ICLG

The International Comparative Legal Guide to:

Product Liability 2019

17th edition

A practical cross-border insight into product liability work

Published by Global Legal Group, with contributions from:

Advokatfirmaet Ræder AS
Allen & Gledhill LLP
Arnold & Porter
AZB & Partners
Bae, Kim & Lee LLC
Bahas, Gramatidis & Partners
Blake, Cassels & Graydon LLP
Clayton Utz
Cornerstone Research
Drinker Biddle & Reath LLP
Eversheds Sutherland
Faus & Moliner Abogados
Hamdan AlShamsi Lawyers & Legal Consultants
Herbert Smith Freehills LLP
Iwata Godo Law Offices
Kellerhals Carrard
Lee and Li, Attorneys-at-Law
Legaltree
Matheson
Noerr LLP
Pinheiro Neto Advogados
Sidley Austin LLP
Squire Patton Boggs
Wilson, Elser, Moskowitz, Edelman & Dicker LLP
Wolf Theiss

glg
global legal group

global legal group

Contributing Editors
Adela Williams & Tom Fox, Arnold & Porter

Publisher
Rory Smith

Sales Director
Florjan Osmani

Account Director
Oliver Smith

Senior Editors
Caroline Collingwood
Rachel Williams

Group Consulting Editor
Alan Falach

Published by
Global Legal Group Ltd.
59 Tanner Street
London SE1 3PL, UK

Tel: +44 20 7367 0720
Fax: +44 20 7407 5255
Email: info@glgroup.co.uk
URL: www.glgroup.co.uk

GLG Cover Design
F&F Studio Design

GLG Cover Image Source
iStockphoto

Printed by
Ashford Colour Press Ltd
May 2019

ISBN 978-1-912509-73-7
ISSN 1740-1887

Strategic Partners

MIX
Paper from responsible sources
FSC® C011748

General Chapters:

Country Question and Answer Chapters:

Chapter 1

European Product Liability Update


Adela Williams


Tom Fox

Arnold & Porter

Introduction

This updating chapter concerns the ongoing evaluation of the Product Liability Directive, 85/374/EEC ("the Directive"). The Directive lays down common rules governing liability for defective products in the European Union ("EU"). It imposes strict (no fault) 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 presentation of the product, its expected use and the time when it was put into circulation.

Evaluation of the Directive

The Fifth Report on the functioning of the Directive was published in May 2018. This concluded, following a consultation exercise, that it was possible that the Directive might need to be adapted to take into account technological developments, but that this was not certain, and further evidence would be needed.

At present, an Expert Working Group is analysing the further development of the Directive in two work streams or 'formations'. The 'product liability formation' is assisting the Commission in drawing up guidance on the Directive. The 'new technologies formation' is assessing the implications of emerging digital technologies for the wider liability frameworks at EU and national level. Guidance on the Product Liability Directive is due to be issued by "mid-2019", as well as a separate report on the broader implications for, potential gaps in and orientations for, the liability and safety frameworks for artificial intelligence, the Internet of Things and robotics.

Revisiting the Commission's Fifth Report

This chapter critically re-appraises aspects of the Commission's Fifth Report on the operation of the Directive in anticipation of the Commission Guidance.

In summary, the Fifth Report flagged the following issues in relation to the functioning of the Directive:

1. The legal understanding of certain concepts (such as 'product', 'producer', 'defect', 'damage', or the burden of proof) requires clarification.
2. There are cases where "costs are not equally distributed between consumers and producers. This is especially true when the burden of proof is complex, as may be the case with some emerging digital technologies or pharmaceutical products.
3. To remain relevant for the future, the Directive would benefit from clarification to address such issues.

These identified issues are sometimes couched in interesting language. First, the use in the Directive of concepts 'product', 'producer', 'defect', 'damage', or the burden of proof is said to limit its effectiveness. Some of the Fifth Report's criticism in this vein appears to proceed on the basis that the Directive's sole purpose is to facilitate the compensation of consumers. However, in line with the terms of its own recitals, the Directive's liability regime represents a fair apportionment of risk between consumer and producer.

Second, the Fifth Report refers to cases where "costs are not equally distributed between consumers and producers" [underlining added]. Looking at the French version ('*équitablement*'), this should probably read 'equitably' rather than 'equally', consistent with the language of the Directive regarding a 'fair' apportionment of risk. The Fifth Report characterises the Directive's aim as being to "ensure effective redress for consumers and investment stability for businesses", thereby acknowledging that the regime is meant to strike a balance rather than just be 'effective' in only one aspect. Plainly, the primary burden is borne by the producer, under the existing regime, who is liable on a no-fault basis for defects. However, that primary liability is tempered by the various balancing factors, including the requirement that the injured party prove the defect and causation between defect and damage. Assuming the word 'equally' should correctly be understood as 'equitably', however, it is clear that the complaint is that the apportionment of risk under the existing regime of the Directive is too unfavourable to the consumer. The burden of proof gets a special mention as a factor making the regime unfavourable and it is said that this is "especially true when the burden of proof is complex, as may be the case with some emerging digital technologies or pharmaceutical products". This appears to be asserted on the basis of complaints from consumer organisations rather than supported by any analysis in the Fifth Report.

Third, clarification, it is suggested, will take the form of Guidance. The aim of the Guidance will be to "help to make these concepts (i.e. 'product', 'producer', 'defect', 'damage' etc.) more effective and highlight their continued relevance", with the ultimate aim of continuing to ensure "a fair balance of the interests of consumers and producers for all products". There is no real explanation of why the existing system is allegedly not already providing such a fair balance. The previous reports into the operation of the Directive all found its operation to be broadly satisfactory, and the Fifth Report itself notes that "even though products are much more complex today than in 1985, the Product Liability Directive continues to be an adequate tool". The evaluation conducted by the Commission

concluded that most product liability claims between 2000 and 2016 were settled out of Court: 46% in direct negotiation; 32% in Court; 15% through alternative dispute resolution procedures; and 7% through other means (e.g. insurers). The fact that a proportion of claimants' cases fail is therefore likely to be because those cases are weak cases, rather than because the Directive causes any unfair impediment to obtaining compensation.

Does Technological Change Require Clarification of the Directive?

Complexity of products generally does not seem to be a strong point in favour of changes to the Directive. It is likely that the average person has no clearer idea about how an everyday product, such as a car, TV or mobile phone, works than they do about artificial intelligence ("AI") or neural networks. For most people, the technical aspects of how products work are a mystery. It makes no difference in that regard whether the technical aspects that are not understood are complex or very complex. And yet claims are successfully brought in respect of defects in such products without any particular hardship arising from the provisions of the Directive. Claimants are able to demonstrate 'defect' to the satisfaction of their national courts; that is, they can show that the product which harmed them lacked the degree of safety which they were entitled to expect. This is arguably, precisely because of the broad, flexible concepts like 'defect' that can be adapted to all products.

The following are reasons why, according to the Fifth Report, technological change may, however, require clarification of the Directive:

1. Industry is increasingly integrated into dispersed multi-actor and global value chains with strong service components.
2. Products can increasingly be changed, adapted and refurbished beyond the producer's control.
3. Products will also have increasing degrees of autonomy.
4. Emerging business models disrupt traditional markets.

A difficulty arising from the integration of industry into global value chains is that this can present problems in distinguishing products from services (e.g. in cybersecurity and the Internet of Things where products and services interact). The resulting uncertainty is unsatisfactory for consumers and businesses in cases where a defect in this area results in damage and loss. Clarification of the status of relevant technological advances for product liability purposes may, however, be sufficient to resolve these concerns.

With respect to the change, adaptation and refurbishment of products beyond the producer's control, this is not a new phenomenon. In practice, a person who changes, adapts or refurbishes a product may meet the definition of a 'producer' in their own right (certainly insofar as they can be said to have placed on the market or distributed for sale a new product or component); or their liability may be based in negligence as a service provider. If the change concerns e.g. a software update then the software update may be a product or a component of a product, and the Directive will apply in the normal way. Alternatively, if the software update is instead viewed as a service, then the Directive will not apply to the update. If a defect arises e.g. because a consumer fails to install a software update to a product, then this is likely to be dealt with under the contributory negligence provisions of the Directive. In essence, the change, adaptation or refurbishment of a product may provide the original manufacturer of a product with a defence under Article 7(b) of the Directive (i.e. that the defect was not present at the time he placed the product into circulation), but the person who carried out the change, adaptation or refurbishment is then likely to be viewed as a producer themselves or to be liable outside the scope of the Directive, in negligence, for the service he has provided. It is not therefore clear that the possibility of change, alteration or refurbishment of products constitutes a significant technological obstacle to the continued effectiveness of the Directive.

