapple with the issues and apportion liability between themselves. All businesses operating in this arena will need to consider these risks and potential liabilities carefully and ensure that they are properly managed.

Conclusions

Medical devices play a key role in the provision of healthcare, and as patients live longer, and demand more from healthcare providers, the efficiency and costs savings which innovative new medical devices provide will be invaluable to the healthcare sector. The UK and EU regulatory and legal frameworks currently provide a robust but flexible framework which should be able to develop with the technologies.

The complexities of the technology and the blurring of the lines between medicine, technology, products, services and professional intermediaries make it inevitable that questions will remain, however, as to the risk of using new devices compared to conventional methods of treatment. Inevitably, the questions as to liability and responsibility when something goes wrong will be equally complex.

As mentioned above, the EU has moved to introduce new Regulations in relation to medical devices. The UK will need to ensure that whatever path is taken in relation to regulation post-Brexit, its own regulatory regime keeps pace with the technology and strikes the right balance between encouraging innovation and protecting patients.

Medical device innovations will continue to provide improved cost and health outcomes for healthcare providers and patients. More than ever before, the legal and regulatory landscape will increase in complexity and it will require close collaboration between manufacturers, physicians, regulators and the courts to ensure that they keep up with the pace of such innovations to ensure that patient safety is protected.

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Acknowledgment

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"They are extremely strong in this area and have an enviable client list, particularly in the food and pharmaceutical sectors. Louisa Caswell has a very good team around her who are also very experienced". *Chambers UK 2016*.

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Product Liability in Asia

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The world is becoming increasingly connected. Consequently, with increasing globalisation, product liability development in one part of the world will have ramifications globally. It is imperative that countries remain cognizant of other developments in the product liability space.

Development

In Asia, generally, the driving force behind the development of product liability law is the increasing awareness of consumer rights propelled by economic development and the realisation by governmental bodies of the need to protect consumers against product manufacturers. However, the different pace of economic development within Asia makes it practically impossible to expect homogeneity in the region. For example, many Asian countries such as Hong Kong, India, Sri Lanka and Singapore do not have specific product liability legislation, but generally subsume such protection under the principles of common law or general consumer protection legislation. On the other hand, countries like Japan and Korea have enacted specific product liability legislation.

One of the key inspirations behind product liability legislation is the European Community's Product Liability Directive ("EC Directive"). The central tenor of the EC Directive was the introduction of the strict liability regime for defective products. With increasing economic development, given that manufacturers have greater resources to anticipate, prevent and investigate product defects than consumers, the introduction of the strict liability regime was inevitable. It was thought that the strict liability regime conferred better protection to victims and increased the safety standards of products.

Countries such as Japan, India, China and Korea have identified with the underlying rationale of the EC Directive and thus followed suit. Brief summaries of the Product Liability landscape of the aforesaid countries are set out below.

a) Japan's Product Liability Law ("PL Law"), which was enacted in 1994, imposes strict liability on defendants for death, injury and damage caused by a defective product manufactured, processed, imported or represented as such by the defendant. A series of cases resulting from defective food or drugs was also the leading reason for introducing a new legislation regulating product liability and consumer safety. Japan has even taken it further to introduce a positive duty on suppliers of any consumer goods to notify the government of any serious product-related accident by way of an amendment in 2006 to the Consumer Product Safety Law.

b) The Bhopal disaster in India, considered as the worst industrial disaster in the world, drew India's attention (and indeed the rest of the ASEAN region) to the need to examine and reform law relating to liability for unsafe productions and production processes. The increasing realisation of helplessness of the consumers caused the enactment of Consumer Protection Act of India in 1986.

c) The People's Republic of China ("PRC") adopted consumer rights' protection legislation in 1993 under the Law of the People's Republic of China on Product Liability. It created statutory liability for the producer and seller.

d) In Korea, the Consumer Standard Act was enacted in 2006 and was amended three times in 2008. It regulates manufacturing safety, and provides for provisions regarding consumer rights, obligations of manufacturers and retailers, as well as the role of the government in regulating consumer protection. The Korean Government also has policies facilitating product recalls with a set of guidelines instituting voluntary and mandatory product recalls.

On the other hand, there remain many countries that have not enacted specific product liability laws. For example, there is no general statutory provision regulating the sale of defective products in Hong Kong despite recommendations being made in the Law Reform Commissioner Paper on Civil Liability for Unsafe Products (issued in 1998). Nor is there statutory enactment in Singapore that creates a comprehensive regime for product liability, though there are specific statutes that govern particular areas of law where product liability issues may arise. Like Hong Kong, product liability in Singapore is largely based on the common law. This is supplemented by the creation of various organisations such as the Hong Kong Consumer Council or the Consumers Association of Singapore ("CASE"). Both provide a complaint system in which they may try and mediate between the parties, but do not have any judicial or quasi-judicial powers. In the event that mediation is not successful, the only recourse is to make a claim through the court system.

Efficacy of Legislation/Consumer Protection

The enactment of specific product liability legislation is not a one-stop solution to addressing all product liability-related issues. Effective protection still hinges on other factors such as the ease of enforcement of such legislation, easy consumer access to the justice system and the integrity of such systems.

Effective product liability protection is especially challenging in the developing Asian countries where the level of awareness and the financial means of the general populace to obtain redress may not be as high as that of the developed world. This is further compounded by the lack of sophistication of the legal systems (such

as under-developed court systems and out-dated legislation) and the inadequate availability of resources to enforce any such laws.

As a compromise, in view of the limited resources (especially in developing Asian countries), some Asian countries such as India and Sri Lanka have set up special consumer tribunals to assist in the progression of product liability protection. Compared to formal litigation, consumer tribunals are preferred as there is speedy and affordable disposal of cases. Its flexibility may cater especially well to developing countries, particularly due to a low-entry initiation mode, a simple but rights-based dispute resolution procedure and a quick enforcement of the outcome. However, judicial or quasi-judicial officers handling these cases tend to be inexperienced with the handling of the judicial process or the evidence put before them, especially by manufacturers or importers in their defence of their product, something leading to somewhat bizarre decisions. Alternatively, each matter is bounced around within the processes and hearings (whether substantive or procedural), and decisions or rulings are made after significant delay. Often there are avenues of appeal to the courts, which in turn causes significant delay and costs. For example, in India, the definition of what constitutes a "consumer" under the Consumer Protection Act 1986 ("CPA") is still uncertain, with two appeals to the Supreme Court of India (that we are aware of) dealing specifically on this issue. Consequently, the Commissions are set up under the CPA to adjudicate consumer claims.

On the other hand, the threat of the immense damages compensation resulting from class actions may propel the speed of development of product liability regime in Asia. Class actions and punitive damages are gaining traction in Asia (such as in Thailand and Indonesia where legislation recognising class actions have been approved by the legislature in principle) because it enhances access to justice through the provision of a remedy to those who have little financial means to seek judicial redress. China's Tort Responsibility Law, which took effect on 1 July 2010, includes the introduction of punitive damages for defective products. Japan has also joined the bandwagon and introduced a bill to introduce class actions which in the current form would not exclude a class action claim based on product liability. In May 2012, many years of debate have given rise for Hong Kong Law reform to release an extensive report on class actions. The reform is more of an opt-out model that would permit product liability and personal injury claims, but it rejected the adoption of contingency fees or punitive damages and urged the preservation of the "loser pays rule". The Consumer Protection Act in India also allows the filing of class action suits by any trade or registered consumer association, any Central or State Government, or a number of consumers where there is a common interest. As such, it is still an ongoing debate as to the extent to which Asia as a region will embrace such an action. In that regard, it is our view that class actions will become a socially accepted normality in the foreseeable future given the increasing awareness of consumers of their legal rights coupled with greater access to information. In short, product liability on a global scale presents new challenges for multinational manufacturers.

Insurance

Another factor that affects the development of product liability is insurance claims. Insurers are generally the first point of contact when a product liability claim is made. The globalisation of the product supply has invariably contributed to the rise of global insurance claims. As such, the principles behind insurers' rights of subrogation are generally well understood. Insurers who indemnify an insured for a loss thereby become entitled to claim against the wrong-doer who has caused that loss, i.e. by paying a claim the insurer "steps into the shoes" of the insured and takes over any rights it has against the third parties who may be responsible for the loss. It is an equitable principle that prevents the insured from the retaining the benefit of a double recovery. Generally, in the automobile sector, a customer may be more inclined to make an insurance claim for any loss or damage resulting from any defect in the vehicle. Thereafter, it is up to the insurance company to proceed with a subrogation claim against the manufacturer or reporter. Again, in this regard, we see different trends in different parts of the Asia Pacific region. We have observed that in jurisdictions such as Japan, Korea and Taiwan, the insurance companies have been more proactive in seeking compensation against the manufacturer and/or importer of the products. However, as we move southward, the numbers of subrogation claims are significantly reduced. This is an interesting phenomenon, especially in countries with more developed legal systems such as Singapore or Malaysia where we might expect insurance companies to use subrogation to recoup the pay-outs if there is good cause to do so. If defective products are simply covered by insurance, there is less pressure on the manufactures to ensure that they continue to place emphasis on the safety of their products.

Conclusion

Despite the non-homogeneity of the levels of development within Asia, the development of a product liability regime is inevitable. It is unmistakable that legislators and courts in Asia are becoming increasingly sophisticated. Naturally, this will result in a gradual push towards more stringent regulation and establishment of enforcement mechanisms to better protect consumers and reduce the instances of safety scandals. Given the development of ASEAN as a potential trading bloc, it is hoped that product liability laws, or indeed consumer protection legislation that address product liability, be promulgated in consultation with each other such that the same basic principles of product liability and the protection of the consumer be consistent. In that regard, it may itself form a model that takes into account the cultural and political diversity in the region. This could very well cause other countries in the Asia Pacific region to look carefully at such legislation for use in their own jurisdictions. If this can be achieved, other non-ASEAN members in the region might be interested in either following the model or taking parts of it that would be useful in their country.

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Liability Risks of Automation and Connectivity in a Technologically Advanced World

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Advancements in technology and automation have led to an increasingly safer, convenient, and connected world. A few areas greatly impacted by these new technologies are autonomous vehicles, manufacturing, and the Internet of Things. While these advancements offer numerous benefits, they also can expose manufacturers, distributors, and insurers to new and potentially greater product liability risks. This article will discuss these advancements and the potential legal exposures they create.

Autonomous Motor Vehicles

The most prominent example of increased automation, and the one most likely to have the biggest effect on society, is the incorporation of increasing levels of automation in motor vehicles. Motor vehicles have become safer since their invention in the early 20th century. Seat belts, airbags, mirrors, indicator lights, anti-lock brakes, children's car seats, Bluetooth, power steering, and other features are taken for granted now, but were at one time pioneering safety features. However, in 2015, motor vehicle accidents were still responsible for the death of more than 35,000 people in the United States. *See* NHTSA, 2015 Motor Vehicle Crashes: Overview, Report No. DOT HS 812 318 (August 2016). The overwhelming majority of these accidents are caused by human error, including drunken driving, poor judgment, poor driving skills, poor reflexes, inattentiveness, poor vision, or criminal negligence. *See Self-Driving Cars and Insurance*, Insurance Information Institute, July 2016 (http://www.iii.org/issue-update/self-driving-cars-and-insurance). A staggering 94 per cent of automobile accidents are caused by human errors. *See Critical Reasons for Crashes Investigated in the National Motor Vehicle Crash Causation Survey*, National Highway Safety Traffic Administration (February 2015) (https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/812115).

A study by the Insurance Institute for Highway Safety (IIHS) concluded that improvements in design and safety technology have led to a lower fatality rate in accidents involving late-model cars. *See Self-Driving Cars and Insurance*, Insurance Information Institute, July 2016 (http://www.iii.org/issue-update/self-driving-cars-and-insurance). The likelihood of a driver dying in a crash of a late-model vehicle decreased by more than a third over three years, and nine car models had zero fatalities per million registered vehicles. Among the factors to which the IIHS has attributed the lower death rate are the adoption of electronic stability control, which has reduced the risk of rollovers, and side airbags and structural changes that have improved occupant safety.

One way for motor vehicles to be even safer is through the increased use of autonomous motor vehicles. Autonomous driving will not only likely lead to significantly safer driving, but also provide greater mobility for people who are currently unable to drive, e.g., handicapped and elderly persons. Many people do not realise the extent to which automation has already improved driver safety. One example is electronic stability control systems, which help drivers maintain control while driving on slippery surfaces.

Motor Vehicle Manufacturer Innovations

Some car manufacturers have incorporated "driver assistance" packages in many of their models. These packages include parking systems with a rear-view camera, settings that allow for different driving modes based on weather and road conditions, side-assist blind-spot monitoring, dynamic variable ratio steering, adaptive cruise control, active lane departure warning systems, and top and corner camera view systems.

Forward sensor systems on several types of vehicles can detect if a forward collision is imminent and engage the automatic braking system at multiple levels without driver assistance to reduce the likelihood of a forward collision. If necessary, these systems can also activate protective measures, e.g., the front seat belts are pre-tensioned electronically, and the windows and sunroof close. Other systems allow the autonomous motor vehicles to analyse driving behaviour and warn drivers if they find any indication that drivers are starting to lose concentration. The systems use data from the radar and ultrasound sensors and a front camera, and guide cars by using gentle steering interventions that enable them to follow the line of vehicles ahead. These systems use roadway markings and other vehicles on the road to orient accordingly.

Preventive measures in certain systems protect against rear-end collisions. While the autonomous motor vehicles are in reverse, these systems assess the surrounding traffic and warn the driver of vehicles whose approach they deem critical. The systems have different levels of warning: visual; acoustic; and, finally, a short jolt of the brakes.

Several car manufacturers are incorporating these features in higher-end vehicles, and some are incorporating them in slightly less expensive models. Over time, the hope is that these features will be the new standard, i.e., they will be as common and required like seat belts. Forecasts predict that there will be 10 million automated vehicles on public roadways by 2020. *See* "10 Million Self-Driving Cars Will be on the Road by 2020", John Greenough, *Business Insider* (July 29, 2015) (http://www.businessinsider.com/report-10-million-self-driving-cars-will-be-on-the-road-by-2020-2015-5-6).

While automation can be used within a solitary vehicle to make driving safer, it can also be used among multiple vehicles to share information that can help mitigate the likelihood of an accident.

The U.S. Department of Transportation has proposed a rule that would require motor vehicle manufacturers to include vehicle-to-vehicle communication technologies, thereby enabling several new crash-avoidance applications that could prevent "hundreds of thousands of crashes every year by helping vehicles 'talk' to each other". *See U.S. DOT advances deployment of Connected Vehicle Technology to prevent hundreds of thousands of crashes* (December 13, 2016) (https://www.nhtsa.gov/press-releases/us-dot-advances-deployment-connected-vehicle-technology-prevent-hundreds-thousands). The rule would require the devices to communicate using the same "language" through standardised messaging within the motor vehicle industry.

A relatively sizable obstacle to the increased use of autonomous vehicles is the United States' unique legal and legislative framework. The U.S. system comprises 50 states, with individual laws, and governed in certain circumstances by federal law. States' laws are often inconsistent with each other and/or contradictory. The National Highway Traffic Safety Administration (NHTSA) realised that it is problematic for international vehicle manufacturers to be governed by disparate regulations and published a set of guidelines intended to bring more uniformity to the manufacture of autonomous vehicles. California, Nevada, Michigan, North Dakota, Tennessee, Florida, and the District of Columbia were the only jurisdictions as of the beginning of 2016 that had legislation regulating autonomous vehicles on public roadways. Even those regulations differ from each other.

NHTSA – Federal Automated Vehicles Policy – September 2016

The NHTSA realises that this legal and regulatory framework is a potential obstacle on the path to safer driving. Accordingly, its Federal Automated Vehicles Policy: Accelerating the Next Revolution in Roadway Safety (September 2016) provides guidelines to consider for federal and state authorities, and motor vehicle manufacturers.

The four main parts of the new policy are:

- **15-Point Safety Assessment**: The Vehicle Performance Guidance for Automated Vehicles for manufacturers, developers and other organisations includes a 15-Point Safety Assessment for the safe design, development, testing, and deployment of automated vehicles. The 15-Point Safety Assessment would cover: (1) data recording and sharing; (2) privacy; (3) system safety; (4) vehicle cyber-security; (5) human-machine interface; (6) crashworthiness; (7) consumer education and training; (8) registration and certification; (9) post-crash behaviour; (10) federal, state, and local laws; (11) ethical considerations; (12) operational design domain; (13) object and event detection and response; (14) fall-back (minimal risk condition); and (15) validation methods.
- **Model State Policy**: Delineates the federal and state roles for the regulation of highly automated vehicle technologies as part of an effort to build a consistent national framework of laws to govern self-driving vehicles.
- **Current NHTSA Regulations/Options for Expediting Introduction**: Outlines options for the further use of current federal authorities to expedite the safe introduction of highly automated vehicles into the marketplace.
- **Modern Regulations/Identifying and Removing Obstacles**: Discusses new tools and authorities the federal government may need as the technology evolves and is deployed more widely.

The policy also adopted the SAE international definitions for levels of autonomous driving. Those levels are as follows:

- Level 0 – the human driver does everything.
- Level 1 – an automated system on the vehicle can sometimes assist the human driver conduct some parts of the driving task.
- Level 2 – an automated system on the vehicle can actually conduct some parts of the driving task, while the human continues to monitor the driving environment and performs the rest of the driving task.
- Level 3 – an automated system can actually conduct some parts of the driving task and monitor the driving environment in some instances, but the human driver must be ready to take back control when requested by the automated system.
- Level 4 – an automated system can conduct the driving task and monitor the driving environment, and the human need not take back control; but the automated system can operate only in certain environments and under certain conditions.
- Level 5 – the automated system can perform all driving tasks under all conditions that a human driver could perform.

The goal of the policy is to set forth a proactive safety approach that provides life-saving technologies for motor vehicle operators while also allowing room for companies to innovate to develop new solutions. The U.S. Department of Transportation (DOT) believes that autonomous vehicles will provide "enormous potential benefits for safety, mobility, and sustainability".

Increased Automation in Other Industries

The effects of automation are not limited to motor vehicles. Automation is a factor in other emerging disrupting technologies such as the Internet of Things, drones, artificial intelligence, nanotechnologies, 3D printing, virtual reality, and blockchains. These technologies will transform life, business, and the economy. For example, while many politicians will use alternative facts to say that the United States has lost factory jobs because of trade, 88 per cent of factory jobs have been lost because of increased productivity via improvements in machinery and automation. *See The Myth and the Reality of Manufacturing in America*, Michael J. Hicks and Srikant Devaraj (June 2015) (http://conexus.cberdata.org/files/MfgReality.pdf). These job losses will not be confined to the past because the automation revolution is continuing. Recent studies from McKinsey and the economists Carl Benedikt Frey and Michael A. Osborne estimate that around 45 per cent of workers currently perform tasks that could be automated in the near future. *See A Future That Works: Automation, Employment, and Productivity*, McKinsey Global Institute (January 2017); and *The Future of Employment: How Susceptible are Jobs to Computerisation?*, Carl Benedikt Frey and Michael A. Osborne, September 17, 2013. The World Bank estimates that around 57 per cent of jobs could be automated within the next 20 years. In December 2016, the White House released a report wherein experts predicted that in the next 10 to 20 years, 47 per cent of jobs performed by humans in the United States could be replaced by advances in automation. *See Artificial Intelligence, Automation, and the Economy*, Executive Office of the President (December 2016) https://obamawhitehouse.archives.gov/sites/whitehouse.gov/files/documents/Artificial-Intelligence-Automation-Economy.PDF). These job losses will mostly affect jobs in the manufacturing, electronics, and pharmaceutical industries.

There are several reasons for the increase in automation, including increases in powerful and energy-efficient processors, open source software, and cheap sensors. These allow for "smart" autonomous products. *See The Age of Autonomous Robots Is Upon Us*, Fortune (March 29, 2016) (http://fortune.com/2016/03/29/autonomous-robots-startups/). Venture funding for robotics has grown to $922.7 million in 2015, up from $341.3 million in 2014. Projections

indicate that the world will spend $135.4 billion on robotics and related services in 2019, up from $71 billion in 2015. *See The Age of Autonomous Robots Is Upon Us*, Fortune (March 29, 2016) (http://fortune.com/2016/03/29/autonomous-robots-startups/). As one might guess, this has led to an increase in desirability among graduates who might have otherwise pursued jobs in other industries. The effects of increased automation can be seen not only on factory floors and in manufacturing plants, but in small businesses, residences, and offices. Business owners, including retail giants like Amazon, use robots to monitor and stock shelves. In the near future, one can expect deliveries to be performed by drones and/or robots.

Homeowners can use a Roomba®, or similar products, to vacuum houses and robots to mow lawns. Consumer electronics, pool systems, plumbing systems, alarm systems, air conditioning and heating, security systems, sprinkler systems, washers, dryers, dishwashers, etc. can all be automated and/or operated remotely.

The Internet of Things

A major component of incorporating automation in products is the ability to connect with other technology, networks, and objects that are not part of the tangible product. New technology, and society's increasing willingness to embrace and rely on it, will have far-reaching consequences for manufacturers' product liability exposure, and accordingly, insurance companies that underwrite the policies that insure against those risks. Society is increasingly connected by software and hardware. The principal force behind that interconnectivity is the Internet of Things. The Internet of Things is the inter-networking of physical devices, vehicles, buildings, etc. embedded with electronics, software, sensors, and network connectivity that enable these objects to collect and exchange data. Several reports and experts estimate that the Internet of Things will consist of almost 50 billion objects by 2020.

The Internet of Things is relatively new, so laws, rules, regulations, and jurisprudence will necessarily evolve with the technology. However, that will not stop its continued growth. The growth of the Internet of Things will increase convenience and connectivity, but it will come with associated risks. Some of those risks will be relatively predictable, but some have assuredly not even been contemplated.

A 2014 Goldman Sachs report identified five key applications in which the use of the Internet of Things is vital: wearables (e.g., Fitbits); connected homes; connected cities; connected motor vehicles; and the industrial internet (including transportation, oil and gas and health care). *See The Internet of Things: Making Sense of the next mega-trend*, Goldman Sachs IoT Primer (September 3, 2014) (http://www.goldmansachs.com/our-thinking/outlook/internet-of-things/iot-report.pdf).

Product Liability Automation Risks

While there are safety benefits, and likely revenue benefits, for manufacturers who rely on automation, there will also be the potential for increased liability exposure. For example, motor vehicle manufacturers have long been subject to product liability lawsuits. However, the number and types of product liability lawsuits will likely increase because of autonomous vehicles. Autonomous vehicle manufacturers, and manufacturers in general, will likely face product liability claims based on various theories of liability, including, *inter alia*, strict liability, negligence, and breach of warranty. Manufacturers of autonomous vehicles will not be the only entities that will have to worry about an increased exposure to product liability lawsuits. Manufacturers of the various component parts, e.g. software and hardware manufacturers, will also be exposed to greater product liability risk.

Assessing liability with autonomous motor vehicles will be complicated by the possible combinations of driving modes, ranging from no autonomy to full autonomy. Potential factors include the comparative negligence of a human operator's actions, the functionality of software and sensors manufactured by potentially dozens of legally separate entities, the designs of the autonomous driving systems, and the training and/or warnings associated with operating an autonomous vehicle, among others.

These liability calculations and apportionments will involve determining which of the many component part manufacturers, if any, played a role in an incident. As software algorithms become more vital to the success and failure of autonomous vehicles, motor vehicle manufacturers will necessarily have to be more focused on the integration of software and hardware. In product liability practice, it is well-established that apportionment of liability can be apportioned up and/or down the supply chain to the cause of a particular failure. These risks are often addressed between component parts suppliers and manufacturers under the terms of supply agreements where a contractual duty to defend and indemnify against damages caused by a malfunctioning device is delineated.

In a technologically advanced setting, apportioning liability will not be as straightforward as it used to be. There will certainly be novel and challenging legal issues. For example, imagine a relatively simple traffic accident between two cars. In the pre-automation era, the liability would most likely be apportioned between the drivers of the two automobiles, and potentially one of the two vehicles if there was a manufacturing defect. On the contrary, imagine an Uber-owned Toyota being driven autonomously and the other car being an autonomously driven Audi. There could be several unrelated injured individuals in the shared Uber. One of the issues will be whether either the Uber or the Audi was taken over by a human driver at the time of the accident. Another issue is whether the hardware and/or software in the vehicles were defective. Did Uber own the vehicle or did it lease the car to a local business and/or individual operating the vehicle? Was either vehicle hacked, thereby potentially exposing to liability the entities responsible for each vehicle's cyber-security? Are autonomous vehicles allowed in that jurisdiction? Was the specific level of autonomous driving in use at the time of the accident allowed in that jurisdiction? Was the driver contractually obligated to have his/her hands on the steering wheel even though the car was in an autonomous mode? Did the drivers of the autonomous vehicles update the vehicles' software to ensure that they were being driven with the most recent software? Did the vehicle manufacturers adequately warn the drivers/owners of the vehicles that the software needed to be updated? Did either vehicle have equipment that was not manufactured by the original equipment manufacturer? If so, depending on the law of that jurisdiction, was that reasonably foreseeable? Liability could potentially be apportioned to various points along the supply chain – and this is a simple hypothetical two-car accident. Imagine the issues extrapolated to an interstate pile-up.

However, that same automation and interconnectivity could also provide a clearer picture to develop via the vehicles' internal software, so it should theoretically be easier to discover what contributed to the accident than in an accident wherein there could potentially only be testimony from the two drivers.

A few examples of other potential product failures connected with increased automation include the potential for software and/or hardware glitches leading to frozen pipes causing water damage;

a sprinkler system malfunction causing water damage; a remote security system failing, leading to a home invasion and/or an abduction; a "smart" consumer electronics system causing a fire; and gas/fuel leaks leading to fires and/or explosions. While the consequences of those may be tragic, they would be confined to residences and those therein. There are potentially even greater consequences when those losses are extrapolated to factories, hospitals, medical facilities, offices, buildings, etc. Those losses could not only cause personal injury and property damage, but also business interruption losses. As machines grow more autonomous, potential failures become more complex and difficult to diagnose. Moreover, because automated processes likely run more efficiently and quickly than manual processes, they are usually more integrated into other operations around a facility and sometimes even beyond that facility. Any failure predictably would increase the cost of that failure and have exponential effects the longer it went undiagnosed.

The increased connectivity via the Internet of Things also poses interesting post-sale considerations and potential responsibilities on manufacturers. A manufacturer's duties to warn at the time of sale are well established. However, if a manufacturer discovers new risks after a sale, the legal framework for a manufacturer's responsibilities is not nearly as established. The Restatement (Third) of Torts, published in 1998, included a post-sale failure to warn duty. However, only some states have adopted that stricter standard. Due to the increased connectivity, manufacturers will likely be held to a higher standard regarding notice of certain failures and notifying consumers/users of those failures.

Once manufacturers become aware of potentially risky software programs and/or product defect issues, they will need to act quickly to provide upgrades and/or recall the defective products. Product recalls are relatively common for certain types of products and are usually handled by various regulatory agencies. Due to the increased connectivity, and access to information regarding products and consumers' information, manufacturers and retailers will have fewer defenses for not recalling almost all products.

A different type of failure arises in connection with cyber-security issues. The necessary reliance on the Internet of Things and increased automation allows for the potential for servers and/or products to be hacked. Users' personal data could be accessed and stolen. If these issues are prevalent with a certain product, manufacturers, including those of the component parts and/or security systems contained therein, would likely be subject to product liability lawsuits and/or class action litigation. The investigations attendant to litigation will also require the use of novel and educated experts in those fields. Since this will be a new area of litigation, identifying the relevant experts will be a significant undertaking.

There are potentially bigger issues when outside parties hack devices connected to the Internet of Things for nefarious, political, and/or criminal motives. The U.S. Federal Trade Commission (FTC) issued a report in January 2015 that highlights these issues. *See Internet of Things – Privacy & Security in a Connected World*, FTC Staff Report (January 2015) (https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-staff-report-november-2013-workshop-entitled-internet-things-privacy/150127iotrpt.pdf). The FTC report noted security concerns for consumers using devices connected to the Internet of Things, such as enabling unauthorised access and misuse of personal identification, facilitating attacks on other systems and creating safety risks. The report noted that while these risks exist with traditional computers and computer networks, they are more prevalent due the increased connectivity associated with the Internet of Things. Moreover, computers and computer networks have decades of experience in cyber-security. Many companies that have never before considered cyber-security in relation to their products will not have decades of that institutionalised cyber-security knowledge on which to rely.

Effect on Insurers

Almost all manufacturers have product liability insurance. Accordingly, insurers will have to consider all of the potential benefits and risks of automation when drafting policies and/or agreements with potential insureds. Insurers will also need to hire claims representatives familiar with the technology incorporated in the respective products, leading to a shift in the types of people employed by insurance companies and/or the qualifications necessary to work at insurance companies.

The framework for insurance will also shift, especially with the increased use of autonomous motor vehicles. The paradigm will likely shift from a user error focused evaluation to a product liability focus. As products become increasingly automated, the burden might be on the manufacturer to prove it was not responsible for an incident. This will be a marked shift from the old paradigm in motor vehicle accident evaluations. There is a small possibility, if the integration of autonomous motor vehicles is not seamless, that the liability issues could threaten the financial viability of motor vehicle manufacturers. However, it is likely that such a scenario would be prevented via regulation and/or legislative action.

Another consideration is that as consumers have more options for transportation, especially in public transportation, autonomous motor vehicles, and/or shared rides, car-ownership might decrease significantly. This could impact the types of insurance available and insurers' financials.

Conclusion

While advancements in automation may provide new risks and product liability considerations, they will also lead to dramatic increases in safety. It is possible that federal and state legislatures will enact legislation protecting manufacturers from the attendant risks and legal exposure. However, at least in the interim, those advances in safety will not be sacrificed because they may lead to more product liability exposure, so manufacturers, retailers, and insurers should be prepared for the new automation and product liability landscape and be willing to evolve as the technology around us evolves.

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Chapter 8

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 legislation.

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 Australian Consumer Law ("ACL").

The ACL is a new federal law which came into effect on 1 January 2011. It applies to transactions occurring on or after that date. The ACL replaces a collection of federal (also known as Commonwealth) and state consumer protection legislation with a single law which applies in all jurisdictions. The ACL is found in Schedule 2 to the Competition and Consumer Act 2010 (Cth) ("CCA"), which is itself the renamed Trade Practices Act 1974 ("TPA"). The consumer protection regime formerly found in the TPA has been transferred to the ACL and, in doing so, has been substantially modified.

The ACL imposes statutory obligations including a strict liability regime for products which are said to have a "safety defect" and statutory guarantees imposed on manufacturers. State fair trading legislation exists to provide for the application of the ACL in each of the states and territories, as well as covering some additional areas such as industry-specific regulation.

Typically, product liability claims for damage to persons will involve causes of action based on negligence and breaches of various provisions of the ACL.

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.

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.

The importance of contract as a cause of action in product liability claims has diminished in recent times as a result of the growth of the law of negligence and the statutory causes of action. The ACL has affected the relationship between contract and product liability by introducing provisions which render void any unfair term in a standard form contract, and it creates "statutory guarantees" which exist independently of any contract of supply (see further below).

Statutory Warranties and Guarantees

Under Part 3-2 of the ACL, manufacturers are liable directly to consumers for:

- goods which do not correspond with their description;
- goods of unacceptable quality;
- goods which do not conform to sample;
- goods unfit for a stated purpose; and
- non-compliance with express warranties.

Privity of contract is no barrier to relief.

The operation of these statutory warranties and guarantees 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 the ACL, 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.

Under the ACL, the definition of "manufacturer" 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?

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 3-3 of the ACL contain 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 the ACL.

2 Causation

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

The statutory consumer guarantees and the defective product causes of action under the ACL are often referred to as "strict liability" provisions. For actions for breach of a consumer guarantee, a claimant need not prove fault, but nonetheless must establish, on balance that, for example, the subject goods are not fit for purpose or are not of acceptable quality in the circumstances. For a defective goods action, a claimant needs to prove that the subject goods have a safety defect, i.e. are not as safe as persons are generally entitled to expect (having regard to all relevant circumstances).

At common law, in contract and in other actions based on the provisions of the ACL, 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 ACL; 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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

The test for causation depends upon the cause of action relied upon.

Prior to reforms to the law of negligence which occurred in 2002 (the Tort Reform Process), 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 for causation in negligence:

- 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.

Defective goods actions under Part 3-5 of the ACL may arise where a person has suffered loss or damage because of a safety defect. A person may be able to recover damages for loss or damage suffered where it is reasonably foreseeable that the consumer would suffer such loss or damage as a result of the failure to comply with a consumer guarantee (Part 5-4 of the ACL).

While there are some who argue otherwise, 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 subject to simply increased the probability of their injury occurring.

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 ACL contains deeming provisions that assist claimants in circumstances where it is not clear who actually manufactured the defective product.

Under the ACL, the definition of "manufacturer" is very broad and can potentially include anyone in the supply chain, particularly when the actual manufacturer is outside Australia.

In relation to the defective/unsafe product cause of action, 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 foreseeable 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 has a safety defect, is unfit for its purpose or is of unacceptable quality under the ACL. In deciding whether the product has a safety defect, is unfit for its purpose or is of unacceptable quality, 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.

Australian courts have, to date, declined to apply the learned intermediary doctrine. 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 it is 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 3-5 Australian Consumer Law

There are a number of specific defences to an action based on a claim that goods have a safety defect:

- 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' or 'state of the art' 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 have a safety defect under the ACL, 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 the statutory guarantee provisions of the ACL, 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 the defective goods action provisions of the ACL, 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 the statutory guarantee provisions of the ACL, 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 that 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?

With one exception, the trial of civil actions involving claims arising from alleged product defects are heard by a judge sitting alone (as both the tribunal of fact and law). The exception is Victoria; where civil trials before a judge (as the tribunal of law) and jury of four (as the tribunal of fact) are still available. However, they are relatively uncommon.

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 the 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 Courts of Victoria and New South Wales. 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 ACL under federal legislation.

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.

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 ACL 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 ACL, including certain provisions of Parts 3-5 (defective goods actions) and 5-4 (remedies relating to guarantees). Under these provisions, the ACCC requires the prior written consent of the persons on whose behalf the application is being made.

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. In addition, the court may require the experts instructed by opposing parties to meet before giving evidence in court, to narrow the issues 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?

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 other's 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 required to be pursued first or available as an alternative to litigation 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.

There are also legislative provisions which expressly encourage parties to explore resolution of disputes before the commencement of some proceedings.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction be brought within the jurisdiction of your courts either as a defendant or as a claimant?

The CCA (including the ACL) regulates the conduct of corporations, including foreign corporations carrying on business in Australia, and trading and financial corporations formed in Australia. The application of the ACL also extends to certain conduct (of both individuals and corporations): which is engaged outside Australia; or involves the use of postal, telegraphic or telephonic services, radio or television broadcasts (sections 4 to 6 of the CCA).

Whether an Australian court has jurisdiction in a product liability matter depends on whether the defendant can be validly served with initiating process. The Service and Execution of Process Act 1992 (Cth) makes specific provision for the valid service of an originating process (e.g. Statement of Claim) on a defendant to proceedings which is a foreign defendant. Ordinarily, a foreign defendant submits to the Australian jurisdiction when it commences proceedings as a plaintiff, enters an appearance as a defendant to proceedings, or agrees with a plaintiff that it will so submit to the jurisdiction.

If a foreign defendant refuses to submit to the jurisdiction, there may be an argument about the proper forum for the hearing of a claim. The choice of laws dictate that the appropriate law for a tortious action is, generally speaking, the law of the place where the wrong occurred.

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?

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 12 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.

Australian Consumer Law

Defective goods actions brought under Part 3-5 of the ACL 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 10-year period of repose, which requires actions to be commenced within 10 years of the supply by the manufacturer of the goods.

An action for non-compliance with a consumer guarantee (Part 5-4 of the ACL) must be commenced within three years after the time the person becomes aware, or ought reasonably to have become aware, that the guarantee had not been complied with.

For personal injury claims that relate to Parts 2-2, 3-3, 3-4, 3-5 or Division 2 of Part 5-4 of the ACL, the applicable limitation period is the later of the "date of discoverability" or the "long-stop period" as defined above (section 87F of the CCA and Part VIB of the CCA more generally).

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 sections 237 and 238 of the ACL 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 ACL.

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

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 VIB of the CCA

Under Part VIB of the CCA, 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 ACL 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. A representative proceeding may not be settled or discontinued without the approval of the Court (e.g. section 33V of the Federal Court Act). 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 (legal aid) 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, if any, funding is made 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 ACL.

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

Historical rules prohibiting lawyers from entering into contingency fee arrangements have been relaxed and a variety of arrangements are now sanctioned. These more recent 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.

7.6 In advance of the case proceeding to trial, does the court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

Australian Courts have broad discretion over legal costs of all proceedings. In effect, a court may make whatever order as to costs that are justified in the circumstances; although, there are court rules that govern the exercise of that power.

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 your jurisdiction.

Australia's consumer product regulator (the ACCC) continues to play an important and influential role in product liability claims and product safety compliance in Australia.

There is a strong interplay between product safety enforcement action taken by the ACCC and claims for compensation by consumers against manufacturers for alleged breaches of the ACL. There have now been several recent examples where the ACCC has successfully prosecuted suppliers for breaches of the ACL which have then triggered actions by consumers seeking compensation for related ACL breaches. Some of these have been class actions.

In a novel prosecution, the ACCC has successfully prosecuted a major Australian retailer for engaging in misleading or deceptive conduct by continuing to offer products for sale following receipt of customer complaints raising concerns as to product safety.

Such developments have added to the product liability risk for consumer product manufacturers and suppliers in Australia.

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Colin Loveday leads the Clayton Utz product liability group and class actions group. He is an experienced trial lawyer with particular expertise in the defence of class actions and has worked extensively with defence lawyers in other jurisdictions in the coordinated defence of multinational mass tort claims.

Since 1990, Colin has been intimately involved in the development of Australia's product liability laws and in the majority of class actions and mass tort cases in this area. His defence work includes a variety of prescription products and medical devices, infrastructure failures, financial products and other consumer products. 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 trials, labelling and advertising issues, product recalls and hazard alerts and priorities management issues. He practised as a barrister in New South Wales between 1985 and 1990, when he became a partner at Clayton Utz.

Colin is a former chair of the international committee of the International Association of Defense Counsel, a member of the Australian Product Liability Association, the Defense Research Institute and a former chair of the product law and advertising committee of the International Bar Association.

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Andrew is internationally recognised as a leading product liability lawyer in Australia. He has over 25 years' experience in the defence of product liability claims including pharmaceutical products and devices, asbestos, motor vehicles and allegedly defective consumer products. Andrew has defended some of Australia's highest-profile class actions involving complex pharmaceutical, competition and commercial claims, with results shaping the development of Australia's class action law.

Andrew is part of the team that has been at the forefront in developing both the procedural and substantive law in this area of practice and has defended claims brought by the major plaintiff law firms. His experience in tort-based group litigation includes most of the major Australian product-related class actions involving intra-uterine contraceptives, breast implants, diet pills, anti-acne medication and non-steroidal anti-inflammatory drugs. Andrew complements this experience with a significant risk management advisory and regulatory practice.

Andrew has twice served as president of Australia's National Product Liability Association. He is an active member of the Defense Research Institute, having chaired the International Issues group with the product liability committee. He is also a member of the International Association of Defense Counsel and the Australian Insurance Law Association.

CLAYTON UTZ

Clayton Utz is one of Australia's leading independent top-tier law firms. Established in 1833, the firm has over 170 partners and more than 1,400 other legal and support staff employees. We have offices in Sydney, Melbourne, Brisbane, Perth, Canberra and Darwin.

We provide the full spectrum of legal services for some of Australia's largest corporations and government agencies. We also act for significant multinational companies, with business interests locally in Australia and overseas, international investment banks, major fund and fund managers and public sector organisations.

Clients come to Clayton Utz because our lawyers are acknowledged for their strong technical expertise and for ensuring that technical legal advice is practically applied within a business environment. We are experienced in putting together multi-disciplinary teams of advisers to provide advice in respect of all aspects of a transaction. Underscoring our approach is our recognition of the importance of exceptional client service and the value of long-term relationships.

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?

Legal consumer relations in Brazil are regulated by the Consumer Protection Code ("CDC") and can be defined as anything relating to production and placement on the market of goods and services, and subsequent acquisition and use of them by the public. These relations are necessarily composed of purchasers and end users on one side, and suppliers on the other. **Consumers** are defined as any individual or legal entity that acquires or uses products or services as an end user.

On the other hand, **supplier** means any individual or legal entity, whether public or private, Brazilian or foreign, as well as any unincorporated entities, engaged in production, assembly, creation, construction, transformation, import, export distribution or marketing activities or in the provision of services.

The CDC distinguishes **two types of liability**, namely: liability as regards the product itself; and liability for a flaw in the product.

Liability as regards the product itself is related to the concept of a **consumption accident**.

In this case, suppliers are only held safe from liability if it is proven that (i) the product was not put on the market, (ii) although it put the product on the market, there was no defect, or (iii) the accident occurred as a consequence of the **exclusive** fault of the consumer.

As for liability arising from a flaw in the product, this does not arise from any damage caused to the consumer. In this case, liability arises from the flaw itself which renders the product improper or inadequate for consumption, or from a reduction in its value or quantity.

In the CDC system, the liability is strict. There is no relevance whether it arises from a contractual or non-contractual relationship. As a general rule, the consumer may file suit against all involved in the chain of production. Those who are not directly responsible will have right of recourse against the responsible party. Only under express cases set forth under the law is there exemption from liability.

In cases in which a consumer relationship does not exist, the Brazilian Civil Code shall apply. The Civil Code provides for indemnity against illicit acts and also for contract liability. In the civil system, the indemnity for damages is irrespective of guild, when the activity normally conducted by the author of the damage implies, by its very nature, a risk against the rights of third parties.

The supplier will be considered liable in case of breach of statutory obligation resulting in a flaw in the product. Regarding a consumption accident, it is necessary that the product is considered defective according to the legal concept.

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

The State has no ancillary liability in relation to any kind of product, unless it is proven that it is directly responsible for the event which caused the damage.

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

The responsibility as regards the product itself is borne by the manufacturer, producer or builder, whether domestic or foreign, and by the importer. The importer is answerable in its capacity as *presumed supplier*, whilst the remaining are answerable in their capacity of effective supplier. The retail supplier (also a *presumed supplier*) has been excluded from the general rule, and is only answerable in a supplementary manner when the manufacturer cannot be identified or the product does not contain clear identification of the manufacturer, or when the merchant does not adequately store perishable products.

All suppliers jointly hold the liability for any flaws in the product, and for this, although it is different in case of a consumer accident, the retail supplier receives no privileged treatment.

The CDC provides for the right of return of the person who has paid against all other joint holders of responsibility, given the solidarity which exists among such 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?

Products that are very harmful or hazardous cannot be placed on the market. However, both law and jurisprudence fail to conceptualise the meaning of "*very harmful or hazardous*", so the interpretation of this phrase is subject to a case-by-case evaluation.

If a supplier acknowledges the harmful and hazardous nature of the product only after it has been placed on the market, it is responsible for immediately informing both consumers and the proper authorities by means of public media advertisements.

Ordinance 487/2012 regulates the procedure to be observed by suppliers in recalls of products and services which, after having entered the consumer market, are held to be harmful or dangerous.

Failure to comply with the Law theoretically subjects the supplier to administrative penalties. If the consumer public authorities (a) acknowledge a lack of communication that the supplier was supposed to have carried out, or (b) decide that the communication is insufficient, it shall initiate administrative procedures to find out whether the supplier has violated the law, and, if so, the penalties shall apply.

On the other hand, a criminal investigation shall be initiated to ascertain criminal liability of anyone that contributed to the lack of the mandatory communication, for late communication or for insufficient mandatory communication.

The supplier may also be sued in a civil court, whether jointly or severally, for providing indemnity for any damages caused to consumers.

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

Yes. Article 7, IX of Law 8137/90 sets forth that "selling, storing to sell or displaying for sale or otherwise delivering raw materials or goods under conditions that are unsuitable for consumption are crimes subject to two through five years' imprisonment or a fine". Article 64 of the CDC establishes that failing to inform or withdraw a product from the market when the supplier becomes aware of the harmful or hazardous nature of the product is also a crime (six months' to two years' imprisonment and a fine).

2 Causation

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

The burden of proof may be shifted to the supplier, at the court's discretion, when (i) the claim brought by the consumer is found to be plausible, or (ii) in the event that the supplier is found to hold a stronger position in its relationship with the consumer. Whenever technical aspects are involved, the courts may order the suppliers *in lieu* of the consumers to submit proper evidence.

With respect to the damage, the burden of proof will always rest with the consumer.

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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

Expert, documentary and testimonial evidence are admitted to prove causation. As a general rule, although suppliers are subject to strict liability, it is necessary that the claimant evidences the causal relation (causation) between the actual damage suffered and an unexpected injurious effect relating to the product and the damage itself.

Nevertheless, some court precedents admit that it is unnecessary to prove a direct causation link, being sufficient to prove that the defective product may have contributed to the increase of the risk and/or to its existence.

It is worth mentioning that Brazilian law does not protect the mere expectation of a right. That is, the duty to indemnify arises from evidence of the actual occurrence of a damage. Therefore, the mere exposure to an increased, but unpredictable, risk or malfunctioning does not create the duty to indemnify if there is no proof of harm from such exposure to the malfunction or risk.

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 legal provision covering the referred hypothesis. Although liability for product defects is strict, proof of causation will, at all times, be required. Thus, it is possible to develop the legal argument that a given producer should not be made liable in the absence of proof that the damage was caused by a product of such producer. On the other hand, since solidarity cannot be presumed, it is therefore inconceivable to determine joint liability among producers based on *market share* or similar criteria.

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. The supplier has a legal obligation to provide adequate and clear information on different products and services, with correct specifications as to quantity, characteristics, composition, quality and price, as well as any risks they entail. Lack of adequate information gives rise to liability on the supplier, particularly as to product risks. Brazilian law does not provide for the "learned intermediary" theory.

CDC expressly provides that in case of consumption accident, the supplier will be released from liability only if it is evidenced that: he did not place the product on the market or otherwise render the service; the defect does not exist; or the accident is exclusively attributable to the consumer.

3 Defences and Estoppel

3.1 What defences, if any, are available?

As mentioned above, the supplier is only released from liability if it is evidenced that: he did not place the product on the market or otherwise render the service; the defect does not exist; or the accident is exclusively attributable to the consumer. The risks reasonably inherent to a certain product or service, as well as proper disclosure to consumers, must always be taken into account for liability purposes.

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 statutory definition concerning the matter.

A significant number of jurists understand that the supplier's good faith and its initial unawareness of the hazard that occurred shall not exempt it from liability for any damages that may arise. There are others who believe that the risk of development-exempt supplier's liability was adopted by the CDC, following a suggestion of the European Economic Community.

Nevertheless, the CDC determines that a product shall not be deemed defective merely because another product, with a better quality, has been placed on 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?

It is a possible legal argument that if a given company complies with all the rules and regulations determined by the State, it cannot be held liable for damages caused by a given product.

There are, however, opinions in the sense that as liability for the product itself is strict, it is not dependent on any actual fault of the supplier who has proof 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?

Awards issued in similar or precedent individual suits are not binding. The court must review each specific case based on its own conviction and analyse the evidence brought by the claimant to his specific suit. Court precedents admit the use of evidence previously used in another case in specific situations; as long as objection was raised as to the production of such evidence, in whose production the party against which the evidence was produced had participated, in addition to the fact of the issue to be proved being identical.

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?

Two situations should be considered for this answer. If the third party responsible for the damage has no relation to the product supply, this excludes liability from the supplier. If the third party is a player in the supply chain, as a general rule the consumer may file suit against all involved in the chain of production. Those who are not directly responsible will have right of recourse against the responsible party.

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

Pursuant to the CDC, the supplier will be released from liability only if it is proved that damage resulted exclusively from fault of the consumer.

4 Procedure

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

The trial shall be issued 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)?

Technical specialists may carry out the work involved for pursuing these purposes. Expert witnesses act as assistants to the court, and it is the court who appoints them for the purpose of conducting a *bona fide* review of the evidence and the facts and to submit, in the form of an expert opinion, a report on his conclusions which can, therefore, be derived.

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 are allowed in Brazil, where it is possible to discuss interests of a class of litigants in the same action. Such class actions may be filed by entities legally recognised as legitimate entities, such as: the Public Prosecution Office; Federal, State and Municipal Governments; and the Federal District, consumer protection government bodies and entities and associations legally set up to protect consumers. Class actions are quite common in Brazil.

The opt-out system applies only to those who file an individual action discussing the same interest addressed in a class action.

It should be noted that Brazil has no system similar to MDL (multidistrict litigation), which is available in the USA, for group individual actions or class actions.

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

Yes. Please, see the answer above.

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

It may extend over a period of five years, on average.

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 must provide for the correctness of the suit as from the moment it receives the initial petition, and may dismiss it if it does not meet the legal requirements. After the initial reply has been submitted, the court can review preliminary issues related to matters of law. Once the proceedings have been cleared and put in due form, the court can issue its award based on the state of the records or order a finding of evidence. There is no trial by jury for civil claims.

4.7 What appeal options are available?

Brazilian procedure establishes a single judge in the first instance and a panel of three judges in the second instance. In specific cases, review by superior courts will be admitted to analyse constitutional matters, federal law violation and case law contradictions.

There are the following types of appeals: (1) appeal; (2) interlocutory appeal (seeks review of interlocutory decisions); (3) request for clarification; (4) special appeal (may be brought before the Superior Court of Justice as a last instance against an award which is contrary to a treaty or a Federal Law); and (5) extraordinary appeal (may be brought before the Supreme Federal Court if the challenged decision contravenes provisions of the Federal 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?

Please refer to the answer to question 4.2.

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 in the Brazilian procedural system. The judge has the power to interrogate the parties and the witnesses. The judge may take the deposition of any party at any stage of the proceedings, but ordinarily parties and witnesses testify only under the final public hearing.

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 is introduced in the initial stage of ordinary proceedings by attachment to the pleadings. The judge will also admit documentary evidence at a later stage to support unforeseen facts or to refute evidence presented by opposing counsel.

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

Mediation and arbitration are alternative methods available and are regulated by law as a faculty. In the Brazilian civil procedural system that came into force in 2016, the plaintiff may require a mediation or conciliation hearing to be scheduled before the defendant presents the answer in a court civil claim.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction be brought within the jurisdiction of your courts either as a defendant or as a claimant?

Brazilian Courts have jurisdiction to analyse conflicts when (i) the defendant, from any country, has domicile, agency, branch or subsidiary in Brazil, (ii) the obligation must be fulfilled in Brazil, and (iii) the action arises from a fact occurred or practised in Brazil.

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?

For apparent defects: 30 days for a non-durable product or service; and 90 days for durable products or services. The terms are calculated as from the delivery of the product or from the completion of the performance of the service.

For hidden defects: 30 and 90 days as in the case of apparent defects, but the term commences at the time the hidden defect becomes apparent.

The CDC stipulates that the right to demand indemnity for damages caused by the product or the service prescribes after a term of five years, to be calculated as from the time the damage and its authorship becomes known.

The court does not have the power to interfere in the terms defined by the CDC. By the same token, the age or the conditions of the consumer do not interfere with the reckoning of the terms.

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

The limitation period starts running when consumers become aware of the defectiveness of the product or the injury. If there is any fraud, the period for claiming damages caused by the product or service will only start running when the damaging act is unveiled.

6 Remedies

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

The consumer can file court claims against suppliers for the redress 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?

Losses and damages encompass: (i) actual damages, which correspond to all losses incurred by the victim by virtue of the harmful event (including those of a material nature and for pain and suffering, i.e. moral damages); and (ii) loss of profits, which represents the legitimate and expected gains which the same failed to receive, due to the accident.

Specifically in terms of consumer rights, there are the following general indemnity obligations:

(i) indemnity of damages caused due to defects arising from design, manufacture, construction, assembly, formula, handling, presentation or packaging of the products, as well as for insufficient or inadequate information concerning its use and risks;

(ii) indemnity for damages caused due to defects related to the rendering of the services, as well as to insufficient or inadequate information concerning the enjoyment and risks thereof;

(iii) indemnity for defects in quality or quantity which render the products improper or inadequate for consumption or which reduce their value, as well as defects arising from inconsistency with information contained in the container, packaging, labels or advertisement, subject to the variations inherent to the nature of the product, the consumer being entitled to demand replacement of the defective parts;

(iv) indemnity for defects in product quantity whenever, and subject to variations inherent to the nature of the product, its net content is less that that indicated in the container, packaging, label or advertisement, the consumer being entitled to demand, at the consumer's option: a) *pro rata* reduction in the price; b) replacement of the product by another of the same kind, free from such defects; or c) immediate reimbursement of the amount paid, subject to monetary indexation, at no detriment to the obligation to provide indemnity for any losses and damages; and

(v) under the provision of services for the purpose of repairing a given product, the supplier will be implicitly bound to use original, adequate and new spare parts or components, or which conform to the technical specifications of the manufacturer, save, as to the last mentioned, upon the express authorisation of the consumer to proceed otherwise.

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 Brazilian law, there is no indemnity for a future or hypothetical damage. Accordingly, expenses incurred for medical monitoring can only be recovered if the damage actually occurred. In this case, such expenses will be included in the calculation of the indemnity for the property damage suffered by the victim.

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

No. However, what has been accepted recently is the theory of discouragement, according to which the amount of the award for pain and suffering must be set at reasonable levels to discourage its repetition.

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 actual number of claims arising from the same incident is irrelevant, since the main purpose of the law is to ensure full recovery for all victims of the incident or accident.

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?

For individual actions dealing with disposable rights, the only requirement is the consent of parties with powers thereto. If there are persons without powers (e.g. minors), an authorised representative and/or the Public Prosecution Office must intervene.

In class actions, the settlement calls for a number of factors that hinder their implementation.

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?

This discussion is not yet effective in Brazil, and there is no precedent thereon.

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 losing party shall pay all court costs, as well as the other side's attorneys' fees. Attorneys' fees are normally fixed at 10 to 20 per cent of the amount of the award. Recovery of the party's own costs does not automatically arise from the winning award, and will at all times be subject to the reasonability criterion and to an effective proof that it is represents a material damage.

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

Public funding is limited to very specific situations in Brazil. Legal aid is one of these situations.

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

Judicial assistance will be granted to those who need it in the manner established by law and restricted to a limited budget. An indigent receiving legal aid is excused from payment of all judicial costs.

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

Public funding cannot be through conditional or contingency fees. The grant of it depends exclusive on the existence of previous circumstances provided by law.

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

Public funding cannot be through conditional or contingency fees. The grant of it depends exclusive on the existence of previous circumstances provided by law.

7.6 In advance of the case proceeding to trial, does the court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

The Brazilian civil procedural system is different from the American system, especially the discovery phase and trial. As a rule, the Court exercises no control over the costs to be incurred by the parties, but expert examination, *e.g.*, has to be conducted by the court who appoints an expert and fixes his fee.

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 your jurisdiction.

An interesting issue in product liability in Brazil is the settlement by the Higher Court of Appeals of the courts' opinion on effects of judicial decisions in class actions: national jurisdiction; or limited jurisdiction. There were discussions on whether article 16 of the Public Civil Action, which limits the effects of judicial decisions rendered in class actions to the jurisdiction of the body responsible for rendering the decision, is applicable or not. In practice, this will show if multiple actions are necessary to discuss the same case or only one action would cover the whole country.

Recently, the Court Assembly of the Superior Court of Justice confirmed the stand, which certain ministers had already been adopting in the sense that the effects of the decision rendered in a class action are not limited to the territorial limits of jurisdiction of the judge who delivered it.

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PINHEIRONETO
ADVOGADOS

Founded in 1942, Pinheiro Neto has played a prominent role in shaping the Brazilian legal and economic landscape. Credibility, innovation and an unyielding commitment to excellence, ethical conduct and quality human relations have the hallmarks of Pinheiro Neto Advogados throughout its 70 years of existence. Having grown and developed a distinctive, tight-knit culture, the firm continuously strives to be at the forefront, whether solving the most technically challenging legal problems, advising its clients on relevant strategic decisions or meeting the community's interests.

True to the firm's position as a leading full-service firm, focusing on both breadth and depth of knowledge, Pinheiro Neto was named *Chambers & Partners* Global Law Firm of the Year: Latin America in 2013, after having been chosen as the *Chambers & Partners* Latin American Firm of the Year in 2009 and 2010, and Brazilian Firm of the Year in 2009, 2011,and 2014. The firm was elected Brazil Firm of the Year by *Who's Who Legal* for 11 consecutive years.

Chapter 10

Canada

Blake, Cassels & Graydon LLP

Nicole Henderson

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 law in Canada is based on: (i) liability in contract; and (ii) fault-based liability under the law of tort (negligence) or, in Quebec, the law of civil liability. Except in Quebec, Canadian law permits concurrent liability in contract and in tort.

In contract, a party to an agreement for the purchase and sale of a product is entitled to sue for damages for breach of contract if the quality, fitness, or performance of the product does not comply with the express or implied terms of the agreement.

Provincial sale of goods legislation will generally imply, as part of any agreement for the sale of goods, terms and conditions regarding the fitness and quality of the products sold. In some provinces, legislation prohibits the exclusion of these statutory warranties and conditions from contracts for the sale of products to consumers (i.e. not for business purposes). Consumer protection statutes in most provinces also provide remedies for unfair practices, including damages or rescission.

In the common law provinces, liability in tort is grounded in negligence and is fault-based. Strict liability has been rejected as a principle of Canadian product liability law. However, manufacturers will, as a practical manner, be held strictly liable if the product has a manufacturing defect (i.e. it was built in a way not intended by the manufacturer), as it will be assumed that there was negligence in the manufacturing process. In Quebec, product liability claims are based on strict liability.

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

In general, there are no publicly-funded compensation schemes for particular products in Canada. There have been instances in which the government, in its capacity as a defendant, has established a compensation scheme as part of a class action settlement (e.g. in connection with tainted blood products distributed by the Canadian Red Cross).

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

All parties in the distribution chain are potentially liable for product liability claims if negligence can be established. It is not uncommon for a claimant to bring proceedings against every party in the supply chain.

Under provincial negligence legislation, joint tortfeasors are jointly and severally liable (or in Quebec, solidarily liable) for a claimant's loss in most cases. The court may determine the degree of fault or negligence of various tortfeasors and apportion it among those parties. The claimant can then recover all damages from a defendant found even partly at fault. However, claims for contribution and indemnity among joint tortfeasors are permitted.

Liability for contractual claims in common law provinces is more limited, as privity of contract is generally required. In Quebec, parties can be held solidarily liable for warranty claims. Consumer protection laws in some provinces permit claims for unfair practices to be brought in the absence of privity.

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, there is no independent "duty to recall". However, in certain circumstances, the duty to warn (discussed below) may entail a duty to recall.

Aside from any common law duties, some statutes give regulators the power to order the recall of particular types of products (e.g. drugs and medical devices, food, certain consumer products).

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

There are no provisions in the Canadian *Criminal Code* specifically directed at the supply of defective products (although in extraordinary circumstances, the supplier of a defective product could be liable for fraud or criminal negligence). Quasi-criminal penalties are available for supply of defective products in certain categories (e.g. under the *Food and Drugs Act*, the *Canadian Consumer Product Safety Act*, and the *Motor Vehicle Safety Act*).

2 Causation

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

In tort, contract, and at civil law, the plaintiff bears the burden of proving each of the necessary elements of his or her case on a balance of probabilities. Legally, there is no reverse onus, although the defendant may face a tactical burden to lead evidence refuting the plaintiff's case.

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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

A plaintiff is generally required to prove causation on the basis that his injury would not have occurred "but for" the defendant's negligence. In exceptional circumstances, where there are multiple tortfeasors and it is impossible for the plaintiff to prove which of them caused his injury, causation may be proven on a "material contribution" standard (i.e. the plaintiff must show that the tortfeasor materially contributed to the cause of his injury).

A plaintiff must prove injury; an increased risk of injury alone is generally not compensable.

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 has not been recognised at Canadian law. Exceptionally, some statutes provide for market-share liability for tobacco 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?

Manufacturers have an ongoing duty to warn users of the non-obvious material risks inherent in the use (or foreseeable misuse) of a product. The nature of the warning required may vary with the severity of the risk and the likelihood that it will occur.

Ordinarily, a warning is provided directly to the user. The "learned intermediary" rule applies where an intermediate inspection of the product is anticipated because the product is highly technical in nature or where a consumer is placing primary reliance on the judgment of a learned intermediary and not the manufacturer. In these cases, the manufacturer may satisfy its duty to warn the ultimate consumer by warning the learned intermediary of the risks inherent in the use of the product. The learned intermediary exception has been applied by Canadian courts for prescription medicines and implanted medical devices.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The failure of the plaintiff to prove any of the constituent elements of his or her claim serves as a defence. There are also affirmative defences to a tort claim, including: a) contributory negligence by the plaintiff; b) intervening act of another (including alteration or misuse of the product by another or an intermediate examination); c) voluntary assumption of risk by the plaintiff; d) contractual limitation of liability; and e) expiry of a limitation period.

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 specific state of the art/development risk defence has been recognised in Canadian law. However, the fact that a product was designed or manufactured in accordance with the state of the art at the relevant time can serve as evidence that the defendant met the applicable standard of care.

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 not a full defence to a tort claim. (Conversely, failure to comply with a statutory requirement is not itself a tort in the common law provinces.) However, evidence that the defendant met the applicable regulatory and/or statutory requirements may serve as evidence that the defendant met the applicable standard of care. In rare circumstances where it can be established that a statute or regulation required the product to be designed, manufactured, or labelled in the specific way that is alleged to be faulty, and in no other way, a defence of statutory compliance may be available.

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, issue estoppel only arises between the same parties (or their privities). However, in some circumstances, other doctrines (e.g. abuse of process or collateral attack) may prevent a party from re-litigating issues against a different party in a different proceeding.

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 defendant may seek contribution or indemnity on the basis that the plaintiff's alleged damages were due to the actions of a third party. A claim for contribution and indemnity may be made in the same proceeding (by way of a cross-claim or third party claim) or in a subsequent proceeding. There are generally limitation periods with respect to the commencement of claims for contribution and indemnity. In some provinces, there are also procedural requirements that govern the timing of third party claims.

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

A defendant may allege that the plaintiff's own conduct caused or contributed to its alleged injuries, either in its statement of defence or, in some provinces, by way of counterclaim.

4 Procedure

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

Most product liability trials are by judge alone, although juries are available in all provinces aside from Quebec. There is no constitutional right to a jury in a civil action in Canada.

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 have the power to appoint experts or other specialists to assist the trier of fact in assessing the evidence. However, this power is rarely (if ever) exercised. Expert evidence is generally led 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?

Class actions are permitted in all provinces in Canada; all but one have enacted specific class action legislation. Whether a class proceeding is opt-in or opt-out varies between provinces, although the opt-out model is more common. Product liability class actions are often brought in Canada.

In the provinces other than Quebec, an action can be certified as a class action if the claim asserts a sustainable cause of action (which will be assessed based on the pleadings alone), there are two or more persons in the proposed class, the claims of those persons have substantial issues of fact or law in common, a class action is the preferable procedure having regard to the objectives of the legislation (access to justice, judicial economy and behaviour modification), and the proposed representative plaintiff can adequately represent the interests of the class.

Quebec has somewhat similar criteria for authorisation (the equivalent of certification). Historically, Quebec was thought to have the lowest threshold for class certification because unlike legislation in the common law provinces, its legislation does not include "preferability" as a requirement. The threshold for class certification in Canadian provinces is generally considered to be lower than in the United States.

Product liability class actions are most often brought in Ontario, British Columbia, Quebec and, increasingly, in Saskatchewan. Although the Supreme Court of Canada has yet to rule on the constitutionality of "multijurisdictional" class actions, national class actions are frequently certified by provincial courts.

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

In general, most provinces do not permit claims by a representative group, such as a consumer association on behalf of a number of claimants, and a judgment in an action only binds the named parties. (However, consumer associations have been known to fund a class action brought by an individual representative plaintiff.) A class action claim can be brought by a representative group in Quebec.

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

Time to trial varies depending on the jurisdiction in which the claim is brought and the applicable procedure (e.g. class action, regular rules, simplified rules, or small claims). In some regions, there are significant trial scheduling backlogs, particularly for long trials. Normally, an action brought under the regular rules would take anywhere from two to five years to reach trial. This horizon can be considerably longer in class proceedings, and shorter in small claims courts.

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?

Preliminary dispositive issues can be determined by judge alone. In most provinces, the court can determine a question of law, based solely on the pleadings, and can also be asked to grant summary judgment where there is no genuine issue for trial. However, summary judgment is not available in Quebec. In addition, some provinces (for example, Alberta) have a summary trial procedure available in certain circumstances, whereby the court can determine summarily all or part of the action even if material facts are in dispute. Some provinces also have simplified procedures for smaller claims.

4.7 What appeal options are available?

Appeal options vary from province to province, often depending on whether an issue is final or interlocutory. In all jurisdictions, appeals are generally available, either with leave or as of right. They are typically as of right on final dispositive decisions, to the highest appellate court in the province. Appeals to the Supreme Court of Canada are only granted with leave on questions of national importance.