The fact that some products will develop increasing degrees of autonomy provides perhaps the most cogent technological change basis for changes to the Directive. Products that learn and change themselves with no human input may appear to constitute a wholly new category of products. However, arguably, the same points about complexity and standard software apply to AI. Like software, an AI may not, necessarily, be a product, but on the other hand, if integrated into physical goods and systems it may be regarded as a product or product component. As with all technologically advanced products, it can take a while to establish what is 'standard' and perhaps particularly where AI can learn and develop it may be hard to discern what is happening by design and what is a mistake or 'defect'. Furthermore, when considering highly autonomous systems, it may not, in practice, be possible for a creator or developer to anticipate its future decisions and actions.

There seems no reason why the general principles of the Directive should not permit the presence of a 'defect' to be found in a machine that functions without direct human agency. The main problem area in this regard in the case of robotics and AI is likely in the definition of standards in a fast-moving technological area to assist with determining what level of safety persons generally are entitled to expect of such products. However, pending such standards, producers of AI-controlled systems will have to operate by considering analogous standards applicable to other complex machinery and ensuring that their products provide at least an equivalent level of safety. The key concern in this area is, however, not that the Directive cannot be used to determine the presence of a defect in technologically advanced products, but that the existing structure of the Directive will stifle innovation and deter producers from launching new AI products onto the EU market, particularly in countries which have derogated from the development risks defence.

The reference to emerging business models and their potential impact on the functioning of the Directive appears to relate (a) to a blurring of the distinction between producers and consumers in the context of the sharing economy (peer to peer instead of business to consumer), as well as the development of certain technical solutions, such as 3D printers which involve complex interactions between a range of participants to produce a finished product, and (b) to difficulties in distinguishing between private and professional use of a product in the context of increased use of smart working arrangements. The application of the Directive in these circumstances will depend on the factual background in individual cases; however, while the issues are novel, there is no clear evidence that the Directive in its current form cannot be applied to these scenarios.

The goal set by the Fifth Report was as follows: "At the end of the day, a producer is and needs to be responsible for the product it puts into circulation, while injured persons need to be able to prove that damage has been caused by a defect. Both producers and consumers need to know what to expect from products in terms of safety through a clear safety framework."

It has not been established that there is any major problem with the framework, insofar as that is represented by the Directive. The Directive itself does not provide detailed safety standards, only a method of establishing that a product is defective. This involves setting broad parameters for a factual inquiry into whether a product

offers the required level of safety or not. The level of safety which persons generally are entitled to expect from a product is specific to the product and the facts in 'all the circumstances'. Relevant circumstances will include any applicable standards established in respect of the product. The 'safety framework' for products is constructed on harmonised legislation and standards, where these apply, on national legislation and standards where there has been no harmonisation, or otherwise, on industry standards and norms. The product liability regime under the Directive is not a part of that framework, although it is of course closely-related to it, in that it describes how liability may be established if something goes wrong with a product. There appears to be no reason why it should not continue to do this for new and technologically complex products, in principle, although clarification in relation to the borderline between products and services will be helpful.

Potential Policy Responses

Some commentators on the review of the Directive[1] have noted that the use of "soft law" has been controversial, without further addressing the issue. Other options have been dismissed: revised legislation may be an 'over-reaching' response, and CJEU case law and Commission infringement proceedings have relatively limited impact. Therefore "soft law" is said to be the answer, being increasingly used at EU level, including in relation to general product safety, and for specific products such as medicines, and cosmetics.

However, "soft law" via guidance and standards is potentially problematic. Standards can effectively have the force of law without ever having been exposed to scrutiny by democratically elected representatives. Where guidance does no more than shed light on practical experience, and flesh out the detail of the core legislation, then it can very helpful. However, the line is not always clear, and it is easy for authorities promulgating standards within a legal framework to stray into what is, in effect, the creation of new law. Proceeding too far down this path risks government by technocratic edict.

For example, harmonised safety standards typically inform whether a product that is covered by general product safety legislation is safe or not. Such standards are meant to be voluntary, but in practice compliance with such standards is obligatory and meeting the requirements of the harmonised standards and safety are frequently conflated as being one and the same thing. Failure to meet the standard may result in recall and regulatory action, including administrative and criminal sanctions. It is difficult to see how such a standard is not really a law in practice. This, incidentally, also makes it objectionable that access to such standards is subject to payment of a fee. Although it could be argued that this is just a form of indirect taxation applied to industry and professionals as the principle users of standards, surely at least any standards with the effective force of laws are of wider interest and should be freely available.

Guidance, unlike standards, is typically made freely available. However, if guidance is authoritative and intended to be relied upon then it can effectively also have the force of law. On the other hand, guidance that is too vague will carry little weight and may confuse rather than add to legal certainty for producers and consumers.

It remains to be seen what form the upcoming Commission Guidance on the Directive takes and whether or not it demonstrates that "soft law" is the appropriate policy response here. The Commission states that the Guidance will be "comprehensive". It is being drafted in parallel with a detailed assessment of the application of the Directive to new technologies.

Whether Guidance proves to be an appropriate tool will depend on how far-reaching the Guidance is and what it sets out to achieve.

The Forthcoming Guidance

Since the Guidance is due to be published in mid-2019, any speculation will be short-lived, but it is interesting to consider what things to watch out for when it arrives.

It is said that the Guidance will be 'comprehensive', so that might mean that it pulls together helpfully in one place and makes accessible all currently existing guidance, whether from case law or official publications on the operation of the Directive. It may make recommendations for legislative amendments, but, in view of the limited evidence that any significant change is required, it seems more likely that it will be published as a "soft law" instrument.

Points that are likely to be covered in the Guidance include:

- Definition of when software is to be viewed as a product for the purposes of the Directive. Is a distinction to be drawn based on whether software is incorporated in a tangible product and/or based on whether the software is bespoke or a standard 'off-the-shelf' commercial offering?
- Illustration, perhaps via worked complex supply chain examples, of who is deemed to be the producer.
- Some further commentary on how the existing regime might apply to complex or networked products and refurbished or updated products with regard to establishing defect.
- Consideration of how the Directive might be applied to technological developments (particularly AI) in the context of the Commission's concern to encourage innovation.

The Guidance might also helpfully:

- Clarify that 'products' do not have to be tangible goods. Currently the Directive refers to 'movables', which might be taken to imply only tangible goods, but electricity is specifically also included as a product.
- Clarify the extension of potential liability under the Directive to the authorised representative pursuant to the Medical Devices Regulation.

Taking into account the lack of a firm basis for more fundamental changes in the Fifth Report, and the limitations of attempting substantive legal changes via "soft law", it is less likely that the Guidance will:

- Recommend the removal of any categories of products from the scope of the Directive on grounds of 'complexity'. This issue is raised in the Fifth Report by reference to the apparent focus in recent case law on pharmaceutical and medical device products.
- Recommend alternative liability models for specific types of products. Since the parallel technological review formation is meant to be "developing principles that can serve as guidelines for possible adaptations of applicable laws at EU and national level relating to new technologies", it is more likely that proposals for e.g. liability insurance models as have been discussed in the context of drones and driverless cars will be addressed in that expert group's output instead.
- Propose any fundamental alterations to the definition of any of the essential legal concepts of the Directive, such as 'defect'.
- Propose the removal of any of the Article 7 defences, limitation, or similar features of the Directive which represent key aspects of the apportionment of risk between producers and consumers.

How Could the Directive be Rebalanced?

If the balance between consumer and industry interests, which is inherent in the key aspects of the Directive, is to be altered, then this should be done transparently via a legislative process that openly acknowledges that what is being undertaken is the re-opening of the 'fair apportionment of risk' settlement represented by the Directive. If such an exercise is to be undertaken, then it should be acknowledged as such, and not confused with necessary adaptations to technological change.

Any re-appraisal should start with a clear statement of the problem that is perceived; i.e. why the current apportionment should no longer be viewed as fair. It should also explain, to a greater extent than has been attempted in the Fifth Report or associated working documents, to what extent any perceived unfairness is actually a function of the Directive, as opposed to the result of factors external to the Directive, such as the traditions and technical rules of national legal systems and national mechanisms to provide access to those systems through costs provisions and public funding.

There are various ways in which risk can be spread across a society. Pooling risks via national health and insurance systems paid for via progressive taxation is arguably the most equitable, and perhaps also efficient, way of addressing risks. However, while such mechanisms do exist (in European countries, at least) as a safety net, they have not hitherto been relied upon as a comprehensive solution for all risks arising from defective products. It seems to be generally understood as desirable that legal systems should have elements that foster a degree of self-reliance and self-responsibility on the part of the consumer, and impose legal duties on manufacturers of products and other economic operators to encourage responsible conduct in relation to the safety of products and to discourage and penalise where appropriate, the lack of such conduct.

Conclusions

Although the Fifth Report identifies a number of challenges, it remains to be seen what will emerge from the Commission's Expert Working Group by way of guidance. While some clarification e.g. of the status of software and certain other technological developments as "products" is desirable, it is not clear that any cogent case has been made for any significant changes to the Directive and its key legal concepts of 'product', 'producer', 'defect', etc. The Directive transfers risk from consumers to industry in a balanced way. Its legal concepts are broad and appear capable of being applied across different types of products, including complex, innovative products. It has successfully stood the test of time.

Endnote

1. Reforming the European Product Liability Directive: Plus ca change, Plus c'est la Mem Chose? D. Fairgrieve 2019 JPIL, Issue 1 33-40.

Adela Williams
Arnold & Porter
Tower 42, 25 Old Broad Street
London EC2N 1HQ
United Kingdom

Tel: +44 20 7786 6115
Fax: +44 20 7786 6299
Email: Adela.Williams@arnoldporter.com
URL: www.arnoldporter.com

Adela Williams is a partner in the London office of Arnold & Porter, specialising in product liability litigation (unitary actions and group litigation), principally involving life sciences clients and including claims involving unlicensed medical products in the research context as well as marketed products. Such litigation has often involved co-ordinating proceedings within the EU and advising on forum and other jurisdictional issues. Past cases include the fetal anticonvulsant litigation and the successful defence of group litigation involving more than 100 claims relating to the "third generation" oral contraceptive pill on behalf of two of the defendant manufacturers.

She also advises clients in relation to the regulation of medicinal products, medical devices, foods and cosmetics in the EU and acts on their behalf in litigation arising from the decisions of regulatory bodies.

She is an Assistant Coroner.

Tom Fox
Arnold & Porter
Tower 42, 25 Old Broad Street
London EC2N 1HQ
United Kingdom

Tel: +44 20 7786 6187
Fax: +44 20 7786 6299
Email: Tom.Fox@arnoldporter.com
URL: www.arnoldporter.com

Tom Fox is a counsel in the London office of Arnold & Porter, whose practice focuses on litigation and general product safety regulatory work. His main litigation practice concerns the defence of product liability claims on behalf of medical device and pharmaceutical companies. He also has considerable experience of commercial litigation and personal injury. He also has experience in bringing judicial review actions based on public and administrative law on behalf of pharmaceutical companies, both at the Court of Justice of the European Union and in national courts. He advises on general product safety and regulatory issues such as conformity marking, labeling, and compliance with standards in relation to a range of consumer products including electrical and electronic goods, clothing, cosmetics and toys.

Arnold & Porter

Arnold & Porter is an international law firm with over 1,000 attorneys in 16 offices in the US, London, Brussels, Frankfurt, Shanghai and Seoul. 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.

Please contact Ian Dodds-Smith, Dr. Adela Williams or Tom Fox in the London Office for UK or EU product liability enquiries, and Anand Agneshwar in the New York Office for US enquiries.

U.S. Product Liability Law: Recent Developments and Future Outlook

Daniel A. Spira

Teri H. Peeples

Sidley Austin LLP

Introduction

U.S. product liability law has continued to evolve over the past year, particularly with regard to the scope of personal jurisdiction and the applicability of federal preemption to tort claims addressing pharmaceutical products. Additionally, given the prevalence of multi-district litigation ("MDL") that now encompasses a substantial portion of civil cases in federal court – especially those involving product liability claims – problems pertaining to MDLs have garnered significant attention in recent years. Proposed MDL rule changes, if implemented, would likely alter the product liability landscape. Finally, as the design, manufacturing, and function of traditional products rapidly evolve through the advent of new technologies, courts, regulators, practitioners, and companies are being forced to re-examine, develop, and adapt product liability law.

This chapter summarises and provides updates on each of the following topics pertaining to U.S. product liability law:

- Personal Jurisdiction;
- Federal Preemption;
- Multi-district Litigation (MDL); and
- Emerging Areas of Product Liability Law.

Personal Jurisdiction

The constitutional requirement of personal jurisdiction protects defendants from being sued in jurisdictions in which they do not have certain minimum contacts. *See Int'l Shoe Co. v. Wash.*, 326 U.S. 310, 316 (1945). For a court to exercise jurisdiction, the defendant must also have purposefully availed itself of the privileges of conducting activities within the forum. *See Walden v. Fiore*, 571 S. Ct. 1115, 1122 (2014).

There are two different types of personal jurisdiction, without either of which a case must be dismissed. "General jurisdiction" exists when a defendant has such substantial contacts with a forum that it is essentially "at home" in the forum and can be subject to any claim there, regardless of whether the lawsuit relates to the forum. *See Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 924-25 (2011). By contrast, "specific jurisdiction" can be invoked even when a defendant has few contacts with the forum, as long as the claim arises directly out of those contacts. *Id*. at 414 & n.8.

In recent years, case law has narrowed the scope of general and specific jurisdiction, with significant implications for product liability suits and other cases.

General Jurisdiction

The U.S. Supreme Court clarified the scope of general jurisdiction in *Daimler Ag v. Bauman*, a landmark case in which the court found that a corporation is typically only "at home" in its "place of incorporation and principal place of business". 134 S. Ct. 746, 760 (2014). Only in an "exceptional" case will "a corporation's operations in a forum other than its formal place of incorporation or principal place of business … be so substantial and of such a nature as to render the corporation at home in that state". *Id.* at 761-62 & n.19 (declining to find general jurisdiction over Daimler in California despite its subsidiary's sales of $4.6 billion in the state) (citing *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985)).

In *BNSF Ry. Co. v. Tyrrell*, the Supreme Court further described the narrow circumstances under which general jurisdiction over a defendant may be found. 137 S. Ct. 1549, 1554, 1559 (2017). The Court held that there was no general personal jurisdiction over BNSF in Montana, when BNSF was not incorporated in Montana and did not maintain its principal place of business there, even though the company had over 2,000 miles of railroad track and more than 2,000 employees in the state. *Id*. at 1559. These contacts were not substantial enough for general jurisdiction, because they represented only a small portion (less than 10 per cent) of BNSF's total presence in the United States. *Id.* at 1554, 1559.

These cases are of significance to defendants in product liability litigation, where hundreds or thousands of plaintiffs may individually sue the same defendant manufacturer over the same product or device. Narrowing the venues in which these defendants are considered "at home" can critically curtail plaintiffs' efforts to "forum shop" in seemingly favourable jurisdictions. In a recent attempt to dull the impact of *Daimler* and *BNSF*, plaintiffs have argued that defendants "consented" to jurisdiction anywhere they are registered to do business. *See, e.g.*, *Bors v. Johnson & Johnson*, 208 F. Supp. 3d 647 (E.D. Pa. 2016) ("[B]ecause [defendant] was authorized to do business in Pennsylvania, it was subject to the exercise of personal jurisdiction by Pennsylvania courts"). Several courts, however, have recently declined to embrace this argument. *See, e.g., Waite v. All Acquisition Corp.*, 901 F.3d 1307, 1318-22 (11th Cir. 2018) (registration to do business in Florida did not subject the corporate defendant in a product liability suit to jurisdiction in the state), *petition for cert. filed*, No. 18-998 (Jan. 31, 2019); *Aspen Am. Ins. Co. v. Interstate Warehousing, Inc.*, 90 N.E.3d 440, at 447-48 (Ill. 2017) ("[T]hat a foreign corporation has registered to do business under the Act does not mean that the corporation has thereby consented to general jurisdiction over all causes of action, including those that are completely unrelated to the

corporations activities in Illinois"). This theory will likely see continued litigation across the country as plaintiffs attempt to circumvent the recent limitations put in place by the Supreme Court.

Specific Jurisdiction

The U.S. Supreme Court's 2017 decision in *Bristol-Myers Squibb Co. v. Superior Court of Calif.* ("*BMS*") significantly limited the forums in which specific jurisdiction may be invoked to those connected to a particular plaintiff's claims. BMS, a pharmaceutical company, was sued in a product liability lawsuit in California state court by a group of plaintiffs, 80 per cent of whom were out-of-state residents. 137 S. Ct. 1773, 1778 (2017). Where plaintiffs lived, purchased, or were prescribed the drug in California, the court had specific jurisdiction over BMS for injuries that arose out of BMS's conduct in that state, and plaintiffs were permitted to bring an action against BMS in California. *Id.* at 1779. But non-resident plaintiffs whose claims had no relation to California were not allowed to piggyback onto the specific jurisdiction over the resident plaintiffs and assert claims in California. *Id.* at 1782.