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 does not typically appoint experts to assist in considering technical issues. The parties present expert evidence. Unlike lay witnesses, experts are permitted to give opinion evidence within the sphere of their expertise. The evidence an expert gives must be information that is likely to be outside the experience and knowledge of a judge or jury. To be admitted, expert evidence must be relevant, necessary and given by a properly qualified expert and it must not violate any exclusionary evidence rules. Novel scientific evidence is subject to special scrutiny to determine its reliability and whether it is essential.

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 parties are required to submit to pre-trial discovery. Generally, a party is only required to present one fact witness for oral examination for discovery (deposition) prior to trial. Discovery of additional witnesses may be available by court order or agreement of the parties, in some circumstances.

Experts are generally not deposed, but are required to deliver reports containing their findings, opinions, and conclusions 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?

Each party to a proceeding is required to disclose all documents in their possession, power or control that are relevant to any matter in issue in a proceeding, and to produce such documents to any other party to the extent they are not subject to a claim of privilege. "Documents" are broadly defined and include such items as electronically stored information. Documentary discovery usually precedes oral examinations for discovery. However, there is an ongoing duty to disclose documents that come into a party's possession, power, or control throughout the proceeding.

In Quebec, parties are only obligated to disclose those documents upon which they intend to rely or that are demanded by the opposing party.

With certain limited exceptions, the parties to an action are not permitted to use the evidence or information elicited from documentary or oral discovery of the other parties to the litigation for any purposes other than those of the court proceeding for which the evidence was obtained, unless the evidence is subsequently filed in court.

In extraordinary circumstances, a court may order pre-proceeding discovery, but this would be very rare in a product liability case.

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

There is no requirement to participate in alternative dispute resolution (ADR) before commencing litigation, unless the parties have contractually agreed to do so. However, in Quebec, the parties are now required to "consider" using ADR before commencing litigation. In certain jurisdictions, pre-trial mediation may be required as part of the court process.

However, parties are permitted submit a dispute to mediation or arbitration before or during the litigation process. In general, the parties are free to choose their own dispute resolution process, which may include mediation, arbitration, or a combination of the two.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction be brought within the jurisdiction of your courts either as a defendant or as a claimant?

A Canadian court will assume jurisdiction over a dispute where the case fits within one of four "presumptive connecting factors":

a) the defendant is domiciled or resident in the province;

b) the defendant carries on business in the province;

c) the dispute relates to a tort committed in the province; or

d) a contract connected with the dispute was made in the province.

Although this list of presumptive connecting factors is not closed, the courts will be slow to recognise new ones. Once the existence of a presumptive connecting factor has been established, the presumption of jurisdiction may be rebutted, but the threshold is high. The fact that the plaintiff resides or has suffered damages in the province, without more, is no longer sufficient to ground jurisdiction.

5 Time Limits

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

There are statutes of limitation limiting the time for bringing or issuing proceedings which vary from province to province. Many provinces have ultimate limitation periods which preclude litigation after a certain period of time, regardless of the discoverability of the claim.

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 the context of product liability, limitation periods generally range from two years to six years from the day on which the cause of action arose, with the possibility of the period being extended if the claim was not reasonably discoverable with the exercise of reasonable diligence until some time after the events in question occurred. The applicable limitation period may be much shorter for claims against government bodies.

The limitation period generally does not run while a person is a minor or is incapable of commencing a proceeding in respect of the claim because of his or her physical, mental or psychological condition.

Within the parameters of the statutes of limitations, the court may have some discretion to determine when a limitation period begins, or in some provinces, to permit an action to proceed notwithstanding the expiry of a limitation period. As a general rule, however, the apparent expiry of a limitation period will present a very high bar to a plaintiff attempting to bring a claim.

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

If the person against whom a claim is made wilfully conceals the claim from or misleads the person with the claim, the limitation period may not run during that time. The person with the claim has the burden of proving any such concealment.

6 Remedies

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

Monetary damages and injunctive relief are available. Particularly under consumer protection legislation, rescission of a contract for the purchase of a product may be available. Plaintiffs in product liability cases also often seek restitutionary remedies, such as a disgorgement of the defendant's revenues and/or profits (in unjust enrichment or the novel and still-controversial "waiver of tort" doctrine). Courts have authority to grant declaratory relief, but may exercise their discretion not to do so where it would not be useful or appropriate.

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

Damages for bodily injury and damage to property are recoverable. General damages ("pain and suffering") are capped by common law. As of the time of this writing, the cap is approximately C$360,000. Damages are not recoverable for ordinary or transient mental upsets that do not rise to the level of psychological injury or for mental injuries that would not be reasonably foreseeable in a person of "ordinary fortitude".

Several appellate courts have held that pure economic loss is not recoverable in negligence in respect of allegedly shoddy but non-dangerous products. However, pure economic loss is often recoverable for failure to warn, negligent misrepresentation, negligent performance of a service, and in contract.

Family members of the primary claimant may be able to recover damages for loss of care, guidance and companionship and certain pecuniary losses. The extent of recovery and circumstances under which recovery is available vary from province to province.

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?

Canadian courts have not yet determined whether the costs of medical monitoring are recoverable in circumstances where the product has not yet malfunctioned and caused injury, but they may do so in the near future. This issue has been certified as a common issue for trial in a number of class action cases.

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

In general, punitive damages are recoverable only where there has been high-handed, malicious, arbitrary or highly reprehensible misconduct that departs to a marked degree from ordinary standards of decent behaviour. Their purpose is not to compensate the plaintiff but to achieve the goals of retribution, deterrence and denunciation of the defendant's conduct. Awards of punitive damages in product liability cases are extremely rare. There is no legislation capping punitive damages, but in general, awards are much lower in Canada than in the US.

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 quantum of damages recoverable from one manufacturer, aside from the above-noted cap on general 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?

Class action settlements require court approval; generally, the court must be satisfied that the settlement is fair and reasonable and in the best interests of class members. Court approval is also generally required in respect of claims by infants or persons under legal disability.

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?

Canadians' medical costs are most often paid by provincial government health insurers, which have a statutory right to sue to recover costs from a tortfeasor. A plaintiff bringing an action for personal injury is generally required to include a subrogated claim on behalf of the provincial health insurer.

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?

While costs are at the discretion of the court, in most circumstances, the "loser pays" principle applies. A successful party is generally entitled to recover some portion of its costs and disbursements from the unsuccessful party. Depending on the billing rates of counsel, such awards often approximate 30 to 50% of the party's actual legal costs. Increased cost awards may be made where the successful party has made an offer to settle that was refused or where the court wishes to sanction a party's conduct in the litigation. In some provinces, specific rules prevent the recovery of costs in certain circumstances in class proceedings.

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

There is a legal aid system in Canada, but it is highly unlikely that a claimant would be able to obtain legal aid funding to pursue a civil claim.

In some provinces, public funding is available for class action plaintiffs. Generally, such funds finance disbursements and indemnify the plaintiff against the possibility of an adverse cost award, in exchange for a share of any eventual award or settlement.

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

Due to scarce resources, the legal aid system generally gives priority to serious criminal, family, and refugee law matters. Legal aid funding of a product liability case would be extraordinary.

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

Contingency fee arrangements are permitted, and are common place in class actions and personal injury actions. They are less common in other types of litigation. Contingency fee arrangements must be in writing and are subject to court approval in class actions; in some provinces, the same rules apply in individual actions.

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

Historically, third party funding was prohibited as champertous. However, third party funding arrangements have been approved in a number of class actions in recent years. They must be disclosed to and approved by the court on a case-by-case basis. In deciding whether to approve a third party funding arrangement in a particular case, the court will consider a number of factors. Generally, the plaintiff will need to satisfy the court that the arrangement is necessary, in the best interests of the class, and will not interfere with the administration of justice.

7.6 In advance of the case proceeding to trial, does the court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

The principle of proportionality is to be applied by the courts in fixing costs at any stage of a proceeding. In some provinces, civil procedure rules also specifically subject the scope of pre-trial discovery to the principle of proportionality.

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 your jurisdiction.

As noted above, product liability class actions are common in Canada. Canada does not have any regime akin to the US Multi-District Litigation (MDL) procedure. However, in recent years, some plaintiffs' counsel have begun advancing an inventory of individual cases, rather than pursuing a class action. Such "mass tort" litigation proceedings may proceed parallel to one or more class actions in respect of the same subject-matter.

There is also a trend of increasing use of summary judgment motions in product liability class actions, particularly in Ontario. In one notable 2016 decision, an Ontario court granted summary judgment to the defendant in a pharmaceutical class action, finding no genuine issue for trial on the central issue of general causation. We expect to see greater use of summary judgment motions to manage class proceedings going forward.

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Nicole's practice focuses on product liability and class action matters, as well as public law, including constitutional, freedom of information, administrative, and regulatory law. She is particularly skilled in large, document-intensive matters involving complex scientific and medical evidence. Nicole has appeared as counsel at all levels of court in Ontario, representing clients across a range of industries, including leading manufacturers of medical devices, pharmaceuticals and heavy equipment.

Nicole was a member of the trial team in the successful defence of the first medical products class action to go to trial in Ontario (146 trial days), which claimed more than C$1 billion dollars in damages, alleging negligent design, testing and warning. The defence was successful and the action was dismissed.

Prior to joining Blakes, Nicole clerked at the Federal Court of Appeal, where she developed expertise in many areas of public law, namely administrative and constitutional law.

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China

Kelly Liu

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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 China, product liability applies to personal injuries and property damages caused by defective products. Even without actual personal injuries or property damages, as long as there is danger to personal or property safety caused by the defective product, a claimant may apply product liability. For manufacturers, strict liability applies in China; however, manufacturers would not be held liable if they can prove that the products have not been put into circulation, the defects were non-existent when the products were put into circulation, or the defects cannot be found at the time of circulation due to the scientific and technological knowledge at such moment. While for the other parties, such as distributors, transporters and storekeepers, the liability is fault based.

Whereas there is a concurrence of product liability and contractual liability, the claimant has to choose one or the other. Once the claimant chooses product liability, the contractual liability shall not apply. Consumer fraud statutes appear as articles in different regulations, and whenever the product fails to conform to safety regulations, the claimant may raise product liability disputes.

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

In China, compensation for defective products depends on the incurred damages instead of the product.

For compensation regarding property damage, it covers the property damaged by the defective product. As to whether it covers the damaged product itself, due to the inconsistency in the law (see question 6.2), different courts might have different opinions.

The law specifies that if personal injury is caused by the defect of a product, the party liable shall pay compensation for medical costs, nursing expenses during medical treatment and lost income due to absence from work; if the personal injury has resulted in disability, the liable party shall also be responsible for the expenses for self-supporting equipment, living allowances, compensation of the disabled person and the living expenses necessary for those under the support of the disabled person; if the defective product resulted in death, the liable party shall pay for the funeral expenses, compensation and the living expenses necessary for those who were supported by the deceased. If the defect of a product causes loss of property of the claimant, the liable party shall be responsible for restoring or compensating for it. If the claimant suffers other major losses, the liable party shall compensate for the losses.

For compensation for mental damage in personal injury cases, the case may also be supported by the court.

Aside from the above, punitive compensation could be available if the manufacturer or seller knowingly produces or sells defective products which cause death or serious damage to the health of others. As to the limit of such punitive compensation, although it is not mentioned in the Tort Law of the People's Republic of China ("Tort Law"), it is mentioned in the Consumer Protection Law of the People's Republic of China ("Consumer Protection Law") that punitive compensation is up to twice as much of the loss.

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

Any party who caused the defect shall be responsible, i.e. the importer, distributor, retailer, transporter or storekeeper. Otherwise, it will be the manufacturer who bears such liabilities, with the exception of the distributor/retailer bearing responsibility if they cannot identify the manufacturer or suppliers of the defective products.

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?

After the products have been put into circulation, if the manufacturer/distributor notices there is defect, there is an obligation to recall the products. In addition, where relevant administrative departments find and determine that the product has defects and may damage personal and property safety, manufacturers may face a recall order. In particular, for vehicle manufacturers in China, upon confirming the existence of defects in the products, they shall immediately implement the recall. Otherwise, they may face fines, confiscation of profits and revocation of relevant certificates.

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

Criminal sanctions also apply to the supply of defective products.

Article 140 of China Trademark law provides that where a producer or seller passes a defective product off as a high-quality one, if the sum obtained through sale amounts to not less than 50,000RMB, such producer or seller shall bear criminal liability. Articles 141 to 149 further stipulate the criminal liability of the producer or seller of particular products i.e. medicines, cosmetics, food, etc.

2 Causation

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

Under the general principle of "the one who claims must prove", the claimant bears the burden of proving defect and damages and the causation between the two, while the manufacturer is allocated the burden of proving the existence of exemptions (see question 1.1).

However, based on our practice in China, some courts hold the opinion that the manufacturer/distributor shall prove that the product has no defect, or put the threshold of sufficient evidence of defect extremely low for the claimant. Only a few courts in major cities like Beijing, Shanghai and Guangzhou have a consistent case law on burden of proof. We must also consider that judicial decisions are not legally binding upon other judges handling similar cases. This causes lack of consistency in court decisions in burden of proof.

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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

As long as the claimant can show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, it will be deemed as the fulfilment of the burden of proof regarding causation relation. Sometimes, the plaintiff can also apply for court-appointed verification of causation. This is because, generally speaking, although different courts may have different opinions, the plaintiff in a product liability lawsuit has the burden to prove the defect, the damage and their causation link. The claimant shall prove the existence of the defect and the damages caused by the said defect to fulfil his burden of proof. There is no need to prove that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction.

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 specific law or regulations that are related to the above assumption are to be found in China. However, under the principle of joint liabilities, all the possible manufacturers of the defective products may be held jointly 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?

Providing proper warning is regulated in Product Quality Law of the People's Republic of China ("Product Quality Law") and the Consumer Protection Law, and it is also an obligation deriving from compulsory national standards for manufacturers in China. Academically speaking, there are basically three types of defect related to warning: the manufacturer did not provide proper and sufficient instructions on how to use the product safely; the manufacturer did not provide a warning as to the danger of the product; or although there is warning on the product, the form of warning is not proper or the content of the warning is not sufficient.

As to whether only the warning information which is provided directly to the injured party can be taken into account, or whether also warnings supplied to an intermediary in the chain of supply between the manufacturer and consumer can be used, there are no specific regulations. In practice, all information, advice and warnings to the customer could be good evidence, even if it was not directly provided to the injured party. There is no principle of "learned intermediary" available in product liability disputes in China.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The following defences are available:

- The limitation period for the action has expired, or it has been 10 years since the product was first delivered to the consumer.
- Jurisdiction opposition.
- The claimant shall have the burden of proof for proving the defect, the injury or damage, and the causation between the two.
- The defending party (excluding the manufacturer) has no fault for the defect.
- The product conforms with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply.
- No causation between the defect and the injury or damage.
- The product has not been put into circulation.
- The defects were non-existent when the products were put into circulation.
- The defects cannot be found at the time of circulation due to the level of scientific and technological knowledge at the time.

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 state of the art/development risk defence, i.e. in case the defect could not be found at the time of circulation due to the scientific and technological knowledge at the time or the defect did not exist at the time of circulation. It is provided in the Some Provisions of the Supreme People's Court on Evidence in Civil Procedures that the manufacturer has the burden to prove the defect was not discoverable given the state of scientific and technical knowledge 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?

Yes, it is a common defence for the manufacturer to show that it complied with regulatory and/or statutory requirements. This can prove that the product is safe and it conforms to any regulations. However, as regulated by the law, industrial products which may be hazardous to human health and personal or property safety shall meet the national standards and trade standards to ensure human health and personal or property safety. In the absence of such national standards or trade standards, the products shall conform to the minimum requirements for ensuring human health and personal or property safety. It means even if a product complies with all of the applicable standards, the manufacturer/distributor may still be held liable. As specified by the current law, as long as the manufacturer can prove that the defects were non-existent when the products were put into circulation, they shall not be held liable.

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 the issue concerns the same product and the same fault, defect or capability of causing a certain type of damage and there is already a legally effective judgment confirming a fault, defect or capability of causing damage, claimants can still re-litigate the same. However, the court can directly confirm the facts unless the claimant has sufficient evidence to overrule it. Generally speaking, there is no estoppel to prevent this. However, if there is a legally effective judgment already ruling on the same issue, the judgment as evidence has very strong probative force.

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 claim that the fault/defect was due to the actions of a third party. This may become an estoppel in the lawsuit. Also, it is applicable for defendants to seek joint liability for any compensation to the claimant, by filing a new lawsuit against the default party or by applying to add the same as a related third party in the current lawsuit.

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

The defendants can allege that the claimant's actions caused or contributed towards the damage and this will become one of the main points of defence. Once it can be proved that it is the claimant's actions which caused the damage(s), the defendant will be able to terminate the causation link between the damages and defect (if this has been proved).

4 Procedure

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

Lawsuits apply the normal procedure consisting of a judge panel which may also contain people's assessors. If summary procedure is applied, there will only be one judge handing the case. However, people's assessors are not equal or similar to the jury system.

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)?

For professional issues, the court has the power to appoint specialists for verification of evidence. As to expertise assessors, a party needs to apply to the court and the court needs to approve the application. The expert assessor can give his professional opinion and verify reports in support of the statement of the party which has invited the person with expert knowledge.

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 specific regulation for class actions procedure regarding product liability claims in China. However, in China, there is a framework of so-called "class action procedure" under the current Civil Procedure Law of the People's Republic of China ("Civil Procedure Law"), which regulates the elements for filing a joint action, whereby "one party or both parties consist of two or more persons" and the object is the same or of the same type. A representative may be elected in a joint action.

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

China Consumers' Association and the consumers' associations established in the provinces, the autonomous regions and municipalities directly under the Central Government have the right to file a lawsuit based on the infringement upon the legitimate rights and interests of numerous consumers. Also, Article 55 of the Civil Procedure Law specifies that "legally designated institutions and relevant organizations may initiate proceedings at the people's

court against conducts jeopardizing public interest such as causing pollution to the environment or damaging the legitimate rights or interests of consumers at large".

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

Normally, the court hearing date is decided by the judge based on his or her schedule and the Civil Procedure Law does not stipulate the period to get to a trial. The court shall decide whether to place the action on its trial docket within seven days from receipt of the claim. The court shall then deliver a copy of a statement of claim to the defendant within five days after the claim is filed; the defendant shall file a statement of defence within 15 days of receiving the copy of the statement of claim, which shall be delivered to the plaintiff within five days of receiving the defendant's statement of claim. Failure by the defendant to provide a pleading will not affect the hearing of the case by the 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?

The Chinese court cannot try preliminary issues; the court can decide matters of both law and fact during the same procedure.

4.7 What appeal options are available?

Any party can file an appeal against the judgment of the first instance to the higher court of the first instance court. In addition, any party can file a retrial application against the legally effective judgment with the supervision 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?

The court can carry out verification procedures when deeming it necessary to verify a professional issue; a party can also file for such procedure. The result of verification is called a verification opinion, which is one type of evidence defined in the Civil Procedure Law. In practice, it is more often the plaintiff that applies to the court for verification in order to prove the claimed defect of the product. The court has the discretion as to whether to grant such application. Once the court has agreed with the application of the plaintiff or the defendant (the defendant can also make such application and the burden of proof lies with them), it will suspend the trial proceeding and initiate the procedure for the selection of the verification institute.

As a parallel procedure in China, any party can apply for up to two persons with expertise to explain or elaborate professional issues in the lawsuit.

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 China at present. However, factual or expert witnesses are required to testify during the court hearing. With justifiable reasons and upon the approval of the court, such witnesses may file a written testimony as well.

Where the verification was conducted in a lawsuit, the party could file a request with the court to invite the experts of the verification institute to testify in court for the verification opinion, while the court may also request such experts to testify in court if it is deemed necessary. Upon the court's notification, if such experts refuse to testify in court without justifiable reasons, the verification report will not be deemed as effective evidence 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?

At present, there is no procedure identical or even similar to the so-called pre-trial procedures in China. However, many scholars and legal professionals have published articles and comments to call for the Chinese litigation system to adopt the pre-trial procedure.

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

Alternative methods of dispute resolution are not required to be pursued first as an alternative to litigation. However, if there is an effective arbitration clause, the parties can only file arbitration instead of a lawsuit.

Actually, mediation and arbitration are alternative dispute resolution methods in China. In practice, the court tends to push for mediation if possible, and if mediation turns out to be fruitful, the mediation will be conducted by the court, which enjoys the same legal effect as a judgment.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction be brought within the jurisdiction of your courts either as a defendant or as a claimant?

In product liability cases, the lawsuit could be filed in China even though the claimant is not domiciled in China, as long as the infringement was committed in China and the consequence of the infringement was also felt in China.

Even if the distributor or manufacturer is not domiciled in China, it can be qualified as a defendant in a product liability case in a court in China.

5 Time Limits

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

Yes, there is time limit for filing a lawsuit.

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 of action based on the cause of product liability was first regulated in the General Principles of Civil Law of the People's Republic of China ("General Principles of Civil Law"), which was

published in 1986. The limitation period is one year. Although the General Principles of Civil Law was amended in 2009, the relevant article remains the same.

However, in accordance to the Product Quality Law, which was published in 1993 and amended in 2000, the validity period for claiming compensation for damages due to defects of a product is two years, starting from the date when the claimant knew or should have known that its rights were impaired. The right of request for compensation claims for damages due to defects of products shall be void 10 years after the products with the defect that caused the damages were first delivered to the users or consumers, unless the specified period of safe use is longer than 10 years.

Although there are conflicting regulations regarding the time limit, in practice, a period of two years as regulated in Product Quality Law is commonly applied.

The aforesaid two-year limitation period in product liability lawsuits does not vary depending on whether the product liability is fault-based or strict. The age or condition of the claimant does not affect the calculation of the time limits.

In accordance with the General Principles of Civil Law, the court may have the discretion to extend the time limits, although this is extremely rare in practice.

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

In theory, since the time limit may start from the date when the claimant should have known that their rights were impaired, issues of concealment or fraud could affect the calculation of the time limit. In practice, however, such cases are seldom seen.

6 Remedies

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

In product liability cases, the available remedies are mainly monetary compensation. Although the obligation for manufacturers and distributors to recall is also regulated in the Tort Law, and there are cases in which the claims include court orders to recall the involved products, so far it is not known that any court has issued a judgment which includes a product recall.

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

As to whether product liability covers the damage of the product itself, the Product Quality Law specifically excludes it, while the wording used in the Tort Law very generally refers to "injury or damage of others". In practice, different courts may have different opinions regarding whether a product can be included in a product liability claim because of the inconsistency in the law. Other types of recoverable damage are commonly held to include compensation for medical costs, mental damages, death, funerals, disabilities, upbringing costs and/or damages to other 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?

If the defect endangers another person's property or personal safety, the claimant can request for any obstacles to be removed, danger to be eliminated, or any other appropriate action to be taken, but costs such as medical monitoring cannot be recovered. In addition, if the claimant is also the consumer, it may consider making a claim for the operator to stop selling the product or providing the service, or even recall the products with potential malfunction, in accordance of the Consumer Protection Law.

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

Yes, with the condition that any manufacturer or distributor knowingly produces or sells defective products that cause death or serious damage to the health of others, the injured party may claim appropriate 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 recoverable damages 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 applied 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?

There is no equal or similar system in China.

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?

For product liability cases, if the claimant is the successful party, it can recover the court fees from the losing party. As to verification costs, it is the party making the application who bears the costs and the party inviting the expert assessor who pays the associated costs. If the product liability case has arisen as a result of personal injury, the claimant may request the recovery of the lawyer fees.

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

Yes, legal aid exists in China.

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

Although there is legal aid in China, it is not possible to claim help for product liability disputes.

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

Legal aid is limited to obtaining free legal service from legal aid organisations and, therefore, conditional or contingency fees are not allowed.

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

There is no equal or similar system in China for third party funding.

7.6 In advance of the case proceeding to trial, does the court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

Yes, it is regulated in Article 101 of China Civil Procedure law that: "*Where the lawful rights and interests of an interested party will be irreparable damaged if an application for preservation is not filed immediately under urgent circumstances, the interested party may, before instituting an action or applying for arbitration, apply to the people's court at the place where the property to be preserved is located or at the place of domicile of the respondent or a people's court having jurisdiction over the case for taking preservative measures. The applicant shall provide security and, if the applicant fails to provide security, the people's court shall issue a ruling to dismiss the application*."

The court could then decide whether to accept the application or not. However, once the court accepts the said application, it shall issue a ruling within 48 hours. Furthermore, the applicant is required to file the lawsuit or arbitration within 30 days after the people's court takes a preservative measure; the people's court shall remove preservation.

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 your jurisdiction.

The court of Haidian District Beijing recently issued a judgment in a product liability lawsuit against the selling dealer of a Japanese auto brand, where the court affirmed that the plaintiff failed to prove the existence of the defect as no verification could be conducted based on the condition of the subject vehicle (seriously damaged during the accident) and the death of the plaintiff's husband was caused his over speeding and failure to wear the seatbelt. However, the judge mediated and in the end the dealer settled the case with the plaintiff from the aspect of social responsibility and protecting the consumer. The dealer then paid 100,000RMB to the plaintiff as compensation to settle the case. It is apparent from the aforesaid judgment that, for product liability claims filed by the consumers, the manufacturers/sellers are not 100% safe even if the consumer fails to fulfil his burden of proof. The court may still mediate in view of their social responsibility and protection of the consumers.

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Chapter 12

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 all of the circumstances, including any instructions or warnings provided with the product and the manner in which it has been marketed. Recent authority suggests that this assessment depends on the facts of the case, but that a wide range of factors may be relevant circumstances, including compliance with regulatory requirements, whether the risks could be avoided, and the risks-benefit balance in the case of medicinal products where safety is always relative (*Wilkes v Depuy International Limited* [2016] EWHC 3096). This conflicts with an earlier decision that adopted a much narrower approach to the assessment of defect (*A and Others v The National Blood Authority and Others* [2001] 3 All ER 298 (the so-called "*Hepatitis C*" case). 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. Even if the dispute is governed by English law, the CPA may not apply to non-EEA claims (*Allen v Depuy International Ltd* [2014] EWHC 753 (QB), where the court held that the CPA did not apply as the damage was caused outside the EEA, the Claimants had no connection with the EEA, and the defective product was supplied outside the EEA).

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.

Consumer contracts are regulated by the Consumer Rights Act 2015, which provides consumers with certain statutory rights. All contracts to supply goods include a term that the goods are of satisfactory quality and comply with the description applied to them or a sample supplied. The goods must also be fit for any particular purpose made known by the consumer to the seller before the contract is concluded. However, 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. 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. These statutory rights may not be excluded. Additional rights apply in respect of standard terms not individually negotiated with consumers.

Business to business contracts are regulated under the Sale of Goods Act 1979, the Supply of Goods and Services Act 1982 and the Unfair Contract Terms Act 1977 ("UCTA"). Although similar standard terms regarding the quality and description of the goods are implied into such contracts, businesses have greater flexibility to exclude liability under UCTA provided the exclusion is reasonable. However, liability under the CPA and for death or personal injury resulting from negligence can never be excluded in any contract, whether with a consumer or a business.

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), 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 he fails to identify the producer or at least the person who supplied the product to him. In Case C-358/08, *O'Byrne v Aventis Pasteur SA*, the CJEU said that the requirement is that "the supplier, against whom proceedings are brought by an injured person, inform the latter, on its own initiative and promptly, of the identity of the producer or its own supplier". Whether these conditions are met is a factual matter to be determined by the national court. The CPA postulates the obligation to identify being triggered by a request by the Claimant and it is questionable whether the plain meaning of the words of the English statute can be interpreted in line with the CJEU's ruling.

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 (the "GPS Regulations"), 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 GPS Regulations. 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 an unlimited fine and/or a 12-month term of imprisonment. 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. The Claimant does not need to prove the cause of the defect or why the product failed, or to identify the defect with precision. He only needs to prove in general terms that a defect exists and that it caused the damage complained of (*Hufford v Samsung Electronics* (UK) Ltd [2014] EWHC 2956 (TCC)). 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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

The Claimant has the burden of proving on the balance of probabilities that the Defendant's product caused or materially

contributed to 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, in a series of decisions (*Fairchild v Glenhaven Funeral Services Ltd and Others* [2002] 3 All ER 305, *Barker v Corus (UK) Plc* [2006] 2 WLR 1027 and *Sienkiewicz v Grief (UK) Limited* [2011] UKSC 10) the Supreme Court has ruled that special rules apply in relation to mesothelioma claims. In such cases, causation will be established where the Claimant demonstrates that the Defendant's wrongdoing materially increased the *risk* of injury (whether the tortious breach of duty was by a single or by multiple tortfeasors). This principle has recently been extended to a claim for lung cancer caused by multiple exposures to asbestos (*Heneghan v Manchester Dry Docks Ltd and Others* [2016] EWCA 86). It is unclear whether the exception will be extended to other classes of claim. In *Heneghan* the Court of Appeal stated that the so-called 'Fairchild exception' could be applied to situations which are 'not materially different' to that case; to date, it has not been applied to product liability claims.

What amounts to a material contribution depends on the facts. Where the alleged injury is non-divisible and there are several possible causes, but it cannot be established which of them caused the injury, causation may not be established (*Wilsher v Essex Area Health Authority* [1988] AC 1074). However, in the case of a divisible injury, such as pneumoconiosis, where the injury is caused by multiple factors which have an additive or multiplicative effect, and the tortious cause materially contributed to the injury, causation may be established (*Bonnington Castings Limited v Wardlaw* [1956] AC 613), but liability is likely to be apportioned to reflect the extent of the tortfeasor's liability for the injury. Where the defendant caused or contributed to an indivisible injury, the defendant will be held fully liable, even though there may well have been other contributing causes (see *Williams v Bermuda Hospitals Board* [2016] UKPC 4). These principles have not been applied to product liability claims, as yet, but are as likely to be relevant as they are to clinical negligence claims.

Although the UK courts have not been asked to address the position on causation where a product is part of a batch of potentially faulty products, the CJEU considered this issue in *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt*, Case C-503/13. In that case, the decision in which is binding on UK courts, the CJEU ruled in the context of a claim under the Product Liability Directive that if a product, such as a pacemaker, has a potential defect, products belonging to the same production series may also be classified as defective without the need to establish that each individual product is faulty. In reaching its decision, the court took account of the increased risks of damage arising from the fact that the relevant products were implanted. Although the decision is concerned with the legal test of "defect", it is clear that in certain circumstances the courts will find liability under the Directive without proof that a product has actually malfunctioned and caused 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?

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. In this context, an important distinction needs to be made between liability based only on marketing a product ("market-share liability") and a fact-pattern closer to *Fairchild* in which the Claimant has been exposed to the same product, such as a medicine, made by different manufacturers and the actual dose or doses of the drug which caused or materially contributed to the cause of the injury 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 specifically identifies the "get up" of the product and any instructions or warnings relating to its use as part of all the circumstances to be taken into account in assessing if the product is defective. In *Palmer v Palmer* [2006] All ER (D)86, the court found a device, designed to allow some slack on a seat belt to enhance comfort, to be defective on the basis that the instructions were incomplete and encouraged misuse, thereby compromising the effective operation of the seat belt itself.

In *Wilkes v Depuy International Limited*, the court ruled that in addition to warnings provided directly to consumers, warnings provided to learned intermediaries, such as doctors, should be taken into account as part of "all the circumstances" in assessing whether a product is defective. In that case, the allegedly defective product was a component part of a replacement hip, which was fitted by a surgeon, so no information about the device was supplied to the patient by the manufacturer. Detailed instructions for use (IFU), including warnings about the risks associated with the device were, however, provided to the surgeon. The court found that the IFU formed part of the circumstances taken into account in assessing defect.

This decision, combined with the decision in *Webster v Burton Hospitals NHS Foundation* [2017] EWCA CIV 62, can reasonably be viewed in the medical product field as increasing the spotlight upon the activities of the learned intermediary and, in practice, making it more likely that a claimant will focus a claim on the negligence of the clinician, rather than advance a speculative claim against the manufacturer that he is strictly liable for injury arising, despite the regulatory authorities having approved the product and patient information supplied with the product. In *Webster*, the court of Appeal determined that there was an overriding obligation for a health care professional to advise the patient directly on any material risks associated with a proposed treatment and reasonable alternative

treatment, unless there was good evidence that this information would itself "damage the patient's welfare". In so doing, the court effectively set aside decades of jurisprudence that treated a doctor as not negligent in the counselling provided to a patient, if the doctor could show that a body of expert opinion would have behaved in the same way as the defendant behaved. This test almost certainly caused many claimants to advance a product liability claim for injury against a manufacturer based on strict liability (or even negligence) rather than seek to prove clinical negligence against a doctor.

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. Failure to warn of design defects identified after marketing may give rise to issues surrounding the application of the development risks defence (see question 3.2 below).

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.

A failure to warn in breach of duty may sometimes 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.

A contrasting approach was adopted in the case of *Coal Pension Properties Ltd v Nu-Way Ltd* [2009] EWHC 824 (TCC). The manufacturer of a gas booster for use in gas heating systems failed to give sufficient warning about the risk of the booster casing cracking if inspection and maintenance were not carried out regularly and effectively. However, the manufacturer was not liable for an explosion caused by a gas leak from a cracked casing because the court held that as a matter of fact the operator of the system would not have heeded the warning and would not have had the casing replaced, whether they had been warned or not.

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
- a producer of component products 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 prosthesis 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, or that no damage was in fact sustained, 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.

In addition, Judges now have an obligation to strike out a personal injury claim where there is a finding of fundamental dishonesty by the Claimant.

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; once the defect was known the defence became unavailable. (Such factors may, however, be relevant to the assessment of defect – see the *Wilkes v Depuy International* case cited above.) 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 is also 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. In the *Wilkes* case, the court held that compliance with regulatory standards carried considerable weight because these "have been set at a level which the …[regulator] has determined is appropriate for safety purposes". Similarly, the court held that compliance with broader regulatory requirements was evidence of the level of safety of the product that persons are entitled to expect. 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 was not liable for supplying a bottle of dishwasher powder with a screw top, 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 group litigation, a judgment or order is binding on the parties to all claims that are on the group register at the time the judgment or order is made, unless the court orders otherwise.

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. 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, assessors have not 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.

There is currently no 'opt-out' class action procedure in England and Wales applicable to 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?

No. Proceedings must be brought by the person/body that has suffered the damage/injury. There is presently no means of bringing a product liability claim through a representative body as part of a collective action. However, representative actions may be brought on behalf of consumers seeking damages for infringement of competition law.

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 Court Statistics Quarterly for July to September 2016, published by the Ministry of Justice, unitary civil actions proceeding in the County Court (excluding certain small claims which are fast-tracked), on average, took 54.5 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. Complex group actions may take many years to come to trial. For example, in the third generation, oral contraceptives litigation it took approximately six-and-a-half 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.

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. In a suitable case, the court also has power to give a summary judgment dismissing a claim which has no realistic prospect of success.

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; 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. The court may make directions limiting the scope of factual and expert evidence by, for example, identifying those disciplines or issues to which such evidence may be directed. Evidence is usually mutually 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. Expert evidence is usually given sequentially, but the court may order that it is given concurrently (so-called 'hot-tubbing').

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 court proceedings are commenced or as part of the pre-trial procedures?

In claims involving personal injuries, the general rule is that 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 (so-called 'standard disclosure'), although the court may dispense with or limit such disclosure in appropriate cases. In other claims (except certain low value claims), the court can tailor the disclosure order to reflect the circumstances of the individual case and can choose from a menu of options including: dispensing with disclosure, requiring disclosure of documents on which a party relies and specific documents requested by their opponent, issue based disclosure, 'train of inquiry' disclosure, standard disclosure, or any other order that the court considers appropriate. In determining the scope of disclosure, the court will take account of the costs of giving wide-ranging disclosure of documents and will ensure that these are proportionate to the overall sums in issue in the proceedings.

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 required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

There are a variety of different methods of alternative dispute resolution (ADR) including mediation, arbitration and neutral evaluation, which can all be pursued as an alternative to litigation. Mediation is also commonly used during the course of litigation in an attempt to compromise the proceedings. The courts encourage the use of 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 or to respond to an invitation to participate in ADR may amount to unreasonable conduct and result in a cost sanction (*PGF II SA v OMFS Company 1 Limited* [2013] EWCA Civ 1288). 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).

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction, be brought within the jurisdiction of your courts either as a defendant or as a claimant?

The rules on jurisdiction in cases involving parties domiciled in the EU are governed by the Judgments Regulation, EC 44/2001. This provides that, in tort claims, a Defendant may be sued in the courts of the place where the tort occurred, which may be either the place where the harmful event giving rise to the tort occurred (in cases involving defective products this will usually be the place where the defective product was manufactured: Case C-45/13, *Kainz v Pantherwerke AG*), or the place where the damage occurred. In contract claims, the Defendant may be sued in the courts of the place where the contract was performed, which in the case of contracts for the sale of goods is the place where the goods were or should have been delivered. In proceedings involving a number of parties, jurisdiction may also be established against a Defendant domiciled in another EU country if they are a proper defendant to proceedings brought in England and Wales against another party and the claims are "so closely connected that it is expedient to hear and determine them together to avoid the risk of irreconcilable judgments arising from separate proceedings".

Where the claimants are non-EU, the English courts generally have jurisdiction to hear cases brought against persons domiciled in England. The courts no longer have discretion to refuse jurisdiction against such English Defendants on the ground that the courts in another jurisdiction would be a more suitable venue for the trial of the action (*Owusu v Jackson* [2005] ECR I-1383).

Proceedings may be brought in England and Wales by foreign claimants against English based corporations or bodies based on their actions or those of their subsidiaries in other jurisdictions. For example, group actions have been pursued in England in respect of actions arising from exposure in South Africa to asbestos mined or processed by an affiliate of an English company (*Lubbe v Cape Plc* [2000] 1WLR 1545); by a group of claimants from the Ivory Coast against a British based oil trader, Trafigura, for damage allegedly caused by the dumping of toxic waste and by a group of Bangladeshi villagers against The Natural Environment Research Council, a British organisation which allegedly conducted a negligent survey, in respect of damage arising from contaminated ground water (*Sutradhar v Natural Environment Research Council* [2006] UKHL 33).

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. Knowledge of attribution may be established where a Claimant's subjective belief that his injury is capable of being attributed to the breach of duty/defective product is held with sufficient confidence to make it reasonable for him to begin to investigate whether he has a valid claim (*Ministry of Defence v AB and others* [2012] UK SC9). The court has a discretionary power to disapply this time limit where it would be equitable to do so. In doing so it can take into account the merits of the case and whether the claim has a reasonable prospect of success (*Ministry of Defence* case above).

Where proceedings are brought under the CPA there is also a general long-stop provision. A right of action under the CPA is extinguished 10 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). In Case C127/04, *O'Byrne v Sanofi Pasteur MDS Limited and Sanofi Pasteur SA*, the CJEU held 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".

In a further reference in the same proceedings (Case C-358/08, *Aventis Pasteur SA v OB*), the CJEU ruled that national legislation cannot permit the courts to substitute one producer Defendant for another company (in this case mistakenly sued as a producer) after the long-stop period has expired. It is unclear whether the English courts would permit substitution after the expiry of a limitation period (as opposed to the long-stop period). Although this was approved in *Horne-Roberts v SmithKline Beecham plc* [2002] 1 WLR 1662, a subsequent decision of the Court of Appeal has cast doubt on the correctness of that decision (*Lockheed Martin Corporation v Willis Group Ltd* [2010] EWCA Civ 927).

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) and damage to property. 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.

In the case of mental injuries, 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).

6.3 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 recoverable only as medical expenses consequential upon the main injury or damage. In addition, the courts will not usually allow a Claimant to recover damages where he/she sustains a recognised, but unforeseeable, 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 (*Grieves v FT Everard & Sons Ltd* [2008] 1 AC 281).

Where claims are pursued under the CPA, it is unclear whether the position set out above remains good law in the light of the CJEU's decision in *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt*, Case C-503/13. In that case the CJEU ruled that if a product, such as a pacemaker, has a potential defect, products belonging to the same production series may also be classified as defective without the need to establish that each individual product is faulty. Damage was construed broadly to include compensation "that is necessary to eliminate harmful consequences and to restore the level of safety which a person is entitled to expect" including, in that case, the costs of replacing the defective device. Although the relationship between the decision in the *Boston Scientific* case and medical monitoring claims has yet to be explored, the widened definition of damage applied by the CJEU may be used by Claimants to argue that the restrictions of English law are no longer appropriate.

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 may be awarded in claims regarding infringements of competition law, but only where the breach was intentional or reckless and the Defendant's conduct was so outrageous as to justify an award (*2 Travel Group Plc (in Liquidation) v Cardiff City Transport Services* [2012] CAT 19). 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?

In general, a Claimant may unilaterally discontinue all or part of his/her claim at any time. However, the court's permission is required for compromise or settlement of proceedings instituted against or

on behalf of a minor (aged under 18) or an adult who is incapable of managing their own property and affairs. Court approval is also usually sought where there is a settlement or compromise of an unlitigated claim made by, or on behalf of, or against, such a person as 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 general rule is that the unsuccessful party pays the legal costs of the successful party, (including expert fees and other incidental expenses such as court fees). However, 'Qualified One-way Cost Shifting' ("QOCS") applies to claims for death or personal injuries (provided a funding arrangement was not entered into prior to 1 April 2013). This means that a Defendant may only enforce an order for costs against a Claimant, without the court's permission, to the extent of any damages and interest ordered in favour of the Claimant. In practice, this means that in most personal injury claims an unsuccessful Claimant will not be responsible for the Defendant's costs, although this principle will not apply if the claim is struck out, or if the court determines that the Claimant is fundamentally dishonest. If the Claimant is successful they may recover their costs from the Defendant in the usual way, subject to a 'set-off' of any costs orders made in the Defendant's favour (provided such costs do not exceed the amount of damages awarded).

The assessment of costs is a matter for the court's discretion and the court can make such orders as it considers appropriate reflecting matters such as the parties' conduct and their success or failure on particular issues in the proceedings (either by reducing the costs award made in favour of the successful party to reflect the fact that they were unsuccessful on certain issues, or by making issue-based cost orders). In determining the amount of recoverable costs, the court will assess whether the sums claimed were reasonably incurred and were proportionate to the overall value of the case. However, they will rarely depart from the costs budgets agreed by the parties or approved by the court as outlined in the answer to question 7.6.

Where a party makes an offer to settle which meets certain procedural requirements (a "Part 36 offer") and this is not accepted by the other party in satisfaction of the claim, unless that other party achieves a better result at trial various sanctions will apply. A party which fails to 'beat' a Part 36 offer becomes liable to pay the costs incurred after the date the offer could last have been accepted. In the case of a Defendant failing to beat a Claimant's Part 36 offer additional sanctions apply: the damages payable will be increased by between 5 and 10% (depending on the amount awarded) subject to a maximum uplift of £75,000, the costs incurred after the offer was made will be payable on an indemnity basis, and interest on the value of the claim will be payable at an enhanced rate.

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

Public funding is available in England and Wales, but such funding is not generally provided in product liability cases (see below).

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

The Legal Aid, Sentencing and Punishment of Offenders Act 2012 largely abolishes public funding for civil claims. Civil legal aid is not available in respect of tort claims, including negligence actions and claims for personal injury and death. There are a number of limited exceptions to this general rule and funding is available in the case of certain clinical negligence actions (involving serious birth injuries and lifelong disabilities) and in other cases, including proceedings concerning family, children, disability, mental health, welfare benefits and immigration matters.

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

Yes, funding is available through Conditional Fee Agreements (CFAs) and Damages Based Agreements (DBAs), a form of contingency fee.

There are broadly two 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. Under a CFA, the client initially pays a reduced (or no) fee to his lawyers, but in the event of "success" the client becomes liable for the standard fees plus a percentage uplift on those standard fees. What is a "success" or "failure" is defined in the CFA, often by reference to a level of damages recovered. The uplift is based on the level of risk associated with the claim. Under a DBA, the lawyers' fees are set as a percentage of the sum recovered as damages in the claim, net of any costs recovered from the losing party.

Rules which came into effect in April 2013 have significantly changed the way CFAs operate and legalised DBAs (which were previously unenforceable). Prior to April 2013, a successful Claimant could recover from their opponent the CFA uplift or success fee in addition to their standard costs and also any premium payable to obtain After the Event insurance purchased to protect

the client against exposure to the other side's costs in the event of defeat. Where agreements are entered into after this date the CFA success fee and the ATE premium are no longer recoverable from the opposing party: a successful litigant will have to bear these costs and can only recover standard costs from their opponent. In addition, in personal injury claims the success fee or percentage of damages payable under both CFAs and DBAs is capped at 25% of damages other than those for future care and loss. In other cases, a CFA success fee of up to 100% of standard costs can be negotiated; the DBA payment is capped at 50% of damages.

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. 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. Third party funders will generally be liable for the defendant's costs on the same basis as the funded party; they may be required to pay indemnity costs even though they are not personally responsible for the matters which caused the order to be made (*Excalibur Ventures LLC v Texas Keystone Inc & Ors (Rev 2)* [2014] EWHC 3436 (Comm)). In the context of proceedings carried out under a CFA, the Court of Appeal has clarified that a firm of solicitors' agreement to indemnify a client against their liability for costs if they were unsuccessful was permissible and was not champertous (*Sibthorpe and Others v London Borough of Southwark* [2011] EWCA Civ 25).

A voluntary "Code of Conduct for the Funding by Third Parties of Litigation in England and Wales" has been agreed by members of the Association of Litigation Funders and sets out standards of practice and behaviour for members.

7.6 In advance of the case proceeding to trial, does the Court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

Yes. In most cases commenced after April 2013, except for some types of high-value claims (where the sums in dispute exceed £10 million excluding interest and costs), the parties are required to file and exchange costs budgets after the defence is served or prior to the first procedural hearing, setting out their estimate of the costs they anticipate recovering from their opponent if successful. Strict time limits are applied to filing these budgets, and if these are not met the party in default may only recover court fees. If they are not agreed, the budgets will be reviewed by the court, which may make a costs management order. This may be revised as the litigation progresses, but only significant developments will justify such revisions. In assessing the amount of recoverable costs at the conclusion of the litigation, the court will not depart from the agreed budget unless it is satisfied that there is good reason to do so. The budget therefore effectively acts as a cap on the level of costs which the winner may recover from the losing party. This does not restrict the freedom of the parties to investigate and litigate claims as they consider appropriate (the parties may exceed the amount of the court-approved budget if they wish to do so), but those costs will not be recoverable from the opposing party on the successful conclusion of the litigation.

The Court can also impose a cap limiting the amount of future costs that a party may recover where there is a substantial risk that without such an order the costs incurred will be disproportionate to the amounts in issue and the costs cannot be adequately controlled through usual case management procedures (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).

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 your jurisdiction.

See above. *Wilkes v Depuy International* is a landmark decision setting out in detail how the English courts approach the assessment of defect under the CPA. The Court adopted a flexible approach to the assessment of safety, concluding that the relevant circumstances that would be considered could not be precisely defined, but depended on the facts of the case. In addition to any instructions or warnings provided with the product, such factors could, in appropriate cases, include assessment of the risks and benefits of the product, compliance with regulatory requirements, whether the risks could be avoided and the costs of doing so. *Wilkes* casts doubt on the much narrower approach followed in the *Hepatitis C* case, which discounted as irrelevant considerations of risk/ benefit, avoidability and cost. Although both decisions are first instance and therefore, technically carry equal weight, *Wilkes* suggests that the English courts may be now be prepared to adopt a broader and more holistic approach to the determination of such matters.

Acknowledgment

This chapter was prepared jointly by Alison Brown and Ian Dodds-Smith of Arnold & Porter Kaye Scholer 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 KAYE SCHOLER

Arnold & Porter Kaye Scholer is an international law firm with over 1,000 attorneys in 13 offices in the US, London, Frankfurt, Shanghai and Brussels. With 40 partners and counsel specialising in product liability matters, the firm 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?

Except particular regulations for specific products, three different systems of product liability are available under French law:

- **Defective Product Liability Law** provided for by the Law n°98-389 of 19 May 1998 (Article 1245 to 1245-17 of French Civil Code, hereinafter the "FCC") implemented the European Directive 85/374/EEC. This regime is based on the strict liability of the producer for the damage caused by a defect of his product, whether he was bound to the victim by a contract or not. Under conditions, the producer incurs liability for both damages to persons and to property, resulting from the defective product, which may be compensated.

  The ECJ held that existing liability systems remain applicable only in the event that the legal grounds invoked are distinguishable from those outlined in the Directive (ECJ, 25 April 2002, C-183/00, *Gonzalez Sanchez*). The *Cour de Cassation* has recently reaffirmed that the fault invoked must be distinct from the product safety defects.

  Additionally, common liability rules also still apply if the subject matter falls outside the scope of the Directive; for example, service providers which are users of products (ECJ, 21 December 2011, C-495/10, *CHU de Besançon*). It must be pointed out that French defective product Law is unusual in that it does not exclude professional goods from its scope, in contradiction to Article 9 of the EU Directive.
- **Tortious Liability** applies when damage is suffered by a party outside a contractual relationship on the ground of fault or negligence or on the ground of strict liability of the custodian, according to the liability for damage caused by objects.
- **Contractual Law** can also apply when the damage arises out of a breach of contract. In addition, certain legal warranties are applicable to sale contracts:
  - The statutory warranty against latent defects (Art. 1641 of the FCC) owed by the seller to the buyer.
  - In matters between consumers and professionals, Article L 411-1 of the Consumer Code provides for a legal warranty in the case of a defect in the conformity of the product.

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

Specific compensation schemes are provided by the National Compensation Office of Medical Accidents outlined in Article L. 1142-22 of the Public Health Code for:

- victims who contracted AIDS, Hepatitis B, Hepatitis C or Human T-Lymph tropic after transfusion of blood products or medicinal products derived from human blood in France;
- victims who suffered a damage caused by Human Growth Hormones mandatory, vaccinations, administration of Benfluorex or of sodium valproate and its derivative products during pregnancy; and
- victims of side effects of drugs stated on the package leaflet of the medicinal products. Such occurrence is considered a therapeutic risk.

There is also a specific fund, the FIVA, for asbestos damages.

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

All of these parties can be held liable in the abovementioned regimes. The product liability law provides for specific rules:

The responsibility is borne by the producer who is strictly liable for a defective product. When they act as professionals, the manufacturer of a finished product, the producer of a raw material and the manufacturer of a component part are considered as producers for the purpose of the product liability regime (Art. 1245-5 of the FCC). The distributor who affixes his name, trade mark or any other distinguishing sign on the product, and the importer of the defective product into the European Community, are also considered producers. The supplier of the defective product is only liable if the producer cannot be identified, unless he names his own supplier or the producer within three months from the date he received notice of the victim's claim (Art. 1245-6 of the FCC).

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?

As soon as a risk of a product is recognised, the producer shall comply with its duty of care and take the necessary actions to limit any harmful consequences. These actions may include a formal public warning, a product recall or, withdrawal of the product from the market.

An administrative or civil action can be brought against the producer who failed to conduct a compulsory recall.

Since the implementation in France of the European Directive 2001/95 of 3 December 2001, the professional, i.e. producer and distributor, has to ensure that the products put on the market are safe (Article L 4211-3 of the Consumer Code). If those products do not comply with the regulations in force, or are likely to be dangerous, notification must be sent to the administrative authorities, who can order that the product be withdrawn, recalled or destroyed.

Specific regulations of recall are also provided in specific areas (medical products, foods products, etc.).

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

When a product or service causes physical injury, several criminal sanctions can apply to the producer, the distributor or service provider, either as legal entities or individuals.

- If the victim has suffered a bodily injury, the professional can be held liable for **involuntary bodily harm**. Negligence is sufficient to establish the offence.
- If the victim has died, the professional can be held liable for involuntary manslaughter. The *actus reus* of **involuntary manslaughter** is defined in the same way as that of involuntary bodily harm.
- In any event, the professional can be held liable for the **administration of harmful substances**. The offence requires the intent to conceal the noxious nature of the substance administered.
- The offence of **deliberate endangerment of human life** can also be retained if the producer has deliberately breached a special duty of safety or duty of care, imposed by law or regulation, which exposes the victim to an immediate risk of death or injury likely to result in mutilation or permanent disability.
- The defendant can be held liable for **fraud** where there has been a deceit or an attempt to deceive a contracting party as to the substantive qualities of the goods or products.

2 Causation

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

As a general rule, the claimant must prove the damage, the fault/defect and the causal link between the two (Article 1353 of the FCC). The same rules are provided under Product Liability Law, Article 1245-8 of the FCC.

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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

In French law, two main theories of causation exist, but there is no express causation test and the lower courts judges have discretion on that matter.

- Pursuant to the theory of equivalent conditions, any event without which the damage would not have occurred shall be considered the cause of the damage.
- Pursuant to the theory of adequate causality, only the events that constitute the determining cause of the damage shall be considered the cause of the damage.

Particular difficulties arise concerning health products.

Even though the causal link cannot be scientifically established with certainty, the legal cause can be determined by the French courts since the proof of a defect and of the causal link with the damage can be brought by any means on the basis of presumption of Article 1382 of the FCC.

French courts apply the test of presumption of facts to decide whether a causal link is present. Several factors are considered, including the period from the appearance of the first disease symptoms to the administration of the product, and the absence of other causes.

According to ECJ, the finding of a potential default of a medical device can lead all products of the same model to be considered defective, without needing to prove the default of each of the product (ECJ, 5 March 2015, C-503/13 and C-504/13, *Boston Scientific Medizintechnik*). This solution has already been applied in French case law, outside the Product Liability Law, granting compensation for anxiety to the patients and covering the monitoring/replacing medical costs.

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 possible wrongdoers can be held liable proportionally to the seriousness of their wrongdoing. In a strict liability regime, liability will be equally shared between the liable persons.

French courts do not apply the system of market-share liability, although scarce lower court decisions have admitted it but remain to be confirmed or quashed by the French Supreme Court.

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 French contract law, a professional has a general obligation to inform its co-contractors. A failure to warn gives rise to liability, which is assessed on a case-by-case basis.

Further, as to tortious liability, insufficient information on the product, even properly manufactured, may characterise a defective product and thus give rise to liability. It is now clearly established that the security which one can legitimately expect depends upon the information provided in the information leaflet. The French Supreme Court has held that the producer of propane bottles

was liable towards a user who had not been given the necessary information, even though the producer was not bound by a contract to the victim.

Under French law, there is no principle of learned intermediary that could discharge the duty owed by the manufacturer.

3 Defences and Estoppel

3.1 What defences, if any, are available?

All defences are available, i.e., challenging the existence of the default/defect, challenging the causal link, etc.

In the contractual liability regime, the limitation of liability clauses can be used as a defence if they comply with the general contractual rules on validity, although they are strictly construed by the courts. As far as the Product Liability Law is concerned, Article 1245-14 provides that clauses excluding or limiting the liability for defective products are prohibited and deemed unwritten, unless they concern damage to goods that are not used by the victim for their own private use, since the clauses limiting liability stipulated between professionals can be valid.

The Product Liability Law provides that the producer is strictly liable unless he meets one of the defences of the exhaustive list provided by Article 1245-10 of the FCC. A producer can escape liability if he proves that:

- he had not put the product into circulation;
- under the circumstances, it is likely that the defect which caused the damage did not exist when the product was put into circulation by him or that this defect appeared afterwards;
- the product was not for the purpose of sale or for any other form of distribution;
- the state of scientific and technical knowledge, at the time he put the product into circulation, was not such as to enable one to detect the existence of the defect (not applicable to products of the human body); or
- the defect is due to compliance with mandatory provisions of statutes or regulations.

The producer of the component part is not liable if he proves that the defect is attributable either to the design of the product in which the component was incorporated or to the instructions given by the producer of that 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?

The current state of the art is not a defence.

The development risk defence has been implemented into French Product Liability Law.

Pursuant to Article 1245-10 n°4 of the FCC, if such state of scientific and technical knowledge, at the time the producer put the product into circulation, was not such as to enable the producer to detect the existence of the defect, the producer is exonerated.

This notion is strictly construed by the ECJ which makes reference to "*the most advanced state of scientific and technical knowledge anywhere in the world when the product was put into circulation*" that is followed by French case law. The ECJ refers to the "*objective and technical knowledge of which the producer is presumed to have been informed*" (ECJ, 29 May 1997, C-300/95).

As it is a defence, it belongs to the producer to prove that the risk 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?

Compliance with regulatory and/or statutory requirements does not constitute a defence.

Under Product Liability Law, the same rules apply (Article 1245-9 of the FCC).

However, if the producer proves that the defect is due to compliance with mandatory legislation or regulation, he will not be held liable (Article 1245-10 of the FCC).

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 estoppel issue preventing a claimant from bringing a claim on issues already decided by the courts, if the three conditions of *res judicata* are not met, except in cases concerned by the new class actions rules.

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 defendant can make third party claims to seek a contribution, either in the same proceedings or in subsequent proceedings. Depending on the cause of action of the third party claim, the time limits will vary.

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

The victim's fault can lead to the exemption or limitation of the producer's liability.

Pursuant to Article 1245-12 of the FCC, the liability of the producer may be reduced if, considering all the circumstances, the damage was caused by both a defect in the product and a fault of the victim or of a person for whom the victim is responsible, but only to the extent the fault has a direct link with the damage. The defendant may be discharged if the claimant's behaviour amounts to "*force majeure*".

4 Procedure

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

In civil and commercial matters, there is no jury, only judges (one or three depending on the claim amount and the complexity of the case).

Even if criminal liability was pursued, the trial would still be held by 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)?

Even though the court may appoint experts, there are no expert assessors before the French courts.

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 France, class action proceedings have recently been introduced in several specific sectors:

- Consumer sector:

Law *Hamon* No. 2014-344 of 17 March 2014 entered into force on 1 October 2014 and introduced class actions for consumers. In this regard, an accredited consumer association may take legal action to obtain compensation for individual economic damages suffered by consumers that result from the purchase of goods or services or from antitrust practices. Moral damages and bodily injuries cannot be compensated. The opt-in system requires consumers to consent individually to the claim.

- Health sector:

Law No. 2016-41 of 26 January 2016 has introduced class action proceedings to the health sector. Only certified associations of users of the health system can bring such class actions in an opt-in procedure, on behalf of victims placed in an "identical or similar situation" who suffered individual bodily injuries. The claim can be brought against a producer or a supplier of health products or their insurers.

- Environmental sector:

Pursuant to Article L 142-2 of the French Environmental Code, approved associations may bring a claim for infringement of the legislative provisions relating to the protection of nature and the environment, to the improvement of the living environment, to the protection of water, air, soils, sites and landscapes, to town planning, to sea fishing, or those whose purpose is the control of pollution and nuisances, nuclear safety and radioprotection, commercial practices and misleading advertising including environmental information and of the enactments for their application.

Under this claim, the court can grant two sorts of reliefs: injunction to cease the violation; and compensatory damages for personal injury and material loss.

This action is only open to associations either approved by Decree or created for the protection of the environment (Article L141-1 of the French Environmental Code).

- Equal opportunity sector:

Law No. 2016-1547 of 18 November 2016 introduced class actions in the equal opportunity sector. In this regard, only associations acting in this sector that have been declared for at least five years can bring a claim in front of a civil or administrative court when several individuals are being discriminated against, directly or indirectly on the same ground and by the same person.

Under this claim, the court can grant an injunction or compensatory damages.

This action is only open to associations which bylaws provide that the purpose of the association is the defence of that interest.

- Personal data protection:

Law No. 2016-1547 of 18 November 2016 also introduced class actions for data protection.

Under this claim, the court can only grant an injunction.

This action is open to associations which bylaws provide that the purpose of the association is the protection of privacy and personal data. It is also open to consumer associations and trade unions.

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

In principle, the claimant has to prove a personal and direct interest to successfully bring a claim. In parallel, associations are entitled to bring a claim limited to the collective interest as defined by their articles.

In the exclusive context of the new class actions, some specific associations are able to bring claims on behalf of a number of claimants (see question 4.3).

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

A claim for civil liability usually lasts two years. It takes at least another year for an appeal, and 18 months more for the recourse before the *Cour de Cassation*.

Several emergency procedures are also available, such as interim relief and fixed-date 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?

As a matter of principle, claimants have to present their procedural claim *in limine litis*, i.e. before any claim is brought on the merits. These procedural issues can lead to an end of the trial without an examination of the merits of the case.

Requests for experts or for a stay of the proceedings could also suspend the examination of the merits of the case and affect the course of the proceedings.

Except from these elements, the French system does not allow preliminary issues to determine the need for a further trial.

4.7 What appeal options are available?

A decision rendered by a first instance court can be appealed before a Court of Appeal. Even though the appellant can raise new grounds and produce new evidence, it may not depart from its original claims except to: plead set-off; reply to the opponent's claims; or obtain a ruling on issues arising from the intervention of a third party.

The Court of Appeal's decision can in turn be subject to recourse before the *Cour de Cassation*, which only has jurisdiction to hear points of law excluding factual issues. This court then has discretion to refer a preliminary question on constitutionality to the French Constitutional Court, if there is a doubt as to the constitutionality of a legal provision applicable to the present case.

It must be highlighted that new rules are under discussion regarding the role of the *Cour de Cassation*, which may lead to a more restricted access before this 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?

The court can appoint experts in case of technical difficulty of its own initiative. The expert's findings are not binding upon the court.

The parties may appoint their own expert and use their report as evidence to support their claim. The value of this evidence will be left to the unfettered discretion of the court.

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?

Factual or expert witness statements are admitted before the courts as evidence. Such statements can be made in writing or (very rarely) orally.

The parties must exchange this evidence in the course of the proceedings to comply with the adversarial principle.

There are no pre-trial proceedings in France.

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

Under French law, there is no discovery. The French system requires each party to rely upon the evidence that they select to support their claim. A party can apply to the court for a disclosure order, which may be admitted or dismissed.

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

Conciliation, mediation and arbitration are available in France as ADR.

Since the Decree n°2015-282 of 11 March 2015, which entered into force on 1 April 2015, the parties must prove that they have taken steps to achieve an amicable resolution of the dispute, unless the urgency or nature of the matter does not allow it. However, a failure to comply with such an obligation is not sanctioned.

Further, since 1 January 2016, professionals are obliged to suggest a mediation procedure to their consumers to solve any dispute before going to court.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction be brought within the jurisdiction of your courts either as a defendant or as a claimant?

In many circumstances, a person not domiciled in France can be brought before French courts. French jurisdiction can be secured when provided by the Recast Brussels Regulation n°1215/2012 of 12 December 2012, which entered into force on 10 January 2015, by French international private law, by contractual provisions or in cases where the harmful event occurred in France.

5 Time Limits

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

Depending on the cause of action, various time limits 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 the French general statute of limitation, a claimant can bring a claim on a contractual or tortious basis within five years from the date it knew or should have known the facts that enabled it to exercise its rights (Article 2225 of the FCC).

For bodily injuries, the time limit is 10 years as from the date of the stabilisation of the state of health (Article 2226 of the FCC).

In any event, no claim may be brought more than 20 years after the facts giving rise to the right except for claims in compensation of a personal injury or actions against health professionals in the public sector.

However, these time limits vary depending on the age or condition of the claimant. As provided for in Article 2234 of the FCC, "*time does not run or is suspended where it is impossible to act following an obstacle resulting from the law, an agreement, or force majeure*". It is suspended for non-emancipated minors or adults with diminished capacity except for specific actions set out in Article 2235 of the FCC.

There are other specific rules which bar the time limit from running.

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

There is no relief for a claimant who is time-barred, except when interruption or suspension is provided by law.

However, the *Cour de Cassation* has already ruled that fraud which affected the proper process of the claim suspended the running of time.

6 Remedies

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

Monetary compensation and injunctive relief are available under French law but declaratory relief is not available for product liability claims.

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

All damages suffered have to be fully compensated under French law.

Any types of lawful damages are recoverable, as long as causation is proved.

However, the damage caused to the defective product itself is not 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?

Medical monitoring costs can be recovered when there is a serial defect, even though the product has not yet malfunctioned or caused an injury.

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

Punitive damages are not granted by French courts.

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 the damages recoverable. Damages are compensated up to the amount to which they have been 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?

Settlement of claims may be given judicial approval to be enforceable before the courts. However, when such settlements are contracted with minors or mentally impaired protected adults, the court must give 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?

National Health Insurance that bears the costs arising from the damages suffered by the victim can then bring an action against the liable third-party or its insurer, and can recover up to the amount it has paid to the victim or incurred on behalf of the victim.

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 losing party bears the court fees and other incidental expenses. A lump sum is also granted to the successful party for their legal costs, taking into account equity and the financial resources of the losing party.

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

Legal aid is available in France. It may cover the costs totally or partially incurred during the trial.

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

As a matter of principle, public funding is aimed at low income litigants. Such financial thresholds are defined by decree and regularly revised. Legal aid can be granted to European citizens, foreigners legally residing in France, and asylum seekers.

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

Contingency fee arrangements are strictly forbidden under French law.

However, a written fee agreement with the client which is subject to uplift in the event of a particularly positive result and where the calculation is set out in advance is permitted.

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

Third party funding is not prohibited in France and is used mainly for international arbitral proceedings. Legal boundaries are not yet precisely defined in France.

7.6 In advance of the case proceeding to trial, does the court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

The court does not exercise a control over the costs incurred by the 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 your jurisdiction.

- French contract law underwent a major reform following Ordinance n°2016-131 of 10 February 2016 and entered into force on 1 October 2016.
- Class actions specific to certain sectors were enacted in 2016 in the fields of health, anti-discrimination, data protection and environmental law.
- The ECJ is expected to issue its decision in response to the French courts' preliminary question, asked on 12 November 2015, as to whether factual causal presumptions complied with the European Directive of 1985, and if so, if a causality presumption could be established. Their decision may affect the current state of French law as to the proof of causation in product liability.
- A reform of French tortious liability is currently under discussion.

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Carole began her career in 1995 as a corporate lawyer in Paris at Price Waterhouse Juridique et Fiscal. She then decided to turn to a litigation practice and joined the Litigation and Insurance department of Norton Rose Paris in 1998. She then co-founded and contributed over 10 years to the development of a French boutique law firm, BOPS, before joining Squire Patton Boggs in January 2015.

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Valérie acts for leading companies in sensitive product liability and life sciences litigation in relation to individual claims but also in large mass claims.

Valérie has also particular experience in complex expert-appraisal proceedings and industrial risks litigation. She has developed a recognised practice in environmental liability and has intervened in several of the massive pollution cases in France over the last years.

She is a member of the French Association of Risk Managers (AMRAE) and of AIDA (International Association of Insurance Law).

SQUIRE PATTON BOGGS

Squire Patton Boggs' Paris office provides a comprehensive service to corporate clients and is proud of its track record of delivering pragmatic French and transnational legal advice to both foreign and domestic clients in a truly international context. The office currently has some 40 lawyers with four dual-qualified English solicitors and several French qualified foreign nationals. All of the office's partners have significant experience of international legal affairs in leading French practices.

The office's clients span all sectors of the business world and include many household names and companies listed on French, English or North American stock exchanges, as well as several of France's largest state-owned concerns. Industry sectors in which the Paris office has particular experience include Chemicals, Marketing Services, Life Sciences, Aerospace & Defence, Energy, Automotive and Diversified Industrials.

Squire Patton Boggs' Paris Office is frequently recommended for Mergers & Acquisitions, Tax, Labour Law and Dispute Resolution.

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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?

German product liability law is based on (i) a strict liability regime under the Product Liability Act ("PLA") pursuant to which Germany implemented the EU Product Liability Directive, 85/374/EC ("the Directive") into national law, and (ii) a fault-based liability system under the law of tort. In addition, a special liability regime applies to medicinal products (pharmaceuticals) under the Federal Drug Act.

There is no theory of implied warranties which could provide the end-user with a direct (quasi-) contractual claim against the producer. Thus, contractual liability only plays a role in the relationship between the end user/consumer and the final seller, and between the members of the supply chain (e.g. in case of redress).

The strict liability regime under the PLA

The PLA sets out three core requirements for establishing liability on the part of the producer: a product defect; damages; and a causal link between these two. All three elements must be proven by the claimant (see question 2.1 below). While liability is not fault-based, the PLA provides the producer with a number of pertinent defences, including a state of the art defence (see question 3.1 below).

Pursuant to the PLA (as is also the case under the fault-based liability system under the law of tort), a product is defective if it does not provide "the safety one is entitled to expect", taking all circumstances into account, e.g. the presentation of the product, the reasonably expected use and the time when the product was put into circulation.

Under the PLA, compensation can be sought for personal injury as well as for damage to goods or property. However, a number of limitations apply: the producer can be held liable for damage to goods or property but not for damage to the defective product itself. Furthermore, damage to goods or property used in a business context is not recoverable under the PLA (e.g. a product defect in industrial machinery which causes the factory building to set on fire). Only damage to goods or property for private use is recoverable; however, the first EUR 500 of any claim is not recoverable by the claimant.

Liability in tort

While nowadays most product liability claims are based on the PLA, the fault-based liability system continues to play a role in legal practice where compensation is sought for damages which are not recoverable under the PLA or to overcome the limitations and liability caps under the PLA. For instance, while not recoverable under the PLA, damage to goods or property used for business purposes can be recovered under tort law. Also, the first EUR 500 of any claim is not irrecoverable where compensation for damage to privately used goods or property is sought (as is the case under the PLA).

Further, the fault-based liability regime comes into play where a producer may be able to defend a product liability claim under the PLA on the basis 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 (see question 3.1). In such circumstances, compensation may be sought on the basis that the producer breached its duties to recall the product once the defect had been discovered post-marketing (see question 1.4).

While liability under tort law is fault-based and thus linked to a negligent breach of a duty of care, the burden of proof is typically placed upon the producer, i.e. the producer has to prove that it fulfilled its duty of care (see question 2.1).

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

There is no general public compensation scheme to cover damage caused by defective products or by particular categories of products. However, a compensation scheme effectively applies as part of the social security system for accidents in the work place or occupational diseases (e.g. caused by exposure to asbestos).

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, liability principally rests upon "the producer", *i.e.* the manufacturer. However, the importer of the defective product into the European Economic Area (EEA), or the producer of a defective component part or raw material, can be held liable in the same manner as the producer of the end-product. Furthermore, an own brander (*i.e.*, a party which, by affixing its name, trademark or other distinguishable sign to a product, gives the impression of being the producer of the product) is also liable as a producer (a so-called "quasi-producer"). If the producer cannot be identified,

each supplier (e.g. retailer, distributor or wholesaler) is treated as being the producer unless the supplier informs the injured person of the identity of the producer or of its own supplier within one month of being asked. The same applies if the EEA-importer cannot be identified, even if the identity of the producer outside the EEA is known.

Under the liability regime in tort, liability rests upon anybody who caused or contributed to a damage by a breach of his/her duty of care. This can, in principle, apply to any member of the manufacturing and supply chain. However, different duties of care of course apply depending on the role within the manufacturing and supply chain and the individual circumstances of each case. For example, a retailer can only be held liable for damages caused by a defective product in extraordinary circumstances (e.g. if the retailer sold the product despite knowledge of its 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?

The producer can be held liable for any damage caused by a breach of its post-marketing surveillance duty, including a failure to recall. In this regard, far-reaching duties apply under tort law but also as a matter of public law, in particular under the Product Safety Act which implemented the EU General Product Safety Directive, 2001/95/EC into national law.

If a producer discovers that products which he has put into circulation may pose unacceptable risks, he must take appropriate action to eliminate or mitigate these risks. In accordance with the principle of proportionality, these measures can often be limited to issuing warnings or instructions as to how to use the product safely. However, where a serious safety hazard cannot be appropriately eliminated or mitigated by issuing such warning or safety instructions, the producer may be under an obligation to initiate a recall.

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

The supply of defective products as such does not typically give rise to criminal liability. Criminal charges can, however, be brought for personal injury or causes of wrongful death. Criminal liability in this context is personal liability, *i.e.* it is incurred by the managers or staff of the company who have caused or contributed to the injury or death by a culpable breach of their individual duties of care.

While there is no corporate criminal liability in the context of product liability, a company can be fined for administrative offences. Also, in certain circumstances, a court can order that any excess profit which a company has gained by selling defective products must be paid to the government.

2 Causation

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

Under both liability regimes, the claimant has to prove that the product is defective and the damage that such defect has caused. Both must be proven to the satisfaction of the court and the standard of proof in this context is "beyond reasonable doubt". However, the producer has the burden of proof with regard to any defences it claims under the PLA (see question 3.1).

While liability under the law of tort is fault-based and thus linked to a negligent breach of a duty of care, the burden of proof is typically placed on the producer, *i.e.* the producer has to prove that it complied with its duty of care. A producer can thus defend a product liability claim by proving that its production process, including quality control processes, complied with the state of the art processes at the relevant time. In this way, the producer can avoid liability for any "outliners", *i.e.* manufacturing defects which occur despite application of state of the art processes. The courts have, however, set high thresholds for such a defence, and no such defence is available for manufacturing defects under 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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

Under both product liability doctrines, the burden of proof with regard to causation rests upon the claimant. Causation must generally be proven beyond reasonable doubt (see question 2.1). However, *prima facie* evidence can apply in favour of a claimant if the damage is a typical result of the product defect. If, however, the producer is able to prove a possible alternative cause for the damage, such *prima facie* evidence will no longer be sufficient to satisfy the burden of proof placed on the claimant. For a product recall, it is sufficient that a product can cause injury so that proof of an actual injury is not required. Further, it is not required that a specific product actually malfunctions as long as a malfunction is potentially possible in all products of a batch.

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 or similar doctrine under German law. Where more than one product caused or contributed to the damage, the producers will be jointly and severally liable for the damage (see question 3.5).

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 be the basis for a claim under both liability

regimes. A product is considered defective if it does not provide the level of safety which one is entitled to expect. Among other aspects, the legitimate safety expectation of course depends on any warnings and instructions for use which have been supplied along with the product. However, the producer does not need to warn of risks that are obvious or a matter of common knowledge.

Neither of the two liability regimes acknowledges any concept of a "learned intermediary". The producer can generally not rely on a third party to provide necessary safety warnings to the consumer/end user in its stead.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The producer can avoid liability under the PLA if it proves that:

- it did not put the product into circulation;
- the circumstances of the case justify the assumption that the product was free from defect when it was put into circulation;
- it did not manufacture the product for sale or another form of distribution with an economic intent;
- the defect was due to compliance with mandatory regulation at the time the product was put into circulation; or
- the state of scientific and technical knowledge at the time when it put the product into circulation was not such as to enable the existence of the defect to be discovered (development risk defence).

Furthermore, a producer of a component part is not liable if it proves that the defect is attributable to the design of a product in which the component part has been fitted or to the instructions given by the producer 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?

A state of the art/development risk defence is available under the PLA (see question 3.1). However, this defence only applies to defects in the design of the product and not to manufacturing defects. Under both liability regimes, the burden of proof is placed on the producer.

No state of the art defence applies under the special strict product liability system for pharmaceutical products under the Federal Drug Act.

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?

There is no general principle that compliance with regulatory or statutory requirements constitutes a defence for the producer. An exception applies in the rather theoretical case that the producer is able to prove that the defect itself was caused by compliance with mandatory regulatory or statutory requirements.

While compliance with regulatory or statutory requirements does not constitute a defence as such, these requirements can usually be considered in order to determine the level of legitimate safety expectation, the relevant state of the art processes and the standard of care to be applied by a producer.

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 is conclusive as between the parties to the proceedings (and their successors), and the parties cannot bring the same matter in front of a judge for a second time (*res iudicata*). No estoppel, however, applies with regard to proceedings between other parties even if they share the same issues. The judge of the second proceeding is not bound by the findings of the court in the previous proceeding nor by its assessment of the evidence.

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 parties which have contributed to the damage are jointly and severally liable and can thus make a claim for indemnity or contribution against the other parties. Contribution can only be claimed in subsequent proceedings. A defendant can file a third party notice to make sure that the findings in any adverse judgment against it are also binding upon the other parties in a subsequent proceeding for contribution.

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

Contributory negligence is a defence under all product liability regimes. The liability of the producer is limited if and to the extent that he can prove that the claimant negligently caused or contributed to the damage. In extreme cases, this can even lead to an exclusion of the producer's liability.

4 Procedure

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

Trial is always by judges. German civil procedural law does not provide for the involvement of a jury. Most cases in the courts of first instance will be decided by a single judge. A panel of three judges may decide specific cases, in particular more complex cases. In disputes between commercial parties, two laymen (with a professional commercial background) can act as judges alongside a legally trained judge. Their role would not be comparable to a jury as they would not act as fact finder but as judges, and would thus decide on legal questions as well.

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 German approach to presenting a case in court differs from

common law jurisdictions. The parties have to state the facts they rely upon in written submissions. Such submissions must state what evidence they suggest the court to take. The court will take evidence only for those facts which are disputed between the parties and which the court regards as relevant for its decision. If a party has suggested presenting evidence by way of an expert opinion, the court may appoint such an expert. After giving his/her written opinion, that expert can then be requested to attend an oral hearing and can be questioned by the court and 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?

German law does not recognise class or group actions. In particular, it is not possible to bring a claim for a class or group of unknown claimants. It is possible to join individual claims of identified claimants in a single proceeding. However, a judgment in such a proceeding will only bind these identified claimants and the defendant. There are some exceptions to these rules, in particular in securities litigation where courts can make legal findings in sample proceedings which can bind other claimants as well.

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

Theoretically, consumers can mandate a consumer association to bring claims against businesses on their behalf. This is only possible where the specific claims have been individualised and the consumer association would only be acting on behalf of the individual claimants. In a product liability context, such proceedings have rarely been used.

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

A trial will not start on a given day and then continue until the case is concluded, but rather consists of a series of oral hearings. Usually, a first oral hearing will be set within six months after a complaint has been filed. Such hearing would not normally last more than an hour. The court will then decide how many further hearings are required based upon its decision as to which facts necessitate the taking of evidence. There can be a gap of several months between hearings. Most civil cases in Germany's first instance courts will settle or will be decided by judgment within one year after the filing of the complaint. In complex product liability cases, this period can be significantly longer.

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?

German courts can decide preliminary issues first. This is often done when questions of jurisdiction are relevant. The courts are free to give preliminary decisions on other issues as well. For example, when causation and the amount of damages are both disputed, a German court can decide on causation first. The amount of damages can then be decided later. German courts do not often take such preliminary decisions.

4.7 What appeal options are available?

The appeal options in Germany depend on the value of the claim with which a party has lost. An appeal is only available where this value exceeds EUR 600, unless specifically admitted by the court of first instance. A further appeal to the German Federal Supreme Court is possible on questions of law only under limited circumstances where permission for this further appeal has been granted either by the court of second instance or by the German 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 mentioned above, the court can appoint an expert to give evidence on technical issues (see question 4.2). The parties have the possibility to file expert opinions together with their written submissions. If the conclusions of such experts are disputed, e.g. by a conflicting expert opinion by the other party, the courts will usually appoint an independent expert to give 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?

German law does not recognise any form of pre-trial discovery. Therefore, neither experts nor witnesses have to present themselves for deposition, nor are expert reports or witness statements exchanged prior to trial. However, each party has to submit the facts that it relies upon to the court in writing and has to also state which evidence the court may take to establish these facts if they are disputed and relevant.

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

Although no pre-trial discovery exists, parties in a proceeding in Germany would have to submit documents they wish to rely upon to the court as evidence along with their written submission. They do not have to submit documents which may harm their case, although false statements to the court may constitute a criminal offence.

Under specific circumstances, a party may demand that documents are disclosed by the other party. However, the demanding party would have to identify those documents specifically. Another option, which is relevant in particular for pharmaceutical product liability cases, is the claim for information according to § 84a of the Federal Drug Act. This section of the statute provides that a potential claimant may demand the disclosure of information by a pharmaceutical company in particular in relation to adverse events.

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

Alternative dispute resolution is available and recognised under German law. In particular, mediation conducted by court appointed mediators has become increasingly common. Arbitration is widely used in business litigation. Most product liability cases are still conducted in German state courts, as in most cases there will be

no arbitration agreement between the claimant and the defendant. On 1 April 2016, a statute was enacted that promotes alternative dispute resolution in consumer disputes. However, this scheme is not mandatory for consumers and businesses and only applies where a contract is in place, i.e. not in tort cases.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction be brought within the jurisdiction of your courts either as a defendant or as a claimant?

German courts have jurisdiction when the defendant is resident in Germany regardless where the claimant has its residence. Beyond this basic rule, there are several specific provisions which can establish jurisdiction over foreign defendants in Germany. Most relevant for product liability cases is that the courts have jurisdiction when a tort or a violation of the duties of the manufacturer under the PLA has occurred in Germany. To meet this requirement, either the actions causing the liability have to have taken place in Germany or the damage has to have occurred in Germany. In essence, any person resident in Germany and suffering damage in Germany in a product liability case can bring a claim against a foreign manufacturer in Germany. Furthermore, German courts can have jurisdiction based on contractual agreements.

5 Time Limits

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

A claim will be dismissed if the action is time-barred and the defendant invokes 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?

For the strict liability under the PLA, § 12 of this act provides for a statute of limitation. According to this provision, a claim becomes time-barred three years after a claimant should have become aware of the defect, the identity of the defendant and the damage it suffered. However, according to § 13 of the PLA, any claim under this act is time-barred 10 years after the product has been brought to market.

For claims based upon tort or contractual liability, the general statute of limitations in the Germany Civil Code applies pursuant to which the limitation period is three years. Such limitation period begins with the end of the year in which the claim has arisen and the claimant becomes aware of the circumstances upon which the claim may be based. For claims based upon an intentional bodily injury, the limitation period is 30 years.

In any event, any limitation period will end 30 years after the damage occurred, regardless of the knowledge of the potential claimant.

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

Fraudulent acts or concealment may hinder the ability of the claimant to establish knowledge regarding the defect and the potential defendant and thus delay the starting of the aforementioned three-year period. In no event will fraudulent concealment influence the above-mentioned 10-year period under the PLA or the 30-year period under the German Civil Code. In short, any claims in Germany will become time-barred 30 years after the damaging event, regardless of the knowledge of the claimant or any fraudulent acts of the potential defendant.

6 Remedies

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

Monetary compensation and injunctive/declaratory relief are all common in Germany. In product liability cases, monetary compensation is most common. German courts regularly do not grant a lump sum payment for future damages, but would rather grant damages to be paid in instalments.

In many cases, the relief in product liability cases will include a declaratory judgment declaring that the defendant has to bear all future costs arising from damages caused by a product.

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

In principle, there is hardly any limit to the type of damages recoverable. However, claims may have to be based upon different legal grounds. Under the PLA and under tort, damage to the defective product itself is not recoverable. Such damage would be recoverable under contract.

Damage to other property, as well as bodily injury and psychological damage, is in principal recoverable. It is difficult to establish a precise amount for psychological damages in particular. However, German courts can and will grant payments for non-material damages such as bodily injury and psychological damage as well.

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, medical monitoring costs are generally not recoverable.

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

Punitive damages do not exist under German 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 limit on the amount of recoverable damages under the German Civil Code. However, those statutes establishing strict liability provide for a maximum limit to the producer's liability. The PLA sets a limit of EUR 85 million for any damages to persons caused by the same defect. However, should the defect have caused damages to property other than the product itself, such limitation does not exist. Nevertheless, in these cases, only damages exceeding EUR 500 are recoverable.

A similar provision exists under the Federal Drug Act pursuant to which liability is capped for lump sum payments to EUR 600,000 and for annual pension payments to EUR 36,000 per claimant, and lump sum payments of EUR 120 million or annual pension payments of EUR 7.2 million for damages caused by one pharmaceutical 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?

As class or group actions do not exist under German law, no special requirements for settling such actions exist either. Any action in a German court can either be settled in court or out of court by agreement between the parties. Such an agreement does not need 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?

If a social insurance carrier has paid for treatment of an affected person or paid employment benefits to such a person, any claims of that person will have been transferred to that social insurance carrier. The social insurance carriers can and will enforce claims against the manufacturer. If, as part of a settlement agreement, an affected party obtains payments for damages covered by social insurance, the social insurance carrier would have a reimbursement claim against that person.

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 German law, the successful party is entitled to recover its costs. First of all, the advanced payment for the court fees, which has to be made by the claimant, is recoverable in full, if the claimant succeeds in full. If the claimant is only successful in part, it can recover the equivalent proportion of its advance payment of court fees. The same applies to any advance payments for witnesses or experts.

In addition, the successful party can also recover its attorney's fees from the losing party. However, such a reimbursement claim is limited to the statutory minimum fees.

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

Legal aid is available; however, it will be capped to the statutory minimum fees.

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

When applying for legal aid, a party would have to submit either its draft claim or the claim and its draft statement of defence together with information about its financial situation to the court. Only if the court finds that the potential claim or defence has merit will it grant legal aid.

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

Contingency fees are not permitted in Germany. In certain circumstances, a success fee can be agreed upon with a lawyer when it would not be possible to bring the case before courts without the agreement of a success fee. Such success fees are very rarely agreed upon in Germany.

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

There exists a wide range of insurances for legal costs which can cover product liability cases as well. Furthermore, third party financing for litigation also exists. However, this is usually only available for claims with a significant claim value.

7.6 In advance of the case proceeding to trial, does the court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

Although the successful party can recover its costs, the recoverable costs are limited to a statutory fee schedule of minimum fees. As the German legal systems do not know any form of discovery or disclosure, the costs of taking evidence in court cases is limited. Experts will be engaged by the courts and courts will usually monitor the costs of such experts.

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 your jurisdiction.

In the PIP breast implant scandal, TÜV Rheinland, a German provider of certification services which acted as the Notified Body for the French producer, was sued by a number of patients. Most courts held that TÜV Rheinland was not liable to the patients. Yet, upon submission by the German Federal High Court (Bundesgerichtshof, BGH), the European Court of Justice (ECJ) had to consider the scope of duties of a Notified Body under EU medical device regulation and whether a breach of any such duties constituted a tort that would entitle patients to hold the Notified Body liable for any injuries suffered as result of the breach. On 16 February 2017, the ECJ ruled that under the EU Medical Device Directive (93/42/EEC of 14 June 1993), a Notified Body is not obliged to carry out unannounced audits of a producer unless there are indications that the medical device may not comply with the requirements of the Directive. More importantly, however, the ECJ ruled that the duties of the Notified Bodies under the EU Medical Device Directive did serve the protection of the health and safety of the patients and users of the devices so that third parties could generally hold the Notified Body liable for damage caused by any breach of these duties under the laws of the respective EU Member State. The ECJ ruling is not only of interest to the medical device sector but will likely impact the role of Notified Bodies in the

many other areas of EU regulation which require a producer or EU importer to have its products or quality management systems certified for compliance with applicable standards by accredited service providers acting as Notified Bodies.

The German Federal Government plans to present a draft bill on a collective test case regime following the sectoral example of its Capital Markets Model Claims Act (KapMuG). Designated consumer associations shall have standing to bring a collective claim. Claimants can opt-in to such action via a plaintiff registry. Registration would interrupt the statute of limitation. The collective claim shall lead to the identification of test cases to litigate issues common to all claimants. A declaratory judgment in the test case would be binding on all claimants. While the draft bill is still subject of political debate (e.g. as to the minimum number of claimants required to bring a collective action), it is likely that Germany will see some form of new collective redress mechanisms in the near future.

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Philipp is member of IADC and DRI where he is the Country Chair for Germany and serves as Vice Chair of DRI's International Committee.

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Taylor Wessing is a leading international law firm with over 1,000 lawyers working across 26 offices in Europe, the Middle East and Asia, and with two representative offices in the USA. With a particular focus on the industries of tomorrow, the firm offers an integrated service across the full range of practice areas.

Taylor Wessing has one of the largest litigation and dispute resolution practices in Germany. The members of its product liability group have comprehensive experience in defending claims before German courts, as well as in the co-ordination of transatlantic and other international product liability cases.

Greece

Bahas, Gramatidis & Partners

Dimitris Emvalomenos

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 "Consumers' Protection" ("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 (articles 6 and 7). Moreover, Ministerial Decision Z3/2810/14.12.2004 ("MD") implemented EU Directive 2001/95/EC on "General Product Safety". Although the Consumers' Law has been amended several times, extensive amendments were introduced in 2007 (by Law 3587/2007).

The Consumers' Law establishes a strict liability regime, i.e. not fault-based. Article 6 para. 1 of the Consumers' Law provides that "the producer shall be liable for any 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 (established under the prevailing theory of "*causa adequata*"). However, this strict liability system does not preclude other liability systems providing a consumer with greater protection on a specific case (article 14, para. 5 of Consumers' Law). Such additional systems are:

- Contractual liability (articles 513-573 of the Greek Civil Code ("GCC") on contracts of sale of goods also incorporating Directive 1999/44/EC): this liability system requires a contractual relationship between the parties where the buyer must not necessarily be a consumer. The seller is strictly (irrespective of his fault) liable for the sold product's defects or non-conformity with agreed qualities at the time the risk passes to the buyer, the knowledge of the latter releasing the seller from liability under conditions, together with other reasons for such a release provided by law.
- Tortious liability (esp. articles 914, 925 and 932, together with articles 281 and 288 of GCC): although the claimant must establish the defendant's fault in tort claims, case law reverses the burden of such proof in favour of the claimant-consumer, based on the "theory of spheres", thus obliging the defendant to prove absence of fault to be released from liability.
- Criminal liability: derived from the Greek Criminal Code, Law 4177/2013 (Rules Regulating the Market of Products and the Provision of Services) and other special legal provisions (article 13a, para. 2 of Consumers' Law).

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

No, it does not; but under general law (articles 105 and 106 of the Introductory Law to GCC), the Greek State and entities of the public sector may be liable for unlawful actions/omissions of their organs in breach of their duties to safeguard the public's interests, including consumer interests.

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 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 the Consumers' Law and article 3 of the MD, producers are obliged only to 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?

Yes (see above under question 1.1).

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. 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 (see above under 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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

It is not enough for the claimant to generally allege that the defendant wrongly exposed the claimant to an increased risk of injury. A direct connection between the injury caused and the specific defect has to be established by the claimant. As per current case law, it is necessary to be proven that the product to which the claimant was exposed has actually malfunctioned and caused the claimant's 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?

By law, where more than one person is responsible for the same damage, their liability towards the person injured is joint and several whereas they have a recourse right against each other based on their contribution to the damage, this being a matter of proof (article 6, para. 10 of the Consumers' law and 926 of GCC).

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 adequate warnings for the risk evaluation of the specific product, and failure to do this may result in his liability, not only civil but administrative and criminal as well (article 7 of Consumers' Law and MD). The learned intermediary doctrine, although not provided for by law, may work on a particular case taking into account all the circumstances of it, as a defence to manufacturers of medicines and medical devices towards discharge from their duty of care to patients by having provided warnings to prescribing physicians. However, in the case where the use of the product, even according to the producer's guidance, bears a 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. Also, any intermediaries (e.g. doctors) have their own and separate obligations to consumers under the service liability rules (article 8 of Consumers' Law). In any event, a producer's liability is not reduced where third parties are co-liable (article 6, para. 11 of the Consumers' Law).

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 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 so-called *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 (point 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 (point 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 applies. In that respect, re-litigation by other claimants is possible.

The above rule is differentiated where a court's decision is issued following a collective lawsuit. As per the Consumers' Law (article 10, paras. 16 *ff.*), in such cases, the decision issued has an *erga omnes* effect, namely towards non-litigants as well, this being a very special characteristic under Greek law. The same decision has a *res judicata* effect in favour of any consumer damaged, even if they did not participate in the relevant trial, when it 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 a case where the producer does not compensate the consumer at issue within thirty (30) days, the latter may file a petition before the competent court asking for a judicial order to be issued against the producer. Further, individual consumers' rights are not affected by the collective pursuance of a claim, nor by a rejecting decision in the above 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?

The producer's liability cannot be limited due to the fact that a third party is also liable (see above under question 2.4), but the producer has a right of recourse in such a case which may be pursued as long as it does not become time-barred.

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

A 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. As a rule, justices of the peace are competent to examine claims up to €20,000; one-member first instance courts, claims between €20,000 and €250,000; and three-member first instance courts, claims exceeding €250,000 (articles 14 and 18 of the Greek Code of Civil Procedure – "GCCP").

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 (articles 368–392 of GCCP; see also below under 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?

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 questions 3.4 and 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 (article 10, paras. 16 *ff.*).

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

Under the legal regime, up to 31 December 2015, and as an average, an action under ordinary proceedings was fixed for hearing approximately between 18 and 24 months following its filing and the decision was issued six to eight (6–8) months after the hearing, provided that the initial hearing was not adjourned (one adjournment

being rather a practice). The above average times very much depend on the type of the court (see under question 4.1), as well as the place where it is located. To speed up proceedings, a new law was introduced in 2015 (Law 4335), in force as of 1 January 2016. Under the new regime (still to be tested in practice), the hearing is purported to take place around six to seven (6–7) months after the filing of a lawsuit (articles 215 & 237 of GCCP).

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, there are no separate proceedings especially for preliminary issues, such as on court's jurisdiction or competence, and same are dealt with at the time of the main trial, this being either the ordinary or injunction proceedings. However, where the court considers it important to be informed on foreign law or on specific scientific-technical matters, it may issue an interim order thereon.

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 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 from 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. The opinion of the court-appointed expert is not binding on the court. Additionally, the parties may submit to the court an unlimited number of expert/technical reports supporting their allegations. In practice, the reports of party-appointed experts are of lesser evidentiary value than those of the court-appointed ones.

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?

Factual or expert witnesses appointed by the parties may, instead of giving oral evidence before the court, give sworn depositions before a judge of a piece, a notary public or, if outside Greece, before a Greek consular authority. The opponent must be summoned to such depositions before two working days and he is entitled to obtain a copy prior to trial. Non-compliance to the procedural requirements renders the depositions inadmissible. There are restrictions to the number of sworn depositions (articles 421–424 of GCCP).

Court-appointed experts have to submit their reports at the time ordered by the court, adjourning the hearing for that purpose.

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 proceedings. Each litigant has to disclose all documents supporting his case (except from a serious reason) by his submissions filed at the specified time, depending on the court and kind of proceedings. The general principles of good faith, *bonos mores* and honest conduct apply (esp. articles 116 and 450 of GCCP). A litigant may request from the court to order disclosure of documents in the possession of his opponent or a third party under conditions (articles 450 *ff.* of GCCP and 901–903 of GCC).

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

Parties may choose (but are not obliged to opt for) mediation or arbitration as the means for resolving their disputes, even for actions pending before the court. Also, before initiating actions, they may voluntarily address the competent justice of the peace, asking for the latter's intervention in order for the dispute to be settled at an early stage (with very limited applicability) or recourse to judicial intervention (see more below under question 6.6).

Further, the 2013 EU legislation on alternative dispute resolution ("ADR") applies to Greece; specifically, Ministerial Decision No. 70330/30.6.2015 implemented ADR Directive 2013/11/EU and set supplementary rules for the application of ODR Regulation 524/2014. Registered ADR entities per the above Ministerial Decision are: a) the Consumer Ombudsman ("CO"), being the key ADR authority for consumers; b) the (sectoral) Ombudsman for Banking and Investment Services (also part of the FIN-NET for credit/financial trans-boundary disputes); and c) "ADR point", a private organisation.

Also, the following bodies/authorities exist for ADR, namely: i) the Committees for Friendly Settlement, initially managed by the local Prefectures, then supervised and overseen by the CO and as from 1.1.2011 managed by the local municipalities; ii) the Hellenic European Centre of Consumer, supported by the CO and regarding trans-boundary EU ADR; iii) the SOLVIT network regarding the improper application of Internal Market rules by the EU public administrations at a cross-border level supervised by the Ministry of Finance; and iv) the Citizen's Ombudsman, which deals with disputes between citizens (in general) and public authorities.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction be brought within the jurisdiction of your courts either as a defendant or as a claimant?

As a rule, any person, either Greek or non-Greek, is subject to a Greek court's jurisdiction, thus he may sue or be sued, provided a Greek court is locally competent to try the case (article 3 of GCCP). Such competence is determined by a rather detailed categorisation; among the various legal bases and regarding a tortious act, the one regarding the place where the event that caused the damage either took place or is to occur establishes competence, thus jurisdiction, of a Greek court (articles 22 *ff.* and esp. article 35 of GCCP). At EU level, one may also mention Regulation 44/2001 ("Brussels I"), as in force, as also being applicable to Greece.

5 Time Limits

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

Yes (see under 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?

For strict liability and according to article 6, para. 13 of 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 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.

In case of a collective lawsuit, it must be brought within six (6) months from the last unlawful behaviour challenged, unless the mere recognition by the court that an unlawful act had taken place is sought, where the general five- (5-)year prescription period for torts applies (article 10 para. 18 of the Consumers' Law).

For a claim in tort, a general five- (5-)year prescription period applies, whereas the claim is in any case extinguished twenty (20) years from the date of the tortious act (article 937 of GCC).

Contractual liability claims under a contract of sale of goods are time barred after two (2) years for movables and five (5) years for immovable property, whereas further detailed regulation applies (articles 554-558 of GCC).

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

The Consumers' Law does not contain specific provisions. Article 6, para. 13 sets, as the starting point from which the time limitation runs, the day on which the plaintiff became aware or should 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.

Under the contract of sale of goods provisions, the seller's concealment or fraud deprive him from invoking prescription (article 557 of GCC).

6 Remedies

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

Monetary compensation under civil proceedings is available to the victim (see below under question 6.2). Criminal or administrative proceedings possibly pursued as well do not aim at compensating the victim. Especially under a collective claim, consumers' associations may ask: a) that a producer abstains from an 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 consumers' right to restore the damage caused to them by the producer's unlawful behaviour (article 10, para. 16 of the Consumers' Law).

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 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 by the defective product to any consumer's asset other than the defective product itself, including the right to use environmental goods, provided that i) the damage exceeds €500, and ii) the product was ordinarily intended for and actually used by the injured person for his own private use or consumption. Compensation for moral harm or mental distress (to the family of the deceased) may also be claimed.

Under a claim in tort, full damages may be recoverable (article 914 *ff.* of GCC).

Lastly, under contractual liability (sale of goods), the buyer may request (esp. articles 540-543 of GCC): a) repair or replacement of the defective product; b) a reduction of the consideration; c) rescission of the contract; and/or d) compensation, under conditions.

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 provided actual damage suffered by the consumer is proven.

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

No. In collective claims, however (see above under question 6.1), the way they are structured, including 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 closer 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?

Yes, although they are rarely applied by the interested parties. An option is a party's referral to a justice of the peace prior to the filing

of a lawsuit for the latter's intervention in order to try and obtain a settlement (article 209 *ff.* of GCCP). Another option is a settlement between litigants until the issuance of a final decision and provided the substantive law requirements (see below) for the same are met; such settlement may or may not be certified by the court, as per the litigants' choice (article 214A of GCCP, as in force). Another alternative was introduced in 2012, titled "judicial intervention"; actually, it is an extension of the old justice of the peace intervention and it provides for a permanent mechanism set up in each court of the first instance where nominated judges may assist the litigants to reach a settlement, if the parties choose so (article 214B of GCCP). Additionally, the court may propose to litigants recourse to judicial intervention and, if accepted by them, the hearing of the case is adjourned for three months (new article 214C of GCCP in force as from 1.1.2016).

On substance, the 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 a case where the claimant received the amount of damages awarded or settlement paid 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 duty; c) counsels' minimum fees set by the Greek Lawyers' 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, whereas the court very often sets-off the expenses between the litigants on the basis of complex legal issues involved in the litigation (article 173 *ff.* of GCCP).

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

Yes. Law 3226/2004 on the provision of legal aid to low income citizens (implementing Directive 2003/8/EC) sets the relevant requirements, together with articles 194 *ff.* of GCCP.

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

As per Law 3226/2004, 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 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.

Further and as per the GCCP, legal aid in civil and commercial matters purports to an exemption from the payment of part or all 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 primarily stamp duty payment and judicial revenue stamp duty. Also, the beneficiary is exempt from paying the remuneration of witnesses and experts and the lawyer's, notary's and judicial bailiff's fees.

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

Yes. Contingency fees and other conditional arrangements are allowed between clients and lawyers as per the Lawyers' Code under the basic restrictions that they are made in writing and the maximum fee percentage agreed may not exceed 20% of the subject matter of the case at issue (or 30% if more than one lawyers are involved). Further detailed regulation is provided by the Lawyers' Code (article 60 of Law 4194/2013).

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

No, it is not.

7.6 In advance of the case proceeding to trial, does the Court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

No, it does 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 your jurisdiction.

a) The Consumers' Law has been amended several times (see above under question 1.1). Important changes introduced in 2007 on the product liability rules were: a) the expansion of the defectiveness concept to not only include the standard *safety* consideration, but to also take into account the product's "expected performance per its specifications"; b) the subjection of the moral harm and mental distress compensation to the ambit of the strict product liability rules (formerly covered under the general tort legislation); and c) new rules on collective actions to the extent they concern product liability infringements.

In 2012, the right to bring collective actions under the Consumers' Law was extended to other EU Member State entities authorised for this, as per the respective list provided for by Directive 2009/22/EC (article 10, new para. 30 of Consumers' Law).

Further, in 2013 and 2015, changes were introduced, among others, to the financing of consumers' organisations, the sanctions that may be imposed for non-compliance with its provisions, and the categorisation of complaints filed under it (articles 10, 13a & new article 13b of Consumers' Law).

Overall, there is a continuing trend towards increased consumers' rights and sanctions for relevant breaches.

b) Also, a trend towards ADR for the avoidance of litigation may be seen in the 2012 amendments to the Civil Procedural Rules, enforced by the 2015 ones (see above under question 6.6); such trend is also mirrored in the 2012 enactment of additional regulation regarding entities that pursue ADR (new article 11a of Consumers' Law implementing EU Commission's Recommendations Nos 98/257/EC and 2001/310/EC).

This trend is broader in Greek law (see above under question 4.11) and within the same frame one may also note Law 3898/2010 which implemented Directive 2008/52/EC "on certain aspects of mediation in civil and commercial matters".

However, thus far, application of ADR remains limited.

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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 Offices of Athanassios Felonis & Associates and 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 on business in Greece, from commercial regulatory matters to regulatory compliance. The Firm has developed a unique expertise in product liability/safety recognised worldwide. The Firm is a part of an established network of contacts promoting, among other topics, product liability and related issues such as 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

David Goh

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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?

Hong Kong does not yet have a specific legal regime relating to product liability, particularly in relation to civil proceedings, nor does it have a statutory regime of "lemon law" or strict liability regime as in some other countries, such as the United States.

A product liability claim is found within the existing laws of contract and tort. Civil liability arises under the tort of negligence for a breach of a duty of care, breach of contract for failure to comply with the terms of the contract, or breach of statutory duty (such as under the Sale of Goods Ordinance (Chapter 26 of the Laws of Hong Kong)) for supplying a product that does not meet specific requirements imposed by statutes.

The main legislation in this area includes the Consumer Goods Safety Ordinance (Chapter 456 of the Laws of Hong Kong), the Control of Exemption Clauses Ordinance (Chapter 71 of the Laws of Hong Kong), the Sale of Goods Ordinance, the Toys and Children's Products Safety Ordinance (Chapter 424 of the Laws of Hong Kong), the Pharmacy and Poisons Ordinance (Chapter 138 of the Laws of Hong Kong), and the Dangerous Goods Ordinance (Chapter 295 of the Laws of Hong Kong), which considerably improve the position of consumers.

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

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

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

Under the Sale of Goods Ordinance (Chapter 26 of the Laws of Hong Kong), the contracting party, usually the retail supplier, is liable to the buyer for the defective products. However, the manufacturer, the importer and/or the distributor could also be liable in tort.

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?

Section 9 of the Consumer Goods Safety Ordinance (Chapter 456 of the Laws of Hong Kong), for instance, states that the Commissioner may serve on a person a notice requiring the immediate recall of consumer goods that do not comply with the approved safety standard. Section 22 of the same ordinance provides that non-compliance with such notice would constitute an offence. The penalties are set out in section 28.

Similarly, for safety reasons, recalls of electrical products and food may be required under the Electricity Ordinance (Chapter 406 of the Laws of Hong Kong) and the Public Health and Municipal Services Ordinance (Chapter 132 of the Laws of Hong Kong), respectively.

As for voluntary recalls, there are guidelines issued by the Government for those who wish to carry out a voluntary recall of certain products, e.g. consumer goods, toys and children's products.

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

Yes. Criminal liability for defective products in Hong Kong is established by statutory provisions. For example, section 6 of the Consumer Goods Safety Ordinance (Chapter 456 of the Laws of Hong Kong) provides that a person shall not supply, manufacture, or import into Hong Kong consumer goods unless the goods comply with the general safety requirement or the applicable approved standard for those particular consumer goods. Punishment for an offence may be by way of a fine, imprisonment, or both. A person who is found guilty under the provisions of the Consumer Goods Safety Ordinance is liable for a fine at level 6 (i.e., HK$100,000) and for imprisonment for one year upon the first conviction, and a fine of HK$500,000 and imprisonment for two years upon any subsequent conviction.

2 Causation

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

The burden of proving fault or defect and damage lies with the claimant. In a civil case, a party must prove a fact in issue on a "balance of probabilities". This means that the claimant's evidence must prove that it is more probable than not that the fault/defect occurred and damage suffered is due to the fault/defect.

However, it is open to the claimant to invoke the doctrine of *res ipsa loquitur*. The requirements are: (1) the injury is of the kind that does not ordinarily occur without negligence; (2) the injury is caused by an agency or instrumentality within the exclusive control of the defendant; (3) the injury-causing accident is not due to any voluntary action or contribution on the part of the plaintiff; or (4) the defendant's non-negligent explanation does not completely explain the plaintiff's injury. Once the court accepts that this doctrine applies, the onus of proof is shifted to the defendant to rebut the inference of negligence.

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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

To claim under the Sale of Goods Ordinance (Chapter 26 of the Laws of Hong Kong), the claimant must prove a causal link between the defect and breach of implied terms, that "but for" the defect, the plaintiff would not have sustained the injury or damage and that the injury or damage incurred is not, in law, too remote a consequence of the defect.

On causation in fact, the claimant must prove that the defendant's negligence has caused his loss; whilst on causation in law, the loss suffered must be one that is not too remote from the breach of the defendant's duty of care.

It is necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury or loss to the claimant. It is insufficient to show that the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction.

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 claimant is required to identify the manufacturer and prove that it was responsible for the defect. The failure of proving such allegation will result in the claim being dismissed. The concept of "market-share" does not exist 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?

Manufacturers and suppliers owe a duty of care to consumers to adequately warn and advise the use of products manufactured and supplied. It is largely a question of fact if adequate warning has been given to an intermediary or a consumer. However, certain law imposes obligation on the requirement of warning; for example, section 7 of the Consumer Goods Safety Ordinance (Chapter 456 of the Laws of Hong Kong) gives power to the commissioner to serve a notice to require a person, at his own expense and by his own arrangement, to publish a warning that the consumer goods may be unsafe unless the steps specified in the notice are taken, in the form and manner and on such occasions as may be specified in the notice. Failure to comply is an offence.

There is no principle of "learned intermediary" under Hong Kong law.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Apart from the defences that are available under the usual principles of contract and tort law, a manufacturer or supplier may avoid liability by establishing that: (1) the manufacturer or supplier was not negligent or the damage was not one that is foreseeable, and that even if it had taken all reasonable care, the defect could not have been prevented; (2) the claimant was, at all material times, aware of the risks associated with the product and chose to accept those risks (the defence of *volenti non fit injuria*); (3) there was contributory negligence or fault on the part of the claimant; or (4) the causal link was broken by a supervening act, and that act is the sole effective cause of the damage. The manufacturer can also rely on the state of the art defence (see 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?

Yes, there is a state of the art/development risk defence. The manufacturer can rely on the defence to establish, on the balance of probabilities, that it exercised all reasonable care and precautions in light of the state of scientific and technical knowledge at the time of distribution. Generally, it is for the claimant to prove that the fault/defect was discoverable once the manufacturer successfully raises this 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?

Compliance with mandatory standards or requirements with respect to the alleged defect is a viable defence. However, when taking into account that the intention of the legislation is to protect personal safety or property, the court may still be persuaded to judge that a product is defective even if it complies with the national standard.

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 of estoppel preventing a different claimant from bringing an action against a defendant in separate proceedings. However, if a separate court has considered the same issue of fault and/or defect, such judgment would be persuasive and may provide an indication on the chances of success in similar claims, provided they share the similar 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?

Yes. According to section 3 of the Civil Liability (Contribution) Ordinance (Chapter 377 of the Laws of Hong Kong), 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 occurred.

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

Yes. Defendants may allege that the claimant's actions or negligence have caused or contributed towards the damage.

4 Procedure

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

Except for defamation cases, all civil trials in Hong Kong are heard by a judge without 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 courts in Hong Kong have the power to appoint their own experts through Order 40, Rule 1(1) of the Rules of the High Court (Chapter 4A of the Laws of Hong Kong), upon the application of a party to the action. However, there have been few applications under this order. In practice, it is up to the parties to come forward with their own proposed appointments, and the parties are usually given the opportunity to oppose the appointment of expert candidates or to make recommendations to the court on the experts they wish to appoint, based on the knowledge or experience of the 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?

The sole machinery for dealing with multi-party proceedings in Hong Kong is a rule on representative proceedings, whereby a claimant may bring a representative action on behalf of a group of claimants where those claimants have the same interest in the proceedings. A judgment of order given in representative proceedings will be binding on all persons so represented. However, claims cannot be brought by a representative body (e.g. a consumer association) on behalf of claimants. Parties may also choose to have their cases consolidated or heard together. The court may also order that cases be consolidated and tried at the same time if it appears to the court that the matters have some common question of law or facts, the rights to relief claimed therein arise out of the same transaction or series of transactions, or for some other reasons it is desirable to do so. Nevertheless, all claims (even after consolidation) remain individual actions in their own right.

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?

The time to take a case from commencement of proceedings to judgment varies greatly depending on the nature, size and complexity of the proceedings. However, a relatively straightforward civil litigation action, involving witnesses of fact and expert witnesses, may take approximately one to two years from commencement of proceedings to judgment at first instance.

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 try preliminary issues that relate to both facts and law.

4.7 What appeal options are available?

Generally, an appeal lies as of right from a decision on a final matter from a Court of First Instance Judge to the Court of Appeal. However, no appeal against the following decisions in a civil case can be made: (1) a decision of a judge in the District Court; (2) a decision of a judge of the Court of First Instance in an interlocutory matter; and (3) an appeal against the decision of a Court of First Instance judge solely on the question of costs, unless leave to appeal has been granted.

An application for leave to appeal should be made to the judge or master of the respective court who gave that decision. If the judge refuses to grant leave, the party may further apply to the Court of Appeal for leave to appeal within 14 days from the date of such

refusal. The Court of Appeal may give leave on such terms as to costs, security, etc. as it deems fit. The decision of the Court of Appeal on whether to grant or refuse leave is final and not appealable.

If the party is not satisfied with the decision of the Court of Appeal, he or she may lodge an application for leave to appeal to the Court of Final Appeal. The type of cases that can be heard by the Court of Final Appeal for civil matters is appeal at the discretion of the Court of Appeal or the Court of Final Appeal if, in the opinion of either court, the question involved in the appeal is one which, because of its great general or public importance, or otherwise, ought to be submitted to the Court of Final Appeal for decision.

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?

Yes, the court can appoint experts to assist it in considering technical issues, but usually the court prefers parties coming forward with their own proposed expert appointments, and the parties can each appoint their experts. Each expert called by a party is subject to cross-examination by the other parties if the opinions of the experts diverge. Each expert should only address the specific issue of which they are asked to give their expert opinion. The court will not accept evidence provided by the expert of matters in which he/she is not an 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 pre-trial deposition in Hong Kong.

Witness statements and expert reports are generally exchanged prior to trial. Factual and expert witnesses may be required to present themselves at the hearing or trial if any party wishes to cross-examine them on their statements or reports.

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 can seek discovery of all relevant documents and facts relating to the matters in questions in the action. It is possible to apply for discovery before commencement of proceedings, but usually discovery is done after the pleadings have closed. Discovery may continue up to trial.

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

Since the Civil Justice Reform came into force on 2 April 2009, under the Practice Direction 31, parties are required to go through mediation in the litigation proceedings right after filing the statement of claim. Parties may also agree to use mediation to resolve a dispute. Similarly, parties may arbitrate a dispute if they agree to do so.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction be brought within the jurisdiction of your courts either as a defendant or as a claimant?

A claimant can generally issue a claim in the Hong Kong courts unless the jurisdiction is challenged by the defendant. Where a defendant, whether a real person or a legal entity (such as a company), is domiciled overseas and has no real presence in Hong Kong, upon the application of the claimant, the court may grant leave for a defendant to be served with proceedings. The kind of matters the court can handle is very broad – see Order 11 rule (1) of the Rules of the High Court (Chapter 4A of the Laws of Hong Kong). There are similar provisions the Rules of the District Court (Chapter 336H of the Laws of Hong Kong). In particular, this includes matters involving breach of a contract made in Hong Kong or a claim for damages in Hong Kong for breach of Hong Kong law and for a claim in tort, where the damage was sustained or resulted from an act committed in Hong Kong.

5 Time Limits

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

Yes; and the time limits depend on the cause 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 Ordinance (Chapter 347 of the Laws of Hong Kong) provides that no action in contract or tort may be brought after the expiration of six years from the date on which the cause of action accrued.

In any action for damages for negligence, nuisance or breach of duty that results in personal injuries, the time limit for bringing an action is three years from the date on which the cause of action accrued or the date (if later) of the claimant's knowledge.

For latent damage other than personal injuries, the period is either six years from the date on which the cause of action accrued or, if later, three years from the date when the claimant had the necessary knowledge required to bring an action for damages in respect of the relevant damage. However, there is a long stop of 15 years from the date the cause of action accrued.

Generally, the age or condition of the claimant has no effect on the calculation of time limits and the court rarely exercises its discretion to extend the time limits.

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 discovered the fraud, concealment or mistake, or should have, with reasonable diligence, discovered it.

6 Remedies

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

Monetary compensation, injunctive 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?

In an action in contract, damages are intended to place the claimant in the position he or she would have been had the contract been properly performed. This entitles the claimant to compensation for loss that arises as a natural result of breach of contract. In addition, such damages must have been contemplated at the time the contract was formed by the parties to be likely to result from a breach.

To claim under tort, the underlying principle of an award of damages is the same as in the contract law. In tort claims, losses arising from personal injury (including mental injury), death or damage to property other than the product itself are recoverable. As for pure economic loss (financial loss suffered by a claimant that does not flow from any damage to his own person or property), the courts have taken a conservative approach in determining the scope of liability of a wrongdoer and such loss is normally irrecoverable unless it is fair 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?

To succeed in a claim, the cause of action and damage need to be proven. In circumstances where the product has not yet malfunctioned and caused injury, it is an uphill task to convince the court to award damages. The court may find that the medical monitoring costs are too remote and refuse to make such an award.

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

Punitive damages, also referred to as exemplary damages, are designed to punish and deter the wrongdoer. Unlike the United States, punitive damages are available only in very limited circumstances. The three key considerations for which punitive damages may be awarded are: (1) oppressive or arbitrary or unconstitutional acts by government servants; (2) the defendant's conduct has been calculated to make a profit for himself which might well exceed compensation payable to claimants; and (3) an express statutory provision. In practice, the Hong Kong courts hardly, if ever, award exemplary 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, there is no maximum 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?

Generally, as long as parties are agreeable to settlement, court approval is unnecessary. However, for claims by infants, the approval of the court is required and there is a specific procedure governing this.

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 such claim by the Government authorities is contemplated under Hong Kong law.

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 payment of costs in Hong Kong is a matter at the discretion of the court. The practice is generally in line with the "loser pays rule" under the common law system. That is, an unsuccessful party is liable to pay the successful party's reasonable legal fees and expenses incurred during litigation.

Under the Rules of the District Court (Chapter 336H of the Laws of Hong Kong) or the Rules of the High Court (Chapter 4A of the Laws of Hong Kong), where a sanctioned offer/payment is accepted, that party accepting the sanctioned offer/payment is entitled to costs of action up to the date of serving the notice of acceptance.

However, if a party refuses a sanctioned offer/payment and at trial fails to do better than the sanctioned offer/payment, the court may: (a) disallow all or part of the interest otherwise payable in respect of the period after the latest date on which the sanction offer/payment could have been accepted; (b) order the refusing party to pay the other party's costs, on an indemnity basis, from the latest date on which the sanctioned offer/payment could have been accepted; and (c) order interest on those costs at a rate not exceeding 10% above the judgment rate.

In the event of a dispute as to the amount of legal costs, parties may apply for taxation during which a judicial officer reviews the costs accrued by the successful party and assesses the costs to be reimbursed by the unsuccessful party.

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

Yes, legal aid is available to any person in Hong Kong except for proceedings expressly excluded under the Legal Aid Ordinance (Chapter 91 of the Laws of Hong Kong) (such as defamation proceedings, relator actions, election petitions and proceedings where the only question before the court is the time and method of payment for debt and costs). Legal aid covers civil proceedings in the District Court, High Court, Court of Final Appeal and Lands Tribunal. It also covers costs of representation by a solicitor and counsel (if necessary).

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

Generally, legal aid is available to any person in Hong Kong, regardless of whether that person is a resident or non-resident of Hong Kong.

To be eligible for legal aid, the applicant must satisfy the Director of Legal Aid of his or her financial eligibility and the merits of the case. Depending on the amount of damages successfully recovered, an aided person may be required to reimburse all or part of the legal costs incurred or expenses paid by the Legal Aid Department on his or her behalf.

Potential defendants may submit an application to contest the grant of such aid, either to the Director of the Legal Aid at any time or to the court at any time during the proceedings. In such an event, the person receiving legal aid has to be given an opportunity to provide reasons why the certificate should not be revoked, or, as the case may be, discharged.

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

In Hong Kong, contingency or conditional fee arrangements with lawyers are not permissible.

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

For public policy reasons, third party litigation funding is not allowed. However, a fairly recent court case that highlighted two categories excluding the application of public policy – "common interest category" and "access to justice consideration" – seems to suggest that the court may choose to adopt a more liberal attitude towards the support of litigation by third parties in the future.

7.6 In advance of the case proceeding to trial, does the court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

The assessment of costs is at the courts' discretion. The court does exercise control over the costs to be incurred by the parties so that it is fair and proportionate to the value of claim. Increasingly, courts are taking the initiative to ensure costs are reasonable and appropriate through pre-trial hearings and other occasions when parties are before the court.

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 your jurisdiction.

The continuing increase in higher expectations of product safety has led to greater awareness of and demand for consumer protection among consumers in Hong Kong. However, the prohibition of contingency fees or conditional fee arrangements with lawyers, and the rarity of punitive damages awards render it unlikely that consumers would receive large windfalls in the event of favourable judgments. In November 2009, the Class Actions Sub-committee of the Law Reform Commission ("Sub-committee") published a consultation paper ("Paper") seeking the public's view on proposals to introduce a comprehensive regime for multi-party litigation. In the Paper, the Sub-committee stresses the limitation of the "same interest" requirement, namely that few actions could be brought under the representation actions rule. The courts sought ways to relax the requirements in various cases so as to make it easier to bring representative proceedings by (a) moving from the "same interest" test to a "common ingredient" test, (b) making the existence of separate contracts no longer a hindrance to establishing the requisite "same interest" element, (c) allowing separate defences against different class members to be raised, and (d) allowing damages to be awarded in representative actions. To reduce the risk that a class actions regime might encourage litigation, the Sub-committee recommends a mechanism (such as via certification by the court) to filter out unsuitable cases, to implement rules to ensure the system is fair, expeditious and cost-effective, and to adopt an "opt-out" approach. The draft law on class action, once introduced and promulgated, will considerably promote access to justice to small consumers.

The trend in Hong Kong appears to be following the worldwide tendency towards imposition of much more comprehensive regulation in the areas of consumer protection; suggestions to legislate strict product liability and draft Consumer Protection Law. However, given the lack of consumer activism, it is unlikely that a specific legal regime for product liability will be formed in Hong Kong in the immediate future.

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David Goh has more than 20 years' experience in large, complex and international commercial disputes, with particular emphasis on corporate issues (such as shareholders' rights and directors' duties) and product liability matters. He also advises clients on regulatory matters, compliance and antibribery/corruption cases, including the Foreign Corrupt Practices Act and the UK Bribery Act. His experience includes leading or coordinating investigations on behalf of both corporations and regulators, as well as advising or acting in the defence of any prosecutions.

In his more recent roles in senior management at various multinational corporations, David developed significant experience in handling corporate and commercial matters, in particular, M&A transactions across the Asia Pacific region. He has developed proven methodologies in assisting companies to coordinate and manage their in-house and external legal service and continues to be consulted on such matters.

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Bindu Janardhanan's main area of practice is dispute resolution and arbitration. In her more recent roles, she has focused on the defence and coordination of complex product liability cases, especially for a large German automobile manufacturer. Bindu has also defended commercial and other legal disputes. In addition, Bindu has significant experience in banking, finance and intellectual property matters in Hong Kong and India. She has advised financial institutions and other companies on their documentation in various sectors in Hong Kong and India. She has extensive knowledge of the Indian markets and has built up an excellent network with many Indian and overseas leading law firms, banks and investment houses. She is an active member of the Indian legal and business community. Her international background, knowledge of many Indian languages and understanding of foreign cultures and business practices, combined with hands-on litigation acumen, uniquely qualifies her to advise and defend multinational companies. In addition to her legal qualifications, Bindu also holds a master's degree in business administration (with honours) from a prestigious business school in India.

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Chapter 17

India


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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 India, product liability law governs the liability of manufacturers, wholesalers, distributors, and vendors for injury to a person or property caused by dangerous or defective products.

Product liability in India is governed by:

a) The Consumer Protection Act, 1986.

b) The Sales of Goods Act, 1930.

c) The law of Torts.

d) Special statutes pertaining to specific goods.

Previously, the Monopolies and Restrictive Trade Practices Act, 1969 (hereinafter referred to as the "MRTP Act") dealt with provisions in respect of unfair trade practices. The Act now stands repealed and the pending cases of unfair trade practices have been transferred to the National Commission set up under the Consumer Protection Act, 1986.

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?

Any person who trades in the goods (manufacturers, importers, distributors, wholesalers, etc.) may be made liable under Indian law.

As per the Consumer Protection Act, the definition of trader (Section 2(1) (q)) and manufacturer (Section 2(1) (j)) is exhaustive and includes: any person who sells or distributes any goods for sale; manufacturers; assemblers; dealers; or any person who causes his or her own mark to be put on any goods made or manufactured by any other manufacturer and claims such goods to be goods made or manufactured by himself or herself.

Bearing in mind the law on privity of a contract, if a consumer finds a defect in the goods, he or she usually sues the person from whom he or she has bought the goods. However, if the defect is a manufacturing defect, the consumer may sue the manufacturer along with the seller, particularly under the law of tort. This is an option for 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?

Section 14(1) (h) states that the District Forum under the Consumer Protection Act can require direct withdrawal of all hazardous goods from the market and direct compensation to be paid to affected parties.

As per Section 27 of the Consumer Protection Act, if a trader fails or omits to comply with any order of the District Forum, such person shall be punishable with a term of not less than one month, but which may be extended to three years or a fine of 2,000 rupees, but which may be extended to 10,000 rupees, or both. Also, Section 25 of the said Act empowers the District Forum or State Commission or National Commission, as the case may be, to attach property of the person who does not comply with its orders. If a person fails to pay an amount as per an order passed by a district court, then such person may move an application before the District Forum which shall issue a certificate to the collector of the district, and such collector shall proceed to recover the said amount from such person as arrears of the land revenue.

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

Under the Consumer Protection Act, as per Section 27, where a trader or a person against whom a complaint is made or the complainant fails or omits to comply with any order made by the District Forum, the State Commission or the National Commission, as the case may be, such trader, person or complainant shall be punishable with: imprisonment for a term of not less than one month, but which may be extended to three years; a fine, which shall not be less than 2,000 rupees, but which may be extended to 10,000 rupees; or both. Criminal sanctions may also be imposed under other statutes specifically providing for such sanctions.

2 Causation

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

The burden of proof generally lies with the party who is alleging the fault/defect and damage or who initiates the civil action (plaintiff).

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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

In order to recover damages under tort of negligence, a plaintiff must prove the following:

1. the manufacturer owed a duty to the plaintiff;
2. the manufacturer breached a duty to the plaintiff;
3. the breach of duty was the actual cause of the plaintiff's injury;
4. the breach of duty was also the proximate cause of the injury; or
5. the plaintiff suffered actual damages as a result of the negligent act.

The law requires that a manufacturer exercises a reasonable degree of standard of care akin to those who are manufacturing similar products. In case the plaintiff can prove that a manufacturer has failed to exercise the reasonable standard of care, the plaintiff still needs to prove two parameters of causation. The plaintiff must first show injury was caused to the plaintiff due to the manufacturer's negligence and further that the defendant could have foreseen the risks that led to such an injury.

On the other hand, in a contract, the plaintiff is required to prove that the breach of contract was the actual and effective cause of the loss which has been sustained.

The burden lies with the party alleging a fault has been made by the other party or the goods were defective. There needs to be a proximate cause and effect relationship and goods are considered defective where there is a high risk of malfunction.

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 generally apply. In many such cases, the claim stands dismissed.

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 goods are transferred under a contract, the liability of parties is governed by the contract itself. In certain cases, there is an implied condition that goods will be reasonably fit for the purpose for which they are required by the buyer. If, while selling goods under a contract, the defendant expressly excludes his liability, he cannot be made liable for the loss caused to the plaintiff. Liability may arise.

Section 16 of the Sale of Goods Act prescribes implied conditions as to quality or fitness. Section 16(1) requires that the goods shall be reasonably fit for the purpose, made known to the seller by the buyer expressly or by implication. Section 16(2) requires only that the goods should be of merchantable quality. Secondly, Section 16(1) is excluded where the buyer does not rely on seller's skill or judgment. Section 16(2) is not so limited, although it does not apply when the buyer examines the goods with regards to defects and such examination ought to have revealed the defects. Where a defect is revealed to the buyer, not only is Section 16(2) excluded, but that fact will normally indicate that it is unreasonable for the buyer then to rely on the seller for the purposes of Section 16(1).

In addition, liability may be found under tort law. When a tin had a defective lid to the knowledge of the seller and he failed to warn the buyer about it, the defendant will be liable for injury caused to the buyer as a consequence thereof (*Clarke v Army and Navy Cooperative Society ltd* [1903] 1 K.B. 155).

Liability towards the ultimate transferee could be based on fraud where there is false representation that goods are safe. In the case of dangerous goods, such as loaded firearms, it is required to give added precaution and warning to the intermediary, as well as the ultimate transferee. In *Dixon v Bell* (1816) 4M&S 198, the defendant gave a servant a loaded gun which she fired on the plaintiff who was seriously injured. The defendant was held liable for the same.

In case of things which are not dangerous *per se*, but known to be so, the transferor owes a duty to warn about the known dangers not only to the immediate transferee, but to all persons likely to be endangered by such thing.

For the third category, things neither dangerous *per se*, nor known to be so by the transferor, but are in fact dangerous, the application of *Donoghue v Stevenson* principle requires the manufacturer to take reasonable care (when something is to reach the ultimate consumer without any possibility of intermediate examination) and is liable for not taking such care despite there being no privity of contract. This liability principle has extended to repairers, assemblers, builders and suppliers of products.

3 Defences and Estoppel

3.1 What defences, if any, are available?

A probable defence could be that the defect had occurred due to the negligence or contributory negligence of the buyer. An additional defence would be that the buyer had examined the goods prior to purchase. Also, the parties can rely on contractually agreed warranties or waivers or disclaimers and clauses on limitation of liability. The expiration of limitation periods for filing or initiating claims can also be a 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?

In general, in the Consumer Protection Act, onus is on the plaintiff to prove fault could have been discovered by 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?

Yes, if the product complies with statutory standards relating to manufacturing, licensing, marketing and supplying, the same can be argued as a defence.

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 the doctrine of *res judicata*, parties are estopped between themselves from re-litigating issues determined by the final judgment of any competent court or tribunal. Different claimants may be able to re-litigate issues in separate proceedings; however, a claimant could be prevented from re-litigating an issue decided in a previous proceeding on the grounds of abuse of process by re-litigation.

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 joint tortfeasors is joint and several. No tortfeasor is allowed to claim that the decree against him should be only to the extent of his fault. The court may apportion damages between tortfeasors for the purpose of respective liability *inter se* (*Amnthiben v SC, ONGC*). In *Amnthiben v SC, ONGC* [1976] ACJ (72) (Guj.), due to the negligence of the driver of a jeep and the driver of a bus, there was an accident and a passenger sitting in front of a jeep was thrown and killed. The ratio of the negligence of the driver of the bus compared to the driver of the jeep was 75:25. A decree against the defendants was passed making them liable jointly and severally to pay damages. Apportionment of damages was *inter se* made to work out the respective liability of the defendants. The limitation period to begin a case for recovery is generally three years from the cause of action.

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

Yes. For example, where a pedestrian tries to cross the road all of a sudden and he is hit by a car, he is guilty of contributory negligence.

4 Procedure

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

As the Indian legal regime is based on the common law system, the court system is adversarial and an impartial judge adjudicates a case. The jury system does not exist in India.

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, experts may be appointed by courts for any expert testimony if required under the Code of Civil Procedure, 1908.

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 the Consumer Protection Act, 1986, any voluntary consumer association registered under the Companies Act, 1956, or under any other law for the time being in force, can file a consumer complaint, and where there are numerous consumers having the same interest, they can file a consumer complaint with the leave of the court (forum).

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

Yes, a complaint for a class action can be filed by any trade association, consumer or registered consumer association or by the Central or State Government, where one or more consumers have a common interest. (Section 2(1) (b) Consumer Protection Act, 1986.) *In Consumer Protection Council, Rourkela v Indian Oil Corporation Ltd & OTHERS, ORIGINAL PETITION NO. 224 OF 2001*, dated 16 August, 2007, the National Consumer Disputes Redressal Commission (NCDRC) dealt with a case wherein the Consumer Protection Council, Rourkela, a voluntary organisation, had filed a complaint against the Indian Oil Corporation Indane LPG that the refill received by consumers was less than the represented weight. The NCDRC directed the Ministry of Petroleum, as well as the Ministry of Consumer Affairs, to ensure that all marketing companies issue necessary instructions and that the distributors will provide the delivery person with a proper weighing scale for the purpose of weighing the LPG Gas Cylinder in the presence

of customers. They are also required to give it due publicity by publishing the same in the vernacular language of each and every State, and in English and Hindi in newspapers, as well as providing a similar type of advertisement on TV for consumer information.

The NCDRC directed the Indian Oil Corporation to pay a sum of 50,000 rupees to the Complainant-Council to meet the expenses incurred by it in protecting the interest of consumers, and to continue to protect the interest of consumers, for a period of four weeks.