Courts across the country have consistently applied *BMS* to stop forum shopping by out-of-state plaintiffs asserting product liability claims. *See, e.g., Jordan v. Bayer Corp.*, 4:17-cv-00865, 2018 WL 837700, at *4 (E.D. Mo. Feb. 13, 2018) (granting motion to dismiss because non-Missouri plaintiffs' "allegations are simply too attenuated to serve as a basis for specific personal jurisdiction over Bayer"); *Hinton v. Bayer Corp.*, No. 4:16-cv-1679, 2018 WL 3725776, at *4 (E.D. Mo. July 27, 2018) (similar); *Campbell v. Acme Insulations, Inc.*, 2018 IL App (1st) 173051, 105 N.E.3d 984 (2018) (In *BMS* "the United States Supreme Court rejected the notion that specific jurisdiction could be asserted under a 'sliding scale' theory"; rather, "for purposes of specific personal jurisdiction, there must be a connection between the forum and the specific claims at issue") (internal quotations omitted).

In the context of class actions, several courts have similarly recognised that *BMS* requires dismissal of non-resident putative class members' claims that have no connection to the forum. *E.g., Mussat v. IQVIA Inc.*, No. 17 C 8841, 2018 WL 5311903, at *5 (N.D. Ill. Oct. 26, 2018) ("Following the Supreme Court's lead in [*BMS*] and applying its core reasoning here, due process … requires a connection between the forum and the specific claims at issue. This recognition bars nationwide class actions in fora where the defendant is not subject to general jurisdiction. Whether it be an individual, mass, or class action, the defendant's rights should remain constant"); *DeBernardis v. NBTY, Inc.*, No. 17 C 6125, 2018 WL 461228, at *2 (N.D. Ill. Jan 18, 2018) ("The Court believes that it is more likely than not … that the courts will apply [*BMS*] to outlaw nationwide class actions in a for[u]m, such as in this case, where there is no general jurisdiction over the Defendants"). Other courts have maintained that *BMS* is inapplicable to proposed class members' claims, resulting in a split of authority. *See, e.g., In re: Chinese-Manufactured Drywall Prod. Liab. Litig.*, No. 09-2047, 2017 WL 5971622, at *12 (E.D. La. Nov. 30, 2017) ("[*BMS*] was not a class action …. [T]his factor materially distinguishes this action from *Bristol-Myers* because in class actions, the citizenship of the unnamed plaintiffs is not taken into account for personal jurisdiction purposes") (internal quotations omitted); *Cabrera v. Bayer Healthcare, LLC*, No. CV 17-08525, 2019 WL 1146828, at *7-8 (C.D. Cal. Mar. 6, 2019) (discussing split of authority and holding that "decisions concluding that *Bristol-Myers* does not apply in the class action context are more persuasive").

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. 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). Preemption with respect to pharmaceutical products and medical devices approved by the U.S. Food and Drug Administration ("FDA") has received considerable attention from federal courts in recent years and remains one of the most hotly contested issues in product liability cases.

Pharmaceutical Preemption

In *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), a case with far-reaching implications for pharmaceutical preemption, plaintiffs alleged that manufacturers of a generic drug failed to adequately warn of the risk of a severe neurological disorder. 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*. at 610.

Plaintiffs argued that the manufacturers could have independently modified the warnings by: (1) using FDA's changes-being-effected ("CBE") process; (2) sending Dear Doctor letters to physicians; or (3) 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 cannot unilaterally strengthen its labelling through the CBE process or disseminate a Dear Doctor letter. *Id*. at 614-15. As to the third basis, the Court held that it was not clear that the FDA would have permitted a new warning. *Id*. at 619-20. Accordingly, plaintiffs' claims were preempted: "[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 that state tort claims against the manufacturer of a generic drug were impliedly preempted. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013). In *Bartlett*, as in *Mensing*, a defendant 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 labelling. The Supreme Court held 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.

Subsequent to *Mensing* and *Bartlett*, manufacturers of *brand name* pharmaceuticals have succeeded in arguing that state law failure-to-warn claims are likewise subject to "impossibility preemption", particularly where plaintiffs have not identified "newly acquired information" required for manufacturers to invoke the CBE process. *See, e.g., McGee v. Boehringer Ingelheim Pharms., Inc.*, No. 4:16-cv-2082, 2018 WL 1399237 (N.D. Ala. Mar. 20, 2018) (dismissing failure to warn claim where "the complaint at best contains ambiguity about the newly-available data that [the defendant manufacturer] had or should have had after [its drug's] approval and before [plaintiff's] injury"); *Maze v. Bayer Healthcare Pharms. Inc.*, No. 4:18-cv-21, 2019 WL 1062387 (E.D. Tenn. Mar. 6, 2019)

(dismissing claims based on failure to warn where plaintiff's "complaint cannot plausibly be read to contain any newly acquired information or even a new analyses of previously submitted data, on the basis of which [the defendant manufacturer] could have changed the [drug] label using the CBE process", and thus federal law "would not have allowed [defendant] to modify the [drug] label, which had already been approved by the FDA, in the way that plaintiffs suggest is necessary to make its stroke warning adequate"). *But see, e.g., In re Fosamax Prods. Liab. Litig.*, 852 F.3d 268, 293 (3d. Cir. 2017) (reversing district court's ruling that plaintiffs' claims were preempted due to FDA's denial of additional warnings on the drug's label, and holding that what FDA would have done had plaintiffs' requested warnings been presented to FDA was a question for the jury). The U.S. Supreme Court has granted *certiorari* in *In re Fosamax*, 138 S. Ct. 2705 (2018), and held oral arguments on January 7, 2019. Regardless of outcome, the Court's opinion will likely provide significant guidance on the scope of implied preemption of failure-to-warn claims related to pharmaceutical products.

Several noteworthy opinions have also recently addressed whether *design defect* claims are pre-empted, where defendants similarly could not unilaterally make "major changes" to pharmaceutical drug designs without FDA approval. *See, e.g., Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 298-300 (6th Cir. 2015) (claims were 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"); *Gustavsen v. Alcon Labs.*, Inc., 903 F.3d 1, 10 (1st Cir. 2018) ("federal law preempts plaintiffs' [design defect] cause of action because defendants cannot lawfully make such a [design] change without prior FDA approval"); *Robinson v. Eli Lilly & Co.*, No. 5:17-cv-338, 2018 WL 4039703, at *6 (E.D. Ky. Aug. 23, 2018) (dismissing design defect claim as preempted, because defendant "could not have independently made such fundamental changes to [its drug's] formula"). *But see, e.g., Guidry v. Janssen Pharms., Inc*., 206 F. Supp. 3d 1187, 1206-08 (E.D. La. 2016) (rejecting "the Sixth Circuit's reasoning in *Yates* concerning preemption in the *pre*-FDA approval context", because "[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").

In 2013, FDA proposed a rule that would have permitted generic drug manufacturers to change labels through the CBE process, which, as discussed in *Mensing*, is currently only available to brand-name manufacturers. If implemented, the rule change would have curtailed preemption of failure to warn claims brought against generic manufacturers, who could no longer argue the inability to independently supplement product warnings. However, the FDA withdrew the proposed rule in December 2018. Among other reasons, the Agency explained that "the new policy would have resulted in labels for the same drug that varied between different generic manufacturers", which "could have led to consumer and provider confusion". FDA Statement (Dec. 13, 2018), available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628339.htm.

Buckman Preemption

In *Buckman Co. v. Plaintiffs' Legal Comm*., the U.S. Supreme Court addressed claims that plaintiffs suffered injuries from the use of orthopaedic 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 preempted 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. Almost 20 years later, courts continue to apply *Buckman* inconsistently.

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". *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1232 (9th Cir. 2013) (*en banc*). The court distinguished *Buckman* on the ground that the plaintiff's "claim specifically alleges, as a violation of Arizona law, a failure to warn the FDA", *id.* at 1233, 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.