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

In practice, a civil suit may take two to three years to get to the trial stage and another three years for final disposal; while in a consumer forum, a typical case is disposed of within one to two years. Once the complaint is received by the District Forum, the District Forum may either admit or reject a complaint, generally within 21 days from the date from receipt thereof. Once the complaint is admitted, the District Forum shall refer a copy of the admitted complaint within 21 days from the date of its admission to the opposite party, directing it to give its version of the case within a period of 30 days or such extended period (not exceeding 15 days) as may be granted by the forum.

The Consumer Protection Act requires the District Forum to decide a complaint within a period of three months from the date of receipt of the notice by the opposite party where the complaint does not require analysis or testing of commodities, and within five months if it requires analysis or testing of commodities. Further, the Consumer Protection Act prescribes that an appeal filed before the State Commission or the National Commission shall be heard and finally disposed of within a period of 90 days from the date of its admission.

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 matters on preliminary issues such as *res judicata*, limitation periods, or other legal grounds. Courts will not assess facts at preliminary stages before trial.

4.7 What appeal options are available?

Action under the Consumer Protection Act, 1986

Any person aggrieved by an order made by the District Forum may refer an appeal against such order to the State Commission within a period of 30 days from the date of the order. Provided the appeal is referred by a person who is required to pay any amount in terms of an order of the District Forum, the appeal shall be entertained by the State Commission only if the appellant has deposited in the prescribed manner 50 per cent of that amount or 25,000 rupees, whichever is less. (Section 15 of the Consumer Protection Act, 1986.)

Any person aggrieved by an order made by the State Commission may refer an appeal against such order to the National Commission within a period of 30 days from the date of the order. Provided the appeal is referred by a person who is required to pay any amount in terms of an order of the State Commission, the appeal shall be entertained by the State Commission only if the appellant has deposited in the prescribed manner 50 per cent of that amount or 35,000 rupees, whichever is less. (Section 19 of Consumer Protection Act, 1986.)

Any person aggrieved by an order made by the National Commission may refer an appeal against such order to the Supreme Court within a period of 30 days from the date of the order.

Provided the appeal is referred by a person who is required to pay any amount in terms of an order of the National Commission, the appeal shall be entertained by the Supreme Court only if the appellant has deposited in the prescribed manner 50 per cent of that amount or 50,000 rupees, whichever is less. (Section 23 of Consumer Protection Act, 1986.)

Action under civil courts

A suit is instituted in the lowest court competent to try such suit. An order or a decree passed by a district court is appealable before the high court. An order passed by the high court is appealable to the Supreme Court, which is the apex 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?

Experts may be appointed by courts or consumer forums, depending upon the facts and circumstances of each case.

However, the case should be complicated enough to require the opinion of an expert. As per Section 45 of the Indian Evidence Act, expert testimony is possible, but generally cross-examination does follow. The expert testimony or opinions should be limited only to highly technical points.

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?

Generally, in product liability cases, expert opinions are not taken, except if the court thinks it is necessary to determine important facts. Depositions, reports, and cross-examination all take place 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 Indian law, it is for the party claiming a relief to supply to court all documents upon which it relies. The court may also entertain applications seeking relief of discovery or production of records depending on the facts of every case. In *Ramrati Kuer v Dwarika Prasad Singh &amp*; Ors., AIR 1967 SC 1134, this court held:

"*It is true that Dwarika Prasad Singh said that his father used to keep accounts. But no attempt was made on behalf of the appellant to ask the court to order Dwarika Prasad Singh to produce the accounts. An adverse inference could only have been drawn against the plaintiffs-respondents if the appellant had asked the court to order them to produce accounts and they had failed to produce them after admitting that Basekhi Singh used to keep accounts. But no such prayer was made to the court, and in the circumstances no adverse inference could be drawn from the non-production of accounts.*"

(See also: *Ravi Yashwant Bhoir v District Collector, Raigad &* Ors., AIR 2012 SC 1339.)

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

Parties to a contract may agree to adopt alternative means of dispute resolution (ADR) in their contract before resorting to litigation.

Such means could be negotiation, mediation or conciliation or other forms of ADR. Such contractual terms are binding on the contracting parties. In India, courts encourage settlement of disputes through ADR.

Alternative means of dispute resolution are not generally adopted in product liability cases wherein the consumer is aggrieved. Statutory forums, such as consumer forums, decide such cases.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction, be brought within the jurisdiction of your courts either as a defendant or as a claimant?

The Consumer Protection Act can be applicable to a foreigner who avails service or purchases a product from India, as it does not limit its application to only Indian citizens. As a defendant, a plaintiff can file an action in Indian courts against a foreign service provider or manufacturer if he provides a service or sells goods in India. This judgment obtained by a plaintiff can be enforced in India if the defendant has any assets in India or enforced abroad if a reciprocal arrangement exists with the government/country in question. In case a judgment is passed by an Indian court, by virtue of Section 38 of the Code of Civil Procedure, a decree may be executed either by the court which passed it or by the court to which it is sent for execution. According to Section 51 of the Code of Civil Procedure, an execution order may entail delivery of any property specifically decreed or attachment and sale of any property, by arrest and detention in prison, by appointing a receiver, or other manner as the court may deem fit.

5 Time Limits

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

In an action under the Consumer Protection Act, the District Forum, the State Commission or the National Commission shall not admit consumer complaints unless they are filed within two years from the date on which the cause of action has arisen.

Whereas, in an action under the Indian Contract Act, Sale of Goods Act and other applicable statutes, a person will not be able to initiate a product liability claim after three years from the date of which the cause of action (product defect) which gives the right to initiate a product liability claim occurs.

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 of time does not vary depending on whether it is fault-based or strict liability.

The age of the claimant does not affect limitation. The court has discretion to extend time or condone delay if the plaintiff proves that there was sufficient cause for condoning the delay.

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 upon fraud or the right of action is concealed by fraud, the period of limitation only begins to run when 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?

Generally, in tort cases under product liability, two remedies are common: one is damages such as to remove the defect from the goods or to seek replacement of the goods with new goods of similar description which shall be free from any defect; and, if damages is an inadequate remedy, the court may grant an injunction for discontinuance of unfair trade practice or restrictive trade practices, as the case may be and for withdrawal and to cease and desist orders in the manufacturing of hazardous goods from being offered for sale. A refund of the purchase price can also be availed by the aggrieved party in the form of monetary compensation.

(Section 14 of the Consumer Protection Act.)

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

In order to recover damages, damages must be foreseeable.

Foreseeable damages generally include pecuniary losses, such as those incurred by the plaintiff for damaged goods, medical expenses, and lost money. Recoverable non-economic damages include awards for pain and suffering and emotional agony. The court may award punitive or exemplary damages in certain severe cases of negligence.

Under the Indian Contract Act, 1872, the party who suffers loss on account of breach of a contract by the other party is entitled to receive, from the party who has breached the contract, compensation for any loss or damage caused to it, which directly arises from such breach, or which the parties knew, when they entered into the contract, to be likely to result from the breach of it. However, no compensation is to be given for any remote and indirect loss of damage sustained by reason of the breach. Thus, as per Indian law, indirect damages are generally not 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?

Yes, compensatory damages can be recovered by the injured party if any damage stems or is likely to stem from the dangerous or defective product in future. For example, in the case of *Union Carbide Corporation etc v Union of India* (1991) 4 SCC 584, the Supreme Court, in addition to the compensation, directed Union Carbide Corporation to bear the expenses towards the setting up of specialised medical and research equipment for periodical medical checkups for victims of a toxic leak. Thus, in this case it has been witnessed that the court awarded damages towards the costs of medical surveillance.

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

As far as the award of punitive and exemplary damages is concerned, such damages can only be allowed at the discretion of the courts and in certain exceptional cases.

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?

Apart from the Consumer Protection Act where consumer associations can file a combined action to seek remedies as provided in Section 14 of the said Act, under Article 32 and Article 226 of the Constitution of India, any person may file a public interest litigation in larger public interest, wherein courts grant relief in case of infringement of fundamental rights of the public. The Supreme Court (under Article 32) and high courts (under Article 226), depending on facts of a case, can grant injunctions, damages, oversee the implementation of legislation or draft appropriate guidelines in the absence of a specific legislation.

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?

Usually, the relevant government departments are party to the litigation itself.

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 claimant usually seeks the reimbursement of litigation costs, interest, etc. It is at the court's discretion to order costs to be paid to the claimant if he wins a case.

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

Yes. Legal Aid clinics have been set up under the Legal Services Authority Act, 1987.

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

Legal aid clinics are governed by provisions of the Legal Services Authority Act, 1987, which receives funds and has policies for its utilisation.

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

Conditional or contingency fees are not generally adopted in India.

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

Third-party litigation funding is available only through legal aid and is subject to the terms as specified under the Legal Services Authority Act, 1987. The prevalent legislation, the Public Liability Insurance Act, 1991, aims to provide public liability insurance for the purpose of providing relief to the persons affected by an accident occurring while handling any hazardous substance for matters connected therewith. Every owner, i.e. a person who has control over handling any hazardous substance, has to take an insurance policy so that he is insured against liability in case of death or injury to a person, or damage to any property, arising as a result of an accident occurring while handling any hazardous substance. Further, the Motor Vehicles Act, 1988 makes the insurance of motor vehicles against third party risks compulsory.

7.6 In advance of the case proceeding to trial, does the Court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

No; the court does not exercise any control over costs to be incurred by parties so that it is proportionate to the value of the claim. However, it can direct the respondent to pay the costs of litigation if the consumer succeeds.

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 your jurisdiction.

In India, consumer awareness is on the rise. A separate Department of Consumer Affairs was also created in the central and state governments to exclusively focus on ensuring the rights of consumers as enshrined under the CPA. CPA aims at providing speedy and cost-effective redressal to the consumers by award of compensation and other injunctive reliefs. Courts have generally awarded the claimant damages along with reimbursement of costs of litigation. Non-governmental organisations, such as the Consumer's Association of India, the Consumers' Forum and the Citizen Consumer and Civil Action Group, are actively working towards increasing awareness and informing consumers with regards to their rights and remedies under CPA.

The courts in India are providing effective redressal of consumer complaints.

In *M/s Avery India limited v M/s kaybee Sulphates limited*, MANU/CF/0002/2014, the respondent/complainant filed a consumer complaint against the petitioner alleging deficiency in service in not setting up the weigh-bridge at his Industrial Unit and supplying him a defective transfer lever. The National Consumer Rights Redressal Commission held that the respondent did not qualify as a consumer since it runs a Sulphate industry and had purchased the weighbridge from the petitioner for the purpose of above industry only. Further, the commission observed that it was a commercial transaction between the petitioner and the respondent and the same is not a Consumer dispute.

In another case, *Tata Motors v Rajesh Tyagi, and HIM Motors Showroom*, I (2014)CPJ132(NC), the Commission held that it was the duty of both the manufacturer and dealer to attend to the defect when a consumer complained of the defect in a vehicle and make it defect-free, and if they were not in position to do so, they should either refund the cost of vehicle or provide a new vehicle to the consumer.

In the matter of *Rediff.com India limited v M/s Urmil Munjal*, II(2013)CPJ522(NC), the Commission held that both the District Forum and State Commission did not hold the respondent, an online shopping platform, liable for any defects in the goods supplied, but for failure to inform the complainant about the manner in which defective goods were to be returned to their seller and the Commission upheld the decision of the forum.

In *Raj Bala v Managing Director, Skoda Auto India Pvt Ltd & Anr (Revision petition decided on 23.10.13 from the order dated 26.09.2012 in First Appeal Nos. 824/2009 of the Delhi State Consumer Disputes Redressal Commission)*, the National Consumer Dispute Redressal Forum considered a case where there was no inherent defect found in a vehicle, as per a report given by an expert, which may necessitate its replacement or refund of the value of the vehicle to the Complainant. The District Forum, *vide* their order, had already allowed a sum of 40,000 rupees to the Complainant for inconvenience caused to the Complainant for taking the vehicle to a workshop frequently within a short period and also directed the Respondents to extend the warranty of the vehicle by at least one year. The said order was not challenged by the Respondents before any higher authority. The State Commission had also endorsed the order of the District Forum and the Commission upheld the same.

Courts in India have upheld the limitation of liability clauses, which parties have specifically agreed to in the contract, as recognised by the Supreme Court in *Bharathi Knitting Company v DHLWorldwide Express Courier* (1996) 4 SCC 704. Nonetheless, such clauses may be struck down if found to be unconscionable in nature.

In *Maruti Udyog v Susheel Kumar Gabgotra*, (2006) 4 SCC 644, the manufacturer of the vehicle had stipulated a warranty clause limiting its liability to merely repair the defects found, if any. In view of this clause, the Supreme Court reversed the findings of the National Commission to replace the defective goods and held that the liability of the manufacturer was confined to repairing the defect. Compensation was, however, awarded to the complainant for travel charges which were incurred due to the fault of the car manufacturer.

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Indonesia

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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 general provisions under the Indonesian Civil Code ("**ICC**"), product liability is specifically regulated under Law No. 8 of 1999 concerning Consumer Protection ("**Law 8**"). Both instruments adopt a system of fault-based product liability. As regulated under Article 19 (5) of Law 8, a business actor (any person or entity doing business in Indonesia) is not liable for the losses incurred by a consumer for consuming its products/services if the business actor can prove that the consumer was at fault.

Contractual liability under the ICC also applies where a valid contract exists between the business actor and the consumer.

If a business actor violates his/her statutory obligations, he/she will be subject to both civil and criminal sanction as stipulated under Law 8 and under other relevant laws and regulation.

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?

It depends on the circumstances of the case. Generally, the business actor is liable to pay compensation to the consumer for any losses incurred as a result of consuming the goods/services produced or traded. Law 8 stipulates the following provisions:

a. The manufacturer is responsible for the products it has manufactured.

b. An advertising business agent is responsible for the advertisements produced and also for all consequences incurred by such advertisements.

c. An importer of goods is responsible (as if it is the manufacturer) for the goods imported if the importation is not conducted by an overseas agent or representative of the manufacturer.

d. An importer of services is responsible (as if it is the provider of foreign services) if the said provision of foreign services is not conducted by an agent or representative of the provider of foreign services.

e. A business actor selling goods and/or services to another business actor must answer a claim for compensation and/or a lawsuit filed by a consumer if:

   i. the other business actors sell said goods and/or services without any modifications to the said goods and/or services; or

   ii. the other business actors are unaware during the transaction that a change has been made to the goods and/or services by the first business actor or the goods and/or services do not conform to the specification, the quality and composition.

f. The business actor is obligated to provide spare parts and/or after-sales services, fulfil the warranty in accordance with what is agreed upon, and must answer claims for compensation and/or lawsuits from a consumer if the said business actor:

   i. fails or neglects to provide spare parts and/or repair facilities; or

   ii. fails to fulfil the warranty.

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?

Article 8 of Law 8 stipulates that business actors are required to recall their products if they:

- do not fulfil or conform to the required quality standard and the prevailing laws and regulations;
- do not conform to the condition, warranty, superiority or efficacy as stated in the label or description of the said goods and/or services;
- do not conform to a certain quality, level, composition, processing, style, mode or use as stated in the label or description of the said goods and/or services;
- do not conform to the promise stated in the label, description, advertisement or sales promotion of said goods and/or services;
- do not comply with the provision to produce the goods according to halal methods, as denoted by the "halal" mark put in the label;
- do not have a label or provide an explanation of the goods including the name of the goods, the size, the net weight/volume, the composition, the direction of use, the manufacturing date, the side effects, the name and the address

of the business agent and other information which must be included in the label;

- do not mention the information and/or direction of use of the goods in the Indonesian language pursuant to the prevailing laws; or
- are goods for trade which are damaged, flawed or used, and contaminated without providing full information about such goods.

Further, it is also regulated under the Minister of Trade Regulation that a product can be recalled from distribution if it is proven to endanger the safety and health of the consumer, or the environment.

Law 8 does not expressly stipulate the specific procedure to be taken to file a claim for failure to recall such goods and/or services. However, failure to comply with Article 8 may result in imprisonment for a maximum of five years or a maximum fine of Rp 2 billion. As such, criminal procedures apply for breach of Article 8 of Law 8.

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

Yes, they do.

2 Causation

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

Pursuant to Article 28 of Law 8, the business actor must prove that there is no fault or negligence in relation to 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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

The consumer must prove that the product was utilised in accordance with the product manual and that the damages suffered were caused by the use of the products. It is necessary to prove that the product to which the claimant was exposed has actually malfunctioned, but not necessary to prove that the malfunction caused 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 commonly applied in Indonesia. Generally, the business actor who makes the product available to customers (the ultimate manufacturer) will be held liable unless the business actor can prove that another party was negligent/at fault.

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?

There is no single regulation regarding the requirement to put warnings on labels. Article 7 of Law 8 simply stipulates that business actors must provide correct, clear, and honest information as to the condition of the goods/services and the direction for the use, repair, and maintenance of the goods/services.

Warning requirements are regulated specifically pursuant to the kind of goods to be traded. Commonly, warnings are required for goods which might be dangerous to the consumer, such as food products, drugs, technology products, cigarettes. The warning is usually required to be put on the label of the goods in a readable position so that the consumer is able to read it carefully. Failure to comply with this requirement may cause the business actors to be liable for damages/losses caused to the consumer from using the goods.

The term of "learned intermediary" is not adopted under Law 8. In this regard, unless the intermediary makes changes or additions to the goods/services, the manufacturer is liable for any damages arising from the use of the goods/services.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The ICC provides a defence for strict contractual liability. A party cannot be held liable for unforeseeable harm or foreseeable harm if it has taken all reasonable care. Further, no liability arises in the event of a *force majeure* event which prevents the contracted party from carrying out its contractual obligations, or forces a breach of contractual duty.

Law 8 provides the following defences for manufacturers of goods:

- the business actor has not been negligent/is not at fault;
- the goods were not intended to be distributed;
- the flaw in the goods emerges later;
- the flaw emerges as a result of compliance with provisions on the qualification of the goods;
- the damage is caused by the negligence of the consumers; or
- the claiming period of four years after the purchase of the goods, or the passage of the period agreed upon, has lapsed.

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 such defence stated in the regulations.

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, this can be used as a defence for the manufacturer. However, the acceptance will be based on the judge's discretion.

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?

Indonesia does not acknowledge the concept of issue estoppel as adopted in the common law system. As such, every disadvantaged consumer may file a claim against a business actor regardless of previous actions taken by other 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?

Yes. The defendant may seek contribution or indemnity from a third party on the basis of general civil law procedures. The defendants may also include the third party in the same proceedings under a procedure called *vrijwaring*, or they can submit a subsequent claim against the third party.

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

Yes. However, the defendants must prove the allegations.

4 Procedure

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

Indonesia adopts the Civil Law system. As such, trials are conducted by a 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)?

No, the procedures do not recognise the concept of expert assessors. However, the court or the parties (the plaintiff or the defendant) may summon an expert witness to state their opinion regarding the case based on their expertise.

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. The basis for class action procedures is regulated under Article 46(1)(b)of Law 8 and Regulation of the Supreme Court No. 1 of 2002 regarding Procedures for Class Action Lawsuits ("**Perma**"). Pursuant to Law 8, a group of customers who have the same concern or interest may file a class action lawsuit against a business actor. Pursuant to the Perma, a claim may be filed via class action procedures if:

a) the number of class members is so large that it is ineffective and inefficient to make a claim severally or jointly in one claim;

b) there are common questions of fact or situation and common questions of law that are substantial, and there are typical claims among class representatives and their class members; and

c) a class representative fairly and genuinely protects the interests of the class members being represented.

The formal requirements for a class action petition should follow the formal requirements of the applicable law of civil procedure, in addition to those requirements sets out under the Perma.

At the beginning of the hearing, the judge must examine and consider the requirements for a class action. If it is a valid class action claim, a notice is issued containing a description of the possible class members belonging to the class definition. The notice provides further details on how class members can opt-out of the class membership and the address to submit the opt-out. The party who has stated to opt-out of the class action will not be legally bound by any judgment of the class action concerned.

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

Yes, this is regulated under Article 46(1) (c) of Law 8. Pursuant to Article 46(1)(c), a lawsuit may be filed by a non-governmental institution to protect consumers' interests if the non-governmental institution fulfils certain requirements. Namely: that the institution is a legal entity or a foundation; the institution's articles of association clearly state that its purpose of establishment is to protect consumers; and that the institution conducts its activities in accordance with its articles of association.

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

The time for a lawsuit to get to trial varies depending on whether it is a civil or criminal case. The time for civil cases to get to trial is usually less than the time taken for criminal cases. This is because the steps required prior to commencing a civil action are simpler than the necessary investigative steps required in criminal cases.

Pursuant to the Decision of the Head of the Supreme Court of the Republic of Indonesia No. 026/KMA/SK/II/2012 regarding the Standard of Judicial Services ("**Kepma**"), the court should determine the date of a civil trial at least three working days after the receipt of the claim by the court. Aside from this, there is no exact

timeline on how long after the receipt of the claim the trial should commence. However, the Kepma regulates that the procedures of the trial should be finished within six months as of the registration date of the lawsuit.

As for criminal cases, the timeline to get to trial, from the time the alleged crime was reported to police is necessarily longer in order to account for the proper investigation and inquiry which must occur prior to trial. However, the Kepma regulates that the procedures of the trial for criminal cases should be finished within:

- six months from the date of registration of the indictment by the prosecutor (if the defendant is not arrested);
- ten days before the end of a temporary detention period; or
- a special period as regulated under the prevailing laws and regulations for specific 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 Indonesian Civil Law system does not conduct a preliminary issues hearing for civil or criminal cases.

4.7 What appeal options are available?

The appeal options in the Indonesian court system are divided into: (i) Ordinary Legal Remedies; and (ii) Unordinary Legal Remedies, as follows:

Ordinary Legal Remedies:

- Appeal to the District Court pursuant to the decision of the agency for the settlement of consumers' disputes (this appeal option is available to consumers who attempt to settle disputes outside of court via the agency for the settlement of consumers' disputes).
- *Verzet*: Appeal for a *Verstek* ruling (shall be filed by defendants who appeal a court ruling which implied that the defendant was not present at the trial).
- Appeal: Appeal to challenge a District Court ruling.
- Cassation: Cassation is a legal remedy to challenge the ruling of a court of appeal. Cassation can only be submitted if the petitioner has been through the appeal process, unless stipulated otherwise by law.

Unordinary Legal Remedies:

- Civil Review: Civil review can be filed to the Supreme Court against a ruling/decision of the Supreme Court which has become final and binding. The civil review can be filed as long as there is a *novum* (new evidence) related to the case which had not been discovered at the previous level of 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?

The court or the parties (the plaintiff or the defendant) might summon an expert witness to give their opinion regarding the case based on their expertise. The expert witness must not have a conflict of interest with the subject and/or object of the 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?

Under the Indonesian civil law system, there is no concept of pre-trial deposition. Witness statements/expert reports are exchanged during the trial and not before 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?

As for civil cases, there is no obligation to disclose documentary evidence. In general, the evidence is disclosed by the plaintiff as an attachment to the claim. This evidence is further investigated during the proceedings. As for criminal cases, the evidence is investigated during the inquiry and the investigation phase. Later, this evidence is attached to the indictment by the prosecutor and is further verified during trial.

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

No, Article 45 (2) of Law 8 stipulates that the disputing parties may voluntarily choose the method of dispute resolution, either through the court or outside of the court. Arbitration and mediation methods are available as an alternative to litigation and, in addition to this, Law 8 also provides an alternative mechanism for product liability claims via an agency for the settlement of consumer disputes outside of the court.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction, be brought within the jurisdiction of your courts either as a defendant or as a claimant?

In theory, whenever someone (either a citizen or foreigner) conducts an unlawful act on Indonesian territory, the Indonesian court has the jurisdiction to hear and decide the case. Claimants that are not domiciled in Indonesia can file a claim before an Indonesian court. Further, defendants that are not domiciled in Indonesia can be summoned to appear before an Indonesian court. However, in practice, it is difficult to enforce the court's decision if the defendant or claimant is not domiciled in Indonesia.

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 on bringing or issuing proceedings vary between criminal law and civil law.

In criminal law, as regulated under Article 78 Criminal Code:

- for violations/crimes committed by means of printing tools, the expiration period is one year;
- for crimes carrying a penalty of less than three years' imprisonment, the time limit is six years;
- for crimes carrying a penalty of over three years' imprisonment, the time limit is 12 years; and
- for crimes punishable by death or life imprisonment, the time limit is 18 years.

In civil law cases, pursuant to Article 1967 of the ICC, the time limit to submit a claim is 30 years counting from the date of the dispute. However, a shorter period may apply in specific types of civil litigation.

Aside from the above, please note Law 8 stipulates that a claim brought under Law 8 will only be valid for four years from the date of the purchase of such goods/services.

The age of the claimant will not affect the calculation of time limits.

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

The issues of concealment or fraud do not affect the running of any time limit.

6 Remedies

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

The available remedies are, among others: refund or replacement of goods and/or services (similar or equivalent); medical expenses; and/or compensation for damages.

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

There are no specific types of recoverable damages under the applicable law. As long as the consumers can prove that the damages are caused by the use of goods/services, the consumer may claim damages from the business actors.

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. A party can only claim for damages which have been suffered.

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

Indonesian courts do not acknowledge the concept 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?

There is no maximum limit for the damages recoverable from one manufacturer in a civil claim. However, in criminal claims, Law 8 stipulates a maximum fine and imprisonment period that can be imposed on business actors.

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?

For settlement in a class action, the judges conduct a preliminary hearing to review whether the requirement of a class action has been met. If the requirements are met, the class action procedure can continue. As for claims relating to infants, the claim is usually made by their legal guardian/s.

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 government authorities concerned with health and social security are not listed as legitimate claimants under Law 8. Hence, they cannot claim from the settlement or awarded damages.

Pursuant to Law 8, the government can only submit a claim if the use of goods/services causes a substantial material loss and/or victims.

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 winning party can request to recover the court fees from losing parties. However, under Article 182 of the Indonesian Civil Procedural Code, the winning party cannot request to recover lawyers' fees.

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

Legal aid funding is recognised under the Legal Aid Law, Law No. 16 of 2011, as supplemented by its implementing regulation, Government Regulation No. 42 of 2013. In practice, legal aid funding is implemented by means of the establishment of legal aid posts in Indonesian district courts.

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

The beneficiary must be economically poor in order to receive legal aid services.

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?

Yes. It can be in the form of a grant or a donation.

7.6 In advance of the case proceeding to trial, does the Court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

No, it does 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 your jurisdiction.

Lately, the number of flight delays has increased in Indonesia, especially carried out by the low-cost airline. For some crucial routes and in the midst of the holiday seasons, some passengers may experience more than five hours of delay. This is obviously very harmful for the consumers.

Under Law 8, these incidents can be assumed as the violation of the consumer rights.

Violation to the above provisions is subject to imprisonment, fines and/or administrative sanctions in the form of, among others, payment of compensation, revocation of business licence, etc.

In addition to the above, when flights are delayed, passengers are entitled to compensation under the Regulation of Ministry of Transportation Number PM 89 of 2015 regarding Flight Delay Management on Scheduled Commercial Air Transport Business Entity in Indonesia ("**Regulation 89**"). Regulation 89 specifies that passengers are entitled to certain reimbursements depending on the six categories of delay. However, in practice, the enforcement of the reimbursements has yet to be executed properly and, moreover, the reimbursements are still considered inequitable than the losses suffered by the consumer.

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Ali Budiardjo, Nugroho, Reksodiputro, usually abbreviated to ABNR, was established in Jakarta in 1967 as a partnership of legal consultants in Indonesian business law. The firm is one of Indonesia's largest independent full-service law firms. The commitment we make to clients is to provide a broad-based, personalised service from top quality teams of lawyers with international experience that includes ground-breaking deals and projects. ABNR's reputation has been recognised around the world by independent industry surveys and law firm guides. ABNR was selected, based on its high level of integrity and professionalism, to be the sole Indonesian member of the world's largest law firm association Lex Mundi and of the prestigious Pacific Rim Advisory Council (PRAC).

Ireland

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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 Ireland, liability for defective products falls under four main headings:

- Statute.
- Tort.
- Contract.
- Criminal.

Statute

The principal product liability statute in Ireland is the Liability for Defective Products Act 1991 ("the 1991 Act"), which was enacted to implement EC Directive 85/374. This Act supplements, rather than replaces, the pre-existing remedies in tort and contract (see below). S.2(1) of the Act provides for strict liability, making a producer:

> "*[L]iable in damages in tort for damage caused wholly or partly by a defect in his product*."

It is worth noting that the 1991 Act covers only dangerous, defective products. Products which are safe, but shoddy, do not fall within its scope.

Tort

Manufacturers, repairers, installers, suppliers and others may be sued in tort for reasonably foreseeable damage caused to those to whom they owe a duty of care. As opposed to liability under the Liability for Defective Products Act 1991, liability in tort is fault-based.

For an action to lie in tort, there must be:

- a duty of care owed by the producer or manufacturer of the product;
- a breach of that duty of care; and
- a causal relationship between the breach and the damage caused to the user of the product.

Unlike under the 1991 Act, a plaintiff suing in tort may, in certain circumstances, succeed in a negligence action for non-dangerous defects.

Contract

Contracts for the sale of goods are covered in Ireland by the Sale of Goods Act 1893 ("the 1893 Act") and the Sale of Goods and Supply of Services Act 1980 ("the 1980 Act"). S.10 of the 1980 Act operates to add an implied condition to contracts for the sale of goods: that the goods are of "merchantable quality" where a seller sells them in the course of business. This means that the goods must be:

> "*[F]it for the purpose or purposes for which goods of that kind are commonly bought and durable as it is reasonable to expect having regard to any description applied to them, the price (if relevant) and all other relevant circumstances*."

Contractual liability under the 1980 Act is strict. It must be borne in mind, however, that the principle of privity of contract applies, which often makes it difficult for an injured party to sue the manufacturer of a product in contract, since his contract is likely to be with the retailer of the product.

Criminal Liability

The principal legislation imposing criminal liability in the area of product liability is the European Communities (General Product Safety) Regulations 2004, as amended, ("the 2004 Regulations") which implemented EC Directive 2001/95. These Regulations make it an offence to place unsafe products on the market and specify the duties of producers and distributors in this regard.

Under the 2004 Regulations, the Competition and Consumer Protection Commission ("**CPCC**") is given the authority to ensure that only safe products are placed on the market. There is also a duty on producers and distributors to inform the CPCC where they know, or ought to know, that a product which has been placed on the market by them is incompatible with safety requirements. The CPCC has also been given the power to order a product recall, as set out in question 1.4 below.

In May 2016, the Irish government published a draft Corporate Manslaughter Bill. This draft bill includes the separate indictable offences of "corporate manslaughter" and "grossly negligent management causing death". The Bill is based on the Law Reform Commission Report on Corporate Killing dated October 2005 which recommended that a new offence of corporate manslaughter be created. The Bill is currently at the initial parliamentary review stage.

Criminal liability is fault-based and must be proven beyond reasonable doubt.

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

This has been known to happen in Ireland in circumstances where some organ of the State may have a liability. The National Treasury Management Agency (the "**NTMA**") manages personal injury and

property damage claims against the State. When performing these functions, the NTMA is known as the State Claims Agency (the "**SCA**"). Whilst this particular case was excluded from the SCA's remit, the most notable instance was the Hepatitis C Compensation Tribunal, which was set up in 1997 to compensate women who had become infected with Hepatitis C having been transfused with infected blood during pregnancy. More recently, the 'Surgical Symphysiotomy Ex-gratia Payment Scheme' was set up in 2014 to compensate women who underwent historical symphysiotomy procedures in the State. There is also a scheme to compensate haemophiliac plaintiffs of contaminated blood products. Such schemes are *ad hoc*, rather than statutorily required. The SCA issued a report in 2010 recommending that the compensation scheme providing for Irish Thalidomide survivors' compensation be revisited in order to place Ireland on a similar footing with other countries that have put Thalidomide compensation schemes in place.

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

Statute

As stated above, S.2(1) of the 1991 Act makes the "producer" of the defective product liable in damages caused wholly or partly by the defect in his product. In this regard, S.2(2) of the Act defines "producer" as:

- the manufacturer or producer of a finished product;
- the manufacturer or producer of any raw material, or the manufacturer or producer of a component part of a product;
- in the case of products of the soil, of stock-farming and of fisheries and game, which have undergone initial processing, the person who carried out such processing;
- any person who, by putting his name, trademark or other distinguishing feature on the product or using his name or any such mark or feature in relation to the product, has held himself out to be the producer of the product;
- any person who has imported the product into a Member State from a place outside the European Communities in order, in the course of any business of his, to supply it to another; or
- the supplier of the product where the manufacturer of the product cannot be identified through the plaintiff taking reasonable steps to establish his identity and where the supplier fails to identify the manufacturer of the product within a reasonable amount of time of a request being made.

Tort

Under the law of tort, the test to be applied is whether a particular individual, e.g. the manufacturer, retailer, supplier or importer, owes a duty of care towards the injured party. If such a duty is owed and has been breached, that person is capable of having responsibility.

It is clear that the manufacturer of a product will owe a duty of care to all those who may foreseeably be injured or damaged by his product. The same will apply to retailers, suppliers and importers, though the scope of their duty will typically be narrower than that of manufacturers, extending to, for example, a duty to ensure that their stock is not out-of-date. In practice, a plaintiff will not be required to choose which of a number of possible defendants to sue, and any or all potential tortfeasors are likely to be sued.

Contract

Under the 1893 Act and the 1980 Act, the seller will, subject to certain conditions and exemptions, have a contractual responsibility to the buyer in respect of faults or defects.

Criminal

In terms of the criminal law, the 2004 Regulations make a "producer" who places or attempts to place an unsafe product on the market guilty of an offence. The 2004 Regulations define a "producer" as:

- the manufacturer of a product and any other person presenting himself as the manufacturer by affixing to the product his name, trademark or other distinctive mark, or the person who reconditions the product;
- the manufacturer's representative, when the manufacturer is not established in the Community or, if there is no representative established in the Community, the importer of the product; or
- other professionals in the supply chain, in so far as their activities may affect the safety properties of a product placed on the market.

The 2004 Regulations also make distributors who supply or attempt to supply a dangerous product, which they know, or it is reasonable to presume that they should know, is dangerous, guilty of an offence. In this regard, a "distributor" is defined as any professional in the supply chain whose activity does not affect the safety properties 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?

Under S.9 of the 2004 Regulations, the CPCC is given the power to "*take all reasonable measures*" to ensure that products placed on the market are safe, including issuing a direction ensuring "*the immediate withdrawal of [a] product from the marketplace, its recall from consumers and its destruction in suitable conditions*". Under S.9(2) of the 2004 Regulations, in taking this, or any other measure under the Regulations, the CPCC must act "*in a manner proportional to the seriousness of the risk and taking due account of the precautionary principle*".

A person who fails to comply with a direction of the CPCC with respect to the recall of products is guilty of a criminal offence and is liable on summary conviction to a fine not exceeding €3,000, or to imprisonment for a term not exceeding three months, or to both.

In addition, the common law duty of care imposed by the law of tort (see above) may extend to product recall depending on the circumstances of the particular case. Thus, a failure to recall in particular circumstances may be a breach of such duty, giving rise to a civil action.

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

Yes, under the 2004 Regulations, "producers", or "distributors", as defined, may be made criminally liable where unsafe products have been placed on the market. Please see questions 1.1 and 1.3 above for details.

2 Causation

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

As a general principle, it is for the injured party to prove the defect to the product and the damage caused. This is stated in S.4 of the 1991 Act and is a general rule of the laws of contract and tort.

In tort and contract, the standard of proof is "*on the balance of probabilities*", while in criminal cases, the guilt of the accused must be proved "*beyond reasonable doubt*".

In certain circumstances, particularly in tort, the doctrine of *res ipsa loquitur* can be applied to, in effect, reverse the burden of proof and place the onus on the defendant to disprove an allegation of negligence. Since the 1991 Act operates a system of strict liability and is thus unconcerned with the negligence or otherwise of the defendant, *res ipsa loquitur* will have no such application in the context of a claim relying solely on the provisions of the 1991 Act. However, for this reason, in practice, claims will seldom, if ever, be brought relying solely on the provisions of the 1991 Act.

In criminal cases, it is for the prosecution to prove the guilt of the accused. Under the 2004 Regulations, the prosecutor in such offences is the CPCC.

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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

S.4 of the 1991 Act provides that the injured person must prove the damage, the defect and the causal relationship between the two.

In general, wrongful exposure to an increased risk of injury will not, in itself, provide a claimant with a cause of action. The causal relationship to a concrete loss or injury must be proven. If a claimant cannot prove, on the balance of probabilities, that an injury would not have occurred without exposure to the product in question, he/she has not discharged the civil burden of proof on causation.

However, the recent CJEU judgment *C-503/13 and C-504/13, Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt – and Others* has the potential to expand the scope of liability beyond what was previously understood. This case held that where it is found that products belonging to the same group or forming part of the same production series have a potential defect, such a product may be classified as defective without there being any need to establish that the particular product in question has such a defect. This is a significant decision and it remains to be seen how it will be interpreted by the Irish courts, whether they will apply the decision only in cases of high-risk product groups (such as implanted medical devices as in the *Boston Scientific* case) or whether they will take a broader approach.

As stated above, where the claimant encounters problems in proving a causal relationship, the doctrine of *res ipsa locquitur* may be of assistance.

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?

As stated above, under S.2(3) of the 1991 Act, where the producer of a product cannot be identified through the plaintiff taking reasonable steps, the supplier of the product may be treated as its producer unless he informs the plaintiff of the identity of the producer, or of the person who supplied him with the product, "within a reasonable time" of such a request being made.

In terms of the law of tort, it would be usual, in circumstances where a plaintiff cannot, with absolute certainty, identify the producer of a defective product, that the plaintiff would institute proceedings against all parties whom he reasonably suspects could have been responsible for its manufacture. Notices of Indemnity and Contribution may be served by each of the defendants on their co-defendants and ultimate liability (or an apportionment thereof), if any, will be decided by a court at trial of the issue.

Market share liability has not, to date, been applied by the Irish courts 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?

As in other Member States, Ireland's membership of the European Union has necessitated the introduction of regulations in many industries stipulating specific information and warnings which must be provided to consumers as to the nature, ingredients/contents and safety of products. Failure to comply with these regulations can have consequences for product manufacturers and distributors. Such consequences vary depending on the provisions of the individual regulations.

Specific statutory requirements aside, however, the issue of whether warnings must be provided to consumers falls within the question of compliance with the standard of reasonable care under the Irish law of tort. It should be noted that an increased level of awareness in society of product safety, and increased expectations on the provision of product information, have made it more likely in recent times that the absence of an express warning in respect of a danger attaching to a product will be deemed to constitute negligence.

As further evidence of the pro-consumer approach within this jurisdiction, the relevance of intermediate examination has been consistently undermined by the law over the years. Formerly, it was not considered negligent to allow a potentially dangerous product into circulation if the danger could reasonably be discovered by way of intermediate examination by the consumer or a middleman in the chain of distribution. However, S.34(2)(f) of the Civil Liability Act 1961 provides that, while the possibility of intermediate examination may be taken into account as a factor in determining negligence, it is no longer conclusive. Whether the release of the product is seen as negligent will, therefore, depend on all of the circumstances.

While the concept of a "learned intermediary" has not yet received specific judicial examination in Ireland, it is likely that the fact that an examining intermediary has some expertise in the composition and safety of the product could be pleaded to the benefit of the manufacturer in arguing that the release was not negligent in all the circumstances.

As regards criminal law, S.6 of the 2004 Regulations provides that a producer must provide consumers with "*all relevant information*" relating to a product which it has put on the market to "*enable [the consumer] to assess the risks inherent in the 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*". In addition, powers are granted to the CPCC under S.9 of the 2004 Regulations to issue a direction that a particular product be marked with a risk warning.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under S.6 of the 1991 Act, a Producer is freed from liability under the Act if he proves:

- that he did not put the product into circulation;
- that it is probable that the defect causing the damage came into being after the product was put into circulation by him;
- that the product was not manufactured for a profit-making sale;
- that the product was neither manufactured nor distributed in the course of his business;
- that the defect is due to compliance of the product with mandatory regulations issued by the public authorities;
- 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 defect to be discovered ("State of the Art" Defence); or
- in the case of a manufacturer of a component of the final product, that the defect is attributable to the design of the product or to the instructions given by the product manufacturer.

Furthermore, if the damage was caused partly by a defect in the product, and partly by the fault of the injured person, or a person for whom the injured person was responsible, the provisions of the Civil Liability Act 1961 in relation to contributory negligence apply (see below).

Tort

Contributory Negligence:

In Ireland, this defence is regulated by the Civil Liability Act, 1961 ("the 1961 Act"), which provides, with some exceptions, that where the plaintiff is partly at fault, damages will be reduced in proportion to that fault. It has been held that the fault necessary is to be equated with blameworthiness and not to the extent of the causative factors moving from each side. Equally, a plaintiff will be responsible for the acts of a person for whom he is vicariously liable (imputed contributory negligence). Finally, failure by a plaintiff to mitigate damage is also considered to be contributory negligence.

Voluntary Assumption of Risk (Volenti Non Fit Injuria):

This defence is regulated by S.34(1)(b) of the 1961 Act. A defendant may escape liability in two cases:

- where he shows that by contract he is not liable (though the contract will be construed strictly against the party claiming the benefit of the exception); or
- where he shows that, before the act, the plaintiff agreed to waive his legal rights in respect of it.

In both cases, the burden of proof is on the defendant to prove that the defence applies. In practice, this defence is difficult to prove.

Contract

To have a workable contract, the basic rules of contract formation must be complied with, i.e. there must be an offer, acceptance and consideration. The absence of these essential elements can act as a defence to an action in contract. Likewise, mistake, misrepresentation and duress will affect the validity of a contract. Furthermore, "illegal" contracts are invalid or, in some cases, may have the offending provision severed. Inadequate capacity to contract may also affect the validity of a contract.

Criminal

Under S.5 of the 2004 Regulations, a product shall be deemed safe if it conforms with any specific rules of the law of the State laying down the health and safety requirements which the product must satisfy in order to be marketed, or with voluntary Irish standards transposing European standards. However, notwithstanding this, the CPCC may take "*appropriate measures*" to impose restrictions on a product being placed on the market, or to require its withdrawal or recall, where there is evidence that, despite such conformity, the product is dangerous.

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), under the provisions of the 1991 Act. Where the defence is raised by a manufacturer, the burden of proof lies with the manufacturer to prove the state of scientific and technical knowledge at the relevant time, and 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, under S.6 of the 1991 Act, where this compliance can be shown to be the cause of the defect itself, this will be a defence to any cause of action based upon the 1991 Act. It may not necessarily, however, be a defence to a cause of action based upon breach of duty or breach of contract.

With respect to criminal law, please see question 3.1 above. While compliance with regulatory and statutory requirements will, *prima facie*, be taken to show that the product is safe, the CPCC is given the power, under the 2004 Regulations, to take "*appropriate measures*" where there is evidence that the product is, nonetheless, dangerous.

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?

Provided they arise in separate proceedings brought by a different claimant, findings on issues of fact, as opposed to issues of law, are of no precedent value and are not binding in a court. Issues of fault, defect and capability of a product to cause damage are issues of fact and unless the parties, of their own volition, or the court, by order, consolidates two or more claims into one set of proceedings, findings of fact will not be binding in respect of other 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?

Yes, in such circumstances where a defendant wishes to claim an indemnity or contribution against a person who is not a party to the proceedings, they may apply to join that person as a third party to the proceedings. This third party procedure can be availed of where the plaintiff's claim against the defendant coincides to some extent with a similar claim by the defendant as against the third party. If a defendant wishes to join a third party to the proceedings, they must take steps to do so "*as soon as is reasonably possible*", and there is extensive case law in relation to what is considered to be a reasonable timeframe.

Assuming the plaintiff's claim against the third party would not be statute-barred at the time the application is being made to join a third party, the plaintiff can indicate that they wish the third party to be joined to the proceedings as a co-defendant. If the plaintiff does take this step, it is open to the existing defendant to serve a Notice of Indemnity or Contribution on the "new defendant" which would be similar in its effect to a Third Party Notice.

If a defendant fails to bring third party proceedings as soon as is reasonably possible, such defendant may still bring separate proceedings for contribution. However, the court has discretion to refuse such an order for contribution, particularly if it considers that such proceedings would impose an unnecessary and unreasonable burden of costs on the proposed contributor.

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

Yes, it is open to a defendant to plead a defence of contributory negligence against a plaintiff, i.e. that the plaintiff's own actions or negligence caused, or contributed to, the damage which he or she suffered. If accepted by the court, the plea of contributory negligence will reduce any damages awarded to the plaintiff by a percentage in proportion to the percentage fault deemed to have been involved on the part of the plaintiff. For more information, 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?

In civil cases for product liability, cases are heard by a judge, sitting without a jury.

As regards criminal liability, since the 2004 Regulations provide for summary prosecution only, it is not open to the accused to opt for a trial by jury. These cases will, therefore, also be heard by a judge sitting without 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 court does not appoint technical specialists to sit with the judge. It is up to the parties to an action to either adduce their own expert evidence or to agree on a single expert to provide evidence to the court. The judge alone must make the decision in any 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?

There is no mechanism under Irish procedural rules for a class action. Thus, litigation is conducted by individual named parties. There is a tendency in Irish multi-party litigation to take one or more test cases, whereby a small number of cases are selected from the group and progressed to trial. However, in the absence of agreement (see question 3.1 above), these cases are not binding on the parties in other cases.

Order 18 of the Rules of the Superior Courts provides that a plaintiff may apply to court to unite in the same action several causes of action if they can be conveniently disposed of together by the court and they meet certain limited criteria. Order 49 of the Rules of the Superior Courts provides that causes or matters pending in the High Court may be consolidated by order of the court on the application of any party.

The Law Reform Commission published a Consultation Paper in 2005 on Multi-Party Litigation and has recommended the introduction of a procedure to be called a Multi-Party Action ("**MPA**"). The private multi-party litigation would operate as a flexible tool to deal collectively with cases that are sufficiently similar and should be introduced by way of Rules of court. The MPA procedure should operate on the basis of an opt-in system whereby individual litigants will be included in the group only where they decide to join the group action. This is different to the US class action approach. A single legal representative would be nominated by the MPA members to deal with the common issue arising within the MPA.

On 11 June 2013, the European Commission published a Recommendation calling on all Member States to adopt collective redress systems for both injunctive and compensatory relief. Although Member States are encouraged to implement the principles set out in the Regulations, the Recommendation is not binding. The Recommendation deals with "mass harm situations" where by two or more persons (natural or legal) claim to have suffered harm from the same illegal activity carried out by another person (natural or legal) in breach of EU rights. The Recommendation, which may form the basis for future implementing legislation, addresses a number of issues in collective redress, including: standing to bring a representative action; funding; cross-border disputes; ADR; damages; and legal costs and lawyer fees.

As of yet, however, there have been no steps taken by the Irish legislature to implement the recommendations of either the Law Reform Commission or the European Commission in this regard.

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

No. Representative and consumer associations will generally lack the necessary *locus standi* to bring such actions.

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

Following the enactment of the Personal Injuries Assessment Board Act 2003, any party wishing to bring personal injury proceedings

must first submit their claim to the Injuries Board (save for certain exceptions). This Injuries Board is an independent body set up by the government to assess the level of compensation payable to those who have suffered personal injuries. If the respondent to a claim notifies the Injuries Board that they intend to rely upon legal issues to defend their position, the Injuries Board will serve the claimant with an Authorisation, thereby enabling the claimant to issue proceedings before the courts.

The length of time between service of proceedings and the actual hearing of the matter depends to a large extent on how quickly the procedural steps and delivery of pleadings are complied with by both parties. In a straightforward product liability personal injuries action, with no interlocutory applications, a hearing date might be obtained within one year. In reality, however, most matters are not heard for a period of 18 months to two years from service of proceedings. In more complex cases or cases where procedural time limits have not been complied with and/or a number of interlocutory applications (for example, for discovery, particulars or interrogatories) have been made, it is not unusual for a case not to be heard for three years or more.

The Commercial Court, which is a division of the Irish High Court dealing with commercial disputes with a value in excess of €1 million, has procedures to streamline litigation and can lead to a much speedier conclusion of cases (although it does not apply to personal injury litigation).

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. Orders 25 and 34 of the Rules of the Superior Courts provide for the preliminary trial of an issue of law where such is deemed expedient by the court for the saving of costs and/or time.

4.7 What appeal options are available?

First instance rulings in all civil cases may be appealed to a higher court. Following the commencement of the Court of Appeal Act 2014, decisions of the High Court may be appealed to the recently established Court of Appeal.

In limited circumstances, decisions of the Court of Appeal and High Court may be appealed to the Supreme Court. The Supreme Court will hear such appeals only if it raises a matter of general public importance or is necessary in the interests of justice.

Directions of the CPCC under the 2004 Regulations with respect to product recall or any other measures adopted may be appealed to the Circuit Court within 21 days of receipt of the direction. An appeal to the High Court on foot of the decision of the Circuit Court on the direction may be appealed to the High Court on a question of law only.

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 are free to appoint their own experts to put forward their opinion as evidence at trial. Such experts are never appointed by the court. Such experts are, however, entitled to be questioned on their evidence by the judge, and, indeed, cross-examined by the opposing party.

General evidentiary principles apply to their evidence, so that, e.g., it must be relevant to the issues at hand and within their field 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?

Experts are not required to present themselves for pre-trial deposition.

In High Court personal injury actions, there is an obligation on the parties under SI 391/1998 to exchange all written expert reports (but not statements of fact witnesses) in advance of the hearing of the action. In other cases, it is for the parties to decide between them whether to voluntarily exchange expert reports and/or 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?

As a general rule, discovery of documentary evidence may only be sought by either party once pleadings have closed, i.e. once a defence has been delivered by the defendant. Discovery may be sought by a party to the proceedings against any other party to the proceedings, against third parties or against non-parties, subject to proof of relevance and necessity.

Discovery should be sought firstly on a voluntary basis and, if voluntary discovery is refused, it can then be sought by way of motion if necessary. Discovery relates to all documentation in the power, possession or procurement of a party to the proceedings (or non-party) which may enable the other party to advance their case.

Discovery prior to the institution of proceedings will only be granted in very exceptional circumstances e.g., Norwich Pharmacal Orders.

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

Article 11 of the 1991 Act states that this Act shall not affect any rights which an injured person may have under any enactment or under any rule of law. This may allow for the possibility that if a claim is based on contract and there is a valid arbitration clause, the parties may seek a remedy through arbitration rather than instigating proceedings in the court.

In the case of personal injuries claims, S.15, 17 and 18 of the Civil Liability and Courts Act 2004 (the "2004 Act") may also be invoked. Under S.15, the court may, at the request of any party to a personal injuries action prior to trial, direct that the parties to the action hold a mediation conference to discuss and attempt to settle the action. There has recently been a successful appeal against such a direction, on the basis that mediation would not have actually assisted in reaching a settlement, which is a statutory pre-condition for a S.15 order (*Ryan v Walls Construction Ltd* [2015] IECA 214). Under a S.15 mediation, a nominated chairperson or a court-appointed one will report on the mediation conference and note any settlement made to the court. Where one party fails to attend, the court will take this into account when making a final award for costs.

To further facilitate settlement prior to trial, S.17 of the 2004 Act provides that both the plaintiff and defendant must make an offer of settlement to each other at any time between the issue of proceedings and before the expiration of two weeks after service of

the Notice of Trial. Where no settlement is agreed, the judge may take into account these offers and the reasonableness of the parties' conduct when awarding costs.

Finally, S.18 of the 2004 Act provides for pre-trial hearings for the purposes of determining what matters relating to the action are in dispute. There has been limited use of both mediation conferencing and pre-trial hearings to date.

There has been significant growth in the use of mediation generally in Ireland in recent years. Either party can suggest mediation as a means of attempting to resolve the dispute. Order 56A of the Rules of the Superior courts, as inserted by SI 502/2010, allows the High Court, either on the application of any of the parties to a dispute or on its own motion, to invite the parties to use an ADR process to resolve the proceedings. In this context, an ADR process is mediation, conciliation or other dispute resolution process approved by the court, but does not include arbitration. If a party refuses or fails to partake in an ADR process without good reason, the court can take this into account when deciding any issue of costs (although it has not imposed such costs penalties to date). The recent case of *Atlantic Shellfish Ltd & anor v Cork County Council & ors* [2015] IECA 283 held that the court should only invite the parties to consider mediation if it considers it appropriate having regard to "*all of the circumstances of the case*" (for example, the nature and potential expense of the proposed form of ADR or whether the issues in dispute are amenable to ADR).

Pursuant to S.32 of the Arbitration Act 2010, the High Court and Circuit Court can adjourn civil proceedings to allow the parties to consider whether the dispute before the court is capable of being resolved by arbitration.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction, be brought within the jurisdiction of your courts either as a defendant or as a claimant?

As a Member State of the European Union, Ireland is subject to the rules of jurisdiction as provided for by the recast Brussels Regulation (Regulation (EU) 1215/2012) (the "Recast Brussels Regulation"). The Recast Brussels Regulation took effect from 15 January 2015. Previously, the relevant jurisdictional rules were found in EC Regulation 44/2001 (the "Brussels Regulation").

As with the previous Brussels Regulation, the general rule under the Recast Brussels Regulation is that a defendant to proceedings having an international element should be sued in his state of domicile, although there are certain exceptions and alternative grounds on which the court may have jurisdiction.

The most obvious circumstance in which a party which is not domiciled in Ireland can be brought before the Irish courts is where the parties have submitted to the exclusive jurisdiction of the Irish courts. The Recast Brussels Regulation provides that, subject to certain formalities and specified exceptions, a court in a Member State will have jurisdiction to hear a dispute where there is a jurisdiction agreement in favour of that court, even if none of the parties to the jurisdiction agreement is domiciled in a Member State.

Absent an exclusive jurisdiction clause in favour of the Irish courts, parties domiciled in a Member State other than Ireland can nonetheless be sued in Ireland in certain circumstances. Although Article 4 of the Recast Brussels Regulation provides that a party "*shall*" be sued in his country of domicile, proceedings relating to product liability will often fall within the special rules provided for in Article 7 of the Recast Brussels Regulation, which provides that, in the case of a tort, jurisdiction is granted to courts of the state in which the harmful event occurs. Therefore, if it can be shown that the harmful event caused by a defective product occurred in Ireland, a foreign producer may be sued in the Irish courts.

Further, the provisions in relation to exclusive jurisdiction agreements do not apply to consumers, who must be sued in the courts of the Member State in which they are domiciled. The jurisdiction rules relating to consumer contracts are set out in Articles 17 to 19 of the Recast Brussels Regulation. Where a cause of action in a contractual dispute relates to product liability, a consumer is entitled to bring the suit in the jurisdiction in which the producer is domiciled or in the country in which the consumer is domiciled. A foreign producer can thus be subject to the jurisdiction of the Irish courts where a consumer using his product is domiciled in Ireland.

Special jurisdiction rules apply where a party is domiciled in a Third State (Non-Member State). Articles 33 and 34 of the Recast Brussels Regulation give discretion to Member State courts to stay proceedings in favour of proceedings pending before the courts of a Third State, subject to satisfying certain conditions. However, a degree of uncertainty remains where the provisions of Articles 33 and 34 are not met. Following the decisions of the *European Court of Justice in Owusu v Jackson (Case C-281/02)* and *Group Josi Reinsurance Co SA v Universal General Insurance Co Ltd* (Case C-412/98), which were made under the previous Brussels Regulation, once an action comes within the scope of the Recast Brussels Regulation, a national court cannot decline jurisdiction on the ground of *forum non conveniens*. It is arguable that, save as provided for in Articles 33 and 34, *Owusu* and *Group Josi* continue to apply. Given this uncertainty, it is likely that Articles 33 and 34 will be the subject of further clarification.

5 Time Limits

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

Statute

Under S.7(1) of the 1991 Act, a limitation period of three years applies to proceedings for the recovery of damages under the Act. The limitation period runs for three years from the date on which the cause of action accrued. The limitation period under the 1991 Act has been reduced to two years in one respect following the enactment of the 2004 Act and the subsequent decision of the Irish High Court in *O'hAonghusa v DCC PLC & Others* [2011] IEHC 300. Where the limitation period runs from the date on which the plaintiff became aware of, or should reasonably have become aware of, the damage, the action must be brought within two years of this date. This is due to the "knowledge" provisions of the Statute of Limitations (Amendment) Act 1991 being amended by the 2004 Act.

Interestingly, S.7(2)(a) provides for a "long stop" provision, which extinguishes the rights conferred on the injured party pursuant to the 1991 Act on the expiry of 10 years from the date on which the producer put into circulation the actual product which caused the damage, unless the injured person has in the meantime instituted proceedings against the producer.

Tort and Contract

In actions in tort or contract, the various time limits within which proceedings must be instituted are laid down in the Statute of Limitations 1957 and the Statute of Limitations (Amendment) Acts 1991 and 2000.

In an action for tort, these provisions set a general time limit of six years from the date on which the cause of action accrued − that is, the date on which the negligent act occurred.

In an action claiming damages for negligence, nuisance or breach of duty where the plaintiff claims damages for personal injuries, the limitation period is shorter. This was formerly three years from the date of accrual of the action or the date on which he became aware of the accrual of the action, whichever is later (i.e. the date of discoverability is relevant). However, the Civil Liability and Courts Act 2004 reduced the limitation period for personal injuries actions to two years for dates of accrual/knowledge on or after 31 March 2005.

In contract, there is a limitation period of six years from the date of the accrual of the action. This is the date on which the breach of contract occurred, not when the damage is suffered.

The courts have the discretion to strike out proceedings where there has been an inordinate and inexcusable delay or want of prosecution on the part of the plaintiff and the defendant has suffered prejudice as a result of this, so as to make it unfair to allow the case to proceed.

In December 2011, the Law Reform Commission published a report and draft bill on the limitation of actions in respect of all claims (except those relating to land). The report recommends a uniform basic limitation period for 'common law actions', which would include actions in tort and contract, of two years, to run from the date that the claimant knew or ought to have known of the cause of action. 'Knowledge' includes both actual and constructive knowledge. The report recommends the introduction of a uniform ultimate limitation period of 15 years to run from the date of the act or omission giving rise to the cause of action. It also recommends that this period should apply to personal injuries actions, and that there should be a statutory discretion to extend or disapply the ultimate limitation period. These proposals have not yet been implemented.

Criminal

As regards criminal sanctions, the 2004 Regulations do not provide for a period within which prosecutions must be brought. However, the general period applicable to summary offences is six months.

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?

There are special limitation rules concerning persons who are under a disability:

- infants;
- persons of unsound mind;
- convicts subject to the operation of the Forfeiture Act, 1870, in whose cases no administrator or curator has been appointed under that Act; and
- plaintiffs of sexual abuse, committed while they were under age, or suffering from consequent psychological injury that impaired them from bringing an action.

Furthermore, in proceedings in which the Liability for Defective Products Act 1991 is pleaded, the 'Long Stop Date' of 10 years from the date the product is put into circulation by the producer would apply as per S.7(2)(a) of the 1991 Act.

Fraud on the part of the defendant may also prolong limitation periods.

No proceedings are maintainable in respect of any cause of action which has survived against the estate of a deceased person unless the proceedings were commenced within the correct limitation period and were pending at the date of his death; or that the proceedings were commenced within the correct limitation period or within two years after his death, whichever period first expires.

The court does not have discretion to disapply time limits statutorily imposed.

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

In accordance with S.71(1) of the Statute of Limitations 1957, where there has been concealment or fraud, the limitation period does not begin to run until the plaintiff has discovered the fraud or could, with reasonable diligence, have discovered it. Therefore, issues of concealment or fraud may prolong limitation periods.

6 Remedies

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

In Ireland, damages are usually by lump sum payment, rather than by annuity or smaller payment over a period of time. Damages are awarded to place the injured party back in the position he would have been in had the wrong not occurred.

There are two main categories of damages, special and general damages. Special damages or out-of-pocket expenses compensate for actual pecuniary loss suffered in the past and to be suffered in the future, for example, loss of earnings. These are not recoverable unless proven, or agreed between the parties. This type of damages is usually formulated on the basis of actual expense and liabilities incurred up to the date of trial and future loss, the estimated anticipated loss being usually based on actuarial evidence.

General damages compensate for non-pecuniary loss both present and future, such as pain and suffering or loss of life expectation. General damages can be divided into two figures, one representing pain and suffering up to the trial, and another figure for pain and suffering in the future. However, some lower courts will not make this division and simply award a single global figure. The award of damages is at the discretion of the judge, considering all the evidence and medical reports, which are comparatively high in Ireland by European standards.

In exceptional circumstances, exemplary/punitive or aggravated damages may also be awarded.

Under S.54(1)(b) of the Personal Injuries Assessment Board Act 2003, one of the principal functions of the Injuries Board is to prepare and publish a document known as the Book of Quantum, containing general guidelines as to the amounts that may be awarded or assessed in respect of specified types of injury.

S.22 of the 2004 Act states that the court shall, in assessing damages in a personal injuries action, have regard to the Book of Quantum. S.22(2) does allow the court to take other matters into account when assessing damages in a personal injuries action.

The Civil Liability (Amendment) Bill 2017, published on 13 January 2017, proposes to empower the courts, as an alternative to lump sum awards of damages, to make consensual and non-consensual periodic payments orders to compensate injured victims in cases of catastrophic injury where long-term permanent care would be required. However, this bill is still in an early stage.

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

Statute

S.1(1) of the 1991 Act defines "damage" as:

- death or personal injury; or
- loss of, damage to, or 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 injured person mainly for his own private use or consumption.

It is interesting to note that this definition excludes damage to the product itself, preferring to leave such claims to the law of tort. It should also be noted that the final line of the definition above excludes damage to property used in the course of a trade, business or profession.

"Damage" under the 1991 Act includes damage for pain and suffering caused by the defective product.

Tort and Contract

The laws of tort and contract allow an injured party to claim damages for death or personal injury caused by the defective product, as well as for pain and suffering (both physical and mental), damage to property and, in contrast to the 1991 Act, 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?

There is no Irish precedent for the court to allow damages to be recovered in such circumstances and it is of significance that the Supreme Court has disallowed the recovery of damages in what have been referred to as asbestos "worried well" cases – i.e. cases where claimants sued for damages for mental distress in respect of an apprehension of injury or illness arising from having come in contact with asbestos in the past, where there was no evidence of actual injury or illness.

However, given the *Boston Scientific* decision (discussed at question 2.2), it is possible that the broad definitions of "damage" and "defect" applied by the CJEU will be used to argue that the costs of medical monitoring are recoverable, particularly in cases of implanted medical devices.

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

Punitive damages may be awarded in exceptional circumstances. This would include, e.g., circumstances where there has been a deliberate and conscious violation of rights. In Ireland, awards of punitive damages tend to be in fractions of the general damage award, rather than in multiples.

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. The ordinary jurisdictional rules of the courts apply. There is no upper limit on the amount of damages which can be awarded by the High Court against a single manufacturer.

However, S.3 of the 1991 Act does provide for a *minimum* threshold of damages, stating that the provisions of the Act will apply only where damage exceeding €444.41 in value has been suffered by the injured party. This provision was clearly motivated by a fear that the strict liability provisions of the Act might release a rush of trivial claims.

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?

Claims can be settled at any time, prior to and during a court hearing. Where a plaintiff is a minor or is under a disability, leave of the court is required before an action is settled.

The District Court Rules provide for the lodgement of money in satisfaction of a plaintiff's action, with or without acknowledging liability. Where the plaintiff is a minor or under a disability, a Notice of Motion must be filed and served seeking to have their acceptance approved by a judge. Similarly, a minor or a person under a disability seeking leave to accept a lodgement or tender offer in the Circuit Court will have to make an application by way of Notice of Motion and grounding Affidavit. The acceptance of a lodgement or tender offer in the High Court, by or on behalf of an infant or a person of unsound mind suing either alone or in conjunction with other parties, as governed by Order 22, rule 10(1) Rules of the Superior Courts, must be approved by the High Court. This approval is sought by an *ex parte* application on Motion grounded on Affidavit.

As there is no provision for group or class actions in this jurisdiction, no specific 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?

The Social Welfare and Pensions Act 2013, which commenced with effect from 1 August 2014, introduced the Recovery of Certain Benefits and Assistance Scheme (the "**Scheme**"). The Scheme requires a "compensator", being the party paying compensation to a plaintiff, to reimburse the Department of Social Protection for certain Specified Benefits, e.g. illness benefit or disability allowance, which were paid to the plaintiff by the Department in respect of the injury being compensated. The compensator is the party responsible for ensuring compliance with the Scheme.

Some private insurance companies can seek to be reimbursed when fees paid by them are later recovered by the plaintiffs in a court award or settlement.

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 general rule is that "costs follow the event". The judge has full discretion in this matter, however. Costs will include lawyer costs, court fees and incidental expenses, necessarily incurred in the prosecution or defence of the action.

In criminal prosecutions, under the 2004 Regulations, the CPCC will recover the costs of a successful prosecution from the convicted party, including the costs of investigations and detention of products, unless, under S.21 of the Regulations, the court is satisfied that there are "*special and substantial reasons*" for not ordering the recovery of these costs.

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

There exists a civil legal aid scheme in Ireland, but limited funding would only very rarely be made available for personal injuries actions.

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

Yes. The applicant must satisfy financial criteria, i.e. a means test, must have reasonable grounds for proceeding with the litigation as a matter of law, and must be reasonably likely to succeed in the litigation. In practice, nearly all personal injury actions are run without the benefit of legal aid.

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

The practice of charging contingency fees is illegal in Ireland, as it is considered to be champerty, i.e. aiding a claimant to litigate without good cause and taking a share of the profits. An exception relates to recovery of a debt or a liquidated demand.

However, the lack of a comprehensive civil legal aid scheme has meant that many solicitors now operate on a "no win no fee" basis, in other words, the client will not be charged a professional fee unless the claim is successful. This is deemed to be acceptable practice (and indeed, in the personal injury sphere, is widespread), and in fact reduces the pressure on the Government to provide a more comprehensive Legal Aid scheme.

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

Both maintenance and champerty are prohibited by law and this has prevented the development of third party funding of litigation in Ireland. Maintenance is the agitation of litigation by furnishing aid to a party in order that he or she might bring or defend a claim without just cause. In this regard it should be noted that a charitable motive is a good defence to an action for maintenance.

Champerty occurs when there is, additionally, an agreement that the person funding such aid shall receive a share of what is recovered in the action brought or the promise of remuneration over and above ordinary costs. A person who assists another to maintain or defend proceedings without having a *bona fide* interest acts unlawfully and contrary to public policy and cannot enforce such an agreement.

7.6 In advance of the case proceeding to trial, does the Court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

No. However, if at the conclusion of proceedings an order is made allowing one party to recover their legal costs from another, the party who has been ordered to pay can require that the costs be "taxed" (i.e., reviewed and independently adjudicated upon by a "Taxing Master").

In deciding whether or not to make a court order, particularly in the discovery process, a court may consider the proportionality of the costs of fulfilling that order.

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 your jurisdiction.

The Competition and Consumer Protection Act 2014 created the newly formed Competition and Consumer Protection Commission ("**CCPC**"). On 31 October 2014, the new agency took over the product safety role of the former National Consumer Agency under the 2004 Regulations, including the responsibility for taking prosecutions and ordering product recalls. The CCPC has a broad mandate for conducting market surveillance in relation to the safety of products under various EU Directives.

The *Boston Scientific* CJEU decision, as discussed at questions 2.2 and 6.3, is significant, although its implications are yet to be explored by the Irish courts.

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Matheson

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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 governed in Italy by Legislative Decree no. 206 of September 6, 2005, the so-called Consumer Code, and is the last of a series of legislative acts, the first of which is dated back to 1988, whereby EU Directive no. 374 of 1985 has been implemented.

The Consumer Code sets forth a strict, non-fault-based kind of liability. This liability can be claimed by the consumer for personal damages, consisting of death or physical injuries, or for damage caused to goods which are normally destined for private use, which has been caused by a defective product.

This liability is alternative to contractual and tort liabilities, as already governed by the Civil Code.

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

In particular circumstances, where a violation occurred on a large-scale basis entailing a right that is constitutionally safeguarded, the State may operate indemnity schemes. Indemnity cannot be regarded as a form of compensation, but rather as a kind of welfare measure. Thus, having the right to receive an indemnity does not *per se* prevent the damaged consumer from raising claims seeking full compensation for the relevant damage.

By way of example, Law no. 210 of 1992 provides for a monthly publicly financed monetary indemnity for subjects suffering permanent injuries or illness as a result of transfusions of infected blood or blood derivatives, or as a result of the injection of defective vaccines.

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, the manufacturer is the first subject liable for damage caused by the defective product. The manufacturer is anyone:

- manufacturing the product in the EU;
- presenting itself as manufacturer by placing a name, a trademark or any other distinctive sign on the product, or reconditioning the product;
- representing the manufacturer whenever the former is not established in the EU, and importing the product whenever the manufacturer has no representative established in the EU; or
- included in the supply chain, insofar as its activity may affect the standards of safety of the product.

The distributor (any professional operator that is part of the supply chain of a product, provided that it does not impact the safety of the same product) may also be held liable, but only residually, in the event that the manufacturer is not identified. Nonetheless, the distributor can escape such a liability by allowing the identification of the manufacturer.

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 Code, the manufacturer has to manufacture and market safe products.

The manufacturer and/or distributor who knows or should know, on the basis of the information in their possession and in their capacity as professionals in the sector, that a product they placed on the market exposes consumers to risks that are incompatible with general safety requirements, must adopt corrective measures commensurate to the characteristics of, and to the risks posed by, the same product.

Corrective actions have to be evaluated taking into account the risk that the product poses to consumers. The assessment of said risk is usually made on the basis of the following steps:

- identification of the defect, with details of the nature and cause of the same, the total number of products affected and who could be affected by the defect;
- an estimate of the level of risk, which depends on both the severity of the possible injury to those using the product and the probability of injury; and
- evaluation of the acceptability of the risk for consumers.

In case a serious level of risk emerges from the above-mentioned elements, the corrective measure to adopt usually consists of the recall of the product. If necessary, lacking any initiative on the part of the manufacturer in this regard, the relevant authority may impose the same recall.

Failure to undertake a recall or other corrective actions aimed at keeping a dangerous product off the market is punishable under Criminal Law. In addition, such a failure may represent evidence in favour of the consumer in cases of litigation aimed at seeking compensation for damages caused by the dangerous product.

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

The manufacturer and/or distributor that fails to adopt measures aimed at remedying the risks deriving from a defective product placed on the market may incur criminal liability. Unless the conduct constitutes a more severe criminal offence (for instance, in the event the defect causes death), the manufacturer/distributor may be subject to arrest for a period of between six months and one year, or to pecuniary sanctions ranging from Euro 1,500 to Euro 50,000.

2 Causation

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

The consumer who claims to have been injured by the defective product has the burden of proving:

- the defect of the product;
- the damage allegedly suffered; and
- causation, in terms of existence of a causal relationship between the aforesaid defect of the product and the damage claimed.

In line with a trend in the case-law of merits Courts, it has emerged that the existence of the defect of a product could be inferred by the damage. Thus, no specific evidence of the defect would be needed.

Nonetheless, such a trend appears to change following a decision of the Supreme Court. Such decision can be now regarded as a benchmark in the matter. Specifically, in accordance with this decision the defect of the product has to be proved. In other words, evidence has to be offered that the same product lacks the general safety conditions which are required and can be expected with regard to the common use for which it has been manufactured and marketed (Court of Cassation, decision no. 6007 of March 15, 2007).

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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

The proof that the damaged party has to provide depends on the nature of the alleged defect.

When the product itself is safe and only a single product, which the damaged party was exposed to, malfunctioned or was defected, the same damaged party has to prove the relevant defect (however, some Authors affirm that said burden of proof could be satisfied by demonstrating that such single product differs from all other products of the same set).

In the event the injury derives from a defect which is common to all similar products (i.e. the product itself is unsafe or it has been wrongfully designed, or there is a lack of information provided by the manufacturer), it will be sufficient for the damaged party to prove the defect of all the category of products, not necessarily of the single product he or she entered into contact with.

In cases where said proof is not easily reachable, presumptions may be considered sufficient by the judges.

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 Consumer Code, in the event several subjects caused the damage together, each of them is jointly liable and obliged to provide compensation. Should only one of the subjects compensate the damage at issue, it has the right to act against the others to recover the amount due by each of them. Said amount has to be determined taking into account the extension of risk, the seriousness of the wrongdoing and the relevant consequences attributable to each subject. Should this assessment not be possible, depending on the circumstances, all the subjects involved have to be considered equally liable.

If the damage is not caused by a common activity but by a single manufacturer to be identified, the relevant burden is on the plaintiff, and no form of market-share liability is applicable.

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 Code, the manufacturer has to provide the consumer with useful information to assess and prevent risks deriving from the use of the product as foreseeable given its scope, unless such risks are immediately obvious without any specific indication.

The content and extent of the information to be provided has to be determined having regard to the qualities and characteristics of the product. The ways the product is submitted to the attention of the public, including for instance packaging, warnings, handbooks, instructions and intermediaries, also have to be taken into account to this end.

Should the manufacturer fail to provide adequate information as above, preventing the consumer from understanding and consequently avoiding the risks arising from the use of the product, it may incur liability for defectiveness of the same product.

In general terms, in addition to publicly available information, only information provided to the consumer by the manufacturer is relevant in making an evaluation of the defectiveness of the product.

A slightly different situation occurs when the consumer can obtain the product only through an intermediary, who then has a personal duty to evaluate the suitability of the product. In this case, the intermediary, as a result of its professional skills and capacities, may incur personal liability should it make an inappropriate evaluation or in turn fail to provide the consumer with adequate information in its possession. Despite the liability of the intermediary, if a product turns out to be defective, the manufacturer will also be liable (but it could ask for compensation from the intermediary).

No principle of "learned intermediary" is applicable.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under the Consumer Code, liability is excluded in case:

- the manufacturer did not place the product on the market. In general, a product is considered as marketed if it is delivered to the purchaser, to the user or to an assistant of one of them; which also includes products to be viewed or tested only;
- the defect which caused the damage did not exist at the time the manufacturer placed the product on the market;
- the manufacturer did not manufacture the product for sale or distribution against payment of consideration, or did not manufacture or distribute it in the exercise of its business;
- the defect is due to the compliance of the product with a mandatory legal provision or with binding public measures; or
- the scientific and technical knowledge available when the manufacturer placed the product on the market did not allow the manufacturer to consider the product as defective.

In terms of exclusion of liability of the distributor, please refer to the answer to question 1.3 above.

Provided the above, liability is also excluded if the consumer *per se* caused the relevant damage. Specifically, compensation is excluded if the consumer, despite having been aware of the defect of the product and the related risks, voluntarily exposed himself or herself to them.

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?

Please refer to the answer to question 3.1 above.

In accordance with some Authors, however, the actual application of this exemption of liability would be limited, due to the provisions set forth by product safety regulations imposing on the manufacturer post-selling obligations.

In any case, the burden to prove that there is no liability 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?

Please refer to the answer to question 3.1 above.

According to the majority of Authors, liability can be escaped only when the mandatory legal provision or the binding measure imposes specific conditions or formalities on the manufacturer, and not when it sets forth minimum safety standards. As a matter of fact, compliance with such minimum safety standards would not amount to a valid defence.

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?

Different consumers, all allegedly damaged by the same kind of product, can each initiate separate proceedings and raise claims based on different legal grounds. No form of issue estoppel can prevent a different consumer from re-litigating issues related to liability for a certain product.

Provided the above, however, previous rulings over cases regarding liability for the same product, albeit not binding, may be regarded by judges as a precedent to be followed when evaluating the relevant claims.

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 allegedly liable for the damage claimed by the consumer can in turn raise a claim, in the same or in subsequent proceedings, against any third party that caused or contributed to the fault or defect of the product at issue.

Such a claim would be subject to its own statute of limitation period, in general:

- ten years for contractual liability;
- five years for tort liability;
- three years for product liability (please refer to the answer to question 5.2 below); and
- one year for liability of the seller in case of the sale of a defective product to a professional. A professional is considered to be anyone purchasing goods within the exercise of its business.

Each of the above terms starts running from the day on which the relevant right can be exercised, i.e. respectively, in general when:

- the non-performed obligation became due or the breach of the relevant contractual obligation occurred;
- the damaged event occurred;
- the consumer became aware or should have become aware of the damage, the defect of the product and the identity of the liable subject (please refer to the answer to question 5.2 below); and
- the purchaser became aware or should have become aware of the defect of the sold goods.

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

Liability is excluded in cases where the consumer who has been damaged by the defective product *per se* caused the relevant damage; specifically, compensation is excluded if the consumer, although

having been aware of the defect of the product and the related risks, voluntarily exposed himself or herself to the same risks.

Furthermore, in cases where the consumer who has been damaged by the defective product contributed towards the relevant damage, compensation is reduced proportionally having regard to the seriousness of the negligence attributable to the same consumer and the extent of the consequences arising therefrom.

4 Procedure

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

Civil proceedings are held by a single judge (as a general rule) or by a panel of judges in some specific cases.

Juries are not contemplated in civil proceedings.

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)?

Should the case require specific technical knowledge, the judge may appoint, also upon a party's request, one or more experts (*Consulente Tecnico di Ufficio* – "CTU") to act as the judge's assistants and provide technical expertise.

The CTU is selected from lists of experts filed in each court. Otherwise, the CTU's appointment has to be previously authorised by the President of the Court. The parties can oppose the appointment of the CTU on proper grounds, such as risk of impartiality or bias.

Each party can appoint its own retained expert to work together with the CTU (*Consulenti Tecnici di Parte* – "CTPs").

The CTU cannot make legal assessments, establish the existence of legal provisions or assess documentary evidence. His/her role is strictly limited to technical questions posed by the court.

The expertise proceeding is carried out in writing. The CTU shares a preliminary report with the CTPs; subsequently the CTU files a final report, including comments or remarks of the CTPs.

The content of the final report filed as above is not binding for the judge, who may disagree with the relevant outcome and provide adequate grounds in support of his/her 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?

A modification of the Consumer Code dated back 2008 has introduced class actions as a mechanism to seek damage compensation for certain kinds of multiple claims, including claims arising from the same defective product.

A class action can be brought in relation to wrongful events which occurred after 15 August 2009.

The relevant procedure consists of a preliminary admissibility stage (certification), which may be followed by the merit stage for the assessment of liability and damage. Homogeneity of the rights claimed by the members of the group is an essential condition for admissibility.

Class actions are based on an opt-in system.

The decision of the court, ruling in panels, can provide for a direct condemnation or set forth the criteria to calculate the amount due to the members of the group or the minimum amount due to each of them. Assessment of individual damage can be remitted to a subsequent settlement or litigation.

Since class actions have been introduced in Italy, approximately 70 cases have been initiated, but only a very limited number of them have been certified. In fact, so far this procedural instrument does not seem to be very commonly used. An average of only 10 cases per year have been brought by this procedural instrument. This is a very small result, considering that approximately four million new civil cases are initiated in Italy every year.

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

Class actions can be brought by any single consumer as a class representative, providing there is evidence that the claims raised are worthy of being litigated in this way due to the existence of homogenous rights to protection within the potential group.

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

In Italy, there is no formal distinction between the trial and pre-trial phase.

The certification phase (pre-trial phase) may last some months; including the appeal on certification, this phase can last up to a year.

On average, the complete first instance proceedings may last from one to five years. Timing may vary depending on different factors, such as the workflow of each court or the way the specific case develops, for instance whether evidence-gathering activities have to be carried out or not.

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 decide to evaluate preliminary issues first. They include preliminary procedural matters (e.g. lack of jurisdiction, lack of venue, lack of legal capacity to sue) or preliminary matters on the merits (e.g. time-barred claims).

In practice, however, judges tend to evaluate both preliminary and non-preliminary issues together at the end of the proceedings.

There is no jury in civil litigation.

4.7 What appeal options are available?

All parties have the right to appeal.

In general, in Italy there are three levels of courts:

- first-instance courts (justices of the peace and tribunals);
- second-instance courts (courts of appeal for judgments rendered by tribunals, and tribunals for judgments rendered by justices of the peace); and
- the Court of Cassation (Supreme Court).

Decisions issued in first instance proceedings can be appealed before courts of second instance, which can rule again on the merits of the case. Nonetheless, new claims and new challenges are not

admissible; new evidentiary means or requests cannot be admitted unless they are deemed as essential for deciding the case or unless the party proves that they could have not been submitted during first instance proceedings for reasons not attributable to the same.

All parties have the right to challenge the merit decision before the Supreme Court, which stands at the top of the court hierarchy. It is the court of last resort and its task is to ensure the consistent interpretation and application of the law. The Court review is limited to issues regarding the interpretation and correct application of the law, without any further evaluation on the merits.

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 refer to the answer to question 4.2 above.

The parties may appoint their own experts, even if the judge fails to appoint a CTU, in order to draft written reports which shall be filed in the proceedings. In general, there is no restriction on the nature or the extent of this kind 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?

Pre-trial deposition or exchange of witness statements or expert reports is not admitted.

Pre-trial technical investigations can be initiated whenever there is the need to ascertain a factual situation which may be subject to modification or deterioration before evidence-gathering activities in subsequent proceedings are initiated. In general terms, these proceedings, which are court-ruled, are not widely used.

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

No discovery rule is applicable.

Pending the proceedings, during evidence-gathering activities, the judge may, upon a party's request, order the counterparty or any third party to exhibit documents.

In case the counterparty or any third party as above refuses to do so and fails to provide a valid reason to support the refusal, the judge may infer from its conduct to rule over the case.

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

There are no pre-filing requirements to begin a formal, ordinary lawsuit for product liability. As a result of a recent reform of the Italian procedural law, since 9 February 2015, for claims for payments of any amount between €1,100 and €50,000, before litigating in court parties to a dispute have to carry out negotiations in the presence of their attorneys at law to try to amicably settle their dispute (assisted negotiation). Assisted negotiation is not mandatory in the case of disputes that arise as per obligations set forth by agreements entered into by professionals and consumers.

In addition, Law no. 28 of 2010 set out a "mediation procedure" for an out-of-court settlement, to be carried out before a mediation authority. Said mediation procedure is compulsory before trial in some specific matters (listed by Art. 5 of Law no. 28 of 2010), some of which (damages arising from medical and healthcare liability) may be at stake in product liability suits. In all other cases, the choice of initiating said mediation procedure is up to the parties.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction, be brought within the jurisdiction of your courts either as a defendant or as a claimant?

Jurisdiction over product liability cases is governed by EU Regulation no. 1215 of 2012, as well as Law no. 218 of 1995, setting for conflict of law provisions.

In general, on the basis of the above, Italian courts have jurisdiction over claims for compensation of damages due to an event which occurred or which may occur in Italy, irrespective of the fact that the claimant or the defendant is domiciled in Italy. Cases involving foreign companies are grouped before selected specialised courts.

Italian Courts also have jurisdiction over claims raised by a claimant who is not domiciled in Italy against any defendant who is domiciled in Italy.

5 Time Limits

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

The limitation period for product liability claims is three years, running from the day on which the consumer was allegedly damaged by the defective product, becomes aware or should have become aware of the damage or defect, or the day on which the consumer becomes aware of the identity of the liable party (please refer to the answer to question 3.5 above).

In any case, the right to be compensated for the defect of a product expires after 10 years, running from the day on which the manufacturer or importer within the EU placed the relevant product on the market.

However, the claimant may bring an ordinary tort action instead of a product liability action and exploit the relevant five-year term.

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?

Please refer to the answers to questions 3.5 and 5.1 above.

The limitation period does not vary based on the age or condition of the claimant. The court has no discretion in this regard.

A limitation period can in any case be interrupted. In general, this occurs whenever proceedings are initiated to raise the relevant claim or such a claim is raised in pending proceedings. In case of interruption, the limitation period starts running again afresh, as soon as a binding decision is issued as an outcome of aforesaid proceedings.

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

No specific provision is set forth in relation to effects of issues of concealment or fraud over limitation periods. Nonetheless,

the aforesaid issues may impact the running of the same period. Indeed, as per the general rule set forth by the Consumer Code, the limitation period starts running from the day on which the consumer acknowledged or should have acknowledged, *inter alia*, the defect on the basis of ordinary diligence and the overall circumstances; therefore, a concealment or fraud could postpone the running of the term (please also refer to the answers to questions 3.5 and 5.1 above).

Provided the above, in general, should such issues of concealment or fraud amount to criminal offences, the longer limitation period, generally of six years, provided by the criminal law to prosecute the offender, applies instead of the period indicated above.

6 Remedies

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

As a general remark, product liability claims can be raised to seek compensation for personal damage, causing death or physical injuries, as well as for damage to objects normally used for private purposes and destroyed or damaged by the defective product.

Having said that, both pecuniary and non-pecuniary damages suffered by the consumer (as above) are recoverable.

The Consumer Code does not provide for injunctive/declaratory relief for individual consumers, but only for consumer associations.

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

For some decades now, both case-law and authors have identified four categories of damage:

- economic damages, which consist of monetary damage due to pecuniary loss or loss of profits;
- biological damages, affecting the psychological and/or physical integrity of a person, directly related to his or her health;
- moral damages, essentially consisting of pain and suffering to be awarded only in cases provided for by law (mainly as a result of a criminal offence); and
- existential damages, as 'created' by case-law to consent compensation of damage, not included within the above category of moral damage, essentially consisting of any event that negatively affects someone's 'quality of life'.

By a fairly recent stand-out ruling, the Joint Sections of the Court of Cassation maintained that non-pecuniary damages are compensable only in cases provided for by the law, i.e. whenever compensability is expressly acknowledged in a law provision and whenever, even lacking such a law provision, the damage entails the violation of a personal right which is constitutionally safeguarded (Court of Cassation, decision no. 26972 of 2008). In view of the above and on the basis of such ruling, existential damage is no longer compensable as an autonomous category of damage. Decisions from Italian courts, even those issued by the Supreme Court, do not amount to binding precedents; however, they may have a persuasive effect. So far, the trend of lower level courts is to follow the above interpretation.

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 general terms, compensation is admitted only as restoration of damages actually suffered as a consequence of the defective product. Otherwise, in principle, no compensation is possible.

Having said that, once the damage has occurred, compensation may also cover costs for future medical monitoring, including costs related to investigations, tests and treatments, whether or not they were foreseeable as a result of the ascertained injury.

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

Punitive damages are not admitted.

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 limit is set forth.

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 specific rule applies in the case of settlement of claims or proceedings. As far as class actions are concerned, in general, conciliation or settlement between class representatives and the defendant do not affect class members who are not party to the out-of-court agreement.

Regardless of the product liability rules, some kinds of settlements involving minors have to be authorised by the judge.

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 specific regulation is set forth, nor is there any case-law to report in this regard.

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 the final decision the judge also awards costs of the proceedings. In general, it is the responsibility of the losing party to refund the winning party's court expenses and legal fees incurred during the

proceedings. Nonetheless, depending on the circumstances, the judge may rule that each party bears its own costs. As a matter of fact, judges frequently deem that it is not appropriate for a company to recover costs against losing individuals.

Provided the above, in case they are awarded, recoverable fees are very rarely those actually paid by the winning parties. Fees are calculated to this end on the basis of parameters included in tariffs set forth by the Ministry of Justice; quite frequently, these parameters do not reflect the economic conditions applied by law firms.

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

In general, an indigent party can access legal aid and file an application to this end to the local Bar Association.

Legal aid is granted on the condition that the claim to be raised is not clearly groundless. Legal aid can be revoked at any time, also pending proceedings, should the judge ascertain that the income of the relevant party actually exceeds the threshold set forth by the law, that the requirements provided by the law are not actually met or that the same party acted or defended itself with malice or gross negligence.

Legal aid includes both costs and fees related to the proceedings. When legal aid is granted, some of the costs are paid by the State and others are waived.

Legal aid is not widespread, given strict limits of admissibility. Moreover, litigation in Italy is not particularly expensive.

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

Please see the answer to question 7.2 above.

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

Contingency or conditional fees have become admissible only in the last few years. Accordingly, parties can agree for legal fees to be calculated keeping the awarded sum as a parameter. Such agreements are only valid if they are in writing and there are particular limitations.

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

Third party litigation funding is not regulated in Italy. In general, it is admissible, but at least so far it is not common at all.

7.6 In advance of the case proceeding to trial, does the Court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

The court does not exercise control over the costs to be incurred by the parties and the claim filed to the court. The (allegedly) damaged party quantifies its claim, if possible, when starting the case. The costs of the proceedings may be influenced, sometimes significantly, depending on the development of the evidence-gathering phase, and in particular when it is necessary to obtain the opinion of a court-appointed expert. In order to avoid these costs from discouraging damaged parties to file their claims, Art. 120 of the Consumer Code allows the judge to initially place these costs on the defendant when the claim of the damaged party is plausible.

As for legal fees, the losing party is generally condemned to refund these to the winning counterparty (in application of the general "loser pays" principle). They are always quantified by the court with its final decision and are proportionate to the parameters set out by Law no. 247 of 2012 (said parameters depend on the value of the claim, the complexity of the case, the number of parties, etc.). This mechanism avoids the risk of the losing party being condemned to refund to the counterparty a disproportionate amount in relation to the value of the claim, even if, on the other side, the winning party may be only partially refunded (amounts set out by the parameters are often lower than the amounts effectively disbursed as legal fees).

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 your jurisdiction.

In the last few years Italian case-law on product liability has developed in line with previous trends as per: (i) the burden of proof – the Supreme Court of Cassation (no. 15851/15) confirmed that the damaged party is solely exonerated from the proof of negligence/wilful misconduct by the damaging party, not from the proof of the "defect"; and (ii) the notion of "defective product", when it lacks safety in comparison with consumers' safety expectations – the Supreme Court of Cassation (no. 3258/16) rejected a claim for compensation for damages allegedly caused by the explosion of a toxic house detergent, stating that the product itself could not be considered "defective", since it was manufactured and distributed in line with the safety standards required for this kind of product.

On this second profile, it is worth mentioning a relevant decision of the Court of Justice of the European Union (CJEU judgment of 5 March 2015, Case nos. 503 and 504 of 2013) regarding medical devices to be implanted in humans for therapeutic purposes, assessing that all the medical devices that had been placed on the market had to be considered defective – irrespective of whether or not anomalies in their functioning had actually been reported in the treated patients – since they did not provide the standard level of safety that consumers or patients may legitimately expect (said decision is also significant for the quantification of damages suffered, which should include, according to the court, the surgical intervention required to remove the defect in the medical devices).

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He has been referred as a recognised expert in product liability in "Who's who in Product Liability" (since 2005, on a continuous basis), Legal Media Group "Guide to the World's Leading Product Liability Lawyers" (since 2007), www.LegalComprehensive.com (2013) and Expert Guides "Litigation and Product Liability" (2014).

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She has been awarded "Product Liability Lawyer of the Year in Italy" by Corporate INTL Global Awards (from 2014 to 2017) and by Global Law Experts Practise Awards (2015 and 2014), and Lawyer of the Year in Consumer Law – Milan, Italy by Corporate LiveWire – Global Awards (2015).

GIANNI·ORIGONI
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& PARTNERS

Gianni, Origoni, Grippo, Cappelli & Partners ("GOGC&P") is an award-winning – awarded "Italian Law Firm of the Year" at the Chambers Europe Awards for 2017 and again in 2013 and 2012 – business law firm providing legal advice in all areas of commercial law. Established in 1988, the firm to date comprises more than 360 highly specialised lawyers based in Italy (Rome, Milan, Bologna, Padua and Turin) and abroad (Abu Dhabi, Brussels, London, Hong Kong and New York).

GOGC&P has vast experience in all areas of litigation and arbitration and is the clients' choice for all major and most challenging cases. GOGC&P has developed extensive expertise and experience in Product Liability. In this matter, GOGC&P represents domestic and foreign companies in several proceedings and advises them on several matters.

GOGC&P was awarded "Product Liability Law Firm of the Year – Italy" by the magazine "Deal Makers" in 2010, and also by the "Acquisition International Magazine" in 2012, 2013 and 2014.

Japan

Shinya Tago

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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?

A. Traditionally, product liability claims had been brought as tort claims under the Civil Code of Japan. However, since 1995, claims can also be brought under the Product Liability Act (Law No. 85 of 1994) (PLA), which gives a plaintiff more flexibility to seek compensation for damages caused by a defective product. Products covered by the PLA are movable property which is manufactured or processed (therefore excluding real estate, electricity or agricultural products). If a defective product causes any damage to the buyer's life, body or property (excluding the product itself), the buyer can bring a product liability suit against the "manufacturer" (see definition in question 1.3) (Article 3 of the PLA).

The plaintiff is not required to prove that the manufacturer owed a duty to the plaintiff and negligently or intentionally injured the plaintiff. The plaintiff only needs to demonstrate that the product was defective, and that the defect caused the injuries. A product can be deemed defective if it lacks the level of safety which it should normally possess, taking into account its nature and characteristics, its ordinarily foreseeable uses, state of the art (scientific or technical) knowledge at the time of delivery and other relevant circumstances relating to the product.

B. Alternatively, if a claim cannot be brought or is unsuccessful under the PLA, the injured party may bring a tort claim under the Civil Code. This type of claim, which is still relied upon in civil cases to obtain monetary damages, is viewed as a last resort for persons injured by a defective product. Article 709 provides that a person who has intentionally or negligently infringed any right or legally protected interest of another will be liable for any resulting damage. In contrast with the PLA, the plaintiff must prove the defendant's intent or negligence, and the burden of proof is subject to a high standard. Causes of action under Article 709 include fraud and misrepresentation.

C. The Consumer Contract Act (Law No. 61 of 2000) (CCA) protects consumers in their dealings with merchants (business operators). Article 8 of the CCA provides that the following clauses are void if they are included in a contract made between a consumer and a business operator:

- Clauses which totally exempt a business operator from liability to compensate a consumer for damages arising from the business operator's fault.
- Clauses which partially exempt a business operator from liability for damages arising from the business operator's fault (limited to default arising due to an intentional act or gross negligence on the part of the business operator, its representatives or employees).
- Clauses which totally exempt a business operator from liability for damages to a consumer arising from a tort under the Civil Code committed during the business operator's performance of a consumer contract.
- Clauses which partially exempt a business operator from liability for damages to a consumer arising from a tort under the Civil Code (limited to cases in which the tort arises due to an intentional act by, or the gross negligence of, the business operator, its representatives or employees) committed during the business operator's performance of a consumer contract.
- If a consumer contract is a contract for value, and there is a latent defect in the subject matter of the consumer contract (including where a consumer contract is a contract for services, and there is a defect in the subject matter of that contract), clauses which totally exclude a business operator from any liability to compensate a consumer for damages caused by such defect, except in the event that:
  - the consumer contract provides that the business operator is liable to deliver substitute products without the defect, or to repair the goods when a latent defect exists in the products which are the subject matter of the consumer contract; or
  - the consumer contract is concluded between a consumer and a business operator simultaneously with, or after another contract is concluded between, the consumer and another business operator entrusted by the business operator, or between the business operator and another business operator for the benefit of the consumer, and that other contract provides that the other business operator is responsible to provide compensation for all or part of the damage caused by a defect, deliver substitute products without defects or repair the defective products where a latent defect exists in the products covered by the consumer contract.

Although the CCA limits the extent to which the seller of a product may disclaim warranties relating to a product or restrict the remedies available to a buyer injured by a product sold by the seller, it does not offer any specific cause of action for damage caused by defective products.

D. A claim based on breach of contract must be made by a party to the contract. A plaintiff (generally a buyer) can bring a product liability claim against a seller who is his counterparty in a sale and purchase

contract, either for breach of contract or breach of implied statutory warranties under the Civil Code, provided that there is a direct contractual relationship between the injured party and the seller of the defective product. Nowadays, in most consumer transactions, the end-user/buyer does not typically have a direct contractual relationship with the manufacturer as several intermediaries can be involved in the supply chain (manufacturers, suppliers, importers, wholesalers, retailers and so on). As a result, there may often be no cause of action based on breach of contract by a consumer against a manufacturer. Depending on the circumstances, there may be other legal avenues allowing a buyer to seek remedies against a manufacturer under the Product Liability Act or based on tort as explained above.

Article 415 of the Civil Code addresses liability for incomplete performance of obligations, while Article 570 and Article 566 govern warranties against latent defects. Also relevant in this context is Article 526 of the Commercial Code of Japan, an equivalent provision to Article 566 that applies to latent and visible defects in transactions between merchants (business operators).

The parties to a contract can be released entirely or partially from their liability under the PLA or tortious liability under the Civil Code by entering into an agreement on indemnification excluding or capping such liability. However, liability exclusions and limitations are strictly limited by the CCA with respect to contracts entered into between a consumer and a business operator. Notwithstanding any special agreement excluding statutory warranties, a seller's liability would not be excluded in the event of fraud or concealment of known facts (Article 572 of the Civil Code).

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

The Government operates special compensation schemes for pharmaceuticals and products deemed to have specific risks. One scheme is operated under the Preventive Inoculation Law (Law No. 68 of 1948), which compensates victims of injuries caused by inoculations and is entirely funded by the Government. Another scheme, industry-funded and administered by the Pharmaceuticals and Medical Devices Agency (PMDA), Pharmaceutical and Medical Devices Act (Law No. 145 of 1960) provides compensation covering the medical and funeral expenses of individuals and their families in the event of illness, disability or death caused by the side effects of pharmaceuticals.

Another scheme is administered by the Consumer Product Safety Association (*Seihin Anzen Kyoukai*) under the Consumer Products Safety Law (Law No. 31 of 1973). The "SG-Mark" (safe goods mark) is a product certification system. The Association prescribes stringent safety standards covering products that could be dangerous and cause injuries or death and only products complying with the safety specifications and requirements of the Association can bear the SG-Mark. The consumer compensation scheme operates for the benefit of persons injured by these products. Compensation from the Association is capped at 100 million yen per person and depends on the seriousness of the injury and the cause of the accident.

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

Any natural or legal person classified as a manufacturer under the PLA can be held liable. The PLA defines a manufacturer as:

- Any person who manufactures, processes, or imports the product as a business.
- Any person holding himself out to be the manufacturer of a product by putting his name, trade name, trade mark or other indication on the product, or any person who puts his name on the product in a manner that misleads others into believing he is the manufacturer.
- Any person who puts his name on a product and who, in light of the manner in which the product has been manufactured, processed, imported or sold, or any other relevant circumstances, may be recognised as a "substantial manufacturer" (*de facto* manufacturer).

Unless they fall within any of the aforesaid categories, the PLA does not provide any cause of action against distributors or sellers of a product. Claims against these persons must be brought under the Civil Code on other grounds (breach of implied statutory warranty, breach of contract or tort).

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 are several pieces of legislation governing product safety in Japan, including the Consumer Product Safety Act (CPSA), the Electrical Appliances and Materials Safety Act, the Gas Business Act, the Act on the Securing of Safety and the Optimisation of Transaction of Liquefied Petroleum Gas, the Household Goods Quality Labelling Act, the Act on Control of Household Goods Containing Harmful Substances, the Food Sanitation Act, the Poisonous and Deleterious Substances Control Act, the Industrial Standardisation Act (JIS Mark Labelling Act) and so on. In addition, separate laws apply to ships, road transport vehicles, cosmetics, quasi-drugs, pharmaceutical products and medical equipment. These types of product are not included in, or are excluded from, the definition of consumer products regulated by the CPSA. Consumer products are defined as products to be supplied mainly for use by general consumers for their routine everyday activities

The PLA does not contain provisions that would force a manufacturer (including an importer, distributor and so on) to recall or repair a product found to be defective in a product liability lawsuit. However, the CPSA vests powers in the competent Minister (for the majority of consumer products, the minister with regulatory oversight is the Minister of Economy, Trade and Industry) 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 if the minister finds it necessary to prevent the occurrence or decrease the risk of a danger. Under the CPSA, a person engaging in the manufacture or import of consumer products is legally obligated to investigate the cause of product accidents, and if he finds it necessary to prevent the occurrence and decrease the risk of a danger, he must endeavour to recall said consumer products or otherwise take preventive action (Article 38, Paragraph 1). In the event of a serious product accident, or where serious danger has occurred to the lives or bodies of general consumers or the danger is considered to be imminent, the competent Minister may order the person engaging in the manufacture or import of said consumer products to recall the consumer products or otherwise take measures to prevent occurrence (Article 39, Paragraph 1).

Separate statutory rules apply to road transport vehicles, pharmaceutical products and other products which are not treated as Consumer Products regulated by the CPSA, for example: Article 63-2 of the Road Transport Vehicle Act; and Article 68-9 of the Pharmaceutical and Medical Devices Act.

A manufacturer/importer must report the occurrence of a "serious product accident" to the Consumer Affairs Agency (CAA) (Article 35). The CAA may publicly announce the serious incident (Article 36). Those that are not serious may be reported to the National Institute of Technology and Evaluation (NITE) where eletrical appliances and materials are concerned or to the CAA.

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

Generally not, except under the Penal Code (Law No. 45 of 1907) in the case of death or injury caused by a failure to exercise due care. Moreover, certain violations of the CPSA can give rise to criminal sanctions.

2 Causation

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

A. As a general rule, the party bringing a liability claim (buyer or injured party) bears the burden of proof.

Under the PLA, the manufacturer's liability is strict once it is found that the product sold was defective. Proof of the manufacturer's fault/negligence or wilful misconduct is not required to seek monetary compensation. A plaintiff seeking monetary damages under the PLA must prove that the manufacturer's product is defective and that the defect has caused the plaintiff's injuries or damage. In practice, the plaintiff must at least prove that:

- The defendant is a manufacturer (see question 1.3).
- There is a defect in the product that the defendant has manufactured, supplied, placed on the market, or delivered.
- The plaintiff's life, body or property has been injured or damaged as a result of the defect in the product.
- The occurrence of damage and the amount claimed as damages.
- A causal link between the product defect and the injury or damage.

B. In a claim under Article 709 of the Civil Code, the plaintiff must prove that:

- The injury was caused by a defect in the product.
- The manufacturer negligently or intentionally breached a duty owed to the plaintiff and this breach of duty caused the plaintiff's injuries or damage.

In practice, the plaintiff is at least required to prove:

- The existence of the plaintiff's right or legally protected interest.
- The existence of a breach of the plaintiff's right or interest.
- The defendant's intention or negligence in relation to the breach.
- The occurrence of damage and the amount claimed.
- The causal link between the breach and the damage.

C. For breach of contract claims, the plaintiff must prove that the manufacturer has breached the contract through the supply of a defective product in breach of an express or implied warranty and that such breach has caused some damage to the plaintiff.

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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

The PLA does not prescribe any specific test for proof of causation. Instead, the courts will apply the standard test for causation used under the Civil Code. Under Article 709 of the Civil Code, the plaintiff must prove causation between the defendant's negligence and the resulting damage. The requirement has been somewhat relaxed over time, especially as a result of mass-torts cases such as environmental pollution, where causation has been almost presumed in light of circumstances (namely serious disease and contamination and inexperienced victims at a loss to show causation), thereby shifting the burden of proof onto the defendant. The Supreme Court sought to define the degree of proof necessary for causation in *Miura et al. v. Japan et al.*, Supreme Court, 29-9 MINSHU 1417, 24 October 1975, a medical malpractice case, indicating that proving causation in litigation differed from proving causation in a scientific context and that it was sufficient to show a high probability of causation between facts and the occurrence of a specific result.

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 in Japan and one or more specific manufacturers must be sued. When several manufacturers are involved in a product liability suit, they are jointly and severally liable under the PLA or based on tort. A named defendant who has compensated the victim in excess of the share of damages he is otherwise required to bear is entitled to seek indemnification from the others tortfeasors.

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 defect may be found where the manufacturer has failed to warn consumers about the risks associated with the products, in particular by failing to provide adequate instructions or warnings that can

minimise or eliminate foreseeable risks. Japanese courts do not recognise the "learned intermediary" doctrine, but some lower court rulings seem to have admitted a similar defence in relation to prescription medicine.

3 Defences and Estoppel

3.1 What defences, if any, are available?

A. Defences can be asserted under both the PLA and the Civil Code to avoid liability or to transfer all or part of the liability to another party.

A common defence available under the PLA and the Civil Code (under Article 722 of the Civil Code referring to Article 418) is comparative negligence, which may be a partial or complete defence. Comparative negligence can also be claimed in relation to product defect claims brought under the PLA where the manner in which the plaintiff has handled, used or stored the product can be deemed to constitute unforeseeable misuse.

Statute of limitations may also provide a valid defence under Article 5 of the PLA and Article 724 of the Civil Code if the claim is time-barred and brought beyond the applicable three- or 10/20-year statute of limitations (see question 5.2).

Article 4 of the PLA provides for two more defences:

Under Paragraph 1, a manufacturer will not be liable if he could not have discovered the product defect given the state of scientific or technical knowledge at the time of delivery of the product. The manufacturer must prove that the state of scientific or technical knowledge at the time of delivery was such that the existence of a defect could not have been known. Basing a manufacturer's defence on the then current state of the art is rather difficult as Japanese courts have generally interpreted the state of scientific or technical knowledge very narrowly as knowledge meeting the highest scientific or technical standards then in existence.

Under Paragraph 2, a manufacturer of products to be used as a component of, or raw material for, another product is not liable when the defect has occurred primarily because he has complied with the design specifications and instructions given by the final product manufacturer, and he is not negligent with respect to the occurrence of the defect. The component manufacturer (e.g., a subcontractor) must prove that he could not have foreseen or prevented the defect in the product which was integrated into the final products.

B. For breach of contract claims, customary defences are available. The seller may argue that a claim is time-barred under the applicable statute of limitations (see question 5.2).

The other defences available to the seller are:

- Lack of simultaneous performance of the buyer's payment obligations in a contract where the parties' duties are concurrent (in other words, the seller is not under an obligation to perform its duty if the buyer has failed to fulfil its own obligations under the contract).
- Buyer's knowledge of the defect (or negligence in failing to spot the defect; see comparative negligence below).
- A special agreement between the parties disclaiming warranties and liability.

In addition and without limitation, the seller may seek to rely on:

- Comparative negligence, which can be invoked in a situation where the plaintiff can be shown to have assumed a certain level of risks, and therefore the plaintiff's own negligence contributed to the injury. The Japanese courts have adopted a comparative negligence approach as opposed to strict contributory negligence, where each party's negligence for a given injury is considered by the judge when determining damages.
- An agreement between the parties limiting compensation (for instance, the provision of liquidated damages) and liability.
- The absence of fault attributable to the seller.

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 question 3.1. The development risk defence is available but narrowly interpreted as the state of technical and scientific knowledge is determined by reference to the highest standards available at the time. As a result, manufacturers may not easily avail themselves of this 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?

Compliance with applicable laws and regulations is an important factor in determining whether a product is defective. However, compliance or the failure to comply with applicable laws and regulations is not decisive and does not *per se* rule out or trigger 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?

Claims may be brought by different claimants having suffered a damage caused by the same product. Unless there are new grounds to re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, the court might dismiss the case under the doctrine of *res judicata*.

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 seek a contribution or indemnity from a third party for damages incurred by the defendant in subsequent (or concurrent) proceedings if the third party is liable for the delivery of a defective product by the defendant.

Filing a motion asking for the consolidation (*heigo*) of actions pending between two parties while actions are pending between a third party and either party is allowed as long as the following requirements are satisfied: (i) the existence of a nexus and commonality between claims sufficient to justify a common judgment (Article 38 of the CCP); and (ii) the handling of claims through similar proceedings or the satisfaction of other objective consolidation requirements (Article 136 of the CCP). Based on

this procedural option, a defendant can initiate proceedings against such third party and then seek to combine the proceedings with the original product liability suit.

There are time limits for claims against a third party depending on the type of claim: under the PLA, based on tort or breach of contract (see question 5.2).

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

Comparative negligence is a defence available under the PLA and the Civil Code (under Article 722 of the Civil Code cross-referring to Article 418) (see question 3.1). To mitigate the damages a defendant may have to pay, the courts have adopted a proportionality rule under which a portion of damages may be borne by the plaintiff if the defendant is able to prove his comparative negligence claim. The proportionality rule can go beyond comparing the negligence of the tortfeasor and the victim to reflect the role of, e.g., family members partially at fault in the resulting injury.

4 Procedure

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

Judges preside over civil trials and there is no jury system.

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 may order the appointment of expert witnesses (see question 4.8) but, in principle, such experts do not "sit" literally with judges. Yet, under the expert commissioner ("*senmon iin*") system (Article 92-2 of the CCP), expert commissioners can be appointed to support judges and provide support in arranging the contested issues, taking charge of and assisting in reconciliation, conducting research and providing opinions on issues requiring specialised knowledge, participating in the examination of evidence, etc. in their own specialised 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?

There are currently no US-style class actions in Japan. The Act on Special Provisions of Civil Procedure for Collective Recovery of Property Damage suffered by Consumers (Law No. 96 of 2013) introduced a special procedure known as the Japanese class action system. This system provides for a two-tier opt-in procedure. During the first stage, a qualified consumer organisation files a lawsuit requesting the court to confirm the liability of a business operator for a common obligation arising under a consumer contract on behalf of potential consumer claimants. If the action is confirmed, the quantum of damages will be determined based on individual claims filed by consumers having elected to opt-in. However the scope of claims under this Act is limited and only covers claims arising from consumer contracts and to certain categories of property damage, including claims for performance based on contractual obligations, for unjust enrichment, breach of contract, warranty against defects, and claim for damages arising out of unlawful acts. However, damage to property other than the subject matter of the consumer contract, lost profits, personal injury, and pain and suffering are expressly excluded by the Act.

There is also the so-called "appointed party" mechanism under Article 30 of the CCP, which allows certain plaintiffs (or defendants) appointed by other claimants (or defendants) to act on their behalf in pursuing (or defending) civil actions. Appointments can be made when there are enough claimants/defendants sharing a "common interest" (i.e., the main allegations or defences are common amongst them). The appointed party can pursue the case on behalf of the appointing parties and the result will be binding upon the appointing parties, including a settlement.

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. There is no such mechanism under the PLA.

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

In 1996, the former CCP was replaced by a new CCP. One of the key objectives of the reform was to speed up the course of trials. This goal was further emphasised through the enactment of the Law Concerning the Speeding up of Trials in 2003 which provides that legal proceedings must be closed within two years of their commencement. First instance proceedings can last eight months on average but complex cases can take a longer time to resolve. Generally, the courts schedule the initial hearing within one to one-and-a-half months after the plaintiff has submitted a statement of claims and require the defendant to submit an answer about a week before the 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?

Significant authority and powers to conduct the proceedings are vested in the courts and the judges may decide to close the proceedings and enter a judgment at any time. Unless the matter is straightforward, various procedures are available under the CCP which are designed to facilitate pre-trial arrangements relating to points at issue (preliminary proceedings, preparatory proceedings for oral argument and preparatory proceedings by document such as briefs).

4.7 What appeal options are available?

A "*kouso*" appeal can be filed with the appellate court against a final judgment rendered in trial by a court of first instance (a district court or summary court). In principle, it is possible to appeal judgments twice. The first appeal is for the *ex-post facto* review of judgments entered by the first instance courts, and whether claims made in the first instance courts are right or wrong is not directly reviewed. In a sense, the first level appeal is a continuation of the first instance trial. The parties may introduce new evidence or new arguments not previously raised. The appellate court (most often the High Court in a product liability context) may conduct its own fact-finding within

the scope of the complaint based on lower court materials or those submitted to the appellate court. A "*joukoku*" appeal against the final judgment rendered by a lower court (against "*kouso*" judgments; i.e., rendered by a District Court or the High Court) lies to the Supreme Court (or the High Court) as a second appeal. A "*joukoku*" appeal is permitted only when filed for a limited number of reasons (matters of law, excluding questions of fact) such as a violation of the Constitution, serious misinterpretation of laws and regulations, lack of sufficient legal basis and inconsistency of reasoning. The period during which a "*kouso*" or "*joukoku*" appeal can be filed is 14 days from the date on which the judgment has been served.

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 CCP contains a number of provisions governing the appointment and examination of court-appointed experts (Articles 212 to 218). These expert witnesses who have experience and technical expertise can assist the court in understanding any issue in dispute by providing explanations and in dealing with fact-finding. Expert opinions can be delivered in writing or verbally and expert witnesses can be called to testify (and be challenged) before the judges at the hearing. In Japanese litigation practice, the parties often appoint their own experts who can also be summoned as witnesses to testify before the court. These experts are more willing to testify in support of the party that has hired them as opposed to court-appointed experts.

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 principle, there are no restrictions to admissibility in evidence. Any person or item, including hearsay evidence and expert opinions, can be called or submitted as evidence, and judges determine whether or not evidence is admissible at their own discretion. Evidence that violates confession agreements made between the parties or agreements restricting methods of evidence gathering is not admissible. Examination of witnesses is performed in open court after the parties have filed petitions with the court and after the court has designated the witnesses to be admitted and summoned them in order to be examined on the examination date (Articles 180 and 181 of the CCP). Although there is no law or ordinance regarding witness statements, written witness statements are often exchanged instead of direct oral examination 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?

In Japan, there are no disclosure obligations or an extensive discovery process in contrast with common law jurisdictions. Documents submitted as evidence by the parties are typically collected by the parties through their own efforts. Accordingly, if a manufacturer is not cooperating, critical evidence may be concealed from the plaintiff, which is both relevant and admissible in a product liability case, including, but not limited to, notice to the manufacturer of the existence of a defect in one or more of its products, causation, the existence of a defect, and the feasibility of safer alternate designs. It is nonetheless possible to petition a court to issue an order to submit documents after an action has commenced by providing valid reasons to compel the counterparty or a third party keeping certain documents, listed in Article 220 of the CCP in his possession, to submit said documents (Article 221 of the CCP). The person who is filing a motion must indicate (insofar as possible) the document, the identity of the person keeping it, its significance, what needs to be proved with it and the reasons why it is necessary. The obligation to produce documents has been recognised in the following situations: (i) documents a party has referred to for the purpose of presentation of assertion of proof; (ii) documents that a party submitting evidence has the right to require delivery or inspection of while in the possession of another person; (iii) documents showing legal relations which support the rights or legal position of the person filing a motion or documents showing a legal relation between the person filing a motion and the holder of the documents; or (iv) documents that are not excluded. Excluded documents include documents exclusively prepared for use by their possessor and documents that contain confidential technical or professional information (there are a few other exceptions listed under the CCP). Before filing an action, if the (future) plaintiff has given advance notice of the filing to the (future) defendant, the plaintiff or the recipient of the notice may, within four months of the date of the notice, make inquiries to the other party on matters necessary to substantiate his allegations or collect evidence (Article 132-2 of the CCP). In addition, the court may order the submission of documents and the commissioning of examinations when a motion is filed by a party and it is difficult for that party to collect documentary evidence from the other side that would be clearly necessary to prove his case (Article 132-4).

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

There is no obligation to pursue alternatives to litigation. Japanese people and corporates typically prefer amicable settlement of disputes through negotiation over court litigation. Even then, a negotiated settlement (*wakai*) can be made at any time before or during the court proceedings.

ADR is available on a voluntary basis in the form of civil mediation under the Law Concerning the Promotion of the Use of Alternative Dispute Resolution Procedures (the ADR Law). The ADR Law has introduced an accreditation system (not mandatory though) for private dispute resolution services. If the parties can reach an agreement, this agreement is put on record by the court and becomes enforceable in the same manner as a final judgment. Civil mediation procedures are simple and cost-effective (costs are fixed) and proceedings are confidential.

Civil litigants can also agree to refer their dispute to civil conciliation (*chotei*) under the Civil Conciliation Law (the CCL). Conciliation under the CCL is conducted by a conciliation committee composed of one judge and two or more civil conciliation commissioners appointed from a group of knowledgeable and experienced citizens. The committee assists the parties in finding an amicable settlement and usually submits a settlement plan to the parties. If the parties can reach an agreement, this agreement is put on record by the court and has the same effect as a court judgment and can be enforced accordingly. If the parties are unable to reach an agreement, the plaintiff must file a suit before the ordinary courts to pursue their claims.

Although commercial arbitration (*chusai*) has not been used actively as a means of resolving domestic disputes in Japan, it has gradually become an important option, especially in an international context.

A number of industry-associated (product specific) trade associations have established permanent dispute resolution organisations in the wake of the enactment of the PLA: the Federation of Pharmaceutical Manufacturers Associations of Japan, Japan Chemical Industry

Association; Japan Heating Appliances Inspection Association; Association for Electric Home Appliances; Japan Automobile Manufacturers Association, Inc.; Center for Housing Renovation and Dispute Settlement Support; Consumer Product Safety Association ((in charge of the "SG" mark) which has established the Consumer Product PL Center); Japan General Merchandise Promotion Center; Japan Cosmetic Industry Association; Fire Equipment and Safety Center of Japan; Japan Toy Association; Japan Paint Manufacturers Association; and Japan Construction Material & Housing Equipment Industries Federation.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction be brought within the jurisdiction of your courts either as a defendant or as a claimant?

The Code of Civil Procedure (CCP) lays down international jurisdiction rules applicable to litigation in the Japanese courts without expressly referring to product liability claims. According to the prevailing view, they are classified and treated as tortious claims.

Pursuant to the general forum rules of the CCP, a claimant may initiate legal proceedings based on tortious liability or product liability before the Japanese courts against any manufacturer whose principal place of business or whose business office is located in Japan. Under special forum rules, a claimant can generally file a lawsuit in Japan against the manufacturer if the tortious act has occurred in Japan even if the manufacturer has no office in this country. A tortious act is deemed to happen where the tortious act was committed (including the place where the product has been manufactured) or where the results have occurred (unless the occurrence in Japan of the results of a wrongful act committed abroad was unforeseeable).

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?

A. Limitation periods for bringing a claim under the PLA and based on tort.

Under the PLA, the right to seek damages based on product liability is extinguished by prescription if:

- The victim or his legal representatives do not exercise such right within three years from the time they became aware of the damage and identify the party liable for the damages (the responsible manufacturer).
- 10 years have elapsed since the delivery of the product by the manufacturer.

In the event that damage or injuries are caused by substances which become harmful to human health after accumulating in the body, or where the symptoms linked to damage or injuries only appear after the passage of time, claims become time-barred after 10 years from the time of occurrence of the damage.

Claims brought under Article 709 of the Civil Code follow a similar prescription pattern of three years and 20 years, respectively.

Under Article 724 of the Civil Code, the right to demand compensation for damages in tort is extinguished by prescription if it is not exercised by the victim or his legal representative within three years from the time when he became aware of the damage and identifies the perpetrator. The same applies if 20 years have elapsed after the tort has been committed.

Notwithstanding the above rules, a court may still decide to set aside the statute of limitations in the interest of justice in cases of fraud or concealment of evidence.

B. Limitation periods for bringing a claim for breach of contract.

The extinctive prescription starts running when the right can be exercised (Article 166, Paragraph 1, Civil Code). Generally, contract claims must be brought within 10 years, but this period can vary with the identity of the parties and the nature of the contract.

The rights to claim damages based on liability for fault and liability for defects expire under applicable statute of limitations if they are not exercised within 10 years (Article 167, Paragraph 1, Civil Code). If the seller is a merchant, the right to demand compensation for breach of contract expires if it is not exercised within five years.

Unless otherwise provided in the Commercial Code, claims arising from a commercial transaction will expire if they are not brought within five years. However, in the event that a prescription period shorter than five years is provided in other laws and regulations, these provisions will prevail (Article 522).

With respect to latent defects, unless the sale and purchase contract provides otherwise, the buyer must make a claim within one year from the time it becomes aware of the defect (Article 570 and Article 566, Paragraph 3, Civil Code).

In a transaction between merchants, the buyer may not bring a claim against the seller for a defect that is not immediately obvious unless he gives notice of the defect to the seller within six months of receipt of the goods. The buyer may not pursue remedies against the seller for other defects unless the buyer notifies the seller of the defect immediately after receiving the goods (Article 526, Paragraph 2, Commercial Code).

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 of evidence or fraud by the manufacturer, the court can set aside the statute of limitations in the interest of justice.

6 Remedies

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

A. Only monetary compensation is available as a remedy under the PLA and the Civil Code for claims brought under Article 3 and Article 709, respectively. Damages awarded are divided into monetary damages and non-monetary damages.

Under the PLA, the manufacturer is liable for damage and injuries to the life, limbs or property of the victim (not for damage to the product itself). In addition to physical injuries, compensation for mental pain and suffering resulting from the injury caused by the defective product can be recoverable, as well as medical expenses and lost wages. Similar remedies are available under the Civil Code (covering damage to the product itself). Monetary damages encompass both actual loss, and anticipated profits. The scope of damages permitted for breaches of civil obligations is set out under

Article 416 of the Civil Code and covers losses that would normally arise from non-performance, plus losses arising from special circumstances that parties had foreseen or should have foreseen.

B. A buyer can ask a court to rescind the sale and purchase contract and demand compensation for damages if there is a defect in the product sold (Article 570 and Article 566, Paragraph 1, Civil Code). If the contract cannot be rescinded, the buyer may claim compensation for damages. The plaintiff does not have to prove the manufacturer's or seller's negligence or intent. In addition, although only monetary compensation is available as a remedy under the Civil Code, the buyer can ask the seller to repair the defective goods or provide a substitute for the goods as an alternative to rescinding the sale and purchase contract and making a compensation claim. Orders to void contracts entered into with consumers, as well as prospective orders to prevent unlawful solicitations for new business, can also be applied for under the CCA.

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

See question 6.1.

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 not possible in this case.

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

Punitive or treble damages are not available as a remedy under Japanese 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 cap 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?

There are no special rules.

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 authorities (e.g., Japan Pension Service, etc.) have no right to claim any part of the compensation received by 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?

The losing party generally bears the litigation expenses (court costs such as filing fees, fees paid to witnesses and interpreters and the travel expenses paid to the aforesaid and the prevailing party and document preparation fees, etc.). For other costs, in the absence of an attorney fees clause, the general rule applies that litigation costs are borne by the party incurring the expense, even if they prevail in the dispute. The court may award a (usually small) part of the prevailing party's attorneys' fees as part of the damages when there is a reasonable causal relationship between a tort and the attorneys' fees.

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

The Japan Legal Support Center, an independent public institution, provides civil legal aid services including free legal consultations and loans for attorneys' fees for people who require the assistance of legal experts but who for economic reasons are unable to pay for attorneys' fees and court costs. Criminal matters are excluded.

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

To obtain public funding, the applicant must have financial resources below a certain amount, have some reasonable chance of success, and pursue aims consistent with the purposes of legal aid.

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

Attorneys' fees may be freely agreed upon between attorneys and clients, and lawyers are allowed to charge part of their fees on a contingency basis under the Bar Association rules. Many law firms continue to determine their fees based on a combination of retainer fees and success fees listed in the now repealed legal fee table of the Japanese Federation of Bar Associations.

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

Third party funding is not prohibited *per se*, although there are very few court precedents on this issue. The assignment of claims or causes of action is generally permitted but the entrustment of a claim for litigation purposes is prohibited under the Trust Act (Law No. 108).

7.6 In advance of the case proceeding to trial, does the court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

The court generally does not exercise any control regarding the cost of proceedings or proportionality.

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 your jurisdiction.

The PLA has helped to establish a more level playing field for plaintiffs and victims of product liability accidents (in particular for individuals other than those involved in mass tort cases where relief had traditionally been easier to get). Yet the number of court cases has not increased dramatically following the enactment of the PLA (according to the Consumer Affairs Agency's latest tally (2016), 382 judgments (counting two for the district court trial and its appeal) including 71 court settlements). The development of PL insurance might be one of the reasons underpinning this low number. Another reason might be the nature of the Japanese legal system itself which is largely based on the German and French civil law models. The system lacks the three main ingredients of a robust plaintiff-driven practice compared with what is available in the US: jury trials; punitive damages; and contingent fee agreements. The system's severe limitations on pre-trial discovery, high attorneys' fees, costly court filing fees and protracted trials have curbed the expansion of PL litigation in Japan. The Japanese class action system is still at its infancy and does not offer attractive options in this context. In addition, many manufacturers have been quick to settle complaints and claims with individual consumers rather than risk bad publicity and litigation. Product recalls have nonetheless increased in number and publicity (mass recalls in the automotive industry have included the Takata air bags). Another lasting consequence of the PLA has been the manufacturers' emphasis on warnings and instructions across all industries. Labelling and marking requirements have also become stricter over the years in many industries.

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Iwata Godo's reputation and wealth of experience has built the firm a portfolio of clients comprising many of Japan's leading companies, including Nikkei 225 companies, across all industry sectors. Clients include large manufacturing and consumer products companies, pharmaceutical companies, electric power companies, companies in banking, finance, insurance, and other service industries, as well as start-ups involved in high technology and a variety of other fields.

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IWATA GODO
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Iwata Godo is one of Japan's premier and oldest law firms. It was established in 1902 as one of the first business law firms by Chuzo Iwata, an attorney-at-law who subsequently held various positions, including serving as Minister of Justice and president of the Japan Federation of Bar Associations. It is a full-service firm and each of its practice areas is highly regarded. The firm's litigation practice is among the most prominent and accomplished in Japan and the practice handles a broad range of disputes in all sectors. Our product liability attorneys have taken on challenging cases and achieved excellent results with claims for compensation relating to a broad range of defective products.

Korea

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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?

Korea's legal system is based on civil law and thus all liability arises out of codified law. Product liability is primarily regulated by the Product Liability Act ("KPLA") which imposes liability for bodily injury and property damage caused by defective products. The key feature of the KPLA is that it imposes strict liability on manufacturers for damages caused by defective products. Before the KPLA was enacted in January 2000 (effective July 2002), product liability claims had to be brought as a tort action under the Civil Act, which requires the claimant to prove negligence.

The KPLA requires "manufacturers" to compensate for damages to life, body or property caused by a product "defect". The term "manufacturer" is defined as any person that is engaged in the business of "manufacturing, processing or importing" products, or puts the person's name on the product as having manufactured, processed or imported the product. This means that if the company had any involvement in the manufacturing process (e.g., provided parts incorporated into the end product or assembled the end product), the company can be held liable as a "manufacturer". However, even if the company had no involvement in the manufacturing, the company can be held liable if it imported the product for sale in Korea or if the company put its name or logo on the product.

The KPLA covers all products that have a defect in "manufacturing, design or indication". The key point of this definition is its emphasis on whether the product caused a lack of safety or damages rather than the manufacturer's duty of care and diligence. For example, the KPLA states that a product will be found to have a "defect in manufacturing" if there is a "lack of safety caused by manufacturing" or "processing of any product not in conformity with the originally intended design", and specifically states that whether the manufacturer performed its "duty of care and diligence" should not be taken into consideration. Similarly, in determining whether there was a "defect in design" or "defect in indication", the end result is the deciding factor – whether an alternative design or a warning label would have resulted in less damage or risk – and not the manufacturer's diligence.

The KPLA also contains a clause stating that if a consumer has signed a contract to exempt the manufacturer from product liability, the exemption clause is null and void.

The KPLA overall is a brief statute, which establishes strict liability for defective products, specifies some exemptions to the rule and sets a statute of limitations, but otherwise refers to the Civil Act for rules regarding the calculation of damages.

Aside from the KPLA, if the consumer purchased the product directly from the manufacturer, the consumer can also file suit for a breach of contract if the bodily injury or property damage caused by the product was caused by the manufacturer's negligence. Consumers can also file claims under the Civil Act. However, claims for a breach of contract or tort under the Civil Act are rare since remedy is available under the KPLA.

Korea has also enacted consumer fraud statutes, as well as product-specific safety laws, but these laws do not impose product liability on the manufacturer.

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

The Korean legislature has passed statutes establishing schemes of compensation for three products: pharmaceuticals; asbestos; and humidifier disinfectants. Under these schemes, the government will compensate consumers for bodily injury and property damage caused by the product regardless of the manufacturer's fault. The relevant government agency will usually provide compensation for injured or deceased persons for such costs and expenses as medical expenses, living expenses and funeral expenses. However, if a person has already been compensated by the manufacturer under the KPLA, the person may not seek compensation under the relevant scheme. If the person has been compensated under a scheme of compensation, the person will also be barred from seeking compensation from the manufacturer under the KPLA, although if the amount of compensation provided under the scheme of compensation is insufficient to cover actual damages, the person can seek additional compensation under the KPLA.

The scheme of compensation for humidifier disinfectants was established most recently. The first humidifier disinfectants were sold in the Korean market in 1997. However, it was not until around 2011 when the public became aware that the disinfectants may have caused lung damage and deaths. Compensation by the manufacturers – more accurately, the insufficient compensation in the eyes of the public – was a controversial issue for several years and the civil and criminal litigation against the manufacturers received wide media coverage.

In relation to these events, the legislature passed a statute in February 2017 (effective September 2017) which establishes a scheme of compensation for injured and deceased consumers of defective disinfectants.

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

Under the KPLA, the manufacturer and/or the importer bears responsibility for the defect. More accurately, an importer falls under the definition of manufacturer under the KPLA.

A distributor or retailer could be held liable, however, if the manufacturer cannot be identified and the distributor/retailer knows or could have known the manufacturer's identity and fails to inform the consumer of the manufacturer's identity.

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 can only be imposed by the consumer protection agency and not by a consumer or other third party. Similarly, there is no separate cause of action available to the consumer for a failure to recall and the consumer protection agency must decide to take action for a violation.

Product recalls are generally governed by the Framework Act on Consumers (the "Consumer Act"), which establishes rules for reporting safety issues and handling recalls. Under the Consumer Act, a manufacturer can conduct a voluntary recall by removing, destroying, or repairing the product and providing a replacement or refund, if the manufacturer independently determines that its product causes or is likely to cause bodily injury or property damage. Even if it does not conduct a voluntary recall, if a manufacturer or major retailer discovers a serious product defect that causes or is likely to cause injury or property damage, such company must file a report with the relevant government agency. The government agency will then test and inspect the product and depending on the results, the government may issue a recommendation to conduct a recall or issue an order to conduct a recall.

Aside from the Consumer Act, there are laws imposing recall obligations for specific products including automobiles, food, pharmaceuticals, livestock products, industrial products and drinking water. All recalls, whether under the Consumer Act or product-specific laws, are conducted voluntarily by the manufacturer or ordered by the government agency and there are no procedures by which a consumer can initiate a recall.

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

The KPLA does not impose criminal liability on manufacturers. However, a manufacturer could be held criminally liable under certain product-specific laws if it intentionally violates the relevant safety standards. A manufacturer or seller could also be prosecuted criminally if the defect was caused by negligence in the manufacturer's performance of its business duties and the defect causes serious bodily injury or death.

2 Causation

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

The claimant has the burden of proof pursuant to general principles of law. Since there is no fault requirement under the KPLA, the consumer does not have the burden of proving negligence. However, the consumer has the burden of proving the existence of a defect, damages and causation. The standard of proof with respect to causation, in particular, has been a controversial issue as described further below.