However, in a recent opinion, the Supreme Court of Arizona unanimously rejected the Ninth Circuit's interpretation of Arizona law. *Conklin v. Medtronic, Inc.*, 431 P.3d 571 (Ariz. 2018). Holding that failure to warn claims against the manufacturer of a medical device were impliedly preempted, the court explained that *Stengel* "was based on the unsupported premises that Arizona law contemplates a warning to a third party such as the FDA", whereas "established law does not recognise a claim merely for failing to provide something like adverse event reports … to a government agency that has no obligation to relay the information to the patient". *Id.* at 579 (internal quotations omitted). "Absent an independent state law duty to submit adverse event reports to the FDA, [plaintiff's] failure-to-warn claim, at bottom, is an attempt to enforce a federal law requirement," and is therefore preempted. *Id.* at 578. The Ninth's Circuit's decision also departs 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).

Courts have recently relied on *Buckman* to also hold that other tort claims against pharmaceutical manufacturers are impliedly preempted. For instance, in *Markland v. Insys Therapeutics, Inc.*, -- F. App'x --, 2018 WL 6666385 (11th Cir. Dec. 19, 2018), the Eleventh Circuit affirmed dismissal of plaintiff's state law claims that a pharmaceutical manufacturer "engaged in a 'fraudulent' and 'unlawful' marketing scheme to push doctors to prescribe [the drug] 'off label'". *Id.* at *1. The court explained that plaintiff "has not pointed to any traditional state-law duty owed by [defendant] to [plaintiff] that was breached by the company's marketing of [the product] for off-label use. It is only because of the FDCA and FDA enforcement decisions that the promotion of off-label uses is prohibited". *Id*. at *2. In other words, "[a]s with the *Buckman* plaintiffs, [plaintiff] seeks to enforce a duty that 'exists solely by virtue of the FDCA'". *Id*. (Quoting *Buckman*, 531 U.S. at 353.)

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 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 viable "parallel" state law claims, where PMA-approved medical devices deviate from federally-imposed, device-specific requirements, in violation of both federal and state law. *Id.* at 330.

Numerous courts have subsequently rejected plaintiffs' attempts to circumvent *Riegel*. *See, e.g., Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1340-42 (10th Cir. 2015) (rejecting 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); *Ezell v. Medtronic PLC*, No. 3:17-cv-796, 2018 WL 6928917, at *7 (W.D. La. Dec. 19, 2018) (similar); *Reed v. St. Jude Med.*, No. 17-5560, 2018 WL 4293146, at *4 (D. Minn. July 24, 2018) (similar); *Olmstead v. Bayer Corp.*, 3:17-CV-387, 2017 WL 3498696, at *4 (N.D.N.Y. Aug. 15, 2017) (dismissing plaintiff's negligent misrepresentation, strict liability, failure to warn, and breach of warranty claims because allowing a suit to continue would impose "standards that are 'different from, or in addition to' those imposed by the MDA"). Other courts, however, have diverged from these analyses and rejected arguments that claims regarding PMA devices are expressly preempted under *Riegel*. *See, e.g., Bull v. St. Jude Med., Inc.*, No. 17-1141, 2018 WL 3397544, at *8 (E.D. Pa. July 12, 2018) ("Plaintiff's state law failure to warn claim identified a state duty to warn physicians of risks inherent in its medical devices that is parallel to St. Jude's duty to comply with MDR reporting requirements …. As such, it parallels these federal requirements, and is not expressly pre-empted").

Multidistrict Litigation (MDL) Trends

The nature of product liability litigation can lead to a substantial volume of individual claims in different courts, each alleging, for instance, similar injuries arising from exposure to the same pharmaceutical product or medical device. Handling these cases on an individual basis can become unwieldy and expensive. As a result, one or both sides may support the centralisation or coordination of litigation before one judge in one court. 28 U.S.C. § 1407 provides one mechanism for doing so, allowing 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". The general purposes of an MDL are "to avoid duplication of discovery, to prevent inconsistent pretrial rulings, and to conserve the resources of the parties, their counsel and the judiciary". U.S. Judicial Panel on Multidistrict Litigation, Overview of Panel, http://www.jpml.uscourts.gov/overview-panel-0.

In 2018, there were 207 active MDLs (see, www.jpml.uscourts.gov/sites/jpml/files/JPML_Calendar_Year_Statistics-2018.pdf). By some measures, MDLs now contain more than half of all civil cases pending in federal court (*see*, www.law360.com/classaction/articles/1138928/mdls-surge-to-majority-of-entire-federal-civil-caseload). Of the 207 currently pending MDLs, 68 of them are classified as "Products Liability" litigation, the largest of any category. (*See*, www.jpml.uscourts.gov/sites/jpml/files/JPML_Calendar_Year_Statistics-2018.pdf.)

Defence and plaintiff practitioners have argued, however, that several aspects of MDLs and the manner in which they are litigated undermine their effectiveness for resolving their substantial inventory of cases. Accordingly, in November 2017, the Advisory Committee on Civil Rules formed an MDL subcommittee to consider rules to address commonly raised concerns with MDLs, including, among others, (1) their tendency to attract (and failure to weed out) meritless claims, (2) infrequent appellate review of pre-trial decisions, and (3) high pressure to engage in bellwether trials. (*See*, https://www.uscourts.gov/sites/default/files/2017-11-CivilRulesAgendaBook_0.pdf.)

Industry groups have proposed several Federal Rule revisions to the Committee, including requiring claimants to disclose preliminary evidence showing the cause and nature of the injury alleged; allowing mid-case appellate review of decisions on topics that have litigation-wide implications, such as preemption or expert testimony; requiring disclosure of plaintiffs' outside sources of funding; barring use of bellwether trials without party consent; and increasing pleading standards to discourage meritless claims. *See id.* at 469-542.

In November 2018, the Committee reported that it was "still in the information gathering phase". Meeting of the Advisory Committee on Civil Rules, 35 (Nov, 1, 2018), *available at* https://www.uscourts.gov/sites/default/files/2018-11_civil_rules_agenda_book_0.pdf. Further, the Committee has not yet determined whether "rules are necessary or whether a manual and increased education would be better alternatives". *Id*. at 35. Some Committee members have raised "skepticism about the necessity or ability to devise a specialized set of rules for MDL proceedings", recognising that MDLs require some level of "flexibility, innovation, and discretion". Meeting of the Advisory Committee on Civil Rules, 29 (Apr. 10, 2018), available at https://www.uscourts.gov/sites/default/files/2018-04-civil-rules-agenda-book.pdf. It remains to be seen whether any proposed rule changes will gain traction. Even if they do, their implementation likely remains "at least three years" away. *Id*. In the meantime, MDLs continue to have an immense impact on product manufacturers and other defendants faced with these centralised cases.

Emerging Areas of Product Liability Law

As technologies advance and change at an accelerating pace, new products entering the market are certain to become the subject of future product liability litigation. Two highly publicised developments likely to affect product liability law involve the internet of things and autonomous vehicles.

Internet of Things

The expansive and growing development of internet-connected consumer products, also known as internet of things ("IoT") devices, have prompted consumer privacy and product liability concerns arising out of alleged manufacturing and design defects. Indeed, in May 2018, the U.S. Consumer Product Safety

Commission "conduct[ed] a public hearing to receive information from all interested parties about potential safety issues and hazards associated with internet-connected consumer products", with the goal of "inform[ing] future Commission risk management work". *See* Federal Register, "The Internet of Things and Consumer Product Hazards" (Mar. 27, 2018), available at www.federalregister.gov/documents/2018/03/27/2018-06067/the-internet-of-things-and-consumer-product-hazards.

Case law has similarly begun to develop. In *Flynn v. FCA US LLC*, for instance, the Southern District of Illinois addressed class claims brought on behalf of purchasers and lessees of Chrysler vehicles, alleging design flaws in the cars' "UConnect system", an "infotainment system that allows integrated control over phone, navigation, and entertainment functions in certain vehicles". 327 F.R.D. 206, 213 (S.D. Ill. 2018). The system's "design and installation" allegedly "makes it vulnerable to hackers seeking to take remote control of one of the affected vehicles …". *Id*. Plaintiffs alleged, among other things, that defendants "concealed and suppressed information about the severity of the cybersecurity defects in the class vehicles". *Id.* at 214. Granting in part and denying in part defendants' motions for summary judgment, the court held that there was sufficient evidence "to demonstrate a genuine dispute between the parties as to whether the class vehicles have defects". *Id*. at 215. The court also granted in part plaintiffs' motion for class certification, finding that "there appears to be no difference among [state-wide] class members with respect to proving merchantability and the defectiveness of class vehicles". *Id*. at 226.