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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

Generally, the claimant must prove that the particular product used by the consumer was defective and that the product's defect caused the damages. However, the Supreme Court has recognised that causation can be presumed in certain cases. In 2006, the Supreme Court issued an opinion recognising that a product purchased by a claimant can be presumed to be defective and to have caused damages if: (i) the events leading to the injury or property damage commenced from an "exclusive area of control" of the manufacturer (i.e., an area outside of the control of the user and within the control of the manufacturer); (ii) the product was used for its intended purposes; and (iii) the injury/damage could not have occurred unless the product was defective. This opinion was issued in the context of an automobile case in which the claimant argued that a defect in the engine and related parts caused sudden acceleration and the manufacturer argued that the engine and related parts did not necessarily cause the accident since the claimant had control over the acceleration pedal. The court ruled that causation could not be presumed in this case because acceleration of the vehicle was not in the exclusive control of the manufacturer.

In another opinion issued in 2006, the Supreme Court held that if exposure to a certain risk factor is linked to an increased likelihood of contracting a particular disease, a product will be presumed to have caused the disease if use of the product exposes users to the risk factor.

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 Korean courts have not recognised the theory of market-share liability in the context of product liability and the claimant will be required 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?

Failure to warn does give rise to liability under the KPLA. If damages or risk of damages could have been reduced or eliminated by an explanation, instructions, warning or other indication on the product and the manufacturer failed to provide such an indication, the manufacturer will be held liable for damages. In determining whether an indication would have reduced or eliminated damages (or risk thereof), the courts will look at the nature of the product, the intended use of the product, and a reasonable user's expectations. Thus, for example, if a product is intended to be used by a person with expert or professional knowledge, the manufacturer can prepare the instructions or warning label with this type of user in mind.

The KPLA and Korean courts have not recognised the concept of information to intermediaries or the "learned intermediary" principle which discharges a manufacturer's duty to warn.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The KPLA provides for four exemptions from liability. A manufacturer will be exempt from liability if:

- the manufacturer did not supply the product (i.e., the product was stolen or otherwise distributed without the manufacturer's authorisation);
- the existence of the defect could not be identified given the state of scientific or technical knowledge at the time;
- the defect was caused by the manufacturer's compliance with standards set by law; or
- the defect arose from a design or manufacturing instructions given by another person.

The manufacturer has the burden of proof for these exemptions. Even if one of the above exemptions apply, in most cases, defendants will focus on the issue of causation for their defence, by arguing, for example, that the consumer did not use the product for its intended purpose, the product was not defective or the defect did not cause 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?

As mentioned above, manufacturers can assert as a defence that the defect could not be identified given the state of scientific or technical knowledge at the time the product was supplied. The manufacturer must show that the defect was not discoverable. If the manufacturer conducted testing that indicated any potential safety issues (e.g., adverse results during animal testing), the manufacturer cannot assert this 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?

This is also an explicit defence under the KPLA. There are numerous statutes regulating testing and development of products, manufacturing specifications and maintenance/storage requirements intended to protect consumers, including laws covering automobiles, electronic devices and pharmaceuticals. If a manufacturer complies with these laws, it could be exempt from liability. However, it is not a defence simply for the manufacturer to show that it complied with statutory requirements. The manufacturer must show that the manufacturer's compliance with the statutory standards actually caused the defect. Because safety standards are usually set only after the standards are known to increase safety, it is unlikely that a manufacturer will be able to establish that the statutory standard was the cause of the defect.

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 can re-litigate any issue so long as the issue arises in a separate proceeding and there is no form of estoppel that prevents this.

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?

Under the KPLA, it is possible for a claimant to seek damages against multiple parties such as the manufacturer of the end product, the company that sells the product under its brand (if the manufacturing was outsourced), and the company that supplied the defective parts to the manufacturer – and it is possible for all parties to be held jointly and severally liable.

It is not possible for a defendant to bring other defendants into the proceeding. However, if the claimant has sued multiple parties and one defendant believes it has paid more than its allocation of liability, it is possible for the defendant to seek indemnification from other defendants, provided the defendant brings this claim for indemnification in a separate proceeding. The statute of limitations for such a claim is 10 years starting from the date on which the defendant compensates the claimant.

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

The defendants can allege that the claimant's actions contributed to the damage and the courts will take into consideration such contribution in determining damages. The KPLA states the rules regarding calculation of damages under the Civil Act apply to claims under the KPLA, and the Civil Act provides that a claimant's negligence will be considered in determining the amount of damages to award to the claimant. The Supreme Court has recognised this rule by stating that although the KPLA provides for strict liability, this does not mean the court should not take into account the contribution of the claimant's actions to reduce the amount of damages awarded.

4 Procedure

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

In Korea, the judge will rule on both the facts and the interpretation of the law. For certain types of criminal matters, the defendant can ask for a jury to participate and provide its opinion, but the jury's opinion is not binding on the judge even in this 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)?

Under the Civil Procedure Act, the court has the authority to appoint an expert and/or an appraiser to assess evidence presented by the parties. The expert or appraiser does not participate in the court's deliberations and the court has full discretion in determining the amount of weight given to the expert's assessments.

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 class action procedures generally, or related to product liability, under Korean law that allow a representative to litigate on behalf of absent parties. There is a procedure under the Civil Procedure Act that allows multiple claimants in a lawsuit to appoint one of the claimants to act on behalf of the other claimants in the proceeding. However, in this case, all of the claimants will have explicitly agreed to be a party to the proceeding as a claimant and to appoint the representative to act on his/her behalf.

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 Consumer Act, a consumer association or public interest group can bring a lawsuit against a manufacturer as a representative body if the manufacturer is in violation of the Consumer Act. The consumer association or public interest group must meet certain qualifications, e.g., it must be a registered organisation with the Korea Consumer Agency or with the Korean Fair Trade Commission, in order to bring this type of claim. The remedy available for this type of claim is injunctive relief and not compensation for damages.

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

Civil procedure in Korea is not divided into stages such as pleadings, discovery and trial. After the claimant files the complaint and the defendant files its answer, the court will allow briefs, submission of evidence and hold hearings as it deems appropriate for the particular case before issuing a ruling.

Typically, after the complaint and answer are filed, the court will set a date for a hearing. It usually takes about two to three months for the first hearing. At the first hearing, the judge identifies the facts and legal issues in dispute and hears each party's position. For straightforward cases, the court could issue its decision after the first hearing, but in most cases, the court will require the parties to submit briefs and evidence on the issues in dispute by the subsequent hearing date. The court may repeat this cycle multiple times before issuing its decision. Usually, there is about one to two months between each hearing date. Although the period from the filing of the complaint to the issuance of the ruling varies greatly depending on the complexity of the case, most cases are concluded within eight months to 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?

It is possible for the court to issue a preliminary ruling on an issue of fact or law, but this is rare. Moreover, there is no procedure for a preliminary ruling that would dismiss a case before the final conclusion of the case such as a summary judgment. If it is clear to the court that the claimant does not have a legal or factual basis for a claim, the court will simply issue its final ruling without holding additional hearings.

4.7 What appeal options are available?

If a claimant or defendant is not satisfied with the district court judgment, the party can file for an appeal with the intermediate level courts within two weeks of the judgment. If there is an appeal, the appellate court will review the case *de novo* and rule on both factual and legal issues. After obtaining the appellate court decision, either party may appeal the ruling to the Supreme Court, although in this case, only issues of law may be appealed.

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 in question 4.2 above, the court can, independently or at a party's request, appoint an expert to assist the court in evaluating technical issues. In addition, either party may present expert evidence in written and oral form and there are no specific restrictions in this regard.

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 factual or expert witness will be testifying at a hearing, the party presenting the witness must submit a written summary of the testimony to the counterparty before the hearing so that the counterparty can prepare cross-examination questions. If the party presenting the witness does not submit a written summary for review by the counterparty before the hearing and the counterparty does not object to the omission, the counterparty will be deemed to have waived its right to receive this written summary in advance of the testimony. Although a written summary is required before the hearing, it is not required for a party to present its witness for a deposition before the hearing.

It is also possible for either party to submit a written statement from a factual or expert witness. In such case, the other party can respond to the written statement through its own written rebuttal.

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 obligation to disclose documentary evidence and there are no discovery rules to provide a structured process for obtaining documents from the counterparty or third parties. If a party wishes to obtain documents from a third party such as the counterparty, the party must petition the court to issue a document production order on the third party, but the requesting party must be specific about the scope of its request and the courts will issue orders only on a limited basis.

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

The KPLA does not require any alternative dispute resolution methods before litigation and there is no such requirement applicable to lawsuits in Korea generally. In some cases, the court may recommend the parties to try to resolve the dispute through mediation, but the parties are not required to accept the mediator's recommendations and the parties can continue the litigation proceedings if they fail to come to an agreement through mediation.

If a consumer has agreed to a contract with an arbitration clause, the courts may strike down this clause as a violation of the KPLA.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction be brought within the jurisdiction of your courts either as a defendant or as a claimant?

If the claimant is not a resident of Korea, the claimant will still be able to file a suit against the defendant before the Korean courts if the defendant is a Korean resident or a legal entity incorporated in Korea, since residence by one party is likely to satisfy jurisdictional requirements.

If the claimant is a resident of Korea and the manufacturer is not, the manufacturer can still be sued in the Korean courts if the manufacturer or the matter at hand has "substantial relations" to Korea. In determining whether "substantial relations" exist, the courts will consider whether the manufacturer could reasonably have foreseen that a claim could be brought before the Korean courts. Even if the "substantial relations" test is met, the courts may deny jurisdiction in certain cases, for example, if it would cause undue inconvenience to one party while the other party would greatly benefit for the court to hear the case.

5 Time Limits

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

The KPLA imposes a time limit on claimants on bringing 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?

Under the KPLA, the claimant must file the claim within three years of both becoming aware of the damages and the identity of the manufacturer, but no later than 10 years from the date the manufacturer supplied the product. However, if the damages are caused by substances that accumulate in the body delaying the appearance of substances until a later period, the 10-year period runs from the date the damages actually occur.

The age of the claimant does affect the calculation of time limits in that for minors, the awareness of the damages by the minor's guardian will be considered rather than the minor's knowledge. However, the court does not have discretion to disapply 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 could prevent a defendant from seeking a dismissal based on the statute of limitations since the Civil Act provides that a statute of limitations defence will not be accepted if enforcing the statute of limitations would result in an abuse of rights.

6 Remedies

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

Under the KPLA, the available remedy is monetary compensation. As mentioned above, however, a consumer group or public interest organisation may seek injunctive relief under the Consumer Act.

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

The KPLA holds manufacturers liable for damages to "life, body or property", but specifically excludes damage to the product itself. Damages to "life, body or property" include cost of medical treatment, loss of income, and monetary compensation for mental distress.

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 claimant must prove actual damages and, thus, cost of medical monitoring may not be recovered if the product has not yet malfunctioned and caused injury.

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

Currently, the law does not provide for enforcement of punitive damages. However, as discussed further in question 8.1, the Korean legislature passed an amendment to the KPLA on March 30, 2017 which allows claimants to seek 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 statutory cap on damage awards.

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 settlement of claims generally, or with respect to group actions or claims by infants. As long as the claimants and defendants (in the case of minor, their legal guardians) agree to the settlement, the settlements will be enforced without 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?

Fundamentally, the government does not have authority to claim reimbursement against claimants for any damages awarded to claimants.

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 court fees and expenses including attorneys' fees, but the amount will be determined by the court. Along with the court's ruling on the claim, the court will decide the amount of costs that should be borne by each party. In most cases, the court will allocate the amount of costs to be borne by each party based on the ratio between the amount of damages awarded to the total amount claimed. The court will strictly review whether the litigation expenses claimed should be recoverable and will limit the amount of attorneys' fees recoverable, in particular.

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

The Korean Legal Aid Corporation is a non-profit organisation that provides legal aid including free legal advice and representation for those in need. The court may also grant legal aid, in which case the relevant party may be entitled to deferred or suspended payment of court fees and attorneys' fees.

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

The court can decide on its own to grant legal aid, or grant legal aid upon a party's request, but in order to qualify for legal aid, the beneficiary must be financially unable to legal costs and expenses and it must not be clear that the beneficiary will lose his/her case.

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

Contingency fees are allowed in Korea. In fact, for civil litigation, most attorneys' fees are composed of a fixed amount paid upon commencement of litigation plus a success fee payable after the ruling, based on a percentage of the damages awarded (or denied).

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

There is no specific prohibition on claimants from soliciting funds for a lawsuit. In fact, if a claimant wishes to solicit donations from third parties (where the third parties do not expect repayment or other consideration) to file a claim, the claimant may raise up to KRW 10 million under the Act on Collection and Use of Donations. However, if the claimant intends to solicit funds from third parties with an agreement to share the damages awarded with the third party, it is possible that the third party could be prosecuted for violating the Attorney-at-Law Act, which prohibits non-lawyers from earning fees in relation to legal services (i.e., the third party could be prosecuted for acting as a broker).

7.6 In advance of the case proceeding to trial, does the court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

There is no mechanism for the court to adjust legal costs and expenses incurred by the claimants or defendants.

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 your jurisdiction.

There have been a couple of major developments in product liability law in the past year. Due to the media coverage of the litigation against the manufacturers of humidifier disinfectants and the negative publicity regarding insufficient compensation for victims, the legislature passed a law establishing a scheme of compensation related to the defective disinfectant as mentioned above.

In addition, the legislature passed an amendment to the KPLA on March 30, 2017 to strengthen protection for consumers.

The amendment implements two key changes to the KPLA. First, the KPLA permits claimants to seek punitive damages from the manufacturer if the manufacturer knew about the defect but failed to take corrective measures. In Korea, courts can only impose punitive damages if the statute specifically provides for this remedy and there are few laws that allow the enforcement of punitive damages. In the case of the amended KPLA, the claimant may seek up to three times the actual damages and the court will award the amount taking into consideration several factors including the degree of intent, the amount of profit gained, and the manufacturer's financial condition.

The other key change to the KPLA is related to causation. As discussed above, the Supreme Court issued an opinion in 2006 recognising that the courts can presume causation if the events leading to the injury or property damage commenced from an area outside of the control of the user and within the control of the manufacturer. The amended KPLA codifies this ruling by specifically presuming causation if: (i) the claimant used the product for its intended purpose; (ii) the damage arose from an area within the control of the manufacturer; and (iii) the damage would not have occurred unless the product was defective.

The amended KPLA will be in effect from April 2018.

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Joohan Han is a partner of SEUM and the head of SEUM's litigation team. Joohan began his legal career as a judge of the Southern Seoul District Court in 1993 and held many positions as a judge before eventually retiring from the judiciary as a senior judge of the Suwon District Court in 2008. Over his 16-year judicial career, he held positions as senior judge of Chungju District Court, senior judge of Central Seoul District Court and senior research judge of the Korean Supreme Court. After retiring from public service, Joohan practised law as a partner of the law firms Shin & Kim and Shin & Park before joining SEUM.

Joohan has handled numerous high-profile cases including commercial litigation between Korean conglomerates and white collar criminal defence cases for CEOs of Korean conglomerates. Due to his past experience as a judge, Joohan is able to provide specialised insight to his clients.

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Jinil Park is a partner of SEUM and focuses his practice on commercial litigation and white collar defence. Jinil frequently represents clients on fair trade litigation, product liability litigation as well as administrative proceedings. He has handled a number of major product liability cases involving consumer products, medical devices, and industrial parts. Prior to joining SEUM, Jinil was with ONE Law Partners where he represented public institutions and local governmental bodies on a number of landmark lawsuits.

SEUM
법무법인 세움

SEUM was founded by attorneys from Korea's top law firms to provide top quality legal solutions better, faster and more efficiently. Blazing internet speeds and powerful smartphones have created the opportunity for new companies to disrupt the landscape across many service industries including transportation, accommodation, and entertainment. The legal profession, however, has been immune to such forces. In Korea, SEUM is at the forefront of this innovation. We understand that the key to delivering the best services is to know our clients and to provide solutions and expertise, not just information. Our client-centric approach drives us to act as an advisor, not just a legal technician, and offer practical advice that can be used to make decisions. At the same time, we offer the most competitive rates by keeping our overheads low. We have a small but resourceful team, fast internet, top-of-the-range laptops and powerful software. It's all we need.

Netherlands

Blenheim

Jan Jacobi

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 a number of different sections of the Dutch Civil Code ("**DCC**") that provide for liability for defective products. A distinction can be made between the following 'systems' of product liability:

1. **Strict liability for defective products**: articles 6:185 through 6:193 DCC contain specific provisions on product liability. These articles are the Dutch implementation of the EC Product Liability Directive (European Directive 85/374/EEC) ("**the Directive**"). Under this system, producers are subject to a regime of strict liability with only limited defences available to them. Claimants can only rely on the strict liability in connection with a restricted category of claims and actions.
2. **Fault-based liability**: the Directive has not affected the general system of fault-based liability arising from *onrechtmatige daad* (tort) under article 6:162 DCC. The Dutch principle of tort not only encompasses acts or omissions as such, but also the violation of (statutory) rights and obligations.

   Under this general system, there are no exhaustive limitations with regard to possible claims, causes of actions or defences.
3. **Contractual liability**: a party can also be held contractually liable for a defective product, subject to the particular provisions of the agreement or on the general principle of breach of contract (article 6:74 DCC). A contracting producer cannot contractually exclude or limit its strict liability for a defective product.

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

The Dutch State does not operate any such scheme.

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

Under the product liability system of article 6:185 DCC, 'producers' are liable for their defective products. Article 6:187 paragraph 2 DCC defines the producer as:

a) the manufacturer of a finished product;

b) the producer of any raw material; or

c) the manufacturer of a component part; and

d) any person who, by putting his name, trade mark or other distinguishing features on the product, presents himself as its producer.

Article 6:187(3)-(4) DCC extends the scope of the meaning of 'producer' by providing that strict liability for defective products also applies to:

e) any person who imports into the European Economic Area a product for sale, hire, leasing or any form of distribution in the course of his business; and

f) any supplier or importer of the product, in the event the producer cannot be identified, unless the supplier informs the injured party, in reasonable time, of the identity of the producer or of the person who supplied him with or who has imported the product into the European Economic Area.

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 obligation to recall defective products or pay damages for a failure to recall defective products under the product liability system of articles 6:185–193 DCC. Rather, such obligations or damages claims can flow from the general system of tort, as giving rise to a dangerous situation and allowing the continuation of that situation (by leaving defective or hazardous products in circulation) may be considered as tortious conduct.

An obligation to recall can also be imposed under administrative law. Pursuant to the so called Commodities Act (*Warenwet*) and the General Product Safety (Commodities Act) Decree (*Warenwetbesluit algemene productveiligheid*), the producer and supplier must inform the Dutch Food and Consumer Product Safety Authority (the "**FCA**") of the existence or possibility of dangerous or hazardous products and foodstuffs. The FCA has the authority to order or initiate the recall of such products, should the recall not be undertaken voluntarily or be done inadequately. An English version of the FCA website is accessible at https://english.nvwa.nl/.

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

Yes, criminal sanctions can apply to the supply of defective products. Putting defective products into circulation, either wilfully or by means or culpable negligence, may be punishable by, *inter alia,* a fine (up to EUR 82,000), community service or imprisonment.

2 Causation

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

The product liability system explicitly addresses the burden of proof (article 6:188 DCC), stating that the injured party must prove the damage, the defect and the causal relationship between defect and (actual) damage. As a result of the strict liability, the injured party bears no burden of proof with regard to the *fault* of the producer, which is in principle already established (unless the producer successfully invokes the defences of article 6:185 DCC).

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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

The test applied to establish a causal link between the defective product on the one hand, and the actual damage arising on the other hand, is the "but-for" test (*conditio sine qua non*), embodied in article 6:98 DCC. Courts may, only exceptionally, apply proportional liability in cases where damage has been suffered, but a causal link cannot be established with certainty. Damage claims cannot be brought in the absence of damage (*i.e.* a mere risk of malfunction will not suffice).

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 manufactured the defective product, the injured party:

1) may hold each of the producers jointly and severally liable for the same damage caused by the defective product on the basis of the product liability system (article 6:189 DCC);
2) may hold all of the involved parties jointly and severally liable if the damage resulted from two or more events, for each of which a different party is liable, provided that it has been established that the damage arose from at least one of these events (article 6:99 DCC).

In its decision in the *Des* case (Supreme Court judgment of 9 October 1992, *NJ* 1994, 535), the Dutch Supreme Court held that there is no principle of market share-based liability under Dutch 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?

Pursuant to the general tort provisions of article 6:162 DCC, there is a duty to warn and inform about defective products. Under administrative law, the producer has a specific duty to inform the FCA of dangerous and hazardous products and foodstuffs. Failure to do so may, *inter alia*, result in civil liability and administrative measures (such as a fine).

Information provided to the consumers, as well as to intermediaries, is taken into account. In the *Halcion* case (Supreme Court judgment of 20 June 1989, *NJ* 1990, 652), which related to the side effects of certain sleeping medication, the Dutch Supreme Court held that although a product can only be obtained through an intermediary with a special duty of care (such as a medical practitioner), the producer itself is still under an obligation to inform the consumers of possible risks and side-effects. There is, accordingly, no principle of 'learned intermediary' under Dutch law.

3 Defences and Estoppel

3.1 What defences, if any, are available?

If a claimant relies on the product liability system, the possible defences open to the producer are exhaustively set out under article 6:185 DCC.

A producer will not be held liable for defective products that cause damage if it proves that:

1) it did not put the product into circulation;
2) having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when it put the product into circulation or that this defect came into being afterwards;
3) the product was neither manufactured by him for sale or any form of distribution for commercial purposes nor manufactured or distributed by it in the course of his business;
4) the defect is due to compliance of the product with mandatory regulations issued by the public authorities;
5) the state of scientific and technical knowledge at the time when it put the product into circulation was not such as to allow the existence of the defect to be discovered; or
6) in the case of a manufacturer of a component, 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.

If a claimant relies on another cause of action (i.e. tort or breach of contract), the defendant may be able to rely on other defences.

These defences vary in nature and are not exhaustively provided for under the DCC.

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 defence listed under 5) of question 3.1.

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, see defence listed under 4) of 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?

No specific provision would prevent a claimant from re-litigating its claim in *different* proceedings against a *different* defendant. Issue estoppel under Dutch law can be found in the force of a final and conclusive judgment, preventing the claimant (or its legal successors) from re-litigating the *same* claim against the *same* defendant after a final and conclusive judgment has been rendered.

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 Dutch Code of Civil Procedure ("**DCCP**") allows for (both derivative and subsequent) third-party proceedings. In these proceedings, a defendant may seek contribution or indemnity. A motion to implead a third party in derivative third-party proceedings must be filed prior to the statement of defence in the main proceedings.

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

Yes, on the basis of article 6:101 DCC. If successfully alleged, it can result in the (complete) mitigation of the liable party's obligation to recover the damages of the claimant.

4 Procedure

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

Civil court proceedings are governed by the DCCP. In 2016 new legislation was adopted, providing for the gradual digitalisation of civil proceedings from 2018 onwards. The questions in this chapter have been answered in accordance with the DCCP as currently in force.

All proceedings before a Dutch court, regardless of whether civil, administrative or penal, are trials by judge 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)?

While there is no special provision within the DCCP with regard to the appointment of 'technical specialists', on the basis of article 194 DCCP, the court may, either on its own motion or at the request of one of the parties, appoint 'experts' to provide an opinion or statement on certain issues.

The appointed expert is independent and does not 'sit' with the court or one of the parties. The court is not bound by and may disregard an expert opinion or statement.

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 Dutch civil legal system does not provide for class actions in the 'common law' sense of the word, article 7:907 DCC enables an interest group to have a collective settlement on mass damages declared binding by the Amsterdam Court of Appeal. Article 7:907 DCC was implemented by the Collective Settlement of Mass Damages Act (*Wet Collectieve afwikkeling massaschade*) ("**WCAM**").

The settlement must be reached between one or more interest groups and one or more liable parties. The settlement will be binding with regard to the persons whose interests might be represented by the interest group, unless such person opts out within a timeframe set by the judge of at least three months. Most recently, the Supreme Court held that due to the broad scope of the WCAM, settlements with regard to claims other than the claim for damages (for instance the partial waiver of a debt) may also be declared binding (Supreme Court judgment of 9 December 2016, *NJ* 2017, 13).

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

Article 3:305a DCC allows interest groups (in the form of special purpose foundations or associations) to initiate proceedings for the purpose of protecting the similar interests (as set out in their articles of association) of a defined class of persons. The interest group can bring any claim or action, except claims for pecuniary damages. Prior to initiating proceedings, the interest group must have attempted to reach a settlement with the defendant. The proceedings can be opted out of and are without prejudice to individual class members' right to initiate proceedings on their own (regardless of whether or not they opt out). These proceedings are relatively common and considered to be quite effective.

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

Dutch civil procedural law does not provide for 'trials', in the sense of a full oral hearing where all of the evidence is presented and/or witnesses and experts are heard or examined by the parties.

Consequently, several distinctions must be made between the various types of oral hearings:

- Oral hearings in preliminary relief proceedings: these are accelerated proceedings in which a claimant may apply to the court for provisional relief. A declaratory judgment or a definitive award for damages cannot be obtained by the claimant.

  Preliminary relief proceedings have only one oral hearing in which both parties present their oral arguments. Depending on the urgency of the claimant's case, it usually takes up to 2–6 weeks to get to the oral hearing. The provisional judgment is usually rendered within to 2–3 weeks.
- Oral hearings in proceedings on the merits: these hearings can be divided into:
  a) post defence hearing: a hearing in which the court aims to obtain information from the parties, to inquire whether a settlement can (already) be reached and to instruct on the further course of the case, usually held within 3–6 months after the case has been brought before the court;
  b) hearing of witnesses: only if deemed necessary by the court, this hearing is usually held within 3–6 months after the post defence hearing; and
  c) oral arguments: at the request of the parties, oral arguments may take place, usually as a conclusive hearing before a final judgment is rendered by the court.

The amount of time taken to obtain a final judgment in proceedings on the merits at first instance depends on the number of hearings. Each hearing delays the course of the proceedings. As an estimation, claimants should expect one year in regular proceedings, and 2–3 years in more complex proceedings to obtain a final judgment.

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?

Preliminary issues may, and in some cases must, be referred by a judge in preliminary relief proceedings, a court of first instance or a Court of Appeal to the Supreme Court of the Netherlands or the ECJ to provide an answer or interpretation on issues of law. Preliminary issues cannot relate to issues of fact. Such referrals may be made *ex officio*, or at the request of one of the parties.

4.7 What appeal options are available?

An appeal to a judgment in first instance may be lodged before the Court of Appeal, and before the Supreme Court to a judgment of the Court of Appeal. In principle, a party may lodge an appeal to both a non-favourable and favourable judgment (*i.e.* a claimant may appeal to a judgment in which the liability of the defendant was established, but the height of the awarded damages was less than claimed).

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 4.1 on the appointment of experts.

Regardless of whether an expert has been *appointed* by the court, either party may present expert evidence (expert reports and opinions) or witness evidence as part of their statement of claim, statement of defence or as ordered by an interlocutory order. There is no restriction to the extent or nature of that 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 that factual or expert witnesses present themselves for pre-trial deposition. On the basis of article 1018a DCCP, which is only applicable to the collective settlement of mass claims as mentioned in question 4.4, a court may summon the parties involved to a pre-trial hearing, although no witnesses or experts will be heard.

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 court proceedings.

Once proceedings have been initiated, each party has the obligation to disclose the entire truth and to submit and produce all the documentary evidence on which they rely (articles 21 and 85 DCCP). If a party fails to submit or produce such documentary evidence, the court may draw adverse inferences.

At the request of a party and subject to strict conditions (to prevent 'fishing expeditions'), a court may order the other party to disclose or submit certain specified documents (article 843a DCCP).

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

No alternative methods of dispute resolution are required to be pursued first.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction be brought within the jurisdiction of your courts either as a defendant or as a claimant?

There is no requirement that a claimant be domiciled within the Netherlands to bring a claim before a Dutch civil court.

Whether the Dutch courts are able to exercise jurisdiction over a matter is determined under the rules of private international law. Overall in product liability cases, a claimant can bring proceedings against a defendant domiciled outside the Netherlands before a Dutch court if:

a) the place of event giving rise to the damage (*Handlungsort*) is in the Netherlands; and/or

b) the place where the harmful event occurred (*Erfolgsort*) is in the Netherlands.

If the claim is based on the product liability system and the defendant is domiciled outside the Netherlands but within the EU, the *Handlungsort* will be considered as the place where the product was manufactured and the *Erfolgsort* as the place where the initial damage occurred as a result of the normal use of the product for the purpose for which it was intended.

5 Time Limits

5.1 Are there any time limits on bringing or issuing 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?

Time limits are statutory limitation periods that could result in unsuccessfully upholding a claim, as the court may deem the claim to be expired. Time limits can be interrupted by initiating legal proceedings or, more commonly, by sending a letter in which the claimant or injured party unequivocally reserves its right or title to performance, damages or any other remedy. Most time limits are not examined *ex officio* by a court, and must be raised by the defendant. The age or condition of the claimant has no effect on time limits.

Time limits depend on the legal basis of the claim:

- Non-contractual claims based on:
  - I. The product liability system:
    - three years after the injured party became or ought to have become aware of the damage, the defect and the identity of the producer (article 6:191(1) DCC); and
    - 10 years after the damage-inflicting product has been brought onto the market (article 6:191(2) DCC). The lapse of these 10 years may be raised *ex officio* by the court;
  - II. Fault based liability for wrongful acts:
    - five years after the injured party became or ought to have become aware of the identity of the injuring party and the (existence and extent of the) damage incurred; and
    - 20 years after the damage-inflicting event has occurred, regardless whether the injured party was aware thereof; and
- Contractual claims:
  - promptly after discovery of *the buyer* that the product did not meet the contractually agreed upon or reasonable requirements (article 7:23 DCC in conjunction with article 6:89 DCC); and in any case
  - two years after the buyer has notified the seller that the product did not meet the contractually agreed upon or reasonable requirements (article 7:23 DCC); and
  - five years after *the claimant* became or ought to have become aware of the existence or extent of its claim for damages.

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 a time limit. The time limits aligned with the knowledge of the claimant or injured party, as mentioned in question 5.2, will likely be affected by concealment or fraud and could result in a time limit never having effectively commenced.

6 Remedies

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

Dutch civil law allows for a wide variety of remedies. The nature and applicability of the remedy depends on the legal basis of the remedy.

A distinction can be made between the following categories of remedies:

- pecuniary remedies: compensation for damages; contractual penalties; and recovery of the other party's breach of a judicially imposed penalty;
- general non-pecuniary remedies: declaratory relief; injunctive relief (including product recall); judicial termination; and annulment or nullification of an act or agreement;
- general performance-based remedies: specific performance or other injunctions; and
- performance-based remedies: notably applicable in B2C relationships, allowing a consumer, party to a sales agreement, to demand delivery, repair or replacement of the defective product (article 7:21 in conjunction with article 7:22 DCC).

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

These types of damages are all recoverable if the liability is based on the system of tortious fault-based liability. If the liability is based on product liability system, article 6:190 DCC exhaustively lists the type of damage an injured party can claim:

a) damage caused by death or personal injury (also including psychological harm, as long as the psychological harm is caused by the physical personal injury); and

b) damage to any item of property other than the defective product itself, with a lower threshold of EUR 500, provided that the item of property:

(i) is of a type ordinarily intended for private use or consumption; and

(ii) was used by the injured party mainly for his own private use or consumption.

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 can only be claimed by an injured party if the product has actually resulted in damages or injury. It is possible to recover reasonable costs incurred to prevent the incurrence of damages as well as costs connected to the assessment of the basis and extent of liability and damages (article 6:96 (2) DCC). Should the product not malfunction and only theoretically malfunction in the future, it seems unlikely that a court would award costs made for such 'medical monitoring'.

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

Dutch civil law does not allow for the recovery 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?

There is no statutory maximum limit on the amount or height of damages. A court can *ex officio* or at the request of a party limit the quantum of damages (article 6:109 DCC). Pecuniary claims of EUR 25,000 or less must be brought before a subdistrict court, where parties may choose to self-represent.

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 *conclusion* of a settlement is not subject to court approval. For a collective settlement to have binding effect, the Amsterdam Court of Appeal will consider whether the settlement agreement meets certain formal requirements. The Court of Appeal may rule that these requirements are not met, and consequently reject the request to have the settlement declared generally binding.

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, a government authority will not be able to recover such damages from a 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?

As a general remark, a court may always order a party to pay its own legal costs even if it is the successful party. However, the court will usually issue a costs order against the unsuccessful party (article 237–239 DCCP) covering:

a) the successful party's court fees;

b) bailiff fees, such as costs for service;

c) the successful party's legal costs. These costs are calculated on the basis of a fixed and capped "court-approved scale of costs" and depend on the principal sum in dispute and the number and type of procedural steps in the proceedings. The amounts of the court-approved scale are often considerably less than the actual legal costs incurred by the successful party; and

d) incidental costs, such as costs for experts.

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

Yes, legal aid funded by the Dutch government is available; however, only in certain cases and under the conditions as set out in the Legal Aid Act (*Wet op de Rechtsbijstand*).

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

Pursuant to the Legal Aid Act, litigants are eligible for legal aid depending on:

a) their household's annual income (no more than EUR 26,400 for a single-person household or EUR 37,300 for a joint household); and/or

b) the applicant's net worth (for savings, the maximum amount is EUR 21,330).

The nationality of the litigants is irrelevant, therefore enabling non-Dutch litigants to apply for legal aid. However, the litigant can only apply for legal aid with regard to a case that is related to the so-called 'jurisdiction of the Netherlands', excluding cases that are not connected to Dutch law or fall outside the competence of the Dutch courts (for instance in relation to damage, if neither the *Handlungsort* or *Erfolgsort* is in the Netherlands).

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

As a result of the Dutch Rules of Professional Conduct for Dutch lawyers (*Gedragsregels 1992*), contingency fees or "no win, no fee" arrangements are prohibited with the exception of personal injury cases (although there is a cap on the percentage of the damages awarded that may be charged as a fee).

Fee arrangements, such as fixed fees or capped fees, are allowed and used fairly often.

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

The third party *funding* of claims is in principle permitted and no particular restrictions apply. However, a court may declare that an interest group (as mentioned in question 4.4) has no case to bring forward a collective claim, if the claim is solely brought for the purpose of commercially benefitting that interest group.

7.6 In advance of the case proceeding to trial, does the court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

No, as due to the court-approved scale of costs (question 7.1), there is a maximum of legal and court fees the losing party risks paying to the successful party.

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 your jurisdiction.

In November 2016, a bill (34 608) was presented to the House of Representatives introducing the possibility of collective *damage claims*. The bill can be considered as extension of the scope of article 3:305a DCC (mentioned in question 4.3) and a step forward towards an even more effective collective damage claims system.

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Norway

Ole André Oftebro

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Advokatfirma Ræder DA

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?

Depending on, *inter alia*, the type of product, cause of defect and type of damage, defective products are subject to various product liability systems under Norwegian law.

Most importantly, the Norwegian Product Liability Act (the "**PLA**") imposes a statutory strict liability system in case of personal injury or damage to "personal" property caused by a defective product. With effect from 1 January 1994, the PLA was harmonised with the European Product Liability Directive 85/374/EEC (the "**Product Liability Directive**"). Consequently, Norway's system of strict liability for defective products will in most cases reflect the European product liability system. It is worth noting, however, that Norway maintains a separate system of liability for pharmaceuticals pursuant to the PLA Chapter 3.

Further, as a separate system of liability available in case of damage caused by defective products, Norwegian tort law generally acknowledges liability based on negligence (or intent). In certain circumstances, Norwegian tort law also allows for strict product liability based on case law. Such strict liability would theoretically only be available for damage that falls outside the scope of the PLA, i.e. damage to commercial property. Further, the conditions for such strict liability (as laid down in case law) would normally be hard to overcome for non-consumers. Consequently, recourse for damage to commercial property is rarely awarded unless the claimant is able to produce evidence of negligence.

Contractual liability plays a role in case of damage to property falling outside the PLA, e.g. damage to commercial property or damage to the product itself. Where the end-user is not a consumer, the parties to the contract are free to agree on any warranty/indemnity/allocation of product liability. Where there is a lack of any agreement to the contrary, contractual liability for damage caused by a defective product would be implied through the Norwegian Sale of Goods Act. Unless the claimant can prove negligence, damages would be limited to direct damages, i.e. damages to the product itself and other property closely related to that product.

Where the end-user is a consumer, contractual liability pursuant to the Sale of Consumer Goods Act would apply notwithstanding any agreement(s) to the contrary. Damages would, however, be limited to damage to the product itself and other property closely related to that product, unless the defendant fails to prove that the damage was not caused by negligence.

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

Pursuant to the Norwegian Act on Patient Injury Compensation (No: *Pasientskadeloven*), the state operates a national compensation scheme for damage caused by public and private healthcare. As such, damages from pharmaceutical products, medical devices and medical equipment might be compensated under this government-operated scheme regardless of proof of negligence or defect.

The Norwegian System of Patient Injury Compensation (No: *Norsk Pasientskadeerstatning*) is also acting as claims handler for the Norwegian insurance scheme related to pharmaceutical products (No: *Norsk Legemiddelforsikring*). The pharmaceutical insurance scheme is a private insurance scheme wholly owned by producers and importers of pharmaceutical products, and was established pursuant to the PLA Chapter 3.

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

The PLA is fully harmonised with the Product Liability Directive in this respect, meaning that the following would bear the primary responsibility for a defective product: (i) the manufacturer of the product; (ii) any importer of the product into the European Economic Area; and (iii) any distributor or retailer marketing the product as its own.

In case the defect is caused by a defective part of the product, the sub-supplier of such defective part would be held liable on a joint and severable basis with the main manufacturer.

In addition, the retailer might in certain instances be held liable, e.g. if it fails to refer the injured party to a responsible manufacturer, importer or distributor within a reasonable time.

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 obligation to recall products is covered by, *inter alia*, the Norwegian Product Control Act (the "**PCA**"), which is based on the European General Product Safety Directive 2001/95/EC (the "**Product Safety Directive**").

Manufacturers, importers, distributors, retailers and others dealing with the product might be under the obligation to recall products which involve unacceptable risk of health or environmental damage, i.e. products that pose risks to the consumers that are incompatible with the general safety requirement as more particularly described in the Product Safety Directive.

Once made aware of hazardous products, the authorities may issue a recall order. However, as the PCA implies a duty on anyone dealing with the product to act duly and diligently in order to prevent products from causing damage, the actual duty to recall products normally arises prior to such formal order being issued.

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

Negligent or wilful breaches of the PCA or associated regulations might be sanctioned by fines. In theory, prison sentences might also be applicable for bodily injuries or death caused by defective products, subject to proof of negligence or intentional acts or omissions on the accused.

2 Causation

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

According to the PLA, the claimant has the burden of proving (i) that it has incurred damage, (ii) the existence of a defect in the product, and (iii) that there exists a causal link between the defect and the damage.

The PLA provides a number of possible defences for the defendant; see question 3.1 below. In relation to such defences, the burden of proof may shift from the injured party to the responsible 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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

There is no established test for proof of causation under the Norwegian PLA. Nevertheless, as a general rule, the claimant has the burden of proving a causal link between the damage and the defect; see question 2.1 above. However, in complex cases with contributory causes, the claimant has the burden of proving that the defect in the product represents a necessary condition for the damage. Furthermore, a defect having only an insignificant part of the course of events leading to damage might not be sufficient, although theoretically being a necessary condition for 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 Norwegian PLA does not give rise to any form of market-share liability. However, if the damage is due to a defect in a component which forms an integrated part of the main product, both the manufacturer of the part and the manufacturer of the main product can 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?

If a manufacturer of a product, which may represent a danger, does not provide appropriate warnings or give essential information about risk factors associated with the product, the manufacturer can be held liable if damage occurs. However, lack of warnings and/or information in itself does not give rise to liability. It is a condition for product liability that the damage occurred as a result of a defect. Lack of warnings and/or information is relevant when considering whether the product had a defect, albeit not decisive.

Norwegian law does not operate with any principle of "learned intermediary".

3 Defences and Estoppel

3.1 What defences, if any, are available?

Common defences under the PLA are failure by the claimant to prove (i) the occurrence of damage, (ii) the existence of a defect, or (iii) a causal relationship between the defect and the damage.

Additional defences available under the PLA are (iv) that the defendant did not put the product into circulation, (v) that the defect did not exist at the time the product was put into circulation, or (vi) that the defect is due to compliance of the product with mandatory regulations issued by the public authorities.

Defences relating to non-existence of a defect are closely linked to the ability of the defendant to prove alternative causes of damage, e.g. external influence on the product, lack of maintenance, 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?

By way of allowed derogation from the Product Liability Directive, the Norwegian PLA does not contain an express state-of-the-art/development risk defence. In principle, state-of-the-art products or products containing unforeseen or undiscoverable risks might therefore be deemed defective and the manufacturer/importer/distributor held liable. However, state-of-the-art products are less

likely to be deemed defective than existing products posing greater risks of causing damages.

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 where the defect itself is caused by compliance of the product with mandatory regulations. Compliance with more general regulations relating to development, manufacture, licensing, marketing and supply would therefore rarely suffice as a stand-alone defence, although such compliance makes a good argument where the exact cause of damage is unknown.

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 Norwegian court decision would only be legally binding on the parties to the case. Consequently, claimants may re-litigate issues of fault/defect/capability of damage which has previously been lost by other claimants. However, court cases in favour of the defendants might be submitted as evidence in later proceedings on the same issue.

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 defendant may seek indemnity from third parties such as a sub-supplier. Recourse claims may be heard in the same proceedings or in subsequent proceedings upon the choice of the defendant.

In general, the time limit for initiating subsequent proceedings against the third party is one calendar year after the payment of damages to the injured party. However, in many instances, the third party is entitled to a notice of proceedings within a reasonable time in order to avoid statutory limitation.

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

Yes. A claimant's actions contributing to the damage would be relevant both in terms of whether or not the product was defective and whether or not there was a causal relationship between the defect and the damage (see question 3.1 on defences above).

Even if the defendant is held liable, contributory negligence on part of the claimant may lead to a reduction or annulment of the damages amount pursuant to the Norwegian Damages Act section 5-1.

4 Procedure

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

Juries are not used in court cases related to product liability. As a general rule, only one judge hears product liability cases at the District Court. More rarely, the case can be tried with one judge and two lay judges upon request of one of the parties or the court. In the Court of Appeal, there are three judges (plus five lay judges upon request). Lay judges are not used in the Norwegian Supreme 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)?

The court may appoint two technical specialists to sit with the judge. The parties may also request this.

Also, the court may appoint an expert to give affidavit evidence on the facts in the case (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?

According to the Norwegian Dispute Act, class actions can be brought to trial only if (i) several claimants/defendants have claims/obligations based on the same or substantially the same factual and legal basis, (ii) the claims can be heard by the same court and essentially follow the same procedural rules, (iii) class action is the most appropriate form of proceedings, and (iv) the court is able to designate a class representative.

The procedure is normally "opt-in" (except in case of very small claims amounts), and can be initiated by (i) any natural or legal person with a claim covered by the class action, (ii) associations and foundations, as well as (iii) public bodies with the purpose of ensuring specific interests such as for instance consumer protection.

The class action vehicle is a relatively new possibility in Norwegian law, and although it has been available for some 10 years now, class actions are rarely brought in Norway.

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 it takes to get to trial depends on which District Court handles the proceedings, and the characteristics of the case. On average it takes less than six months from the date the subpoena is sent to the main proceedings, but it may take longer.

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 (procedural issues). Some grounds for dismissal must be invoked by the parties and some should be taken into account by the court *ex officio*. A preliminary decision will be based on the facts provided by the parties.

Material issues, whether related to matters of law or matters of fact, will not be decided upon in a preliminary hearing.

4.7 What appeal options are available?

A party in a civil case may appeal a judgment or decision rendered by the District Court to the Court of Appeal. A judgment by the District Court may be appealed on the basis of errors (i) in the assessment of facts, (ii) application of the law, or (iii) the proceedings underlying the decision.

The Court of Appeal's ruling may be appealed to the Supreme Court with the consent of the Appeals Committee of the Supreme Court. Consent may only be granted if (i) the appeal concerns issues that have an impact beyond the present case, or (ii) if it for other reasons is particularly important to have the case decided by the 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?

According to the Norwegian Dispute Act, there are two types of expert evidence. There are experts appointed by the court to provide affidavit evidence, and there are expert statements or witnesses offered as evidence by one of the parties.

The court can appoint an expert if requested by a party, subject to such appointment being a necessary and proportionate means to get a thorough factual basis for the ruling. Furthermore, if it does not lead to disproportionate costs or delays, the court may appoint more than one expert if the character of the technical questions, the significance of the case or other circumstances make it desirable.

Because of the principle of "free evaluation of evidence", expert evidence does not put constraints on the court. However, expert evidence will often have great importance for the court's decision.

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 Norway, except for cases before the Supreme Court.

Expert witnesses presented by one of the parties have to meet in court and give an oral statement. Experts appointed by the court, on the other hand, submit written reports, which constitute an exception to the general principles stating oral examinations and presentation of evidence in court. It is up to the court to decide whether the experts should meet in court for oral statement. The expert reports must be submitted to the court prior to the trial, and made available to both parties.

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 part of the pre-trial procedure, the parties are obliged to disclose all evidence which is in their possession and which is of relevance to the case. Furthermore, a party must inform the other party of important evidence which is not in the first party's own possession and which it cannot expect the other party to have knowledge of, notwithstanding to whose advantage that evidence might be.

Evidence should be disclosed at least two weeks before the main proceedings.

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

There are alternative methods of dispute resolution available in civil cases, such as mediation.

When a subpoena is sent from the claimant to the defendant, both parties will receive information and offers on mediation. Judicial mediation presupposes as a rule that both parties agree to participate. Judicial mediation makes it possible for the parties to find a settlement to the conflict of matter by using a mediator, and the purpose is to agree on a reasonable solution that meets the interests of both parties.

The Conciliation Board is another option, which gives the parties an opportunity to resolve the dispute. The board consists of only laymen, and both conciliation and judgment have legal force. In certain cases, launching proceedings with the Conciliation Board is a condition for access to court.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction be brought within the jurisdiction of your courts either as a defendant or as a claimant?

According to the Dispute Act, a case can only be brought before Norwegian courts if the facts of the case are "sufficiently connected" with Norway. The application of this might differ depending on whether the case involves only EU jurisdictions or not.

Norway is a party to the Lugano Conventions, and the 2007 Lugano Convention is made statutory law. Consequently, Norwegian courts would take jurisdiction over any case where the defendant is domiciled in Norway. Further, in tort cases such as product liability cases, Norwegian courts would take jurisdiction if the defendant is domiciled within the EU and either (i) Norway is the place where the damage occurred, or (ii) Norway is the place of the event giving rise to the damage, *cf.* EU Case C 189/08 *Zuid-Chemie vs Philippo's Mineralenfabriek*. Insurance companies domiciled in the EU can also be brought within the jurisdiction of Norwegian courts regardless of place of damage, if the claimant is domiciled in Norway. The claimant's domicile is not relevant under the Lugano Convention.

In product liability cases involving non-EU jurisdictions, Norwegian courts would normally take jurisdiction if the defendant is domiciled in Norway or the damage occurred in Norway, subject to the matter having "sufficient connection" to Norway. The court might hold the claimant's domicile relevant in a broader consideration, but this would not be decisive.

Finally, according to the Dispute Act, a defendant may request that a claimant who is not domiciled in Norway provides security for its potential liability for legal costs.

5 Time Limits

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

Yes, see 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?

Claims under the Norwegian PLA are barred three years after the date the claimant obtained or should have obtained sufficient knowledge about (i) the damage, (ii) the defect, and (iii) who the manufacturer is. The time limit will under no circumstances lapse later than 10 years after the manufacturer put the harmful specimen of the product into circulation.

The time limit of three years also applies to claims in tort based on case law; however, for such claims, the maximum period of liability is 20 years from the date of damage instead of 10 years from the date of circulation of the product. For certain personal injuries there is no maximum period at all.

Consequently, the time limits do not vary depending on whether the liability is fault-based or strict, but whether the liability falls within or outside the scope of the PLA.

Age and condition of the claimant might be relevant for the consideration of when the claimant had "sufficient knowledge" of its claim. Certain statutory exceptions from the limitation period also apply to personal injuries to children under 18 years.

Norwegian courts do not have discretionary powers to disapply time limits.

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 any time limits. However, concealment or fraud may be relevant concerning what date the claimant knew or should have obtained the necessary knowledge about his/her claim.

6 Remedies

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

The primary remedy in product liability cases is monetary compensation. However, the claimant is allowed to seek a declaratory judgment on certain aspects of the case, such as whether or not the defendant is liable in tort. Declaratory relief might in some cases be an appropriate step, e.g. if the amount of damages is difficult to assess when initiating proceedings or if the amount of damages is disputed and would be costly to litigate.

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 Norwegian Damages Act, damages in tort may be awarded for death, bodily injuries, mental damage and damage to property, as well as any consequential losses thereof. However, only economic loss caused by the damage is recoverable, which often makes claims for mental damage difficult.

Pursuant to the PLA, there are certain restrictions on what damages are recoverable. The following damages are not recoverable under the PLA: (i) damage to the product itself; (ii) minor damage not exceeding a value of NOK 4,000; and (iii) damage to items of property of a type not ordinarily intended for private use or consumption, or not mainly used by the injured party for his own private use or consumption.

Damage to the product itself will, however, regularly be recoverable as a direct loss under the contractual liability regardless of fault.

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?

Such costs may be recoverable pursuant to the contract between the parties. In theory, such costs may also be awarded in tort. The claimant would, however, in both cases have to prove that the risk of malfunctioning or cause of injury was caused by a defect in the product and that the costs incurred are necessary and adequate in relation to prevent such defect from causing damage.

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

Norwegian tort law does not recognise punitive damages, and the courts would only award damages corresponding to the claimants' economic loss. Norwegian courts would, however, enforce reasonable contractual penalties (if so agreed to by the parties in relation to a potential defect).

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, but the court may reduce the amount of damages if the damages amount would otherwise be unreasonably burdensome for the defendant. Such reductions are rarely seen in product liability cases involving professional manufacturers and/or insurance companies.

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 has to approve settlements in class actions. In all other cases, including cases where the claimant is an infant or child, or otherwise under guardianship, the legal guardian is empowered to settle the case without the court's prior 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?

The Norwegian social security services (No: *Folketrygden*) may only claim recourse for expenses related to (i) bodily injury, and (ii) damage caused by intent, and only to the extent such governmental expenses have led to a reduction of the amount of damages awarded to the injured party from the defendant. The responsibility lies with the liable party, e.g. the manufacturer or distributor of 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?

As a main rule, the successful party will be awarded court fees, legal fees and other costs related to the proceedings from the losing party. However, the court may exempt the losing party from such award (wholly or partially), e.g. if such exemption in the court's opinion appears to be reasonable.

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

Yes, the governmental Legal Aid Office (No: *Fylkesmannen*) may provide legal aid in certain cases.

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

Yes. Only natural persons may be awarded legal aid. Further, legal aid in personal injury cases will only be awarded against demonstration of financial need (both in terms of income and wealth). Legal aid for claims related to property damages would only be awarded in exceptional circumstances.

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

Conditional fees are allowed, but the Norwegian Bar Association explicitly prohibits fees which are based on a share or percentage of the claim. Thus, conditional fees would have to be based on the lawyer's hourly rates rather than a percentage of the claim. There are also restrictions as to whether the lawyer is allowed to charge higher fees on a conditional basis than it would in normal conditions.

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

Yes, third party funding may be provided without any statutory restrictions.

7.6 In advance of the case proceeding to trial, does the court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

No. However, as mentioned above, the Court will conduct a reasonableness test of the legal fees before awarding costs to the winning party. Further, and upon a party's request, the Court may exercise a subsequent control over the legal fees charged by that party's own legal counsel. In both cases, the value of the claim is a relevant consideration, although not necessarily decisive.

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 your jurisdiction.

There have been no statutory amendments and few Norwegian product liability cases recently.

More often than before, injured parties and insurance companies claim recourse for damage to property falling outside the scope of the PLA, e.g. damage to professional property, even where there is no proof of fault/negligence. We are not aware of any precedence relating to strict product liability for damage to professional property. On the contrary, in January 2016, the Court of Appeal acquitted a Norwegian distributor of household appliances after one of their products caused damage to a municipal apartment building. Being advised by Advokatfirma Ræder, the distributor and its insurer had acknowledged that the damage was caused by a defect in the product, but refused liability for any damage falling outside the scope of the PLA on the argument that there was no proof of negligence on part of the distributor, a fact which was not contested. The Court of Appeal held that the distributor was not liable on the basis of strict liability neither under the PLA nor case law. The case has been appealed to the Supreme Court.

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Kyrre also assists his clients with contractual negotiations within the scope of his product liability practice or just outside, including distribution agreements, M&A and financing transactions.

Kyrre co-authors the leading legal commentary on the Norwegian Product Liability Act (Gyldendal, 2015) together with Ole André Oftebro.

RÆDER

Advokatfirma Ræder is a leading law firm with more than 65 experienced lawyers, of which 10 are dedicated to our department for Insurance and Tort. We provide advice within most areas of commercial law and are centrally located at Solli Plass in Oslo.

The majority of our clients are national and international companies, organisations and government authorities. We focus on offering tailor-made, cross-disciplinary advice that suits the needs of each client.

We have an international focus and have built an extensive network of cooperative partners across national borders. Ræder is represented in the board and as members of several chambers of commerce. Our international network and experience mean that we can provide prompt assistance to all our clients, including those situated outside of Norway.

We focus on each client and concentrate on building trust by providing good advice based on solid, specialist legal knowledge and commercial understanding. Our organisation is built on a foundation that is characterised by orderliness, commitment, quality and respect.

Chapter 25

Singapore

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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 is no legislation exclusively or specifically governing product liability of manufacturers as such. The issue of product liability is generally governed by negligence in the case of manufacturers and contract against sellers/suppliers.

Establishing a case in negligence involves proving the existence of a duty of care, a breach of that duty and that the breach caused the damage to the consumer. What amounts to negligence depends on the facts of each case. Where there is a duty to exercise care, reasonable care must be taken to avoid acts or omissions which can be reasonably foreseen to be likely to cause physical injury to the persons or property. Liability for death or personal injury resulting from negligence cannot be excluded. Other liability for negligence may be excluded if such restriction is reasonable.

A right to claim damages under contract is predicated on the claimant having entered into a contract with the supplier of the product and the supplier having breached a term of the contract, e.g. by supplying defective products. Liability is strict where the contract has been breached and will depend on the terms agreed between the parties or implied into the contract.

Standard conditions are implied into all contracts for the sale of goods under the Sale of Goods Act (Cap. 393) (SOGA) and Supply of Goods Act (Cap. 394) (SGA). 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. As against a person acting as a consumer, the Unfair Contract Terms Act (Cap. 396) prevents the exclusion or restriction by contract of the seller's implied undertakings as to conformity of goods with a description or sample, or as to their quality or fitness for a particular purpose.

There are also various statutes that foster consumer protection. When a consumer enters into a consumer transaction involving an unfair practice in relation to goods and services, he has a right of action against the supplier under the Consumer Protection (Fair Trading) Act (Cap. 52A) (CPFTA). Section 4 CPFTA states that:

> *It is an unfair practice for a supplier, in relation to a consumer transaction —*
>
> *(a) to do or say anything, or omit to do or say anything, if as a result a consumer might reasonably be deceived or misled;*
>
> *(b) to make a false claim;*
>
> *(c) to take advantage of a consumer if the supplier knows or ought reasonably to know that the consumer —*
>
> *(i) is not in a position to protect his own interests; or*
>
> *(ii) is not reasonably able to understand the character, nature, language or effect of the transaction or any matter related to the transaction; or*
>
> *(d) without limiting the generality of paragraphs (a), (b) and (c), to do anything specified in the Second Schedule.*

The Second Schedule sets out specific unfair practices, including:

- Representing that goods or services have sponsorship, approval, performance characteristics, accessories, ingredients, components, qualities, uses or benefits that they do not have.
- Representing that goods or services are of a particular standard, quality, grade, style, model, origin or method of manufacture if they are not.
- Representing that goods are new or unused if they are not or if they have deteriorated or been altered, reconditioned or reclaimed.
- Representing that goods have been used to an extent different from the fact or that they have a particular history or use if the supplier knows it is not so.
- Representing that a service, part, repair or replacement is needed or desirable if that is not so, or that a service has been provided, a part has been installed, a repair has been made or a replacement has been provided, if that is not so.
- Using small print to conceal a material fact from the consumer or to mislead a consumer as to a material fact, in connection with the supply of goods or services.

The CPFTA defines "supplier" as:

> *a person who, in the course of the person's business —*
>
> *(a) provides goods or services to consumers;*
>
> *(b) manufactures, assembles or produces goods;*
>
> *(c) promotes the use or purchase of goods or services; or*
>
> *(d) receives or is entitled to receive money or other consideration as a result of the provision of goods or services to consumers,*
>
> *and includes any employee or agent of the person.*

Liability only arises if the unfair practice arose in relation to a "consumer transaction", i.e.:

(a) *the supply of goods or services by a supplier to a consumer as a result of a purchase, lease, gift, contest or other arrangement; or*

(b) *an agreement between a supplier and a consumer, as a result of a purchase, lease, gift, contest or other arrangement, in which the supplier is to supply goods or services to the consumer or to another consumer specified in the agreement.*

Hence, for example, if a manufacturer makes a misrepresentation in his sale to the retailer, but does not address that misrepresentation directly to the consumer, the unfair practice may not be considered to relate to a consumer transaction.

Whether conduct has been misleading or deceptive under sections 4(a) and (b) CPFTA is tested objectively, in relation to one or more sections of the public. However, the state of mind of the supplier may be relevant to whether his conduct conveyed a misleading or deceitful meaning. Some of the specific unfair trade practices listed in the Second Schedule expressly require the establishment of actual or imputed knowledge. The implication is that the other representations which do not specify knowledge do not require knowledge to be established. It is not possible to contract out of the provisions of the CPFTA.

Sections 12A to 12F of the CPFTA came into effect on 1 September 2012 to protect consumers against defective goods that fail to conform to contract, or meet satisfactory quality or performance standards at the time of purchase. Sections 12A to 12F are set out below:

Interpretation of this Part

12A. —(1) In this Part, unless the context otherwise requires —

"applicable contract" means —

(a) a contract of sale of goods;

(b) a contract for the transfer of goods; or

(c) a hire-purchase agreement;

"contract for the transfer of goods" has the same meaning as in the Supply of Goods Act (Cap. 394);

"contract of sale of goods" has the same meaning as in the Sale of Goods Act (Cap. 393);

"delivery" has the same meaning as in the Sale of Goods Act;

"goods" —

(a) in relation to a sale, has the same meaning as in the Sale of Goods Act; and

(b) in relation to any other transfer, has the same meaning as in the Supply of Goods Act;

"hire-purchase agreement" has the same meaning as in the Hire-Purchase Act (Cap. 125);

"repair" means, in cases where there is a lack of conformity in goods within the meaning of subsection (4), to bring the goods into conformity with the contract;

"transferee" —

(a) in relation to a contract of sale of goods, means the buyer within the meaning of the Sale of Goods Act;

(b) in relation to a contract for the transfer of goods, has the same meaning as in the Supply of Goods Act; and

(c) in relation to a hire-purchase agreement, means the hirer within the meaning of the Hire-Purchase Act;

"transferor" —

(a) in relation to a contract of sale of goods, means the seller within the meaning of the Sale of Goods Act;

(b) in relation to a contract for the transfer of goods, has the same meaning as in the Supply of Goods Act; and

(c) in relation to a hire-purchase agreement, means the owner within the meaning of the Hire-Purchase Act.

(2) References in this Part to dealing as consumer are to be construed in accordance with Part I of the Unfair Contract Terms Act (Cap. 396).

(3) For the purposes of this Part, it is for a transferor claiming that the transferee does not deal as consumer to show that he does not.

(4) For the purposes of this Part, goods do not conform to —

(a) a contract of sale of goods if there is, in relation to the goods, a breach of an express term of the contract or a term implied by section 13, 14 or 15 of the Sale of Goods Act;

(b) a contract for the supply or transfer of goods if there is, in relation to the goods, a breach of an express term of the contract or a term implied by section 3, 4 or 5 of the Supply of Goods Act; and

(c) a hire-purchase agreement if there is, in relation to the goods, a breach of an express term of the contract or a term implied by section 6A, 6B or 6C of the Hire-Purchase Act.

(5) The following provisions shall not apply to this Part:

(a) the definitions of "consumer" and "goods" in section 2(1);

(b) section 2(2); and

(c) the provisions in Part IV.

Application of this Part

12B. —(1) This Part applies if —

(a) the transferee deals as consumer;

(b) the goods do not conform to the applicable contract at the time of delivery; and

(c) the contract was made on or after the date of commencement of section 6 of the Consumer Protection (Fair Trading) (Amendment) Act 2012.

(2) If this section applies, the transferee has the right —

(a) under and in accordance with section 12C, to require the transferor to repair or replace the goods; or

(b) under and in accordance with section 12D —

(i) to require the transferor to reduce the amount to be paid for the transfer by the transferee by an appropriate amount; or

(ii) to rescind the contract with regard to the goods in question.

(3) For the purposes of subsection (1)(b), goods which do not conform to the applicable contract at any time within the period of 6 months starting from the date on which the goods were delivered to the transferee must be taken not to have so conformed at that date.

(4) Subsection (3) does not apply if —

(a) it is established that the goods did so conform at that date; or

(b) its application is incompatible with the nature of the goods or the nature of the lack of conformity.

Repair or replacement of goods

12C. —(1) If section 12B applies, the transferee may require the transferor to —

(a) repair the goods; or

(b) replace the goods.

(2) If the transferee requires the transferor to repair or replace the goods, the transferor must —

(a) repair or, as the case may be, replace the goods within a reasonable time and without causing significant inconvenience to the transferee; and

(b) bear any necessary costs incurred in doing so (including in particular the cost of any labour, materials or postage).

(3) The transferee must not require the transferor to repair or, as the case may be, replace the goods if that remedy is —

(a) impossible;

(b) disproportionate in comparison to the other of those remedies; or

(c) disproportionate in comparison to an appropriate reduction in the amount to be paid for the transfer under paragraph (a), or rescission under paragraph (b), of section 12D(1).

(4) One remedy is disproportionate in comparison to the other if the one imposes costs on the transferor which, in comparison to those imposed on him by the other, are unreasonable, taking into account —

(a) the value which the goods would have if they conformed to the applicable contract;

(b) the significance of the lack of conformity with the applicable contract; and

(c) whether the other remedy could be effected without causing significant inconvenience to the transferee.

(5) Any question as to what is a reasonable time or significant inconvenience is to be determined by reference to —

(a) the nature of the goods; and

(b) the purpose for which the goods were acquired.

Reduction in amount to be paid or rescission of contract

12D. —(1) If section 12B applies, the transferee may —

(a) require the transferor to reduce the amount to be paid for the transfer of the goods in question to the transferee by an appropriate amount; or

(b) rescind the contract with regard to those goods,

if the condition in subsection (2) is satisfied.

(2) The condition is that —

(a) by virtue of section 12C(3) the transferee may require neither repair nor replacement of the goods; or

(b) the transferee has required the transferor to repair or replace the goods, but the transferor is in breach of the requirement of section 12C(2)(a) to do so within a reasonable time and without causing significant inconvenience to the transferee.

(3) For the purposes of this Part, if the transferee rescinds the contract, any reimbursement to the transferee may be reduced to take account of the use he has had of the goods since they were delivered to him.

Relation to other remedies, etc.

12E. —(1) If the transferee requires the transferor to repair or replace the goods, the transferee must not act under subsection (2) until he has given the transferor a reasonable time in which to repair or replace (as the case may be) the goods.

(2) The transferee acts under this subsection if —

(a) he rejects the goods and terminates the contract for breach of condition; or

(b) he requires the goods to be repaired or replaced (as the case may be).

Powers of court

12F. —(1) In any proceedings in which a remedy is sought under this Part, the court may, in addition to any other power it has, act under this section.

(2) On the application of the transferee, the court may make an order requiring specific performance by the transferor of any obligation imposed on him by virtue of section 12C.

(3) Subsection (4) applies if —

(a) the transferee requires the transferor to give effect to a remedy under section 12C or 12D or has claims to rescind under section 12D; but

(b) the court decides that another remedy under section 12C or 12D is appropriate.

(4) The court may proceed —

(a) as if the transferee had required the transferor to give effect to the other remedy; or

(b) if the other remedy is rescission under section 12D, as if the transferee had claimed to rescind the contract under that section.

(5) If the transferee has claimed to rescind the contract, the court may order that any reimbursement to the transferee be reduced to take account of the use he has had of the goods since they were delivered to him.

(6) The court may make an order under this section unconditionally or on such terms and conditions as to damages, payment for the goods and otherwise as it thinks just.

(7) Subject to its jurisdiction under section 5 of the Small Claims Tribunals Act (Cap. 308), a Small Claims Tribunal may, in addition to its powers under that Act, act under this section.

Where goods fail to conform to an applicable contract at the time of delivery, the transferee (dealing as a consumer) has the right to require the transferor to repair or replace the goods within a reasonable time and without causing significant inconvenience to the consumer. An "applicable contract" is defined as a contract of sale of goods, contract for the transfer of goods or hire-purchase agreement. Goods will be presumed not to conform to the applicable contract at the time of delivery if they do not conform within six months of the date of delivery of the goods. The presumption is rebuttable if it is established that the goods did conform at the time of delivery, or if the presumption is incompatible with the nature of the goods or the nature of the lack of conformity.

If repair or replacement is impossible or disproportionate, or if the transferor fails to repair or replace the goods within a reasonable time and without significant inconvenience to the consumer, the consumer may require the transferor to reduce the amount to be paid for the transfer of the goods by an appropriate amount, or rescind the contract. The question as to what is a reasonable time or significant inconvenience is to be determined by reference to the nature of the goods and the purpose for which the goods were acquired.

It is also possible for misleading or deceptive conduct to give rise to an actionable misrepresentation under the Misrepresentation Act (Cap. 390).

Another statute that safeguards consumers against unfair practices is the Consumer Protection (Trade Descriptions and Safety Requirements) Act (Cap. 53) (CPTDA), which prohibits the misdescription of goods supplied in the course of business and regulates the affixing of safety marks on certain goods.

Provisions for the recall of products can be found in various statutes; this is elaborated on in our response to question 1.4.

Liability for breach of statutory duty may be imposed where a statute is intended to create a private law right, actionable by the individual harmed by the breach. However, such rights have not previously been found to arise from breach of statutes that regulate consumer protection.

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

No formal schemes exist.

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

The manufacturer, importer, distributor, and "retail" supplier may be liable for the fault/defect. See the response to question 1.1.

In negligence, fault lies with the negligent party. In contract, liability may extend to anyone with whom the plaintiff can establish privity of contract, subject to any exclusions of 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?

Provisions for recall of products can be found in various statutes.

For example, under the Health Products Act (Cap. 122D) (HPA), which regulates the manufacture, import, supply, presentation and advertisement of health products and of active ingredients used in the manufacture of health products, where a manufacturer, importer, supplier or registrant of a health product becomes aware of any defect in the health product, or any adverse effect that can arise from the use of the health product, they shall inform the Health Sciences Authority (HSA) which may then, by notice in writing, require them to recall the health product and secure the immediate stoppage of its manufacture, import, supply, use or administration. The HSA may also require any person who has supplied any health product or active ingredient to recall the same if it does not comply with the HPA.

It is also possible for a manufacturer, importer, supplier or registrant of a health product to voluntarily effect a recall of the health product, and he should notify the HSA of the recall and the reasons therefor. The HSA may then require the manufacturer, importer, supplier or registrant of the health product to issue to the general public a statement informing them of the recall.

Under the Consumer Protection (Safety Requirements) Regulations (Cap. 53, Regulation 1), which regulate goods such as components of the liquefied petroleum gas system, gas cookers, hairdryers, audio products, etc., where the supply of any registered controlled goods is prohibited, SPRING Singapore, as the Safety Authority, may require the Registered Supplier to effect a recall of the goods. Supply of such goods may be prohibited for various reasons, e.g. that the goods do not conform to safety requirements.

Under the Wholesome Meat and Fish (Processing Establishments and Cold Stores) Rules (Cap. 349A, Rule 3), which regulate the slaughtering of animals and the processing, packing, inspection, import, distribution, sale, transhipment and export of meat and fish products, where any meat or fish product that has been processed in a licensed processing establishment is adulterated, contaminated or otherwise unfit for human consumption, the Agri-food and Veterinary Authority (AVA) may require the licensee to recall all stocks and to cease the sale, supply or distribution of the product.

The AVA may also direct local importers and retailers to recall food products which have been voluntarily recalled overseas by their manufacturers.

It is an offence to fail to comply with any notice for recall issued under statute.

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

Under the CPTDA, any person who, in the course of any trade or business, supplies goods that contravene CPTDA regulations shall be guilty of an offence, punishable with a fine and/or imprisonment.

There are also specific regulatory statutes dealing with particular types of products, e.g. food and drugs, contravention of which is an offence punishable with fines and/or imprisonment.

2 Causation

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

Generally, the burden of proof falls on the party who initiates the civil action (the plaintiff) to pursue damages and other remedies in respect of the product defect in question, whether arising under a contract or otherwise.

Under the CPFTA, the supplier must show that he has complied with the provisions of the CPFTA or its regulations. If a defect is found within six months of delivery, it is assumed that the defect existed at the time of delivery, unless the retailer can prove otherwise. Beyond six months, the burden falls on the consumer to prove that the defect existed at the point of delivery.

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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

In negligence, the traditional test for causation is the "but-for test", i.e. whether the plaintiff would not have suffered the loss "but for" the defendant's negligence. The court may also assess whether the defendant's negligence materially contributed to the plaintiff's loss. What constitutes a "material contribution" will depend on the facts of each case.

In contract, the plaintiff must show that the breach of contract was a cause of the loss which has been sustained, i.e. the breach of contract is the "effective" cause of the loss, as opposed to an event which merely gives the opportunity for the claimant to sustain the loss. The courts have generally avoided laying down any formal tests for causation in contract, and have instead relied on common sense as a guide to decide whether a breach of contract is a sufficiently substantial cause of the claimant's loss.

If the product to which the claimant was exposed did not actually malfunction and cause injury, but the products or the batch to which the claimant was exposed merely carried an increased, but unpredictable, risk of malfunction, it is unlikely that the claimant would succeed as no actual loss was incurred. Actual loss is required to succeed in an action for tortious liability.

If there is no actual loss suffered by the claimant, the claimant could argue that under section 14(2A) of the Sale of Goods Act, there is an implied condition that goods sold in the course of a business are

of satisfactory quality. The claimant has to show that the product malfunctioned in a way that does not meet the standard that a reasonable person would regard a product to be in order to be satisfactory. This inquiry is an objective one from a reasonable person placed in the buyer's position armed with his knowledge and background, and considering at every stage any and all factors that may be relevant to the hypothetical reasonable person (*Compact Metal Industries Ltd v PPG Industries (Singapore) Ltd* [2006] SGHC 242).

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 such a case, the claimant cannot satisfy its evidential burden and the claim is likely to be dismissed.

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 potential liability under statute and the tort negligence. In the event that death is caused, there could also be ramifications under the Penal Code (Cap. 224).

Under the CPFTA, it is an unfair practice for a supplier, in relation to a consumer transaction, to do or say anything, or omit to do or say anything, if, as a result, a consumer might reasonably be deceived or misled. Hence, silence on the part of the supplier can result in a breach. Misrepresentations made to intermediaries, which are not addressed directly to the consumer, may not be considered unfair practices relating to the consumer transaction.

Under the Penal Code, a person may be imprisoned and/or fined for causing death by doing any rash or negligent act not amounting to culpable homicide. The failure to warn, or the conscious avoidance of an obvious risk, may constitute a "rash" act.

In negligence, manufacturers and suppliers owe consumers a duty of reasonable care to provide adequate warnings with their products. There is no duty to warn of risks that are obvious or a matter of common knowledge.

The "learned intermediary" doctrine (as described above) has not been specifically recognised in Singapore.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under the CPFTA, the onus falls on the supplier to argue that his statements were unreasonably relied upon by the ordinary consumer, to avoid a finding of "unfair practice".

In the tort negligence, the tortfeasor can raise a defence that the claimant voluntarily agreed to the risk in full knowledge of the nature and extent of the risk. Contributory negligence may be relied on to limit liability where the claimant's conduct fails to meet the standard of care required for his own protection, and is a contributing cause in bringing about the damage.

Under the SOGA, the buyer's primary remedy is a rejection of the goods. However, the buyer will be deemed to have accepted them when he intimates to the seller that he has accepted them, or when the goods have been delivered to him and he does any act in relation to them which is inconsistent with the ownership of the seller, or when after the lapse of a reasonable time he retains the goods without intimating to the seller that he has rejected them.

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/development risk defence" (as described above) has not been specifically recognised in Singapore.

In the tort negligence, the state of scientific and technical knowledge can be relevant to the determination of the scope of the duty of care that should be exercised by the manufacturer in the circumstances. However, in all tort actions, a defendant must take his victim as he finds him. Under the "egg shell skull rule", which normally applies to personal injuries, this concept is adapted to allow recovery even for unforeseeable damage. The "egg shell skull rule" applies in circumstances where, due to a claimant's innate physical susceptibility to illness or injury, he suffers extreme and unforeseeable damage which is triggered by the initially foreseeable damage caused by the defendant's negligence (*Smith v Leech Brain & Co Ltd* [1962] 2 QB 405). Hence, the defendant is made to bear all risks where physical injury to the primary victim is concerned, and the state of scientific and technical knowledge may only be a limited 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?

Compliance with regulatory and/or statutory requirements is generally not a defence, although in some circumstances, compliance with such requirements can establish that a manufacturer took adequate care in production.

In negligence, if a manufacturer intends his products to reach the consumer in the form in which they left him, with no reasonable possibility of intermediate examination, and with the knowledge that the absence of reasonable care in the preparation or putting up of the products will result in injury to the consumer's life or property, he owes a duty to the consumer to take 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?

Under the doctrine of *res judicata*, parties are estopped between themselves from re-litigating issues determined by final judgment

or award of any competent court or tribunal. The narrower principle of issue estoppel prevents the prosecution from calling into question issues determined in the accused's favour in an earlier proceeding.

While different claimants may be able to re-litigate issues in separate proceedings, a claimant could be prevented from re-litigating an issue decided in a previous proceeding, not involving the same parties, on the grounds of abuse of process by re-litigation. Where the doctrines of *res judicata* and abuse of process do not apply, the prior findings of another court based on similar facts can 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?

The Civil Law Act (Cap. 43) provides that any person liable in respect of any damage suffered by another person may recover contribution from any other person liable in respect of the same damage (whether jointly with him or otherwise). Order 16 rule 1 of the Rules of Court (ROC) provides that a third party notice may be issued by a defendant against a person who is not already a party to the action.

Such claims can be brought in either the same or subsequent proceedings. For subsequent proceedings, the claim should be brought within two years from the date of judgment or settlement of the claimant's claim.

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

See the response to 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 Judge. In Singapore, the jury system was abolished in 1970.

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)?

Order 40 rule 1 ROC allows the court to appoint an independent expert at any time, on its own motion or on the application of any party, in any cause or matter in which any question for an expert witness arises, to inquire and report upon any question of fact or opinion not involving questions of law or of construction.

It is more common, however, for the parties to engage their own experts to give or prepare evidence for the purpose of court proceedings. Under Order 40A rule 1, the court may limit the number of expert witnesses who may be called at the trial. If a material issue arises between evidence from the parties' own experts and a report from a court-appointed expert, the experts may be cross-examined.

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?

Order 15 rule 12 ROC provides that the represented group must consist of "numerous persons" who have the "same interest" in the proceedings. One or more of the parties may represent all or all except one or more of them in the proceedings. Although the class members are not required to come forward individually, it is usual for the purpose of costs, the presentation of evidence and other litigation issues that the members of the class are ascertained and invited to join the action. The person who wishes to initiate the representative action may take whatever steps he considers necessary to communicate with the other members of the class.

Representative actions are not commonly brought in Singapore. However, the Court of Appeal considered the application of the representative action rule in the case of *Koh Chong Chiah and others v Treasure Resort Pte Ltd* [2013] SGCA 52, where it underlined a two-stage test. The threshold requirement of demonstrating the "same interest" would first need to be met, and only then would the Court exercise its discretion as appropriate in the circumstances of the case.

With regard to the first part of the test, the Court held that the following legal principles should be applied:

- The class of represented persons must be capable of clear definition.
- The proposed representative(s) must adequately represent the interests of the entire class, and must capably prosecute the interests of the class.
- There must be significant issues of fact or law common to all of the claimants.
- All of the claimants must have the same interest in the relief granted.

With regard to the second part of the test, the Court weighed factors in favour of representative action against the prejudice that might arise from the procedural limitations of representative action and found there would be considerable time and costs savings for both the claimants and the defendant and that any suggestions of prejudice to the defendant were more hypothetical than real. The Court underlined that Order 15 rule 12 ROC is to be applied in a broad and flexible manner so as to preserve the principle of access to justice, describing it as a flexible tool of convenience in the administration of justice.

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

In a representative action, the persons who are to be represented and the person representing them should have a common interest, a common grievance and the relief in its nature must be beneficial to all. A claim cannot be brought by a representative body if it has not suffered the same damage as the claimants.

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

Generally, a case in the High Court takes about 12 to 15 months from the issuance of the writ to the start of the 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?

Order 33 rule 2 ROC provides that the court may order any question or issue arising in a cause or matter, whether of fact or law or partly of fact and partly of law, and whether raised by the pleadings or otherwise, to be tried before, at or after the trial of the cause or matter, and may give directions as to the manner in which the question or issue shall be stated. The court may try preliminary issues of law and fact.

4.7 What appeal options are available?

The High Court exercises both original and appellate civil and criminal jurisdiction. It hears appeals from the District and Magistrates' Courts.

The Court of Appeal hears appeals from decisions of the High Court made in the exercise of its original and appellate civil and criminal jurisdiction.

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 response to question 4.2.

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 procedure for taking pre-trial depositions. Witnesses are required to reduce their evidence in chief to an affidavit which is filed and served on the opposing party about six weeks before trial. The witness must be present in court for cross-examination before his affidavit is admitted by the trial judge 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?

Under Order 24 rule 1 ROC, the court may at any time order any party to give discovery by making and serving on any other party a list of the documents which are or have been in his possession, custody or power, and may also order him to make and file an affidavit verifying such a list and to serve a copy thereof on the other party. The duty to give discovery continues throughout the proceedings.

It is possible for a party to make an application for an order for the discovery of documents before the commencement of proceedings under Order 24 rule 6. The order may be conditional on the applicants giving security for the costs of the person against whom it is made.

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

The main modes of alternative dispute resolution (ADR) practised in Singapore are negotiation, mediation and arbitration. The leading ADR institutions in Singapore are the Singapore International Arbitration Centre (www.siac.org.sg) and the Singapore Mediation Centre (www.mediation.com.sg). Consumers may lodge a complaint with the Consumer Association of Singapore (CASE), which may then invite the retailer and consumer to take part in mediation when the matter has reached a deadlock, or when both parties are agreeable to come forward for mediation.

ADR is not required to be pursued before litigation, although the courts have encouraged parties to consider ADR. In the State Courts, all civil cases are automatically referred to ADR unless one or more party opts out. Refusal to use ADR for reasons deemed unsatisfactory by the registrar may result in cost sanctions under Order 59 rule 5 of the Rules of Court. In the High Court, a party wishing to attempt ADR may serve an "ADR offer". The High Court will take into account the ADR offer and the response to the offer in deciding on appropriate costs orders under Order 59 rule 5 of the Rules of Court.

Section 35B of the Supreme Court Practice Directions provides that it is the professional duty of advocates and solicitors to advise their clients about the different ways their disputes may be resolved using an appropriate form of ADR.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction be brought within the jurisdiction of your courts either as a defendant or as a claimant?

Under section 16(1) of Supreme Court of Judicature Act (Cap. 322) and section 19(3) of the Subordinate Courts Act (Cap. 321), any party may invoke the jurisdiction of the court of first instance, or become amenable to the court's jurisdiction provided only that the defendant has been properly served with the necessary process.

Any plaintiff (Singaporean or non-Singaporean) will be able to commence proceedings in the Singapore Court if he can establish that a cause of action arises and connecting factors enable a Singapore court to take jurisdiction in a matter.

Before commencing an action, a plaintiff should consider if Singapore is the appropriate forum to commence proceedings or risk having the action stayed on the ground that there is clearly a more appropriate forum outside Singapore. A party who wishes to stay an action on such a ground will have to show that it is in the interests of the parties and of justice to try the case in another forum. The court will have to determine whether the other forum has the most real and substantial connection to the dispute, taking into account factors such as the governing law of the transaction, place of manufacture, place of sale, the location of witnesses, etc. In addition, the court will also consider whether there are circumstances which militate against a stay, including whether substantial injustice will be caused in sending the plaintiff to a foreign court.

The court may grant leave to a plaintiff to serve a writ on a defendant outside Singapore. Before a court grants leave, it must be satisfied that the plaintiff has a good arguable case falling under one of the limbs of Order 11 rule 1 ROC which, *inter alia*, include instances where relief is sought against a person who is domiciled, ordinarily resident or carrying on business or who has property in Singapore and/or an injunction is sought ordering the defendant to do or refrain from doing anything in Singapore and/or the claim is founded on a tort, wherever committed, which is constituted, at least in part, by an act or omission occurring in Singapore, and/or the claim is brought in respect of a breach committed in Singapore of a contract made in Singapore. The court has to be satisfied that there are serious issues to be tried. If leave is granted, service outside Singapore has to be in accordance with the laws of the country in which service is effected. The recipient of an

Order 11 service may also apply to set aside such service on the basis that Singapore is not the most appropriate forum to try the dispute.

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?

Under the CPFTA, a consumer may not commence an action for unfair practice against the supplier later than two years from the date of the occurrence of the last material event on which the action is based, or the earliest date on which the consumer had knowledge that the supplier had engaged in the unfair practice, whichever occurs later.

Under the Limitation Act (Cap. 163), for actions founded on a contract or tort, the limitation period is generally six years from the date on which the cause of action accrued. There are exceptions to this rule in the case of actions where the damage claimed consists of latent injuries and damage. For personal injury claims for damages in respect of negligence, nuisance or breach of duty, the claim must be brought within three years from the date on which the cause of action accrued, or the date of knowledge by the claimant of certain facts. In actions for damages for negligence, nuisance and breach of duty which do not involve a claim for personal injury, the claim must be brought within six years from the date on which the cause of action accrued, or three years from the date of knowledge by the claimant of certain facts.

If on the date when the right of action accrued, the person to whom it accrued was under a disability, the action may be brought any time before the expiration of six years or, in the case of personal injury claims for damages in respect of negligence, nuisance or breach of duty, three years from the date when the person ceased to be under a disability or died, whichever event first occurred. Under the Limitation Act, a person is deemed to be under a disability if he is a minor or lacks capacity to conduct legal proceedings.

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 upon fraud or the right of action is concealed by fraud, the period of limitation only begins to run when 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?

Under the CPFTA, a court may order the following types of relief:

(a) restitution of any money, property or other consideration;

(b) damages;

(c) specific performance;

(d) direct the supplier to repair or replace goods or provide parts for goods; or

(e) vary the contract between the supplier and the consumer.

The CPFTA also provides that where there are reasonable grounds for believing that a supplier has engaged, is engaging or is likely to engage in an unfair practice, a specified body, e.g. CASE, may invite the supplier to enter into a voluntary compliance agreement (VCA). The VCA includes an undertaking that the supplier will not engage in a certain unfair practice, and may require the supplier to compensate any consumer who has suffered loss or damage as a result of an unfair practice. If the supplier is unwilling to enter into the VCA, or breaches the VCA, the specified body may obtain a declaration or an injunction.

The court may also make a declaration that a supplier is engaging in an unfair practice or grant an injunction restraining a supplier from engaging in the unfair practice, and require the supplier to advertise the particulars of any declaration or injunction granted.

Under the SOGA, the buyer's primary remedy for a defective product is the rejection of the goods in question, for example, the buyer rejects the goods because of a breach of any conditions that have been implied by the application of the SOGA or the SGA. After rejection, the buyer is also entitled to recover the purchase price and any loss of bargain occasioned by the breach i.e. loss of damage.

However, the buyer may elect to treat any breach on the part of the seller as a breach of warranty. The buyer will then not be able to reject the goods by reason only of such breach of warranty, but may claim against the seller for a diminution or extinction of the price, or maintain an action for damages for the breach of warranty.

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

Damages for a breach of contract are awarded in a quantum which places the innocent party in the position which he would be if the contract was performed according to its terms. The damages claimed must be for losses which were within the reasonable contemplation of the parties at the time of the contract. Unusual losses must have been communicated to the other party at the time of the making of the contract before a claim can be brought to recover such losses. The innocent party may not recover compensation for losses which would not have been suffered if he had taken reasonable steps to reduce his losses or which were caused by unreasonable steps which increased the loss suffered.

Damages in tort are made with the intention of placing the plaintiff in the position he would have been if the tort had not been committed. Damages are subject to the rules of remoteness namely that the loss recoverable will not exceed that which was reasonably foreseeable as liable to result from the breach. Damages are recoverable for physical injury, damage to property or death. There have been developments which improve the innocent party's right to sue for pure economic loss.

Under the CPFTA, the tortious measure of damages is usually applied.

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?

The Court of Appeal has held that the general rule is that punitive damages cannot be awarded for breach of contract (*PH Hydraulics & Engineering Pte Ltd v Airtrust (Hong Kong) Ltd and another appeal* [2017] SGCA 26). The Court of Appeal noted that there are a number of other possible alternative remedies (including the award of damages for mental distress for breach of contract) that could also be invoked by the court to do practical justice while respecting the compensatory function of damages for breach of contract. However, the court also recognised that the instances in which a breach of contract can occur are manifold, and did not rule out the possibility that there might be a "truly exceptional case" to persuade the court that punitive damages should be awarded for breach of contract.

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?

Under the CPFTA, the "amount of claim" shall not exceed the current prescribed limit of S$30,000.

With contractual/tortious claims there is no maximum limit on the damages that are 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?

Under Order 22A rule 7 ROC, a party under disability (a minor or a person lacking capacity) may make, withdraw and accept an offer to settle, but no acceptance of an offer made by him and no acceptance by him of an offer made by another party is binding on him until the settlement has been approved by the court. The court may take into account the settlement terms or the fact that settlement has been reached.

For class actions, the court will have to be satisfied that all aspects of the action have been settled in relation to all parties.

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?

Assessment of costs is at the court's discretion. In civil proceedings, the losing party will generally be ordered to pay the reasonable legal costs and disbursements of the successful party. Costs are normally awarded on a "standard" basis, as opposed to an "indemnity" basis.

Where costs are taxed on a "standard" basis, a reasonable amount in respect of all costs reasonably incurred shall be allowed. On an "indemnity" basis, all costs shall be allowed unless they are of an unreasonable amount or have been unreasonably incurred.

In criminal proceedings, any compensation made to victims may operate as a mitigating factor.

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

The Legal Aid Bureau (www.lab.gov.sg) provides legal aid and advice for civil matters. There is no government funded legal aid for criminal matters.

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

Legal aid is available to Singapore citizens or permanent residents in Singapore.

Applicants for legal aid must satisfy the means and merits tests. Under the merits tests, a person may be granted legal aid if he and his spouse have a combined disposable income of not more than S$10,000 *per annum* and a disposable capital of not more than S$10,000. Under the merits test, aid will be granted if the Legal Aid Board is of the opinion that the applicant has reasonable grounds for taking, defending, continuing or being a party to the legal proceedings.

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?

Third-party funding arrangements may be unenforceable if they are found to be champertous, i.e. where one party agrees to aid another to bring a claim on the basis that the person who gives the aid shall receive a share of what may be recovered. However, the courts have acknowledged that where the third party funder has a genuine commercial interest in enforcing proceedings, funding may not be champertous.

The Civil Law Act has been amended with effect from 1 March 2017 to allow third-party funding but only in the field of international (but not domestic) arbitration and related proceedings, and does not apply to court-based litigation. Such related proceedings include:

(a) court proceedings arising from or out of the international arbitration proceedings;

(b) mediation proceedings arising out of or in connection with international arbitration proceedings;

(c) application for a stay of proceedings referred to in section 6 of the International Arbitration Act; and

(d) proceedings for or in connection with enforcing an award or foreign award under the International Arbitration Act.

7.6 In advance of the case proceeding to trial, does the court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

One way in which the Court helps to manage costs is through holding regular pre-trial conferences (PTCs) to monitor the progress of the case. At PTCs, the Registrar will usually seek an update on the status of an action. Directions will then be given for the parties to progress the action in an expeditious and fair manner, e.g. the filing of interlocutory applications and the timelines therein. An action may go through several PTCs. Parties who reach a settlement at a PTC may record the settlement before the Registrar. Otherwise, trial dates will be given for matters that cannot be settled.

Parties are also encouraged to offer to settle any one or more of the claims in proceedings, to save costs and time for both the litigants and the courts. Under Order 22A rule 9 ROC, a party who rejects a reasonable offer from the other party will, upon being awarded judgment less favourable than the terms of the offer to settle, be penalised with certain adverse costs orders, while the other party will correspondingly be rewarded with such costs.

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 your jurisdiction.

In *TV Media Pte ltd v De Cruz Andrea Heidi* [2004] 3 SLR(R) 543, the plaintiff consumed a weight loss drug and subsequently suffered impending liver failure. The plaintiff sued to recover damages for pain and suffering and medical expenses incurred. The High Court held the importing company, its director, and the sole distributor of the drug liable. The director and sole distributor appealed. The Court of Appeal upheld the High Court decision and found that a distributor or wholesaler owes a duty of care to the ultimate consumer to take reasonable care in ensuring the safety of its products. Also, despite a company being a separate legal entity, a director may be held personally liable for negligent acts.

As mentioned in the response to question 1.1 above, a "lemon law" was introduced (Sections 12A to 12F of the CPFTA) to protect consumers against defective goods that fail to conform to contract, or meet satisfactory quality or performance standards at the time of purchase. This provides for the additional remedies of repair and replacement, beyond just rejecting the goods and getting a refund. This ensures that consumers buy products of good quality, improves the image of the retail industry in Singapore and fosters good business practices among retailers.

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Allen & Gledhill

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Our network comprises Rahmat Lim & Partners, our Malaysian associate firm in Kuala Lumpur, and our local office in Yangon, Myanmar. The firms are staffed by local lawyers familiar with the distinctive business environment, laws, regulations and practices in the respective jurisdictions. With more than 400 lawyers across South-east Asia and our close collaboration with leading law firms regionally and internationally, we are able to ensure our clients with multi-jurisdictional interests are provided with an integrated and seamless legal service. Our experience allows us to take on an effective lead counsel or project manager role in cross-border transactions.

Spain

Faus & Moliner

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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 Spain, the general regime on liability for defective products or services is established in Royal Legislative Decree ("RLD") 1/2007, of 16 November, approving the consolidated text of the General Law on the Protection of Consumers and Users and other complementary regulations. Such regime is found in articles 128 to 146, both inclusive, of RLD 1/2007.

Article 136 of RLD 1/2007 defines which types of products are subject to the regime on product liability, namely any movable asset, even when this is combined or incorporated into another movable or immovable asset, as well as gas and electricity. The concept of "any movable asset" is very broad and comprises practically all equipment and consumer goods.

The regime for product liability established in RLD 1/2007 is of a strict nature.

The actions available under RLD 1/2007 do not affect any other right to damages, including moral damages, that the injured party may have as a consequence of contractual liability, based on the lack of conformity of the goods or services or any other cause of non-performance or defective performance of the contract, or of any non-contractual liability that may apply.

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

The regime on product liability established in RLD 1/2007 does not foresee any scheme 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 responsibility for the defect is borne by the manufacturer or by the importer who introduces the product into the European Union.

In the event that the manufacturer cannot be identified, the supplier of the product (the distributor or the "retail" supplier) shall be considered as such, unless he informs the injured party of the identity of the manufacturer or of the person who supplied the product to him, within a term of three months. This same rule applies in the case of imported products, in the event that the product does not indicate the name of the importer, even if it indicates the name of the manufacturer.

However, the supplier of the defective product shall be liable towards the injured party as if he were the manufacturer in the event that he supplied the product knowing that the defect existed. In such case, the supplier may enforce his right of recovery against the manufacturer.

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?

Article 13 of RLD 1/2007 establishes that any entity involved in placing goods and services at the disposal of consumers and users shall be obliged, within the limits of its activity, to withdraw from the market, suspend the marketing or recover from the consumer or user any goods or services that do not meet the necessary conditions or requirements, or which represent a foreseeable risk to personal health or safety on any other grounds.

In accordance with article 51 of RLD 1/2007, the corresponding public administration may order the precautionary or definitive withdrawal or recall of goods or services from the market on the grounds of health and safety.

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

Criminal sanctions may apply insofar as the supply of the defective product can be considered as an intentional or negligent action. Such action is included as an offence in the Criminal Code and the damage caused is protected by such Criminal Code.

2 Causation

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

The injured party seeking the compensation of damages has the burden of proving the defect, the damage and the causal relationship between the two.

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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

The regime on product liability places the burden to prove the existence of the defect, the damage and the causal relationship between such defect and damage upon the claimant. In order to establish the causal relationship between the defect in the product and the damages suffered, the claimant must provide solid and substantial evidence that supports such link, and the damages must be an appropriate and sufficient result of the defect.

However, occasionally, the Spanish Courts also accept that the causal relationship may be proven by means of presumptions or circumstantial evidence.

In Spain, the principle of generic causation, i.e. that in order to prove the causal relationship it would be sufficient to demonstrate that a product is capable of causing an alleged injury, is not applied. The Spanish Courts have established that the mere fact that a product is capable of causing damage is not sufficient to establish the defective nature of such product. In order to prove that a product is defective, the claimant must prove that the damages that he or she claims to have suffered are effectively caused by the defective product. It is sufficient that the claimant proves the existence of the defect, but it is not strictly necessary that the claimant provides evidence of the specific defect of the product. We can thus conclude that in Spain the proximate causation principle operates.

On 5 March 2015, the Court of Justice of the European Union issued a ruling on In Joined Cases C-503/13 and C-504/13 under which certain kind of products can be considered defective under the proximate causation principle. In these particular cases, the Court of Justice of the European Union concluded that the Directive 85/374/CEE regarding damages caused by defective products should be interpreted in the sense that in the case of medical devices such as pacemakers and cardioverter defibrillators, considering their purpose and the vulnerability of patients who use them, the security requirements that the patients can expect from such products are particularly high. Under these conditions, as they are products of the same model and production series, after a defect has been detected in a unit, the other units of the same model or batch can be classified as defective without it being necessary to prove the existence of the defect in each of the units.

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 event that it cannot be established which of several possible producers manufactured the defective product, all of the manufacturers shall be jointly and severally liable *vis-à-vis* the injured parties. The manufacturer who compensated the injured party shall have the right to claim recovery from the other manufacturers, depending on their involvement in causing the damages.

However, the manufacturer of a part that is integrated into a finished product shall not be liable if he proves that the defect is attributable to the design of the product into which the part manufactured by him was integrated or to the instructions provided by the manufacturer of the finished 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?

In accordance with Spanish doctrine and case law, there are three large groups of defects that products may suffer from: i) manufacturing defects; ii) design defects; and iii) information defects.

The absence of the necessary warnings or instructions for use, or the inappropriateness of such information, may give rise to an information defect. As a consequence, when the information that accompanies a product is inappropriate or insufficient then such product may be considered to be defective and may give rise to liability in the event that the product causes damages.

The information is considered to be appropriate when it allows for the identification, assessment or reduction of the announced risk. The information is also considered to be appropriate when there is a balance between the information on the safety of the product in possession of the manufacturer and the information made available to consumers.

Moreover, the manufacturer or importer shall only be held liable for the lack of information on reasonably foreseeable risks, i.e. risks that he is aware of or should be aware of through the exercise of reasonable diligence. Within the framework of the special regime for product liability established in RLD 1/2007, a defect is defined as "the lack of safety that could legitimately be expected from the product, i.e. based on the criterion of the consumer's reasonable expectations". Further, within the scope of the consumer's legitimate expectations, only the information that was known to the manufacturer or that, in accordance with the state of scientific and technical knowledge, should have been known by him at the moment of placing the product on the market must be included.

In principle, the information and the warnings that shall be taken into account in order to determine whether a product suffers from an information defect shall be the information provided directly to the user of the product.

However, for certain types of product for which the intervention of an intermediary is required, the Courts may take the information provided to the intermediary into consideration, in order to determine whether the information provided to the consumer is sufficient and appropriate.

Specifically, in the case of medicinal products, Basic Law 41/2002, of 14 November, governing patient autonomy and rights and obligations as regards clinical information and documentation, establishes that it is the doctor's duty to guarantee that the patient has the necessary information to decide freely on the therapeutic strategy prescribed by the doctor. As a consequence, the information

provided by the manufacturer to the doctor shall be taken into consideration in order to assess the set of information provided to the patient.

Lastly, we must point out that RLD 1/2007 does not expressly foresee the referred "learned intermediary rule" pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make appropriate product information available.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The manufacturer or importer shall not be liable if he can prove:

a) That he did not put the product into circulation.

b) That, given the circumstances of the case, it may be presumed that the defect did not exist when the product was put into circulation.

c) That the product had not been manufactured for sale or for any other form of distribution with an economic purpose, nor that was it manufactured, imported, supplied or distributed within the context of a professional or entrepreneurial activity.

d) That the defect is due to the fact that the product was elaborated in accordance with existing mandatory rules.

e) That the state of scientific and technical knowledge existing at the time the product was put into circulation did not allow for the discovery of the existence of the defect.

The manufacturer of a part that is integrated into a finished product shall not be liable if he proves that the defect is attributable to the design of the product into which the part was integrated or to the instructions provided by the manufacturer of the finished product.

In the case of medicinal products, foods or foodstuffs intended for human consumption, the persons liable shall not be able to invoke the state of scientific and technical knowledge defence set out in point e) above.

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 fact that the state of scientific and technical knowledge existing at the time the product was put into circulation did not allow for the discovery of the existence of the defect may be used as a defence. However, as pointed out in the answer to question 3.1 above, such defence cannot be invoked in the case of medicinal products, foods or foodstuffs intended for human consumption.

The manufacturer has the burden of proving that the defect could not 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?

Compliance with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product can be used as a defence if such requirements impose the inexcusable obligation on the manufacturer to elaborate the product in strict compliance and observance of such requirements. If this is the case, the manufacturer could invoke the exoneration cause pointed out in point d) of question 3.1 above. In any case, it is not possible to provide a precise answer to this question, and every case should be evaluated on a case-by-case basis.

In case the damages caused by a company by means of its defective product were of criminal entity, that is, constituting an offence under the Spanish Criminal Code, such Code sets forth the possibility that legal entities are held criminally liable. Companies may be held criminally liable as a result of the behaviour of the following persons:

(a) their directors or legal representatives, if they have been appointed to perform their duties or even if they do so without a formal appointment;

(b) other persons authorised to adopt decisions on behalf of the company, including middle management, general and individual proxies, and persons to whom control and organisation functions have been delegated (including the compliance officer); and

(c) those who are subject to the authority of the above-mentioned persons, including the employees of subsidiaries and persons with a commercial relationship with the company, such as self-employed individuals or subcontracted employees, provided that they are within the company's corporate domain.

As a general rule, the company shall only be subject to criminal liability if the criminal behaviour of one of the above-mentioned persons was intentional and wilfully misconducted. Reckless behaviours may only result in the company being held criminally liable when involving crimes regarding "fraudulent insolvency", "natural resources and environment", "financing of terrorism" or "money laundering".

According to the Criminal Code and the rulings of the Spanish Supreme Court on this matter, for a legal person to be held criminally liable, the prosecution must prove that both the offence was committed and that the internal control tools deemed ideal and effective to prevent and try to prevent the criminal conduct in question at the company were either non-existent or ineffective.

To be exempted from liability, the accused company is responsible for demonstrating that the compliance system was in place and effective. In the opinion of the Spanish Supreme Court, if the prosecution is unable to demonstrate that the compliance system was non-existent or ineffective, the company cannot be held criminally liable.

In any case, the criminal liability of a legal person is a relatively new matter in Spain, on which the Spanish Supreme Court has not yet addressed this issue on a regular basis. To this end, we must carefully monitor future statements made by the Spanish Supreme Court, in addition to the interpretation, in general, of the Courts and the Public Prosecutor's Office in terms of the provisions of the Criminal Code.

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 effects of *res judicata* produced by final judgments and consisting in the permanence over time of the efficacy of the judgment as a mechanism for legal safety and certainty have certain limits. One of those limits is the subjective limit, which means that the effects of *res judicata* only apply between the litigating parties, and therefore it is

possible to bring new claims on matters of fault, defect or capability of a product to cause a certain type of damage, provided that the claimant is really different. For example, in the event of personal damages suffered by an individual during a traffic accident as a consequence of the malfunctioning of an airbag, it is possible for the injured person's insurance company to file a claim against the car manufacturer in order to recover the hospital expenses paid by such insurance company, and for the injured person him/herself to file a claim against the car manufacturer for the compensation of personal damages. Of course, such personal damages cannot include the hospital expenses paid directly by the insurance company. In this example, the claim by the insurance company would be brought under insurance law, and the claim by the injured person under the regime on 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?

The manufacturer or importer against whom proceedings for product liability are brought may claim in his defence that the defect was due to the actions of a third party, but his liability *vis-à-vis* the claimant will not be reduced hereby.

Nevertheless, the manufacturer or importer who paid compensation to the injured party shall be able to claim such part from the third party as corresponds to such third party's involvement in causing the damages in subsequent proceedings. Such proceedings against the third party must be brought within a period of one year, counted from the day the compensation was paid to the injured party.

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

The liability of the manufacturer or the importer may be reduced, or even excluded, if it is proven that the damages were caused partially or entirely due to the actions or negligent behaviour of the injured party. However, the behaviour of the injured party must be valued on a case-by-case basis, and must hold direct relation with the defect. For example, in the example of the malfunctioning of an airbag cited in our answer to question 3.4 above, the manufacturer of the airbag cannot defend itself by arguing that the accident was caused due to the reckless behaviour of the driver (injured party). The behaviour of the injured party may have contributed to the accident, but not to the malfunctioning of the airbag.

4 Procedure

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

In the case of court proceedings, the case shall be resolved 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)?

In legal proceedings on product liability, the examination of expert evidence may only be proposed by the parties to the trial. In this type of proceeding, the Court may not *ex officio* propose the examination of expert evidence or appoint technical specialists in order to assess the evidence presented by the parties.

Exceptionally, once the proceedings have been concluded and before judgment is rendered, the Court may *ex officio* order the examination of new evidence (among which expert evidence) on relevant facts, in the event that the evidence already examined should have been insufficient. In practice, this is very rare.

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 Code of Civil Procedure 1/2000 foresees the possibility to bring collective legal proceedings and establishes that legally constituted associations of consumers and users shall have standing in Court to defend the rights and interests of their members and of the association, as well as the general interests of consumers and users, without prejudice to the individual legal standing of the persons who suffered the damages.

When those damaged by a harmful event (e.g. by a defective product) are a group of consumers or users the components of which are perfectly determined or may be easily determined, the standing to apply for the protection of these collective interests corresponds to i) associations of consumers and users, ii) legally constituted entities whose purpose is the defence or protection of such consumers and users, or iii) the affected groups themselves.

In contrast, when those damaged by a harmful event are an undetermined number of consumers or users or a number difficult to determine, the standing to bring Court proceedings in defence of these collective interests shall correspond exclusively to the associations of consumers and users which form part of the Council of Consumers and Users. In the event that the territorial scope of the conflict mainly affects one specific autonomous region, then the specific legislation of such autonomous region shall apply.

The Attorney General's Office also has legal standing to bring any action in defence of the interests of consumers and users.

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

When those damaged are a group of consumers or users, then the claims can be brought by associations of consumers and users and/or the Attorney General's Office, in accordance with what is set out in the answer to question 4.3 above.

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

Even though it is difficult to provide a general answer, it is rather common that a period of 14 to 18 months goes by between the filing of the claim and the rendering of the judgment in first instance.

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 preliminary issues which, due to their very nature, represent

an obstacle to the continuation of the trial and that require prior resolution by the judge are those that refer to i) lack of jurisdiction or competence of the Court before which the claim is brought, ii) lack of capacity or representation of the litigants, iii) *lis pendens* or *res judicata*, iv) necessary passive joinder of defendants, v) inappropriateness of the proceedings, or vi) a legal defect in the way the claim has been filed.

These preliminary issues to be decided beforehand only relate to matters of law.

4.7 What appeal options are available?

In legal proceedings on product liability, it is possible to file an appeal before the Provincial Court against the judgment rendered in first instance by the Court of First Instance.

Against the judgment on appeal rendered by the Provincial Court, there are two appeal options: i) an extraordinary appeal for infringement of procedure; or ii) a cassation appeal, provided that the amount of the proceedings exceeds the sum of 600,000 Euros or the decision on the appeal has reversal interest because the judgment subject to appeal contradicts the Supreme Court's jurisprudence or decides on points and issues on which contradictory case law from the Provincial Courts exists or it applies rules that have been in force for less than five years, as long as, in the latter case, no jurisprudence from the Supreme Court exists concerning previous rules of identical or similar content.

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 proposal of the examination of expert evidence corresponds to the litigants, and the only restriction as regards its nature and scope is that it must be necessary to have scientific, artistic, technical or practical knowledge to ascertain any facts or circumstances that are relevant to the matter or to acquire certainty about them.

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 present themselves for pre-trial deposition and they only declare on the day of the trial.

The reports issued by the experts must be provided by the parties together with the document initiating the proceedings or together with the response to the claim, and in the event that this is not possible, the parties must announce their intention to provide such reports in the claim or in the response to the claim. In such case, the reports shall be provided to the Court five days before the date set for the pre-trial hearing ("*Audiencia Previa*"), so that the Court may provide a copy to the other party.

Expert reports, the necessity or usefulness of which results from the statement of defence or from the allegations and pleas set forth at the pre-trial hearing (i.e., expert report, the need for which becomes apparent at a later stage of the proceedings), shall be submitted by the parties for their transfer to the counterparties at least five days prior to the trial.

If the parties so request, the experts who have prepared the reports shall intervene in the trial in order to ratify, explain or clarify their reports, and in order to respond to any question regarding their reports.

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

After the filing of the claim and the response to the claim or, if appropriate, after the pre-trial hearing, documents and instruments related to the merits of the case presented by the claimant or the defendant shall only be admitted in the following cases:

i) If they are dated subsequent to the claim or the response to the claim or, if applicable, to the pre-trial hearing.

ii) If they are dated prior to the claim or response to the claim or, if applicable, to the pre-trial hearing, provided that the party which submits them justifies not having known of their existence before.

iii) If it was not possible to obtain them before due to reasons which are not attributable to the party, provided that the party duly designated the archive, official file or place where they are located, or the registry, registry book or files of which it seeks to obtain a certification.

When a document regarding facts related to the merits of the case is presented once the acts referred to in the previous section have concluded, the other parties may, during the proceedings or hearing, allege the inadmissibility of taking them into consideration.

No document shall be accepted after the trial, except for judgments, judicial or administrative resolutions, rendered or notified on a date subsequent to the moment of submission of conclusions, and provided that they may be conditional or determining for the decision.

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

RLD 1/2007 establishes the possibility that conflicts between consumers and users and companies may be resolved through the Consumer Arbitration System, with no special formalities and in a manner that is binding and enforceable on both parties, provided that the conflict does not concern intoxication, injury, death or the existence of reasonable evidence that an offence has been committed.

It is also possible to resolve conflicts in the field of product liability through the mediation system established in Law 5/2012, of 6 July, on mediation of civil and commercial matters or through the arbitration system governed by Law 60/2003, of 23 December, on Arbitration.

The submission of the parties to any of the referred arbitration or mediation proceedings is voluntary, and therefore alternative methods of dispute resolution are not required to be pursued before initiating any court proceedings.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction be brought within the jurisdiction of your courts either as a defendant or as a claimant?

Pursuant to Council Regulation (EC) No 44/2001, of 22 December 2000, on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (recasted by Regulation (Eu) No 1215/2012 of the European Parliament and of the Council of 12 December 2012), jurisdiction for product liability claims that derive from a contractual relationship between the claimant and the defendant corresponds to the Courts of the place of delivery of the defective product, unless otherwise agreed upon by the parties in the contract.

In the case of a contract with a consumer, the claim by the injured consumer against the manufacturer or importer may be brought before the Courts of the Member State in which the manufacturer or importer has its domicile or before the Courts of the place of domicile of the consumer.

As to product liability claims that arise from non-contractual relationships, the same above-mentioned regulations establish that the Courts of the place where the harmful event occurred shall have jurisdiction.

If the claimant or defendant is not domiciled in the European Union, a case-by-case analysis will need to be carried out as the applicable bilateral or multilateral treaties will determine whether the person can be brought to Spanish jurisdiction or not.

5 Time Limits

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

The statute of limitations for proceedings for the recovery of damages caused by a defective product initiated under the regime of RLD 1/2007 is of three years, counted from the date the damages were incurred by the injured party, provided that the identity of the party liable for the damages is known to the injured party.

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 the event the claim is brought under the regime of RLD 1/2007 because of the defective nature of the product causing the damages, as defined in such regulation, the liability will always be of a strict nature, and the statute of limitations is three years. In the event of bodily injury, this statute of limitations starts to run from the moment when the final extent of the injury has been defined and established.

In the event that the claim cannot be brought under such regulation, the claim shall have to be brought under the general rules of civil law, the regime for liability of which is fault-based. In the event that the relation is non-contractual, the statute of limitations is one year.

In order to avoid a discussion on whether the product and the defects fall within the definition of RLD 1/2007 and, therefore, to avoid the debate on whether the statute of limitations of one year or three years applies, in cases of non-contractual liability we recommend initiating the proceedings within one year.

The age or the condition of the claimant does not affect the calculation of any time limit and the Courts do not have any discretion to disapply them. As noted above, legal proceedings brought under the product liability regime of RLD 1/2007 may be barred by limitation if they are initiated after a period of three years. However, the Court shall only reject the claim on this ground if the defendant raises the issue of limitation.

The prescription of the action may be interrupted by the injured party by filing a claim before the Courts or by means of an extrajudicial claim, or through any act of acknowledgment by the liable party.

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

The prescription period starts to run from the moment that the injured party has knowledge of the damages suffered and knows the identity of the person liable for such damages. We also refer to our answer to question 5.2 above as regards the running of the time limit in the event of bodily injury.

6 Remedies

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

In accordance with RLD 1/2007, every injured party has the right to receive compensation in the form of an economic indemnity for the damages caused to him or her by the defective product.

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

The regime on product liability established in RLD 1/2007 extends to personal/bodily damages, including death and material damages, provided that such damages have been caused to goods destined to private use or consumption and that they are mainly used by the injured party in such concept.

Damages to the defective product itself are not recoverable under RLD 1/2007. However, the injured party may claim compensation for such damages under general civil and commercial law.

Moral damages may be recovered under general 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?

If the defect has not been proven, no damages have been caused yet, and, as a consequence, it is not possible to establish a causal relationship between the defect and the damages either, it is not possible to obtain a judicial award that imposes the obligation to pay compensation for the costs of medical monitoring. In such scenario, we consider that it would also be very complicated to obtain such compensation as a precautionary measure at the beginning of the proceedings, due to the difficulty of proving *fumus boni iuris*.

In this respect, the previously mentioned ruling of 5 March 2015 by the Court of Justice of the European Union establishes that the Directive 85/374/CEE regarding damages caused by defective products should be interpreted in the sense that the surgical operation for the replacement of a defective product implanted on a patient constitutes 'damage caused by death or personal injuries' for which the producer is liable, if such an operation is necessary to overcome the defect in the product in question, even though the product has not malfunctioned yet.

However, in the particular case at stake, it is important to note that the manufacturer himself noticed the defect on the products and recommended doctors to replace them by means of surgical operations, so the defect of the products was acknowledged even though they had not malfunctioned yet.

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

Under Spanish law, no punitive damages – only compensatory

damages – can be recovered. However, the Courts have some discretionary powers in awarding such compensatory damages and one may expect the conduct of the defendant to have some impact on the amount of damages 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?

The overall civil liability of one manufacturer for damages – death and personal injuries – caused by identical products with the same defect shall be limited to the maximum amount of 63,106,270.96 Euros.

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?

Minors do not have procedural capacity and must be represented in the proceedings by their parents with parental authority, which may be exercised jointly by both parents or individually by one of the parents, with the consent of the other. If for any reason the parents have been deprived of the parental authority, the minor shall be represented in the proceedings by his or her legal guardian, but the guardian will need a judicial authorisation in order to bring the claim.

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 possible right of Government authorities to be reimbursed in the terms set out in the question is not legally protected by the Spanish regime on product liability.

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 costs of the proceedings shall be imposed on the party who has had all his pleas rejected, unless the Court considers that the case posed serious *de facto* or *de iure* doubts.

When the payment of costs is imposed on the party who has lost the case, such party shall pay all Court fees and other incidental expenses, the fees of experts who have intervened in the proceedings and also the fees of the attorneys of the party who has won the case, up to an amount that shall not exceed one third of the amount claimed in the proceedings for each of the litigants who have obtained such award, unless the Court declares the recklessness of the litigant ordered to pay, in which case, such limitation shall not apply.

In the event that the pleas were partially accepted or rejected, each party shall pay the costs generated on its behalf, and half of the common costs, except when there are reasons to impose their payment upon one of the parties due to reckless litigation.

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

Law 1/1996, of 10 January, on Legal Aid, governs the regime of access to legal aid, and according to this Law, Spanish citizens, nationals of other Member States of the European Union and aliens who are in Spain may have access to legal aid for, amongst others, civil and commercial proceedings, if they provide evidence that they do not have sufficient resources to litigate.

The following legal persons may also have access to legal aid, if they prove that they do not have sufficient resources to litigate:

i) Associations of public interest, foreseen in Article 32 of Organic Law 1/2002, of 22 March, that governs the Right to Association.

ii) Foundations recorded in the corresponding Public Register.

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

In order to have access to legal aid, when making the application for legal aid, the litigant must prove that he or she does not have sufficient means and that he or she has access to gross economic resources and income – annually calculated for all concepts and per family unit – that do not exceed the following thresholds:

a) Two times the Public Revenue Index (IPREM for its Spanish acronym) in force at the moment of the application for legal aid, when the litigant does not form part of any family unit.

b) Two-and-a-half times the IPREM in force at the moment of the application for legal aid, when the litigant forms part of any family unit with less than four members.

c) Three times the IPREM in force at the moment of the application for legal aid, when the litigant forms part of any family unit with four or more members.

In the event that the litigant is a legal person, it shall be eligible for legal aid when it does not have sufficient means and the accounting result of the entity – annually calculated – is inferior to an amount equivalent to three times the IPREM.

The current annually calculated IPREM is of 7,455.14 Euros.

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

The amount of the attorney's professional fees shall be one freely agreed upon between the client and the attorney, in observance of the rules on ethics and on free competition. The form in which the fees are to be paid shall also be freely agreed upon, and may include payment of a percentage of the outcome of the claim. In any case, the client shall have to pay all expenses that may arise as a result of the assignment.

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

We are not aware of any regulation that prohibits third party funding of claims, and as a result, such third party funding is admissible. Such funding will be subject to the terms and conditions agreed upon by the parties, provided that they are not contrary to law, ethics or public order.

7.6 In advance of the case proceeding to trial, does the court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

No, the Court does not exercise any kind of control over the costs to be incurred by the parties in order to check if they are proportionate or 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 your jurisdiction.

In our responses to the questions we have already included the newest trends and developments as regards product liability in Spain, with special regard to the ruling by the Court of Justice of the European Union regarding implantable medical devices.

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He speaks Spanish, Catalan and English, and he has wide international experience.

Chapter 27

Sweden

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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?

Under Swedish law, liability for products may arise in different forms, depending on the specific circumstances of the case at hand.

Product liability, i.e. the liability of the producer for personal injuries or damage to consumer property caused by the product, but not to the product itself, is a strict liability, meaning that exoneration is only allowed under special circumstances that are set forth in an exhaustive list. Product liability is regulated by the Product Liability Act (1992:18) implementing the provisions of Council Directive 85/374/EEC.

Besides the strict product liability, liability claims regarding products in non-contractual obligations may be brought under the Tort Liability Act (1972:207). The Tort Liability Act imposes liability on the tortfeasor in cases of personal injuries and property damages caused by intent or negligence. In consumer contractual obligations, the Consumer Sales Act (1990:932) ensures that the consumer is compensated for damages, including damages to the product purchased by the consumer due to the defect of the product. The Sales of Goods Act (1990:931) applies to business-to-business relationships and contains provisions on damages caused by a defective product which may apply if the parties have not agreed otherwise.

Liability issues for products may, therefore, be governed by stipulations in contracts; however, strict product liability may not be subject to any contractual limitations or exclusions.

Special provisions apply to particular products and services, for instance healthcare.

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

State-operated schemes for compensation are mainly related to employment relationships and traffic accidents (where the state imposes a mandatory insurance). However, private insurance schemes are sometimes used for products like medications provided by the owner of the insurance, or services like clinical trials.

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

First and foremost, the producer of the product is liable pursuant to the Product Liability Act for the damages caused by the defective product. Moreover, not affecting the liability of the actual producer, the party importing the product, either to the European Union or to the European Economic Area, in order to put it into circulation, is also held liable, together with any person who has marketed the product by means of placing its name, trademark or any other distinguishing feature on the product.

Should the producer not be identified, the injured party is entitled to bring action against each supplier or distributor of the product. However, such distributors shall not be held liable if they provide information on the identity of the producer or importer of the product within a month after lodging the action.

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 the Product Safety Act (2004:451), the producer shall recall goods from the distributors without delay if it becomes apparent that the goods supplied by the producer are dangerous, if such measure is necessary to prevent the occurrence of an accident. Should this measure be insufficient in order to prevent the occurrence of an accident, the producer must recall the dangerous goods directly from the consumers who possess such goods.

Failure to comply with the obligations to recall dangerous products may lead to administrative fines. Failure to recall dangerous products is not, *per se*, a ground for bringing a product liability claim; however, such an omission might establish product liability, if the product causes personal injury or property damage in connection with the defect concerned.

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

There are no criminal sanctions in the Product Safety Act or Product Liability Act. The general rules under the Swedish Penal Code will apply in applicable circumstances.

2 Causation

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

The injured person has the burden to prove that: first, the damage suffered, which might consist of personal injury and/or property damage; second, that the product was defective; and, finally, the causal relationship between the defect and the damage.

A product is defective if it does not provide the safety that is reasonable to expect from such product, taking into account the expected use of the product, how it has been presented and marketed, manuals and other instructions, and the time when the product was put into circulation.

In tort cases, the claimant has to prove, in addition to the above, the intentional or negligent conduct of 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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

Regarding causation, there is no established test used in these matters in Sweden. The claimant has the burden of proof that the damage is caused by the defective product. In preparatory works, it has been stated that the burden of proof cannot be set too high, and in some court cases it has been stated that the claimant shall have a lowered standard in the burden of proof in relation to 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?

As it has been noted above (question 1.3), in the absence of information on the identity of the producer, the injured party may file an action for product liability against the importer, supplier or distributor of the product. No market-share liability is applicable under Swedish law; however, should two or more persons be liable for the damages, their liability is joint and several.

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 failure to warn the consumer, as such, does not qualify as defect regarding the product. However, the product might be deemed as defective if it does not provide the safety which can be expected taking all circumstances into account, particularly the presentation of the product together with the user instructions and manuals.

Since Swedish product liability does not differentiate between end-users and other intermediaries, any personal injury and/or proprietary damage caused by movables made by a producer may give rise to product liability. Consequently, the principle of "learned intermediary" is unknown under Swedish law with regard to product liability.

The Product Safety Act obliges the producers to provide safety information. Such information must enable the consumer to assess the risks of the goods and to protect him- or herself against these risks. Non-compliance with the provisions regarding safety information may lead to fines imposed by the supervisor authority. Furthermore, in case where it becomes apparent that the product entails risks and dangers, the producer is required to inform those who possess such dangerous goods supplied by the producer about the risks and the means of preventing injuries thereof.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The defendant may be exonerated if it furnishes evidence that: (i) it did not put the product into circulation; (ii) the defect was non-existent when the product was put into circulation; (iii) the defect is due to compliance with mandatory regulations issued by a public authority; and (iv) the scientific and technical knowledge at the time when the product was put into circulation did not allow for the discovery of the defect.

Besides the above grounds for exoneration, the defendant may contest the claimant's claims and evidence regarding the damage, the defect and the causality. Moreover, should the injured person contribute to the damage caused by the defective product, the liability of the producer might be reduced or disallowed.

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, Swedish law provides for a state of scientific and technical knowledge defence (see also above in question 3.1). According to the provision concerned of the Product Liability Act, the producer shall not be held liable if it demonstrates, by means of furnishing evidence, that the defect of the product was not discoverable according to the scientific and technical knowledge at the time 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?

Yes, according to the Product Liability Act, the defendant shall not be held liable if it establishes that the defect is due to compliance with mandatory regulations issued by a public authority (see also above in 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?

The Product Liability Act does not provide any special procedural grounds for the claimant to re-litigate disputes that are already decided by a final judgment, with regard to the same parties on the same factual and legal grounds, which is therefore binding as *res iudicata*. Other claimants may, however, bring a claim against the same defendant on similar or the same grounds as the first claimant (since this is not considered *res iudicata*).

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?

Should the damage be caused by the defect in the product and also by the act or omission of a third party, the producer will be held liable; however, the producer may institute proceedings for joint adjudication with the main claim or may institute subsequent proceedings against the third party in order to recover the costs attributable to the third party's act or omission. The time limit for such actions is determined by the general limitation rules, i.e. a period of 10 years is at the disposal of the producer to commence subsequent proceeding against the third party concerned.

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

Yes; under the Product Liability Act, the injured party's contribution to the damage may reduce or disallow the liability of the producer.

4 Procedure

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

Product liability claims will be tried either by one or three legally qualified judges. The exact number of the judges is mainly determined by the value of the claim, namely, claims below SEK 22,150 (in 2016) shall be heard by one judge. Furthermore, the court will be formed of one judge if the parties agree to it or if the case is simple in character.

In Sweden, only cases regarding freedom of the cases are tried 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)?

The parties may engage technical specialists (*cf.* the answer to question 4.8 below). The court cannot appoint technical specialists to sit with the judge. If the court finds that the matter requires professional knowledge, the court may appoint an expert to give its opinion. This option is not often used.

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 Proceedings Act (2002:599) enables class actions to be instituted in Swedish courts. The claimant, by bringing a class action to the court, will represent other persons who are not actual parties to the proceeding; however, it will have legal force in relation to them. Natural or legal persons having a civil law claim may commence class actions by bringing to court the claim concerned. Furthermore, non-profit associations, e.g. those that are engaged in the protection of consumer interests, may institute class actions with respect to disputes between consumers and enterprises. Authorities are also entitled to lodge class actions. As a main rule, class actions require representation by an attorney. Certain appointed courts have competency regarding class actions. The procedure is opt-in, meaning that a member of the group is required to give notice to the court in writing within a time frame set forth by the court, otherwise his or her claim will be deemed as withdrawn. Class actions are rarely initiated 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?

See the answer to question 4.3.

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

The time to get to trial is mainly affected by the complexity of the case and also by the conduct of the parties. The workload of the competent district court also plays a key role in the length of time it takes to get to trial. In average cases, it usually takes up to eight to 12 months 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?

The court may adjudicate, in the form of a separate judgment, a preliminary claim on which another claim or other claims depend. The court may also issue a separate judgment on certain circumstances that are of importance to the outcome of the case. Such preliminary issues might be of a factual nature and/or might be matters of law. The court may order a stay of proceeding on the issues not covered by the separate judgment until the separate judgment obtains final legal force.

4.7 What appeal options are available?

Product liability claims are tried by District Courts. The judgment of the District Court may be appealed to the Court of Appeal. In order for the Court of Appeal to review the case, a leave to appeal is required, which is granted under the following circumstances: if it is probable that the District Court's judgment requires review or the Court of Appeal would arrive at a different conclusion; or if a review is required for the unity of application of law or there are extraordinary reasons for a review. The judgment of the Court of

Appeal may be reviewed by the Supreme Court, provided that a leave to appeal is granted. Leave to appeal for the review by the Supreme Court is granted if the case is of importance regarding the uniform application 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?

Even though the court may appoint experts, in practice, the parties submit expert evidence to the court. The court rejects expert evidence only in extraordinary cases.

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?

Under Swedish law, written expert statements are submitted to the court prior to the trial. The experts may be heard and their statements may be discussed during the trial. In Sweden, there are no pre-trial depositions.

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 disclosure obligation in Swedish law. A party must present the evidence referred to as part of its case. Upon the request of a party, the court may oblige the opposing party (or a third party) to disclose certain evidence that is in the possession of the party affected by the request. The request might be denied, at the discretion of the court based on a balancing assessment, if the disclosure would entail sensitive information, such as trade secrets.

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

Alternative dispute resolution mechanisms, such as arbitration and mediation, are available. However, consumer contracts are not allowed to stipulate the jurisdiction of an arbitration tribunal.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction be brought within the jurisdiction of your courts either as a defendant or as a claimant?

According to the main rule of EU Regulation No. 1215/2012, persons domiciled in a Member State shall be sued in the courts of that Member State, regardless of their nationality (*actor sequitur forum rei*). Therefore, claimants domiciled outside Sweden shall bring action to the courts of Sweden if the defendant is domiciled in Sweden. The main rule applies, accordingly, to persons domiciled in Sweden suing a third party who is domiciled outside Sweden, rendering the jurisdiction of the other Member State where the opposing party is domiciled. However, in the case of claims arising on the grounds of consumer contracts, the consumer may, in addition to the main rule, bring proceedings in the courts of the Member State where he or she (i.e. the consumer) is domiciled.

5 Time Limits

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

The Product Liability Act sets forth subjective and objective time limits for lodging actions based on product liability. Such proceedings are required to be instituted within three years from when the injured party became aware or should reasonably have become aware of the fact that such claim may be brought. The injured party's right to commence court proceedings extinguishes upon the expiry of a period of 10 years from the time the producer put the defective product into circulation.

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?

Regarding strict product liability, enshrined in the Product Liability Act, the deadlines discussed above in question 5.1 apply.

Non-contractual claims other than the strict product liability claim have to be brought, in accordance with the Limitations Act (1981:130), within 10 years from the accrual of the claim, unless any interruption to the limitation has occurred.

In order for claims to be brought pursuant to the Consumer Sales Act, the consumer is required to give prior notice of the defect to the seller within three years after receiving the goods, except in cases of bad faith or grossly negligent conduct on the side of the seller or if the product was sold regardless of a sales prohibition or entails a clear danger to life or health. Regarding claims accrued on the grounds of defective goods in business-to-business relationships, pursuant to the Sales of Goods Act, the buyer has an obligation to notify the seller of the defect within two years after receiving the goods.

The age or condition of the claimant does not affect the deadlines. The court does not have the discretion to disapply the statutory 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 affect the time limits *per se*. However, such factors might have a crucial influence on the determination of the start of the subjective deadline as discussed above in question 5.1.

6 Remedies

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

Damages caused by the defective product are recoverable by means of monetary compensation. Regarding declaratory reliefs, the general procedural provisions apply requiring uncertainty as to the existence of the legal relationship concerned. Moreover, such uncertainty has to expose the party concerned to a detriment. Other remedies regarding product liability claims based on the Product Liability Act are not typical.

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

The types of recoverable damages under the Product Liability Act are personal injury, property damage and consequential damage. Property damage entails damages above SEK 3,500 caused to movables that are intended for private use or consumption and were mainly used for such purposes by the injured person. However, damages to the defective product itself are not recoverable under a product liability claim.

Personal injury entails physical injuries and non-patrimonial damage, e.g. mental damage. Compensation may include expenses for medical care and/or loss of income due to the injury.

Under general non-contractual liability, the same damages are recoverable, provided that no limitation exists as to the minimum of the property damage and the damage to the defective product itself is not exempted. Within contractual obligations, as it has been discussed above (question 1.1), damages to the defective product itself may be recovered pursuant to the Consumer Sales Act or to the Sales of Goods 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?

An actual personal injury or property damage (as discussed above in question 6.2) has to be caused by a defective product in order for product liability to be established pursuant to the Product Liability Act. Therefore, circumstances entailing risks for damages or acts threatening with damages that may occur in the future are regulated by general tort law.

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

Swedish law does not allow 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?

There is no cap for the maximum limit of damages. Swedish courts do not generally award large amounts of damages, although the main rule under Swedish law is that the claimant shall be put in the same financial situation as if the damage had not occurred.

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?

Product liability claims may be settled prior to or in the course of a court proceeding. Should the parties agree on a settlement, the court will issue, upon request of both parties, a judgment confirming the settlement. Settlements are allowed in the case of a class action following the court's approval. Such approval is issued if the settlement is not discriminatory against certain members of the group or otherwise manifestly unfair.

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?

When determining the sum of damages that the defendant is obliged to pay, the court may take into account subsidies (such as unemployment benefits or sick pay) paid with respect to the injury to the injured party. In theory, the authority could claim reimbursement for costs paid to the claimant, although it does not occur in practice.

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 losing party will be obliged to reimburse reasonable legal costs of the prevailing party, including the party's expenses, costs of preparation for trial and attorney fees. Special provisions apply to cases with a claim amount below half of the so-called base amount, i.e. SEK 22,150 (for the year 2016). In such cases, the possibilities to recover costs from the losing party are limited in amount.

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

Legal aid is accessible in Sweden pursuant to the Legal Aid Act (1996:1619) for natural persons with low income (below SEK 260,000 per year after the reduction of certain maintenance and other costs), and without insurance covering legal expenses. Granted legal aid covers a number of fees and costs that might occur in the course of a proceeding, including, for example, (i) the fees of legal counselling not exceeding 100 hours, (ii) reasonable costs occurring in relation to evidence, (iii) procedural fees (including enforcement fees), and (iv) costs and fees of a mediator if used in the course of the proceeding. Those who are granted with legal aid shall pay a legal aid fee covering from 2% up to 40% of the costs depending on the financial status of the person concerned. Such legal aid fee shall, however, not exceed the fees of the legal counsel.

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

Legal aid may only be granted for natural persons falling under the criteria of eligibility for such benefits as discussed in question 7.2 above. Certain cases and issues are also excluded from the scope of legal aid, such as the preparation of tax returns, marriage contracts, etc. There are also certain restrictions regarding those persons who are not Swedish citizens. As a main rule, cases arising from business activities for a professional business man are excluded from legal aid.