In *In re VTech Data Breach Litigation*, plaintiffs sued the manufacturer of children's learning toys that were linked to certain web-based services, after a hacker bypassed security measures, obtained customer data such as profile pictures, emails, passwords, and nicknames, and provided the data to a journalist. The journalist's story, quoted in the complaint, noted that "[VTech] left thousands of pictures of parents and kids and a year's worth of chat logs stored online in a way easily accessible to hackers". No. 15 CV 10889 (N.D. Ill.) [ECF No. 44] at 11. The court dismissed plaintiffs' initial complaint, holding that they "have not plausibly alleged a substantial risk of harm sufficient to confer standing …. Harm need not be literally certain to confer standing, but allegations of future harm based on poor data security, without allegations to support an inference that someone with potentially malicious intent will access the data, is too speculative to confer standing". *In re VTech Data Breach Litig*., No. 15 CV 10889, 2017 WL 2880102, at *4 n.5 (N.D. Ill. July 5, 2017). Plaintiffs then filed an amended complaint, which the court again dismissed for failure to plead a cognizable claim. 2018 WL 1863953 (N.D. Ill. Apr. 18, 2018).

Medical devices that use integrated autonomous software have also been the subject of recent product liability litigation. In *Ross v. St. Jude Medical, Inc.*, plaintiff brought a putative class action alleging "severe security vulnerabilities found in [defendant's] cardiac devices" designed with remote tracking capabilities. According to the complaint, "by forging, altering, or replying to previously captured transmissions to or from an implanted cardiac device, a bad actor could monitor and modify the implant". No. 2:16-cv-06564 (C.D. Cal. Aug. 26, 2016) [ECF No. 1] ¶¶ 17, 26. The case, however, was voluntarily dismissed in December 2016.

Given the quantity of IoT devices on the market and their rapid development, the number of consumer claims involving IoT devices likely will continue to grow, causing a re-examination of security, privacy, and traditional notions of product liability law.

Autonomous Vehicles

Autonomous vehicles, also known as driverless cars, have the potential to reduce traffic, increase safety, lower greenhouse gas emissions, and generate free time. Nevertheless, they also may lead to new liability risks. Indeed, high-profile product liability lawsuits have already emerged against the manufacturers of self-driving vehicles. *E.g., Nilsson v. Gen. Motors LLC*, No. 4:18-cv-471 (N.D. Cal. Jan. 22, 2018) (suing manufacturer of self-driving vehicle for negligence, where motorcycle driver was struck by vehicle in "self-driving mode"); *Sheikh v. Tesla, Inc.*, No. 5:17-cv-2193 (N.D. Cal. Apr. 19, 2017) (putative class action on behalf of purchasers and lessees of certain Tesla models, based on allegations that "Enhanced Autopilot capabilities" are "unusable and demonstrably dangerous"); "Uber, Ariz. Self-Driving Car Victim's Family Reach Deal", Law360, Mar. 30, 2018 (discussing resolution without litigation of matter involving a self-driving Uber vehicle that struck and a killed pedestrian).

In addition, developing regulations continue to address standards surrounding autonomous vehicles, with most states considering or already enacting legislation. (*See*, www.ncsl.org/research/transportation/autonomous-vehicles-self-driving-vehicles-enacted-legislation.aspx.) The National Highway and Transportation Safety Administration has also released federal guidelines for "Automated Driving Systems". State regulations and federal guidelines remain in their infancy, and will undoubtedly continue to evolve with this developing technology.

Note

This chapter has been prepared for informational purposes only and does not constitute legal advice. This information is not intended to create, and the receipt of it does not constitute, a lawyer-client relationship. Readers should not act upon this without seeking advice from professional advisers. The content therein does not reflect the views of the firm.

Daniel A. Spira
Sidley Austin LLP
One South Dearborn
Chicago, IL 60603
USA

Tel: +1 312 853 7000
Email: dspira@sidley.com
URL: www.sidley.com

DAN SPIRA, a litigation lawyer in Sidley's Chicago office, focuses his practice on the defence of product liability cases and consumer class actions. In both state and federal trial and appellate courts, Dan has represented clients in a wide array of industries, including pharmaceuticals, medical devices, nutritional supplements, food and beverages, automotives, construction products and consumer goods. In addition to first-chair jury trial experience in federal court, Dan has extensive experience managing multi-district litigation, writing and arguing successful motions at various stages of litigation, taking and defending depositions, working with medical and economic expert witnesses and managing complex discovery. Dan's track record of securing favourable judgments for his clients spans every phase of litigation, including motions to dismiss, summary judgment, class certification, trial and appeal. Dan has also advised clients through pre-litigation risk assessments, as well as regarding regulatory reporting obligations to the Consumer Product Safety Commission ("CPSC").

Teri H. Peeples
Sidley Austin LLP
787 Seventh Avenue
New York, NY 10019
USA

Tel: +1 212 839 5300
Email: tpeeples@sidley.com
URL: www.sidley.com

TERI PEEPLES practises in the Product Liability and Mass Torts group in the firm's New York office. Her practice focuses on representing clients in the life sciences industry, including pharmaceutical and medical device companies, in federal and state courts, as well as in multi-district litigation and class actions. Teri advises clients at all stages of the litigation process, but maintains an emphasis on the scientific and medical issues involved in these types of matters. This includes causation and mechanism of action, safety-related allegations and the pre-clinical and clinical development of the products at issue. Teri is critically involved in the development of the defence strategy, identification and development of expert witnesses, preparation of, taking and defending fact and expert witness depositions, arguing discovery motions in state and federal court and day-to-day case management. Teri also counsels multinational pharmaceutical and medical device companies in comprehensive FCPA risk reviews and conducts internal FCPA investigations.

SIDLEY

Sidley Austin LLP is a premier law firm with a practice highly attuned to the ever-changing international landscape. The firm has built a reputation for being an adviser for global business, with more than 2,000 lawyers in 20 offices worldwide. Sidley successfully represents clients on complex and multidisciplinary transactional, regulatory and litigation matters spanning a range of legal areas. From its offices in the commercial, financial and regulatory centres of the world, Sidley harnesses its knowledge to provide thoughtful advice for the myriad legal and business challenges that clients face.

Chapter 3

An Assessment of Analytical Tools in Product Liability Matters – Perspectives from Economics, Marketing, and Consumer Behaviour

Samid Hussain

Vildan Altuglu

Cornerstone Research

1. Introduction

The *Comcast* ruling in 2013 and U.S. case law since then raised the bar for plaintiffs to establish a causal link between their theories of liability and actual harm.[1] In particular, the ruling requires that plaintiffs show, on a common basis, that consumers suffered harm attributable to the conduct of the defendant, and that plaintiffs are capable of determining harm in a way that is consistent with the particular theory of liability offered.[2]

In product liability matters, plaintiffs typically claim that the defendant *misrepresented* the true characteristics and qualities of the products at issue (either through false claims on product labels/advertising communications, or through lack of proper disclosures/omissions). Plaintiffs then claim that, because of such misrepresentations, they did not receive the *benefit of their bargain* and overpaid for the products they purchased, and/or the purchased products *diminished in value* following disclosures of the alleged misrepresentations.[3] In these cases, plaintiffs need to show that individuals who purchased the at-issue products (1) saw the alleged misrepresentations (exposure), (2) relied on the alleged misrepresentations in making their purchase decisions (reliance), or in the case of allegedly omitted information, that the failure to disclose omitted information materially impacted their purchase decisions (materiality), and (3) as a result, buyers paid higher market prices or would have purchased a different product if they were provided with the relevant information at the time of product purchase (impact).

In the following sections, we describe and discuss strengths and weaknesses of empirical tools from the fields of marketing, consumer behaviour, and economics that are typically employed by plaintiffs and defendants in product liability litigation in addressing issues relating to *exposure, reliance, materiality,* and *impact*, including analytical tools usually employed to assess economic harm according to *overpayment* and *diminution in value* theories of harm.

2. Survey Methods

Survey methods have been heavily employed in product liability matters.[4] They are typically conducted by experts who specialise in the fields of marketing, consumer behaviour, and survey methodologies. Below we provide specific examples of the types of surveys that have been used in these matters.

Surveys Relating to Consumer Behaviour and Purchase Decisions

Research in marketing and consumer behaviour sets out a framework to assess the effects of a disclosure or omission of an alleged misrepresentation on consumers' purchase decisions. Specifically, this research indicates that consumers can vary in their purchase processes and reasons.[5] For example, some consumers may perform significant research and consider multiple information sources prior to purchasing a given product, while others may not. Furthermore, while some consumers might rely on information from the manufacturer or from the sales representatives, others might rely on information from third parties (e.g., Edmunds.com, CNET, Consumer Reports ratings, etc.), friends and family, or their own past experiences with a given brand.[6] As a result, while some purchasers of the at-issue product may have been exposed to the manufacturer's communications containing the alleged misrepresentations, others may not.

Similarly, research in consumer behaviour indicates that consumers have different preferences for different features of the same product.[7] This variation (or heterogeneity) in consumer preferences implies that certain product features may be strongly valued by some consumers, but not by others (who may prefer other product features). For example, while buyers of a specific car model may value speed and horsepower above all other features, other buyers may consider fuel economy most important. As a result, disclosure of information about specific features of a product may affect each buyer differently, and for buyers who do not consider these features important, such disclosures may not change their purchase decisions.

Given this setting, in a product liability consumer class action, a marketing expert can review industry sources and product reviews (e.g., Edmunds.com, CNET, Consumer Reports), defendants' internal marketing studies, and existing customer surveys (conducted by defendants in their normal course of business) to empirically assess the information sources and purchase factors considered by putative class members.

When these sources are not available or are inadequate, the marketing expert can also design a survey using a representative sample of buyers of the product at issue. The purpose of the survey would be to (1) uncover the sources of information consumers relied on in their purchase decisions and relative importance of these alternative sources of information, and (2) uncover the factors that consumers considered in their purchase decisions and the relative importance of each of those factors. The results of these surveys can

be used to assess whether and to what extent manufacturer advertising influenced purchasers' decisions to buy the product at issue, the reasons individuals purchased this product, and whether and to what extent the purchasers cared about the misrepresented or allegedly defective feature.

Surveys Relating to Contested Marketing Communications

Research in marketing and consumer behaviour further indicates that the interpretation of marketing communications may differ considerably across consumers.[8] As a result, consumers may take away different messages from the defendant's communications, such as advertisements and product labels. Using a representative set of the defendant's advertisements or other marketing communications, a marketing expert can design surveys to empirically assess consumers' perceptions of the main messages conveyed by the contested advertising.

A marketing expert can also design a survey to assess whether the allegedly false advertising messages were material to consumers' purchase decisions. This typically involves a survey design that includes a treatment group and a control group. Respondents in the control group are typically shown the original advertisement or label, while respondents in the test group are typically shown the same advertisement or label *without the challenged message* (or in cases where defendants allegedly omitted material information, a test group can be shown the same stimulus but *with* the message included that has allegedly been omitted in the contested advertisement or label). After reviewing the stimuli, the respondents in both groups are asked to indicate purchase intent (e.g., indicate their likelihood of purchasing the product based on a scale). If the survey design is robust, any difference in purchase intent measures across test and control groups would likely be due to test group respondents' exposure to the challenged messages. If purchase intent is not different across the two groups, the challenged messages or omitted information is unlikely to be material.

Conjoint

Recently plaintiffs' marketing and economic experts in product liability matters have increasingly proposed conjoint analysis as a method to estimate damages based on theories of harm, such as the benefit of the bargain, overpayment damages, and/or damages from the diminution in the product's value following the disclosure of an alleged misrepresentation.[9]

The use of conjoint analysis has varied across cases. In certain cases, the plaintiffs' expert opinion was limited to a proposal for a conjoint analysis, which outlined the general contours of the conjoint survey instrument without a formal implementation.[10] In other cases, the plaintiffs' expert executed the survey, conducted the conjoint analysis, and presented empirical results.[11] In such instances, these experts attempted to measure the alleged "price premium" plaintiffs paid for the at-issue product because purchasers were not aware of the alleged defect or misrepresentation at the time of purchase.

i. Definition of Conjoint

Conjoint analysis is a survey-based methodology used to analyse consumer preferences for products and product features.[12] The main premise of this methodology is that products are comprised of a multitude of features called "attributes". For example, cars have a myriad of attributes such as brand, body style, engine power, transmission type, fuel economy, and so on. The theoretical underpinning of conjoint analysis is that consumers' utility stemming from the purchase of a product is the sum of the utilities (or "part-worths") originating from each of the attributes that comprise such a product. The goal of conjoint analysis is to measure consumers' preferences for each product attribute.

A conjoint survey contains questions requiring respondents to choose among hypothetical product profiles which vary across the product attributes specified in the conjoint.[13] By examining respondents' choices, conjoint attempts to estimate respondents' stated preferences for each product attribute relative to other attributes, and the rate at which respondents are willing to trade off these attributes with each other and with price. This procedure, if done correctly, ultimately delivers estimates of respondents' willingness to pay (or WTP) for each product attribute, expressed in monetary values.[14]

ii. Challenges in the Use of Conjoint in Product Liability Cases

In the following sections, we identify the main challenges relating to the use of conjoint analysis in product liability matters. First, we explain that while conjoint analysis, if done correctly, can provide average willingness to pay estimates, it is an inappropriate method to estimate an alleged "price premium". Then, we identify the typical flaws that may affect the implementation of conjoint analysis in estimating WTP.

Conjoint Does Not Model the Supply Side of the Market and, at Best, Can Generate Willingness to Pay, Not Market Price Estimates

As we explain above, conjoint analysis was developed to estimate consumers' stated preferences for products and their attributes. There are two fundamental issues that need to be addressed in applying conjoint analysis to estimate harm in product liability matters. First, conjoint analysis reveals stated preferences of the at-issue product and not actual preferences based on actual purchase transactions of the at-issue product. Second, if done correctly, conjoint analysis can at best estimate willingness to pay and not market price. The distinction between these two concepts is crucial – willingness to pay is determined by analysing consumers' demand for a product, while market price is determined based on the interaction between demand and supply in the marketplace.

The fact that conjoint can at best measure demand and willingness to pay, and not market prices, is well established in the literature:

- *"Choice-based conjoint (CBC) surveys ... have become widely used ... to predict the demand for consumer products."*[15]
- *"WTP measures only a shift in the demand curve and not what the change in equilibrium price will be as the feature is added or enhanced."*[16]
- *"In general, the WTP measure will overstate the change in equilibrium price."*[17]

Consequently, conjoint analysis is an inherently inappropriate methodology to determine the market price of a product without an alleged defect or alleged misrepresentation. In conclusion, the results from a conjoint analysis cannot and should not be used to determine economic damages according to the benefit of plaintiffs' bargain or overpayment damages in product liability class actions.

In recent years, courts have reached contrasting conclusions when considering the validity of the conjoint analysis put forward by the plaintiffs' experts and their assumptions regarding supply-side factors. Among others, a number of recent court rulings have recognised that conjoint analysis does not account for the supply-side of the market and, therefore, cannot be reliably used to calculate damages. For example, in *Saavedra v. Eli Lilly & Co.*, the court did not certify the putative class and concluded that:

- "*[The] model looks only to the demand side of the market equation. By looking only to consumer demand while*

> *ignoring supply, Dr. Hay's [the plaintiffs' expert] method of computing damages converts the lost-expectation theory from an objective evaluation of relative fair market values to a seemingly subjective inquiry of what an average consumer wants.*"[18]

In *Morales et al. v. Kraft Foods Group, Inc., et al.* the court de-certified the class and reached the following conclusion:

- "*It is uncontested here that the conjoint analysis conducted by Bodapati [the plaintiffs' expert] did not measure the market value of the Product either with the 'natural cheese' label or without it … [T]he evidence provided by Plaintiffs about their potential willingness to pay a premium due to the use of the 'natural cheese' label is insufficient to establish a basis for calculating restitution.*"[19]

In other product liability class actions, however, courts accepted conjoint analysis. For example, in *In re MyFord Touch Consumer Litigation*, the court appears to have misunderstood accounting for supply-side factors with assuming a fixed quantity of supplied products.[20] As mentioned earlier, a conjoint cannot account for *any* supply-side factors such as costs of production or competitors' reactions, nor does it account for any of the actions that manufacturers could undertake in response to disclosure of an alleged defect instead of lowering prices, such as offering free repairs and recalls, or extending warranties.

Aggregate WTP Estimates from Conjoint Can Mask Individual Responses of No Impact or Irrational Preferences

Conjoint studies performed in product liability litigation can typically provide estimates for each respondent's preferences and willingness to pay for the product features in the survey.[21] However, in many circumstances, the plaintiffs' experts measure the loss by calculating an *average* or *median* willingness to pay measure across respondents. Even if an aggregate willingness to pay estimate may indicate that willingness to pay declines due to disclosure of an alleged defect, this may not be the case for many or most individual respondents. In particular, some consumers may not be affected by the challenged conduct because, for example, they do not attach any value to the allegedly defective feature of the product. An analysis of individual-level willingness to pay estimates can therefore demonstrate lack of common impact if, for many or most respondents, the estimated decline in willingness to pay due to the challenged conduct is zero.