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

Under the Group Proceedings Act, contingency fees are allowed only under certain circumstances, if they follow from a written agreement approved by the court.

Apart from the above, conditional or contingency fees are normally considered in breach of the Code of Conduct of the Swedish Bar Association. Members of the Swedish Bar Association are generally prohibited from using such fee arrangements.

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

Third party funding is not prohibited or subject to restrictions, and such funding is typical by means of insurances covering legal costs.

7.6 In advance of the case proceeding to trial, does the court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

No. Upon submission of the statement of costs, the counterparty may object to the costs incurred. The court shall then assess whether the party's fees are acceptable in relation to the dispute at hand.

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 your jurisdiction.

There are no new developments.

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Synch is a Swedish law firm with an experienced and internationally recognised team of lawyers focusing on digital business and technology. Synch targets the market with an unparalleled flexibility with the award winning blended delivery model where innovative managed services, SynchWherever and digital services, WeSynch, are complemented by the traditional advisory and project services.

Taiwan

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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?

A person is entitled to seek compensation from a product manufacturer/distributor for his/her personal injury or damage to property incurred in connection with defective or faulty products relying upon the following legal bases:

1. If the product distributor has warranted the quality of the products, the consumer may claim for damages according to Article 360 of the Civil Code, which provides that: "If the quality of the product sold is not in accordance with the product which was guaranteed by the seller, the buyer may demand compensation for the damages due to non-performance, instead of rescission of the contract or of a reduction of the price. The same rule shall be applied if the seller has intentionally concealed a defect in the product."
2. If a product distributor fails to perform the contractual obligations due to a reason attributable to the product supplier, the buyer may claim compensation for the damages arising therefrom, if any (Article 227 of the Civil Code).
3. A manufacturer is liable for any damage caused due to the common use of its products, unless the products have no deficiency, or there is no causation between the damage and the deficiency, or the manufacturers have exercised reasonable care to prevent such damage (Article 191-1 of the Civil Code).
4. A manufacturer shall be liable for any damage caused by their products, unless it is able to prove that the products have met and complied with the contemporary technical and professional standards of reasonably expected safety requirements prior to the launching of such products into the market (Paragraphs 1 and 3, Article 7 and Article 8 of the Consumer Protection Act ("CPA")).

A distributor should be liable for any damages caused by the products unless it has exercised due care for the prevention of such damages, or even if they had exercised due care, damages would still have occurred (Article 8 of the CPA).

Furthermore, if the products may endanger consumers' lives, bodies, health or property, a warning and the methods for emergency handling of such danger shall be labelled at a conspicuous place (Paragraph 2, Article 7 of the CPA). Whether a particular warning should be specifically labelled depends on the nature of the subject matter of the warning, i.e., if it is a well-known use of the product, no warning is required. If an enterprise fails to perform its labelling obligations in this regard, it will be held liable for the damage caused thereby (Paragraph 3, Article 7 of the CPA).

For a product liability claim, a manufacturer would be held strictly liable under the CPA and will be presumed to have been negligent under the tort law of the Civil Code while a distributor would be presumed to have been negligent under the CPA. To defend oneself from the product liability claim, a manufacturer has the burden of proof that the products have met and complied with the contemporary technical and professional standards of reasonably expected safety requirements. Nevertheless, according to Paragraph 3, Article 7 of the CPA, if a manufacturer can prove that the defect of the products was not caused by negligence, the court may reduce the compensation.

Claims initiated based on points 1 and 2 above are classified as contractual liabilities in Taiwan. In addition, for a defective product, if a manufacturer/distributor breaches his/her/its statutory obligations, such as fraud, criminal or civil liability may also be imposed on the manufacture/distributor.

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

No. There is no scheme of compensation for particular products in Taiwan.

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

According to Article 7 to Article 9 of the CPA, manufacturers, importers, designers, providers of services, producers, distributors, dealers and retailers bear responsibility for the defect of a 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?

The business operators shall immediately recall goods or discontinue services when any of the following situations occur, unless necessary treatments taken by the business operators are sufficient to remove such danger:

1. Where facts are sufficient to prove the existence of suspicion that goods or services provided will endanger the safety and health of the consumers.

2. Where goods or services are a threat to the lives, bodies, health or property of consumers, and absent of conspicuous warning labels with descriptions of the methods for emergency handling of such danger (Article 10 of the CPA).

In addition to voluntarily recalling goods or discontinuing services, in some circumstances such obligation would become compulsory. The competent authorities of the central or local Government could order the business operators to recall goods and/or immediately cease the design, production, manufacturing, processing, importation and distribution of such goods or the rendering of such services, or take other necessary measures if it is believed that the goods or services provided have endangered or will endanger the lives, bodies, health or property of consumers (Article 36 and Article 38 of the CPA).

If a business operator violates the recall order of the competent authorities under Article 36 or 38 of the CPA, it shall be punished by an administrative fine of not less than NT$60,000 and not more than NT$1,500,000 and which may be imposed successively; if there's a severe violation, the competent authorities may issue an order for suspension of operations and assist consumer protection groups in bringing litigation in their own name as soon as possible (Article 58 and Article 60 of the CPA).

The breach of Article 10 of the CPA will not spontaneously constitute a claim. In this situation, the claim shall be brought only if all legal requirements of the specific Article mentioned in question 1.1 are met.

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

Article 61 of the CPA stipulates that: "Where a certain conduct is punishable in accordance with this law and other laws providing for more severe punishments, then such other laws shall apply; where such conduct constitutes a criminal offense, the case shall be immediately transferred for a criminal investigation." Hence, if a defective product causes damage to any individual or property, criminal sanctions might be imposed on the manufacturer, distributor, or importer of the defective product.

2 Causation

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

With respect to a fault/defect, if an injured person bases its claims on Article 7 of the CPA or tort law under Article 191-1 of the Civil Code, the existence of defects/faults is presumed. The business operator has to prove that there is no defect/fault. If the injured person bases its claims on contractual rights, it is the injured person that bears the burden of proof of defects/faults.

With respect to damages, the injured person bears the burden to prove his/her damage, no matter which legal base is relied upon.

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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

Generally speaking, the proof of causation in Taiwan is similar to the factual causation in the common law system, which means but for the defendant's act, the injury would not have occurred (but for rule). In other words, the claimant has to show that the injury would not have arisen without the defendant's conducts, instead of just proving that the defendant wrongly exposed him/her to an increased risk of a type of injury known to be associated with the product.

Normally, the burden of proof is imposed upon the claimant (e.g., the claims based on Articles 360 and 227 of the Civil Code and Articles of the CPA). However, if the claimant claims for damages according to Article 191-1 of the Civil Code, the causation is presumed and the burden of proof is shifted to the defendant.

Besides, even when the burden of proof is imposed upon the claimant, the judge may shift the burden to the defendant if the situation is significantly unfair to the claimant (Article 277 of the Code of Civil Procedure).

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 Paragraph 3, Article 7 of the CPA, business operators causing injury to the consumers or third parties shall be jointly and severally liable. In addition, according to Article 273 of the Civil Code, the creditor is entitled to demand one or several or all of the jointly and severally liable debtors simultaneously or successively to tender total or partial performance. Before the complete performance of the obligation is fulfilled, all of the jointly and severally liable debtors are jointly bound to tender the performance. According to Paragraph 1, Article 281 of the Civil Code, if one of the jointly and severally liable debtors has caused the other jointly and severally liable debtors to be released from the obligation by virtue of his performance of the obligation, he is entitled to demand from the other the reimbursement of their respective shares in the joint and several liability, plus interest from the date of release.

As such: (1) unless the producers are able to prove that its products have met and complied with the contemporary technical and professional standards of reasonably expected safety requirements, all of the producers should be liable for the defective products; and (2) if a consumer claims for a total amount of the compensation against one of the multiple producers, the producer, based on his joint-and-several liability, shall pay the entire amount to the consumer at first, if the consumer demands so.

In addition to Articles in the CPA, if a consumer claims for damages according to Paragraph 2, Article 191-1 of the Civil Code, manufacturers who attach a service mark to the merchandise, or other characters or signs, which show to a sufficient extent that the merchandise was produced, manufactured or processed by them, shall be deemed to be the producers. Furthermore, if these producers have wrongfully damaged consumers jointly, they are jointly and severally liable debtors under Article 185 of the Civil Code.

There is no a specific principle called "market-share liability" in Taiwan. However, the manufacturers would be jointly and severally liable for a defective product; therefore, a plaintiff (consumer) may claim against a group of product manufacturers for an injury caused by a defective product, even when the plaintiff does not know by which defendant the product is manufactured.

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 the products may endanger consumers' lives, bodies, health or property, a warning, as well as the methods for emergency handling of such danger, shall be labelled at a conspicuous place (Paragraph 2, Article 7 of the CPA). Whether a particular warning should be specifically labelled depends on the nature of the subject matter of the warning, i.e., if it is a well-known use of the product, no warning is required. If a business operator (e.g. a manufacturer or distributor) fails to perform its labelling obligations in this regard, it will be held liable for the damage caused thereby (Paragraph 3, Article 7 of the CPA).

In Taiwan, if information regarding the use of a product is not well-known, the business operator shall label the warning on the product. Therefore, only information, advice and warnings provided directly to the consumer would be taken into account. Even 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, if information regarding the use of a product is not well-known, a business operator cannot discharge its obligations to label a warning on the product.

There is no principle of "learned intermediary" applied in Taiwan.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The following defences are commonly asserted in a product liability action:

1. Comparative Fault or Comparative Negligence

A plaintiff's improper conduct might negate some or all of the defendant's liability for an injury. Under the comparative fault, damages are apportioned according to each party's fault. The plaintiff's recovery would be reduced in proportion to the amount of his or her negligence.

2. Lack of Negligence

If a business operator proves that the defect of the product or a missing label from the products at issue was not caused by negligence, the court may reduce its liability for damages (Paragraph 3, Article 7 of the CPA).

3. State of the Art/Development Risk Defence

According to Articles 7 and 7-1 of the CPA, an affirmative defence of "state of the art" applies in Taiwan. That is, if a manufacturer is able to prove that the products have met and complied with the contemporary technical and professional standards of reasonably expected safety requirements prior to the launching of such products for sale into the market, the manufacturer will not be held liable for the damage caused thereby.

4. Causation Defence

If the damage is not caused by a product's defect, a business operator will not be held liable for such damages.

5. Statute of Limitations

According to the CPA and the Civil Code, a person should exercise his/her right regarding product liability within two years from the date that he/she is aware of the damage and the identity of the liable person or ten years from the date of the wrongful act.

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 Articles 7 and 7-1 of the CPA, an affirmative defence of "state of the art" applies in Taiwan. That is, if a manufacturer is able to prove that the products have met and complied with the contemporary technical and professional standards of reasonably expected safety requirements prior to the launching of such products into the market, the manufacturer will not be held liable for the damage caused thereby. Furthermore, it is the manufacturer's obligation to prove that the fault/defect in the product was not discoverable given the state of scientific and technical knowledge 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?

Generally, if a manufacturer shows that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product, he can defend that he has met the state of scientific and technical knowledge at the time of supply as aforementioned (*see* question 3.2). However, if the injured person can prove that these regulatory and/or statutory requirements were not compatible with the "state of the art", and that the manufacturer ought to know such situation in his business, the manufacturer will still be liable for the injury.

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?

Where part of the injured parties involved in a matter regarding specific product liability have selected one or more representatives among them to initiate a lawsuit against the business operator based on Article 41 of the Code of Civil Procedure and Article 54 of the CPA, the court may, with the consent of the plaintiffs initiating the lawsuit, announce the status of the lawsuit to the public. Thus, other potential claimants could opt in the same procedure. In such a case, the claimants who opt in cannot re-litigate the issues of fault, defect or the capability of a product to cause this certain type of damage in separate 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?

According to Paragraph 3, Article 7 of the CPA, business operators causing injury to the consumers or third parties shall be jointly and severally liable. In addition, according to Article 273 of the Civil Code, the creditor is entitled to demand one or several or all of the jointly and severally liable debtors simultaneously or successively to tender total or partial performance. Before the complete performance of the obligation is fulfilled, all of the jointly and severally liable debtors are jointly bound to tender the performance. According to Paragraph 1, Article 281 of the Civil Code, if one of the jointly and severally liable debtors has caused the other jointly and severally liable debtors to be released from the obligation by virtue of his performance, he is entitled to demand from the other jointly and severally liable debtors the reimbursement of their respective shares in the joint-and-several liability, plus interest from the date of release.

As such, if a claimant claims for a total amount of the compensation towards one of the jointly and severally liable persons, this liable person, based on his joint-and-several liability, shall pay the entire amount to the claimant at first, if the claimant demands so; he can then demand reimbursement from other jointly and severally liable persons who have not paid the compensation. Based on the above analysis, a defendant cannot 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 in the proceeding initiated by the claimant.

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

Yes. According to Article 217 of the Civil Code, defendants can make a defence of comparative fault or comparative negligence. A plaintiff's improper conduct might negate some or all of the defendant's liability for an injury. Under the comparative fault, damages are apportioned according to each party's fault. The plaintiff's recovery would be reduced in proportion to the amount of his or her negligence.

4 Procedure

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

Since Taiwan does not adopt the jury system, a trial will be held before a judge 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)?

According to Articles 326 and 339 of the Code of Civil Procedure, the court may appoint an expert assessor to assist in the assessment of the evidence presented by the parties. Nonetheless, the court has the discretion on the adoption of the assessment report issued by the expert assessor, i.e., the court is not necessarily bound by the assessment report.

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 for multiple claims is permissible in Taiwan. Article 41 of the Code of Civil Procedure stipulates that: "Multiple parties, who have common interests…, may appoint one or more persons from themselves to sue or to be sued on behalf of the appointing parties and the appointed parties." The types of class action commonly used in Taiwan are as follows:

1. Environmental Lawsuit

Where there is a lawsuit involving environmental pollution, the injured parties may sue the polluter(s) based on Article 41 of the Code of Civil Procedure, or Article 44-1 of the Code of Civil Procedure. The latter states that: "Multiple parties with common interests who are members of the same charitable incorporated association may, to the extent permitted by said association's purpose as prescribed in its article of incorporation, appoint such association as an appointed party to sue on behalf of them."

2. Consumer Protection

Article 50 of the CPA stipulates that: "Where numerous consumers are injured as the result of the same incident, a consumer protection group may take assignment of the rights of claims from 20 or more consumers and bring litigation in its own name."

3. Investors Protection

Article 28 of the Securities Investor and Futures Trader Protection Act states that: "For protection of the public interest, within the scope of this Act and its articles of incorporation, the protection institution may submit a dispute to arbitration or institute an action in its own name with respect to a securities or futures matter arising from a single cause that is injurious to multiple securities investors or futures traders, after obtaining authorization from 20 or more securities investors or futures traders."

4. Personal Data Protection

Article 34 of the Personal Information Protection Act states that: "For incidents arising from a single cause that is injurious to multiple data subjects, a qualified foundation or charitable incorporated association as prescribed in Article 32 of the PDPA may bring a lawsuit for damages in its own name, after obtaining written authorization from 20 or more data subjects."

Given the above, it is clear that a class action would be initiated by an individual (e.g., Article 41 of the Code of Civil Procedure) or a group (e.g., Article 50 of the CPA, Article 28 of the Securities Investor and Future Trader Protection Act). In addition, class actions in Taiwan adopt the procedure "opt-in" and such action is fairly common.

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

Yes. According to Article 50 of the CPA, where numerous consumers are injured as a result of the same incident, a consumer protection group may take assignment of the rights of claims from 20 or more consumers and bring litigation in its own name. In addition, Article 44-3 of the Code of Civil Procedure stipulates that: "A foundation or a charitable incorporated association may, after the competent

authority has granted its approval and to the extent permitted by such foundation's or such association's purpose as prescribed in its article of incorporation, bring an injunction litigation against the person causing injury to multiple people."

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

For a civil case, normally it takes around 10 to 12 months to obtain a judgment in the District Court, six to 10 months in the High Court, and eight to 12 months in the Supreme Court. If the amount of claim is no more than NT$ 500,000 or no more than NT$ 100,000, the summary proceeding or small-claim proceedings shall apply, respectively, and it would take less time to obtain a judgment. However, please note that the time may vary depending on the complexity of a case and whether the higher court upholds or overturns the judgment rendered 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. According to Article 383 in the Code of Civil Procedure, where the claims or defences presented are sufficient for the court to render its judgment, the court may enter an interlocutory judgment. In addition, where an interlocutory issue relating to the litigation proceedings is sufficient, the court may also give a ruling on such issue prior to its final judgment. The interlocutory judgment/ruling would bind the judgment of the court for the remainder of the trial. Both matters of law and issues of fact can be determined by the court preliminarily. Given that there is no jury system in Taiwan, the judge would decide the preliminary issues.

4.7 What appeal options are available?

According to Article 437 of the Code of Civil Procedure, a judgment rendered by the District Court can be appealed to the High Court. In addition, a final judgment rendered by the High Court can be appealed to the Supreme Court as long as the amount of the claim is NT$ 1,500,000 or more. However, an interlocutory judgment or a ruling made during litigation proceedings cannot be appealed independently. Thus, the parties may only appeal against the interlocutory judgment or ruling after the final judgment is rendered.

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?

Yes. Expert testimony is usually presented in product liability actions because the determination of relevant factual and legal issues often requires professional knowledge toward a specific product. Therefore, the court may need the assistance of expert testimony to clarify relevant issues in a product liability case. According to Paragraph 1, Article 326 and Article 328 of the Code of Civil Procedure, an expert shall be a person with special knowledge or experience in giving expert testimony, and shall be appointed by the court. Besides, according to Article 284 and Article 286 of the Code of Civil Procedure, the parties may also present expert evidence, since all kinds of evidence may be used as proof of the claim and the court shall accept evidence introduced by the parties.

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 Code of Civil Procedure provides the preparatory proceeding which is similar to the system of pre-trial deposition.

According to Paragraph 2, Article 270 and Article 268 of the Code of Civil Procedure, the court can order the parties to present evidence in the preparatory proceeding. If the court deems that the preparation for oral arguments is not completed, the presiding judge may order the parties to submit a preparatory pleading or defence with complete reasons and also order them to specify or state in detail the evidence which they propose to invoke regarding a certain issue/matter.

Given such, assuming that an expert witness is able to clarify relevant issues in a product liability case, the court may ask the parties to present or exchange witness reports in the preparatory proceeding.

The parties can select an expert to provide his professional opinion in a product liability case in both the first and second instance. According to Point 5 of the Expert Counselling Directive, when a complicated case involves a professional field, the court can counsel the expert when it sees it is necessary. For the same reason, the court can ask an expert witness to present in the preparatory proceeding.

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

According to Article 368 and Article 369 of the Code of Civil Procedure, either before or after court proceedings are commenced, when it is likely that evidence may be destroyed or the use thereof in court may be difficult, or when the consent of the opposing party is obtained, the party may move the court for perpetuation of such evidence; where necessary, the party who has legal interests in ascertaining the *status quo* of a matter or object may move the court for expert testimony, inspection or perpetuation of documentary evidence.

In addition, based on Article 270 of the Code of Civil Procedure, the presiding judge may order parties to disclose evidence during the preparatory proceeding if it is necessary to take the evidence at the place where such evidence is located, if the evidence shall be taken outside the courthouse, or if taking the evidence in the formal proceedings may result in the destruction or loss of such evidence or the obstruction of its use, or it is manifestly difficult to do so. Also, if both parties agree to disclose the evidence during the preparatory proceeding, the judge may order to do so.

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

According to Paragraph 1, Article 403 of the Code of Civil Procedure, if the dispute arises from proprietary rights where the price or value of the object in dispute is not greater than NT$ 500,000, the matter shall be subject to mediation by the court before the relevant action is initiated.

In addition, parties may utilise various forms of alternative dispute resolution, including arbitration, mediation, negotiation and conciliation. Based on Article 1 of the Arbitration Act, parties may enter into an arbitration agreement to resolve a dispute through arbitration. Also, according to the Article 43 and Article 44 of

the CPA, when a consumer dispute arises between consumers and business operators, the consumer may file a complaint with the business operators, consumer protection groups, or consumer service centres or their branch offices. If the consumers' complaint is still not properly responded to, a petition for mediation may be made with the consumers' dispute mediation commission of the municipality or county (city).

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction be brought within the jurisdiction of your courts either as a defendant or as a claimant?

In civil cases, parties may, by agreement, designate a court of first instance to exercise jurisdiction over a dispute between the parties, provided that such agreement relates to a particular legal relationship. Meanwhile, the agreement shall be evidenced in writing.

Without both parties' agreement, persons that are not domiciled in Taiwan may be brought within the jurisdiction of Taiwan courts either as a defendant or as a claimant, provided that the concerned dispute has a connecting factor with Taiwan. However, whether the connecting factor is sufficient enough is subject to determination by the courts on a case-by-case basis.

5 Time Limits

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

According to the CPA and the Civil Code, a person should exercise his/her right regarding product liability within two years from the date that he/she is aware of the damage and the identity of the liable person or 10 years from the date of the wrongful act.

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 does not vary depending on whether the liability is fault-based or strict.

The age or condition of the claimant does not affect the calculation of time limits and the court does not have the discretion not to allow time limits to defence so long as such defence is submitted by the defendant. However, according to Article 129 of the Civil Code, the time limit would be interrupted by any of the following causes: (1) a demand for the satisfaction of the claim; (2) an acknowledgment of the claim; or (3) an action brought for the satisfaction of the claim.

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 does affect the running of any time limit.

6 Remedies

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

In product liability actions, compensation shall be limited to the injury actually suffered and the loss of expected profits based on a fixed plan. In most cases, the plaintiff claims for monetary compensation.

However, according to Article 538 of the Code of Civil Procedure, where it is necessary for the purposes of preventing material harm or imminent danger or other similar circumstances, a petition may be made for an injunction maintaining a temporary *status quo* with regard to the legal relationship in dispute. Moreover, according to Article 53 of the CPA, consumer ombudsmen or consumer protection groups may petition to the court for an injunction to discontinue or prohibit a business operator's conduct which has constituted a material violation of the provisions of the CPA relating to consumer protection.

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 body, mental damage and damage to property are recoverable based on the product liability claim. However, damage to the product itself due to a product defect is deemed to be "pure economic loss" and courts tend to grant compensation for it based on the contractual claim rather than the tort law. Since the claim that is based on the CPA and Article 191-1 of the Civil Code bears the nature of a tort claim, it would be more difficult for the claimant to recover damage of 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?

No. If the product has not yet malfunctioned and caused injury, a customer cannot claim for the cost of medical monitoring based on product liability. The claim for the cost of medical monitoring is only permitted where plaintiff customer has suffered actual physical injury.

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

Punitive damages are available in product liability actions. According to Article 51 of the CPA, in consumer protection-related cases, the consumer may claim for punitive damages up to five times the amount of actual damages as a result of injuries caused by the wilful act of misconduct of business operators; however, if such injuries are caused by gross negligence or negligence, punitive damages up to three times or one time the amount of the actual damages may be claimed, respectively. It is worth noting that a customer is required to prove that the business operators maliciously, wilfully, intentionally or negligently caused 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?

There is no cap on damages recoverable from a single manufacturer for claims arising out of a single incident or accident.

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?

Because the settlement proposal shall be made by the court, court approval is substantially required for settlements made at the court proceedings, including class actions.

According to Paragraph 1, Article 54 of the CPA and Paragraph 1, Article 41 of the Code of Civil Procedure, if a mass of parties get injured out of the same consumer relationship, they can select one or more persons to bring an action for damages from themselves on behalf of the appointing parties and the appointed parties.

In addition, pursuant to Paragraph 1, Article 51 of the Code of Civil Procedure, in cases involving minor or incompetent persons, the legal guardian can represent him/her when conducting litigation or the court will appoint a special representative for minors or incompetent persons.

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?

National Health Insurance is founded for people with Taiwanese nationality. According to Paragraph 2, Article 1 of National Health Insurance Act, this health insurance is compulsory social insurance. Benefits shall be provided during the insured term under the provisions of this Act, in case of illness, injury, or maternity occurred to the beneficiary. The insurance is funded by the Government and the insurance premiums are paid by the insured. Benefits provided to the insured by the Government in respect of the injury allegedly caused by the product are not recoverable from a third 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?

According to Article 78 of the Code of Civil Procedure, the losing party shall bear the litigation expenses, including the cost of filing a suit, appeal, rehearing proceeding, re-appeal and petition for payment order, etc. Therefore, court fees and other incidental expenses could be recovered from the losing party. However, based on Article 82 of the Code of Civil Procedure, if the successful party has failed to present means of attack or defence in a timely manner, or to meet a specified date or period, or otherwise delayed the proceeding, the court may order the successful party to bear all or part of the litigation expenses incurred from the delay.

With regards to their own legal costs of bringing the proceedings, such as attorney fees, for the first and second instance, the litigation expenses do not include attorney fees, so the successful party cannot recover such expenses from the losing party. For the third instance, attorney fees are included as a part of the litigation expenses and can be recovered from the losing party, notwithstanding that the amount shall not exceed NT$ 500,000.

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

Based on Paragraph 1, Article 107 of the Code of Civil Procedure, except in cases where there is manifestly no prospect for a party to prevail in the action, where a party lacks the financial means to pay the litigation expenses, the court shall, by ruling on a motion, grant litigation aid. However, the litigation aid only covers court costs and other incidental expenses; attorney fees are not included in litigation aid. In addition, the Legal Aid Foundation may provide legal services for low income individuals or those who need such assistance, as determined by the Legal Aid Foundation, and the whole or part of the attorney fees would be remitted.

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

For low income individuals, for example, to be eligible for the public funding by the Legal Aid Foundation, a single person living in Taipei shall have a monthly disposable income not exceeding NT$ 28,000 and shall not have disposable assets with an equivalent value of more than NT$ 500,000.

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?

Pursuant to Article 30-2 of the Regulation of Lawyer Ethics, an attorney shall not accept the third party funding for attorney fees unless the client's informed consent has been obtained and unless such arrangement will not influence the independent professional judgment of the attorney.

An attorney shall avoid receiving attorney fees from a third party in order to prevent ethical issues and conflicts of interest, or the violation of the duty of confidentiality and of attorney-client privilege.

7.6 In advance of the case proceeding to trial, does the court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

No. According to the Code of Civil Procedure, the court cost shall be levied on the basis of the price or value of claim proportionately; however, the Court does not exercise any control over the costs to be incurred by the 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 your jurisdiction.

On 15 July 2016, the Ministry of Economic Affairs promulgated the Amendments to the "Rules for Mandatory and Prohibited Provisions of Standard Contracts for Online Retail Business" ("Amendments"), which takes effect on 1 October 2016. The Amendments require that online retailers must provide customers with a mechanism to

confirm the type, quantity, and price of the purchased commodity during the transaction process. Additionally, once the online retailer and the customer confirm that the internet transaction is complete, the retailer shall not refuse to ship the commodity based on the reason of pricing error, so as to lower the potential consumer disputes.

On 15 June 2016, the Court rendered a judgment in the class action against several major local edible oil producers which were found guilty of blending cheaper cottonseed oil into higher-end cooking oils to increase profits. Prior to that, the Court had ordered one of the above-mentioned producers to compensate NT$ 91,056,384 to 3,773 consumers. Nonetheless, the Court ordered another of the above-mentioned producers to compensate NT$ 9,369,000 to 3,123 consumers only this time. In this class action lawsuit, the number of claimants and the amount of the claim accumulated to more than 20,000 people and NT$ 3,700,000,000, respectively, both of which shattered the previous record in Taiwanese judicial history.

Owing to a series of food safety scandals in Taiwan, the members of the Legislative Yuan proposed draft amendments to the Food Safety and Sanitation Act on 9 November 2016. Based on the aforesaid draft amendments, the consumer may claim for punitive damages up to five times the amount of actual damages as a result of injuries caused by the wilful act of misconduct of food business operators; however, if such injuries are caused by gross negligence or negligence, punitive damages up to three times or one time the amount of the actual damages may be claimed, respectively. The draft amendments are still at the early stage of the legislation process and it is too soon to know whether they will be passed by the Legislative Yuan as they look like now.

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Patrick Marros Chu is a partner at Lee and Li and is also an active member of the International Affairs Committee of the Taipei Bar Association. He has successfully represented domestic and international clients in handling numerous product liability, consumer dispute and government probe cases. Patrick is also active in diversified practice areas, such as dispute resolutions, knowledge-based economics, corporate governance, M&A transactions, telecom and media convergence, labour, anti-competition, investor protection and Japanese-related legal matters, etc. He is the co-author of the Taiwan chapter of the Encyclopaedia of International Commercial Litigation and participates in the *Doing Business Report* of the World Bank.

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David Tien is a senior associate at Lee and Li. His primary areas of practice include product liability, commercial transactions, dispute resolutions and general corporate matters. He has deep knowledge about the food and tobacco industry and is experienced in representing multinational companies on various regulatory issues with respect to food, health food, cosmetics, tobacco and alcohol products. He was seconded to Kraft Foods for six months. David obtained his LL.B. from the National Taiwan University, and holds an LL.M. degree in international law from Columbia Law School and an LL.M. degree in global health law from Georgetown University Law Center.

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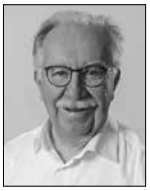
Lee and Li is the largest law firm in Taiwan, with an abundance of expertise in all legal areas and the goal of providing a full range of services. Over the decades, Lee and Li has built one of the largest intellectual property right practices in Taiwan, and has been involved in the phenomenal growth of foreign direct investment since 1970s. Lee and Li was a pioneer in developing banking and capital market practice in the 1980s, and played a pivotal role in the formation of technology law practice in the 1990s. Lee and Li is also active in public construction and government procurement projects, and has built one of the strongest teams in litigation and ADR with respect to product liability, class action and white collar crimes. Lee and Li's services are performed by over 100 Taiwanese lawyers, patent attorneys, technology experts, and specialists in other fields.

Turkey

Didem Bengisu



TURUNÇ

Noyan Turunç

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 rules regarding product liability are regulated under the Turkish Code of Obligations No. 6098 (the "CoO") and the Law of Consumer Protection No. 6502 (the "LCP"). Furthermore, the Law on the Preparation and Implementation of Technical Legislation Products (the "Technical Legislation Law") can also be applied in a product liability case depending on the circumstances of the matter. Besides, the secondary legislation relating to product liability consists of regulations such as Regulation of Liability for Damages arising from Defective Goods (the "Product Liability Regulation") and Market Surveillance Regulation.

Under the Turkish Law, it is a controversial issue as to whether there is a strict liability for product liability cases, since it is only regulated by an article of the Product Liability Regulation and not by law. The mentioned article states that in case the defective product causes a person's death or injury or causes damage to a property, the manufacturer is obliged to indemnify such damage irrespective of the negligence of the manufacturer. The Supreme Courts state that there is no strict liability for the manufacturer; however, it is the party who must take every possible precaution to eliminate the risks.

Since the LCP defines the consumer as a real or legal person who acts for non-professional or non-commercial purposes, a potential dispute that arises between a trader and the seller because of a defective good shall be settled as per the provisions of the CoO. Claiming compensation for material or moral damage from the manufacturer or seller (or both) shall also be a matter of contractual liability under these general provisions.

As for criminal liability, the Turkish Criminal Law foresees the liabilities in cases of selling, supplying or keeping food materials or drugs that endanger human health, as well as producing or selling medical or other substances that endanger human life.

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

The State does not operate any schemes of compensation for particular products. A direct connection between the damage caused and the specific defect must be firstly proven in order to declare direct responsibility.

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

The LCP does not contain a special provision regarding the damages incurred due to the defective products, rather it refers to the Code of Obligations for the compensation claims listed in the Article 11 related to the defective products.

In accordance with the Product Liability Regulation, where two or more persons are liable for the damage, they shall be jointly liable. The LCP foresees that joint and several liabilities exist between the manufacturer, seller and importer for the optional rights of the consumer, in case a damage has occurred because of a defective 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?

The products should have the requirements determined in the technical regulations. Producers, on the other hand, are obliged to investigate if there are any complaints related to the product and perform tests to resolve the current problems. During market surveillances, regulators conduct tests to ensure that such products have been produced in accordance with those regulations. If it is understood that the product is not safe, regulators have the power to require the manufacturer to recall a product. Besides, producers must notify the distributors of the products as well, and take every possible precaution, such as applying product recalls and destroying the affected products, if it is not possible to rectify the problem following the complaints.

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

Criminal liability may arise under certain conditions in the event of injury or death due to the products or services. Article 186 of the Turkish Criminal Code sets forth that "selling, supplying or keeping food materials or drugs that endanger human health are sentenced to imprisonment of one year to five years and a judicial fine corresponding to up to 1,500 days is imposed". Article 187 establishes that persons producing or selling medical products that endanger human life and health can be sentenced to imprisonment from one to five years and a judicial fine is also imposed. Finally, under Article 194, imprisonment of six months to one year has been foreseen for those who give or present substances for consumption which endanger human health.

2 Causation

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

In principle, under Turkey's legal framework, plaintiffs bear the burden of proof unless there is a specific provision by law.

As such, per Article 6/2 of the Product Liability Regulation, the plaintiff is required to prove the defect in the product, the damage it suffered, and the causal link between the defect and the damage. Therefore, the applied interpretation is that the general burden of proof rule applies in this fact as well.

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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

A direct connection between the damage caused and the specific defect must be established by the claimant. Expert and documentary evidences are admitted to prove causation. Testimonial evidence is not generally accepted by the manufacturer/distributor defendant party since the dispute is related on a technical issue and it is hard and legally not possible to prove controversial technical details based on an oral testimony.

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, where more than one person is responsible for the same damage, their liability towards the person injured is joint and several. A party who is exposed to the claims of the consumer shall use its recourse right against the other liable persons as per their internal relationship *pro rata* to their contribution to the defect.

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 case the manufacturers fail to provide adequate warnings for open and obvious risks, this can give rise to their liability. If the use of a product is not safe for the consumer, this fact is required to be submitted to attention. Turkish Law does not apply "learned intermediary" theory. The Product Liability Regulation provides that in the event that the defect of the product arises due to compliance with the technical regulations, the manufacturer will be released from liability.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The manufacturer shall not be liable if it proves any of the below:

a. that the product was not launched onto the market by the manufacturer;

b. that the product was not produced for selling, or was not manufactured during commercial or professional activities;

c. that, having regard to the circumstances, the defect which caused the damage did not exist at the time when the product was supplied to the market;

d. that the defect is caused due to the compliance of the product with the technical regulation; or

e. 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 defect to be known.

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 (point 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?

Under Article 5/4 of the Technical Legislation Law, the manufacturer can be released from liability if it can prove that it did not supply the unsafe product to the market, or the unsafe product derived from following the relevant technical regulations, as is the case with the Product Liability Regulation Article 7.

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?

Every court reviews each specific case within its own conviction. If a separate court has already tried on the same defect, such judgment would be persuasive, provided they share the similar facts. There is no issue of estoppel preventing a different claimant from bringing an action against a defendant in separate 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?

Regardless of being a player in the product supply chain, indemnification can be claimed by the defendant in subsequent proceedings through the right of recourse. Consumers may file a case against all involved in the chain of production. Thus, if the responsible third party for the damage has relation to the product supply, indemnification can be required during the same proceedings.

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

Per Article 6 of the Product Liability Regulation, the liability of the manufacturer may be reduced or removed, if it is proven that the damage is caused by the consumer or any person for whom the consumer is responsible.

4 Procedure

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

There is no jury system under Turkish procedural law. Disputes, including product liability claims, are tried by civil courts and decisions are made by only 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, if the court finds that the issues to be proven require special technical knowledge, technical expert assessors may carry out the work involved for pursuing these purposes. The court 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?

The LCP has some specific provisions related to class actions or representative proceedings. Consumer organisations, relevant public authorities and the Ministry of Customs and Trade have the right to file a lawsuit for the suspension of production and sale of the defective product and for the collection of these products from third parties which possess such products for sale.

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 above under question 4.3).

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

A complex product litigation takes approximately between 18 and 24 months following its filing, and the justified decision is issued one to three months after the final hearing. The above-mentioned periods generally depend on the location of the competent court and its workload. If the justified decision is appealed by one of the parties, the period may extend over four years, on average.

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 try preliminary issues that relate to the law at the time of the main trial.

4.7 What appeal options are available?

A new appeal procedure was introduced a short while ago. There are two types of appeals in Turkey: a) examination of the Turkish Regional Court of Appeal; and b) examination of the Supreme Court. Thus, the Regional Court of Appeal will function as a "court of cassation". In principle, final decisions concerning material rights may be appealed; however, actions for amounts under TRY 3,110 are not included because of being definitive, in other words, they may not be appealed.

Decisions which are appealed before the Turkish Supreme Court hereinafter will firstly be subject to the examination of the Turkish Regional Court of Appeal. It will have the jurisdiction to examine the decision on procedural grounds and merits of the case, and will be able to repeat certain procedural steps, as opposed to the Supreme Court, which can only examine the case over the file. Under the current system, if the claim amount is lower that TRY 41,530, the decision of Turkish Regional Courts of Appeal is not appealable before the 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?

Both parties can rely on expert opinion evidence. The court is also entitled to rule for an expert opinion for technical matters that require specialist knowledge. The court may decide to listen to the expert, who prepared the written opinion. However, if the expert does not accept the invitation to come to the court, the report will not be taken into consideration. The Procedural Law states that the judge cannot decide to have an expert opinion on legal issues and the outcome of the expert report is not binding on the judge. In addition, the parties may submit expert/technical reports supporting their claims to the court.

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 in the Turkish procedural system. Factual and expert witnesses may be required to present themselves at the hearing or trial.

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

Pursuant to the current practice of the Law, each party submits two petitions to the court including their claims and arguments before the investigation phase of the case. In the preliminary investigation hearing, the court shall order the parties to submit their evidences that they have not yet submitted within two weeks. Any party failing to submit its evidences shall forfeit the right to submit additional evidence and the court shall immediately proceed to the "investigation" phase whereby it would evaluate the parties' petitions/evidences collectively and subsequently make its judgment.

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

Arbitration has become a familiar method of alternative dispute resolution within the Turkish jurisdiction. Mediation was not recognised as a method in Turkey until the Law on Mediation for Civil Disputes came into force in 2007. Mediation has officially become another option for the resolution of legal disputes along with the arbitration. Thus, parties can choose mediation or arbitration as the means for resolving their disputes.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction be brought within the jurisdiction of your courts either as a defendant or as a claimant?

In principle, the competent court is determined according to the residence of the defendant. However, the law sets out various alternatives for certain circumstances. According to the International Private and Procedural Law, parties may agree to determine a foreign competent court as long as the dispute has foreign facts. However, parties may not refer disputes relating to insurance, consumer agreements and employment to a foreign venue.

5 Time Limits

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

Yes, please see under 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?

Unless a longer period is agreed between the parties, the claim should be brought before the courts within two years starting from the time of delivery of the goods to the consumer, and in any case, the claim would be time barred 10 years after the damage occurs.

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

If the defect is hidden from the consumer due to the seller's fault or negligence, the statute of limitations period does not apply.

6 Remedies

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

In case of a defect, the consumer is entitled to choose among the rights provided alternatively under the Article 11 of the LCP, which are: (1) the right to ask for free repair; (2) the right to ask for the replacement of the good with a defect-free one; (3) the right to terminate the contract; and (4) the right to demand a discount from the sale price in proportion to the defect. The plaintiff-consumer can also ask to be compensated both for material and immaterial damages.

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

Within the scope of the material damages, funeral costs, treatment costs, damages incurred, including those to be incurred, as a result of the loss or impairment of the injured party's ability to work, and loss of earnings, can be claimed. Within the scope of immaterial damages, an appropriate compensation should be ruled by the court considering the circumstances of the matter for the plaintiff's psychological/mental damages.

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 there exists a causal link between the defect and the damage, the costs may be recovered.

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

No, they 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?

According to Turkish Law, the compensation amount cannot exceed the plaintiff's actual damage.

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?

During the preliminary investigation, the court encourages parties to settle or mediate. If the parties choose not to exercise these options, the court will continue to try the case. Parties may partially or entirely settle the dispute before trial or during the litigation, up until the final judgment is rendered. Settlement is legally binding and equivalent to a final judgment.

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 such claim by government authorities is contemplated under Turkish Law.

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 litigation expenses from the losing party in proportion to the amount awarded. The legal fees to be reimbursed to the successful party shall be determined according to the minimum attorney fee tariff issued by the Turkish Bar Association. With regards to the attorney fees, the litigation expenses do not include attorney fees, so the successful party cannot recover such expenses from the losing party.

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

Yes, Turkish Procedural Law (Articles 334–340) sets out the provision regarding public funding by the State for people that experience financial difficulties.

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

Legal aid may be granted to low income citizens who are unable to afford required legal expenses.

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

Pure contingency fees are not acceptable in Turkey. It is possible to determine the amount of the legal fee, per a certain ratio up to 25% of the total amount to be ruled by the court.

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

Turkish Law does not provide any specific regulations regarding third-party funding; however, litigation funding by third parties is not forbidden in Turkey. Claimants who have a strong case but limited finance to pursue it, or simply prefer to seek external funding, can apply for litigation funding to finance their case.

7.6 In advance of the case proceeding to trial, does the court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

No, it does 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 your jurisdiction.

Previous Law no. 4703 was adopted with the purpose of implementing Council Directive 92/59/EC of European Union Legislation into Turkish Law. The LCP, which was published in the Official Gazette on November 28, 2013, introduces significant regulations and amendments aiming to protect consumers against sellers/suppliers. The LCP resembles European Union Directives and foresees advanced precautions for the protection of consumer rights. To a major extent, the LCP is similar to the European Union Directives and is a major step towards the harmonisation of Turkish Law with European Union Law which places significant emphasis on consumer protection. Levelling up the developing consumer rights under Turkish Law, the LCP responds the requirements of the market. Secondary legislation was also enforced to specify the details on the implementation of the LCP. The scope of the LCP covers all consumer transactions and all other consumer-related practices. It aims at specifically regulating certain acts and practices of private/public commercial or professional entities prior to or after their conclusion of any agreement with consumers.

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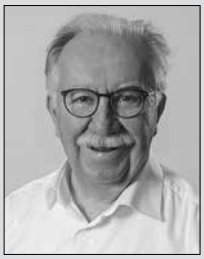
Regarding the corporate field, she has expertise in providing legal consultancy to international corporate institutions. In her recent works, she gained experience in handling M&A transactions and private equity investments.

Didem graduated from Bilkent University with an LL.B. degree in 2012.



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Founding partner Noyan Turunç advises across a range of practices including banking and finance, M&A, insolvencies, project finance, competition (antitrust), labour and employment. He has decades of experience in advising domestic and global corporate and financial institutions in a wide variety of industries including automotive, banking, consumer goods, energy, industrial goods, insurance and reinsurance and telecommunications across many jurisdictions including Turkey, the European Union, the United States, Asia and Latin America. Prior to joining Turunç, he worked as general counsel at multi-national corporations. He has also served for one of the largest insurance companies in Turkey, as an independent board member and chairman of the audit committee.

He is the author of several publications on labour & employment law, including the firm's book, Turkish Labour Law (2010), and the same book's forthcoming second edition.

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TURUNÇ

TURUNÇ is a leading law firm providing a broad range of cutting-edge legal services to a global clientele through the three integrated offices in each of the three largest cities in Turkey.

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TURUNÇ complements the corporate practice with a matching force in the dispute resolution department, which litigates several hundred cases each year in various industries across a wide spectrum of areas including competition, corporate and commercial, finance, insolvency, administrative and tax litigation, and tort and product liability defence. Since its founding in 1990, clients have also been represented with respect to the enforcement of foreign judgments and arbitral awards.

Chapter 30

USA


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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, there are three primary routes of liability: (1) strict liability; (2) negligence; and (3) warranty theories. All three theories are determined by state law with some variance between states. Under any of these theories, the burden is on the plaintiff to prove essential elements of their case. Defendants may be manufacturers, wholesalers, distributors, and retailers of defective products.

Warranty claims are contractual and are based upon Article 2 of the Uniform Commercial Code as adopted by each state. These claims most commonly are based upon express warranties, implied warranties, and warranties of fitness for a specific purpose.

Other theories include violations of state consumer protection statutes, and claims based on unfair and deceptive trade practices.

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

For most forms of personal injury caused by a product, states do not provide compensation. There are some limited federal government programs to compensate individuals injured by certain types of products and exposures.

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

Plaintiffs can name any entity within the distribution chain of a product as a defendant. As the entity responsible for placing the allegedly defective product into the stream of commerce, manufacturers are usually the primary target of defect claims. The extent of responsibility for fault/defect varies among states. Defences, including those known as "seller exceptions," are sometimes afforded to non-manufacturers; exceptions vary by state and often require the non-manufacturer to show that it did not contribute to the alleged defect and had no knowledge of the alleged 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?

Recalls can be voluntary or mandated by statute, regulation, or regulatory agency. Recalls are usually proactive and voluntary in response to regulatory agency requirements, internal policies, or health and safety concerns. Most states do not impose a duty to recall or retrofit a product that was not defective when sold. A manufacturer can be held liable for voluntarily conducting an ineffective recall or for failure to properly retrofit a product with a known hazard.

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

Criminal sanctions do not usually apply in civil suits involving defective products. However, criminal sanctions can be sought by state or federal prosecutors in cases involving conduct, such as concealing known product defects or intentionally misleading regulators regarding product defects.

2 Causation

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

Plaintiffs must prove all elements of their product liability case, including fault/defect and damages. Under strict liability, a plaintiff must prove that: (1) the defendant manufactured or sold the product; (2) the product was defective when it left the defendant's possession; and (3) the defect in the product caused the plaintiff's injuries. To establish that a product is unreasonably dangerous, a plaintiff must establish defective design, defectively manufactured product, or an inadequate warning. In negligence claims, a plaintiff must prove that the defendant failed to use reasonable care and breached a duty owed to the plaintiff, and that the breach caused the plaintiff's 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? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

Causation requires proof of both cause-in-fact and proximate cause. The existence of a defect and an injury are not enough. The jury determines facts, such as whether a defendant's actions had any effect on the plaintiff's injury. Most jurisdictions require plaintiffs to establish that the injury would not have occurred "but for" the defendant's conduct or the defect. Many jurisdictions use the substantial factor test, requiring plaintiffs to show that the defendant's product was a substantial factor in causing the harm. Certain jurisdictions apply both tests.

Proximate cause is shown only when the injury is caused by and connected to the defect. A plaintiff must have been using the product for its intended purpose or, at least, a purpose that was reasonably foreseeable to the defendant.

Proof of increased, but unpredictable, risk of malfunction is insufficient to establish cause-in-fact or proximate cause of personal injury. Risk of malfunction may be sufficient to assert consumer fraud, breach of contract or breach of warranty claims asserting economic damages, rather than personal injuries.

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?

Identifying the actual party responsible for the injury is a critical element of a plaintiff's product liability case. Market-share liability has been largely rejected.

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 of open and obvious risks can give rise to liability. Manufacturers generally have a duty to warn of dangerous propensities. The warning is considered adequate if a fact finder determines the warning would cause a reasonable person to exercise the appropriate amount of caution.

The duty to warn, however, is not always directed to the consumer. For example, in pharmaceutical and medical device litigation, the duty to warn in most states is owed to the prescribing physician; physicians are in the best position to both asses the health concerns of the patient and to conduct a risk/benefit analysis of the prescription drug or device. Physicians – the "learned intermediary" – also determine which warnings should be conveyed to the patient. Some state courts have questioned the applicability of the learned intermediary defence under circumstances when the prescribing doctor prescribes a drug that is also available over-the-counter or when a manufacturer uses direct-to-consumer advertising.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Assumption of risk applies when a plaintiff knows of and appreciates the risks of a product and voluntarily chooses to use the product. This is a complete bar to recovery in certain states while others use it as part of a comparative negligence analysis.

Comparative fault reduces the damages when the jury determines that the plaintiff is responsible for a percentage of the injury. Most states set a threshold percentage which, if the plaintiff exceeds the threshold, completely bars recovery. Other states offer "pure comparative fault" that allows for recovery from a defendant for the relative proportion of fault even as little as 1%.

Estoppel. See question 3.4 below.

Idiosyncratic reaction defences apply when only a few unknown individuals in a population are at risk of plaintiff's injury. The possibility of injury is seen as so remote that it is unforeseeable.

Learned intermediary. See question 2.4 above.

Pre-emption applies in cases when plaintiffs invoke state law causes of action covered by federal statute or regulation. The U.S. Constitution's Supremacy clause provides deference to the federal law. If a product liability action creates a risk that a manufacturer may be held liable for state law claims even though it satisfied federal statutes and regulations, federal law may pre-empt the state law claim. Defendants have the burden of proving that pre-emption applies. There are three types of pre-emption: conflict, express, and implied. Conflict pre-emption occurs when a defendant literally cannot comply with both state and federal law. Express pre-emption occurs when the federal law specifically states an intent of Congress to pre-empt state law. Implied pre-emption hinges on whether the federal scheme is so pervasive that it occupies the field on that area of law.

State of the Art. See question 3.2 below.

Statute of repose limits the number of years that a consumer can use a product during its useful life before filing a lawsuit. After the statute-specified time limit, manufacturers are immune from liabilities. The repose period varies by jurisdiction.

Statute of limitations specify the length of time a plaintiff has to file a claim after an injury occurs or after the plaintiff should have "discovered" a latent injury. The statute of limitations for product liability cases varies by state, generally from two to six years.

Unavoidably unsafe products. Comment k of Section 402A of the Restatement Second of Torts covers products that are incapable of being made safe for their intended and ordinary use. If a product meets this criterion, states that accept this defence require evidence that the product was properly manufactured and contained adequate warnings of the known and unavoidably unsafe propensities 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?

State-of-the-art design is an absolute defence in some states and, in others, can be used as evidence of non-negligence and as evidence that a feasible alternative design did not exist at the time of manufacture. Plaintiffs often rely on expert testimony to put forth an alternative design. To rebut a plaintiff's expert and support a state-of-the-art argument, defendants may submit evidence that: (1) shows compliance with federal regulatory design standards; (2) shows the manufacture submitted relevant material to a regulatory agency before gaining government-approval; and (3) shows compliance with industry standards.

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?

Few states recognise compliance with regulatory requirements as a defence to products liability claims.

Also see questions 3.1 ("Pre-emption") and 3.2 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?

United States courts give full faith and credit to prior judgments in any state court. Claims brought by unrelated claimants are not subject to estoppel; every plaintiff has a right to litigate their claims. A prior plaintiff's case against the same defendant does not preclude a subsequent plaintiff from litigating the same product liability issues. Plaintiffs are precluded from re-litigating issues if the issue has already been the subject of final judgment on the merits, related to a single transaction or injury, and involving 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?

Contribution claims are generally apportioned among the tortfeasors relative to culpability in terms of the percentage of fault for the plaintiff's injury. Indemnity generally shifts liability completely to one party, most often up the distribution chain toward the manufacturer. Indemnification can originate from a contractual agreement or negligence on the part of a third-party. In certain jurisdictions, multiple defendants in a case are considered joint and severally liable for a plaintiff's injury, which makes each defendant liable for the entire judgment. In those cases, defendants who pay more than their apportioned share generally have a right to contribution against other defendants.

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

Several jurisdictions account for such contribution by reducing the damages awarded by the percentage of fault attributed to the plaintiff's own actions in causing the accident. In addition, a plaintiff's contributory negligence can be used as evidence that the defendant's product was not the proximate cause of an accident.

Defendants can also seek to reduce damages by invoking an affirmative defence to show that the plaintiff, through his own actions, assumed the risk. (See question 3.1 "Assumption of Risk".)

4 Procedure

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

Every trial has a judge and a fact finder. A judge always rules on legal issues. The fact finder can be either the judge or a jury. Federal and state rules of procedure allow any party to demand a jury trial on any issue triable. Parties can waive this right and proceed with a bench trial, meaning the judge rules on both legal and fact issues.

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)?

Federal Rule of Civil Procedure ("FRCP") 53 allows a judge to appoint a special master to hold trial proceedings and, in some instances, make findings of fact on exceptional conditions. Special masters may address pre- and post-trial matters that cannot be timely addressed by the judge.

See question 4.8 below for a discussion of Federal Rule of Evidence 706.

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?

FRCP 23 sets forth the following prerequisites for class certification: (1) the class is so numerous that joinder of all members of the class is impractical; (2) there are questions of law or fact common to the class; (3) the claims or defences of the class representative parties are typical of the claims or defences of the class; and (4) the representative parties will fairly and adequately protect the interest of the class. Most states have class action procedures similar to the federal rules.

A plaintiff may seek certification of a class for product liability claims that a defendant manufactured an unreasonably dangerous product. Each plaintiff must have a valid cause of action. In the case of personal injury claims, plaintiffs often have difficulty certifying the class because the extent of alleged injuries among plaintiffs can vary widely, meaning individuals of the proposed class are not representative of others in the class. The individual assessment of each plaintiff's damages and injuries reduces the frequency with which class actions are seen for products liability litigation.

In the case of products liability class actions, plaintiffs opt-out or they are bound by the outcome.

Parties can also file motions before the Judicial Panel on Multidistrict Litigation which determines whether civil actions pending in different federal districts involve one or more common questions of fact such that they should be transferred to one district for coordinated proceedings.

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

Generally, no one other than the injured party can bring a claim against a manufacturer. This includes representative bodies as they have no standing to file claims for injuries sustained by members. Rarely, claims can be brought "in the public interest" by an individual.

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

The time from filing a claim to trial varies depending upon both the case and the jurisdiction. In complex product litigation, the pre-trial process can take one to two years and sometimes longer depending on whether it is a single plaintiff with a single set of issues or a consolidation of hundreds of cases from multiple jurisdictional districts.

State courts' trial calendars also vary significantly by jurisdiction.

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 FRCP 42, when there are common questions of law or fact, courts can order separate trials on one or more separate factual issues, claims, crossclaims, counterclaims, or third-party claims. Deciding a preliminary issue related to several actions can assist the court in avoiding prejudice or expediting and economising consolidated hearings.

Prior to trial, defendants can move for summary judgment to dispose of specific claims or the entire case where there is no genuine issue of material fact and judgment may be entered as a matter of law. During trial, a court can grant a directed verdict or judgment as a matter of law after the plaintiff's case is presented if the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the plaintiff.

4.7 What appeal options are available?

Final judgments can be appealed to a higher court, usually within 30 days after entry of judgment or order appealed from. FED. R. APP. P. 4. Appellate courts apply different standards, depending on the type of issue being appealed. Factual determinations at the trial level are rarely overturned. Questions of law are reviewed *de novo*. The appellate court will not overturn the decision unless the trial court's error was likely to have impacted the outcome. A successful appeal can result in reversal, a new trial, or remand for further proceedings in the trial court.

In rare cases, an interlocutory appeal may be made before final judgment. 28 U.S.C. §1292. State appellate procedures vary by jurisdiction but are generally similar to the federal rules.

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?

Federal Rule of Evidence 706 allows a court to "appoint any expert that the parties agree on and any of its own choosing".

State evidentiary rules and Federal Rule of Evidence 702 allow parties to present an expert's testimony. Rule 702 sets forth four requirements that must be met for a witness who is qualified as an expert by knowledge, skill, experience, training or education to provide expert opinion testimony: "(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied principles and methods to facts of the case."

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 50 U.S. 579 (1993), the Court charged trial judges to act as gatekeepers in assessing the reliability of scientific expert testimony. Several factors can be used to determine whether an expert's testimony is reliable, including: (1) whether the expert's theory can be tested; (2) whether the expert's theory has been subjected to peer review and publication; (3) the known or potential rate of error of the particular scientific technique; and (4) whether there has been "general acceptance" of the expert's theory or technique.

There are often pre-trial hearings to determine the admissibility of 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?

FRCP 26 requires parties to disclose the names and addresses of individuals likely to have discoverable information that the disclosing party may use to support its claims or defences, unless the use would be solely for impeachment purposes, as well as the identity of any witness who may be used at trial to present expert opinion evidence. Disclosure of expert witnesses, unless otherwise stipulated or ordered by the court, must be accompanied by the expert's written report.

State rules vary on the requirements of fact and expert depositions and expert report disclosure.

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

FRCP 26 requires parties to provide, as part of initial disclosures, a copy or description by category and location of all documents, electronically stored information, and tangible things that the disclosing party has in its possession, custody or control that may be used to support its claims or defences. Rule 26 also requires a party, as part of its pre-trial disclosures, to identify each document or exhibit that the party expects to offer or may offer at trial.

Parties may also serve interrogatories and requests for production of documents. Rule 33(b)(3) requires that a party provide answers and/or objections with specificity to each interrogatory, separately and fully in writing under oath. Requests for production must also be responded to either by objections, specifying the reasons for such objection, or state that copy and inspection will be permitted as requested.

If parties fail to disclose such documents as required by Rule 26(a) or respond to discovery requests pursuant to Rule 33 or Rule 34, numerous sanctions are available under Rule 37.

In the *In re: Actos (Pioglitazone) Products Liability Litigation*, a jury returned a $9 billion punitive damages award against defendant manufacturers after the jury heard evidence of the defendant's alleged destruction, or spoliation, of evidence. This verdict was later reduced to $37 million and then voluntarily dismissed pursuant to a $2.4 billion global settlement.

4.11 Are alternative methods of dispute resolution required to be pursued first or available as an alternative to litigation e.g. mediation, arbitration?

Alternative dispute resolution is available in state and federal courts. The types of arbitration available include arbitration, mediation, and negotiation. The programmes for alternative dispute resolution vary by state. Rule 26(f) of the Federal Rules of Civil Procedure requires parties to discuss settlement as part of their initial conference, and judges often encourage parties to consider settlement discussions and mediation at various stages in the pre-trial discovery process. Additionally, courts in certain jurisdictions are authorised by local rules to mandate mediation between parties.

4.12 In what factual circumstances can persons that are not domiciled in your jurisdiction be brought within the jurisdiction of your courts either as a defendant or as a claimant?

Persons or corporations not domiciled in the United States can be subject to suits here if personal jurisdiction exists. To establish personal jurisdiction, due process requires that a defendant has "certain minimum contacts" with the forum "such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice'". *International Shoe Co. v. Washington*. Personal jurisdiction can be established through specific or general jurisdiction.

In 2014, the Supreme Court recently rejected the "agency theory" that would "subject foreign corporations to general jurisdiction whenever they have an in-state subsidiary or affiliate", in *Daimler AG v. Bauman*. The Court overturned the Ninth Circuit's ruling and held that Daimler cannot be subject to suit in California based on claims brought by foreign plaintiffs having nothing to do with events that occurred or had their principal impact in California. The California Supreme Court subsequently expanded a theory of specific jurisdiction allowing plaintiffs from anywhere in the country, to sue companies in California as long as one Californian sued over the same conduct. The US Supreme Court, in *Bristol-Myers-Squibb v. Superior Court*, will soon hear a challenge to this expansion of jurisdiction.

5 Time Limits

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

There are statutes of limitations periods applicable to products liability actions that vary by jurisdiction. See question 3.1 above.

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 periods for products liability actions vary by jurisdiction. Most jurisdictions toll the statute of limitations period for claims brought by minors, incompetents and those in active military duty.

Generally, discovery rules permit the tolling of the statute of limitations period until the plaintiff discovers or through diligence should have reasonably discovered the cause(s) of his or her injuries. If the plaintiff is prevented from discovering the cause of his or her injury because of the defendant's fraudulent conduct, courts will toll the statute of limitations period.

Absent a statute or common law doctrine permitting for the tolling of statute of limitations periods, courts do not have discretion to waive statute of limitations requirements.

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

If a defendant fraudulently conceals information which prevents a plaintiff from learning of the cause of his or her injury, the statute of limitations will usually be tolled until the plaintiff discovers or should have discovered the cause of his or her injury.

6 Remedies

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

Monetary compensation is the usual remedy sought in products liability actions. Some plaintiffs also seek and some courts may permit declaratory 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?

Economic damages related to personal injuries caused by a product defect that are recoverable in products liability actions include property damage, past and future medical expenses, loss of actual earnings, and lost earning capacity. While some courts permit recovery for damage to the product itself, the majority of courts do not permit recovery when the only damage suffered is damage to the product itself.

Non-economic damages are recoverable and include damages for pain and suffering, quality of life, increased risk and/or fear of future illness, emotional or mental harm, and loss of consortium. Some states have caps on non-economic damages.

Punitive damages may also be recoverable. See question 6.4.

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?

Some state and federal courts have recognised claims for medical monitoring; however, the law regarding medical monitoring claims

is not uniform. Of the states that do permit the recovery of medical monitoring expenses, some require proof of a present physical injury to allow a plaintiff to recover medical monitoring damages, while others recognise such claims without proof of a physical injury.

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

Punitive damages are recoverable in products liability actions, but laws vary by jurisdiction. Most states have punitive damages caps, which also vary by statute.

The standard for the burden of proof also varies by jurisdiction. Some states require punitive damages to be proven by the higher standard of "clear and convincing evidence" rather than the lesser burden of a "preponderance of the evidence" applicable to other tort claims.

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 arising from one incident or accident.

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?

FRCP 23(e) states that "claims, issues, or defences of a certified class may be settled, voluntarily dismissed, or compromised only with the court's approval". Court approval is also usually required for claims involving minors, incompetents, and wrongful death 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?

The government can claim benefits to damages awarded or settlements paid to individuals covered by its Medicare or Medicaid programmes. Medicare is the federal health insurance programme for individuals who are 65 or older, certain younger individuals with disabilities, and people with End State Renal Disease. Medicaid is a joint federal and state programme that assists low income individuals with medical costs and expenses.

Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007 (MMSEA) sets forth mandatory reporting requirements for Medicare beneficiaries who receive settlements or judgment awards or other types of payment from liability insurance. These reporting requirements extend to plaintiffs and 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?

Some statutes and court rules permit the recovery of attorneys' fees and costs. However, while attorneys' fees have been awarded, it has also been argued that such fees are inappropriate in products liability actions because this award conflicts with the general policy of products liability litigation of encouraging manufacturers to make safer products.

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

Generally, there is no 5th Amendment right to counsel in civil cases as exists in the United States in criminal cases. There are various state bar associations and legal aid foundations that provide legal aid to civil litigants. Generally, to qualify for *pro bono* assistance, individuals are screened initially based on income eligibility, as there are income restrictions required for various types of *pro bono* aid.

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?

Funding is allowed through contingency fee agreements. Such agreements are governed by the state bar associations. Most ethics rules, including the Model Rules of Professional Conduct, require that contingent fee agreements be in writing. There are also percentage restrictions on contingency fee agreements, which typically range from 25% to 40%.

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 by some states that either allow third party funding by statute or ethics opinion from the state attorney general or similar governing entity. States that allow third party funding do so with particular caveats to follow the Rules of Professional Responsibility, as certain state attorney ethics rules prohibit a lawyer from accepting payment by anyone other than a client when doing so would interfere in the lawyer's exercise of independent professional judgment or with the client-lawyer relationship.

Third Party Litigation is becoming increasingly common and is often used by plaintiffs in pursuing complex litigation claims.

7.6 In advance of the case proceeding to trial, does the court exercise any control over the costs to be incurred by the parties so that they are proportionate to the value of the claim?

FRCP 1 states that the Rules should be construed to "secure the just, speedy, and inexpensive determination of every action and proceeding". A practical manner for controlling costs is court oversight to ensure that cases proceed expeditiously. However, not all courts focus on strict oversight as a cost control measure.

Additionally, courts are empowered to examine the proportionality of costs in considering the merits of discovery requests. Pursuant to amended FRCP 26(b)(1), information is discoverable if it is relevant to the party's claim or defence and is "proportional to the needs of the case". Proportionality factors to be considered include: the amount in controversy; parties' relative access to relevant

information; parties' resources; importance of the discovery in resolving issues; and whether the burden or expense of the proposed discovery outweighs the likely benefit. Courts may deny discovery requests where the burden and cost of compliance is deemed too high; alternatively, while rare, courts may impose cost sharing to compensate for the expense of compliance.

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 your jurisdiction.

In a January 2017 decision, the New Jersey Supreme Court, in *McCarrell v. Hoffman-La Roche*, ruled that the "substantial interest" test is the operative choice of law rule in New Jersey for resolving statute of limitations conflicts. In so ruling, the Court overruled the Appellate Division's dismissal of the case as time-barred under Alabama law, and reinstated a $25 million verdict.

Another major development is the US election results and the uncertainty now posed by the new administration. With a Republican president, a general expectation is legislative efforts to reduce the volume and cost of litigation. That said, the private practices of President Trump signal a potential deviation from this position. As a businessman, Mr. Trump has been an active, aggressive litigant. Further, President Trump did not make litigation reform an issue during his campaign. His comments, including those favouring liberalisation of libel law to allow more suits against the press, contradict expected reform.

There are indicators that the Trump administration will maintain continuity with expected tort reform positions.

Republican congressional leadership will pursue litigation reform ideas, which will likely receive support as they fall in line with President Trump's stance against over-regulation. De-regulation, less federal oversight and diminished directives for federal agencies to utilise enforcement powers can be expected. This may increase civil litigation, as plaintiff's attorneys may attempt to use product liability litigation as check on the actions of product manufacturers in lieu of regulatory action.

Also, expect appointments and nominations of judges supportive of federal pre-emption of certain types of tort claims. This would serve to preclude/pre-empt certain litigation. Proposed legislation to overturn pre-emption will likely no longer receive support.

Overall, it would be surprising if President Trump broke with the prevailing sentiment of the business community and the Republican Party, which favours litigation reform.

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