Furthermore, an analysis of individual-level willingness to pay can reveal that some respondents exhibit an *increase*, rather than a decrease, in willingness to pay due to the challenged conduct, (for example, all else equal, these respondents would be willing to pay a higher price for a defective product compared to a non-defective one). Such irrational preferences would call into question the reliability of the data generated by the conjoint survey.

Selection of the Relevant Population

As explained by Dr. Shari Diamond in the *Reference Guide on Survey Research*, identifying the appropriate population is a key step for every survey.[22] In particular, it is important that the conjoint relies on a representative sample of the target population to whom conjoint results should be extrapolated. Disregarding this basic principle creates a fundamental disconnect between the plaintiffs' theory of liability and the findings presented by the expert.

Realism, Confusion, and Bias in Conjoint

For the conjoint analysis to provide reliable estimates of consumers' preferences, the conjoint survey instrument should be able to reasonably replicate the consumers' purchase decision-making process. In order to achieve this goal, certain fundamental conditions must be met. First, the product attributes included in the conjoint must contain important drivers of consumers' purchase decisions in the real world.[23] In other words, "the menus of products and their descriptions [should be] designed to realistically mimic a market experience".[24] Exclusion of salient product attributes and inclusion of attributes that consumers do not consider important in real markets creates a so-called "focusing bias", whereby the relative importance of the lesser valued attributes are increased. In such cases, the estimated valuations for these attributes are inflated.[25]

Second, the choice questions included in the survey instrument must be clear and unambiguous. Failure to meet this basic requirement undermines the validity and reliability of the data generated by the survey.[26] Third, no aspect of a survey instrument should be leading or suggestive in a way that would unduly influence respondents' responses.[27] If respondents' attention is drawn towards a particular attribute or attribute level (e.g., because the language used to describe an attribute makes it stand out from the others), the data generated by the conjoint survey may be biased.

3. Content Analysis

Plaintiffs and defendants can also perform a "content analysis" of advertising materials and other communications disseminated by the defendant in order to assess the pervasiveness and uniformity of the alleged misrepresentations in these communications. Content analysis is the systematic, objective, and quantitative analysis of the characteristics of various forms of communication (including advertising messages), and is a well-accepted methodology used by academics in various fields, including consumer research.[28]

This analysis is typically performed by two or more human coders, who are "blind" to the purpose of the project. Content analysis may also be performed by a computer-aided text analysis. In either case, the content of advertising materials and other communications are categorised according to a set of objective rules (or a coding scheme) developed by the expert prior to the coding exercise. Content analysis is suitable for expert testimony in litigation because it is replicable and has an error rate that can be measured.[29] The use of content analysis in litigation has expanded in recent years with frequent implementations in false advertising and product misrepresentation claims as well as in other areas such as defamation and securities fraud.[30] For example, the plaintiff in *Beef Products, Inc. et al. v. American Broadcasting Companies Inc. et al.*, a prominent defamation case, relied on an expert testimony, which included several content analyses that contributed to the plaintiff's causation evidence.[31]

4. Regression Methods

Regression methods can be used in product liability matters in measuring economic loss or damages. It is important to note that these approaches can estimate, at best, only an *average* effect, and do not address the question of whether a particular individual was harmed, especially in situations where there is wide dispersion in the prices paid for the at-issue products (as is the case in the automobile industry and other industries, such as consumer packaged goods and consumer electronics). Below we focus on two specific regression methods that are commonly used: "diff-in-diffs" regression models and synthetic control method; and hedonic regression models.

"Diff-in-Diffs" Regression and Synthetic Control Method

In order to assess diminished value and benefit of bargain theories, economics experts may rely on statistical analyses of market data. For example, in cases where an alleged misrepresentation is revealed to the public, an expert may analyse whether the prices of at-issue products declined in response to such information revelation through a methodology called "diff-in-diffs" or difference in differences regression.[32] This methodology requires identifying a product (or a set of products) that is similar to the at-issue product but is not affected by the alleged misrepresentation, and whose price trajectory tracks that of the at-issue product before disclosure (i.e., a "control product").[33] In order to isolate the average change in price that is due to the alleged misrepresentation from normal changes in prices that are due to unrelated reasons (e.g., macroeconomic factors, industry specific factors), one may measure the average change in price after a disclosure for both the at-issue product and the "control product", and then measure the difference across these price changes (thus, difference in differences).

A critical assumption for the diff-in-diffs methodology to yield meaningful results is that at-issue products and "control" products are similar in all ways, except for the alleged misrepresentation. In other words, the diff-in-diffs methodology requires a set of benchmark or comparison products against which to compare the at-issue product, and the methodology assumes that, but for the disclosure, the price of the product at issue would have evolved the same way as the benchmark products.

In many circumstances, it may be hard or impossible to find suitable benchmark products or to fully account for all of the differences between the product at issue and the benchmark products. In these cases, experts can resort to another method closely related to diff-in-diffs, called the "synthetic control" method.[34] The main difference between the synthetic control method and the diff-in-diffs method is that the benchmark product is not just one product but a basket of products. In other words, this method attempts to find the mix of benchmark products that most closely approximates the product at issue (in terms of price and other characteristics) prior to the event or disclosure at issue.

Again, it's important to note that these approaches, if done correctly, only estimate an average effect and cannot answer the question of whether a particular individual was harmed by the challenged conduct.

Hedonic Regression

Hedonic regression methodology is based on the premise that a product is made of a multitude of attributes or features, and each of these features contributes to customers' overall utility for a product. Hedonic regression uses econometrics techniques to determine the price premium or discount determined by the attributes or features of the product at issue.[35] Hedonic regression relies on actual sales data and product features and exploits the variation in products' market prices and actual features to estimate how the presence or absence of these features adds to or subtracts from the market price of a product.

In the context of product liability matters, there are several challenges in using hedonic regression methods to estimate benefit of the bargain or overpayment damages, and/or damages from the alleged diminution in the product's value. For example, one needs to carefully consider and decide which product features to include since many products have a large number of features. If one or more critical features are omitted, hedonic regression models have been found to generate estimates that are biased and unreliable.[36]

In addition, in many settings, it may not be possible to estimate a hedonic regression due to market data limitations. Specifically, in cases where the available market data does not offer sufficient variation to allow the model to isolate the value of product features, use of hedonic regression is not feasible. Further, similar to the diff-in-diffs regression methodology, hedonic regression can, at best, if implemented correctly, identify an *average* value associated with the specific product feature. Thus, use of hedonic regression models in the context of a consumer class action or cases where is there is significant heterogeneity in the circumstances of buyers and sellers is challenging, because such models cannot be used to calculate the amount each individual overpaid due to the challenged conduct. Lastly, in certain product liability matters, there is no specific product feature that can be used to isolate the alleged defect. In such cases, damages estimation based on a hedonic regression model cannot be tied with the theory of harm and would fail to meet the requirements set forth by the *Comcast* ruling. In conclusion, hedonic regression methodology is sensitive to modelling assumptions and specifications. Consequently, one needs to carefully consider the context these models are applied to, integrity of the market data, and the model specifications.

Endnotes

1. *See*, for example, Order Denying Motion for Class Certification, *Davidson et al. v. Apple, Inc.*, United States District Court for the Northern District of California, No. 16-CV-04942-LHK, May 7, 2018, pp. 19–20; Order Denying Plaintiffs' Amended Motion for Class Certification, *In re NJOY, Inc. Consumer Class Action Litigation*, United States District Court for the Central District of California, No. CV 14-428-JFW, February 2, 2016, pp. 6–8.
2. At the class-certification stage, "any model supporting a plaintiff's damages case must be consistent with its liability case . . . [and] courts must conduct a rigorous analysis to determine whether that is so". *Comcast Corp. et al. v. Behrend et al.*, 133 S. Ct. 1426, 1433 (2013).
3. *See*, for example, Fourth Amended Class Action Complaint, *Davidson et al. v. Apple, Inc.*, United States District Court for the Northern District of California, No. 5:16-cv-4942-LHK, January 3, 2018, ¶ 165; Second Amended Class Action Complaint, *Elizabeth Callaway et al. v. Mercedes-Benz, LLC*, United States District Court for the Central District of California, No. 8:14-cv-02011 JVS, June 8, 2015, ¶¶ 17, 53–54; Amended Class Action Complaint, *Flynn et al. v. FCA US LLC et al.*, United States District Court for the Southern District of Illinois, No. 3:15-cv-855, December 22, 2015, ¶¶ 72–74; Second Amended Consolidated Class Action Complaint, *In Re Chrysler-Dodge-Jeep Ecodiesel® Marketing, Sales Practices and Products Liability Litigation*, United States District Court for the Northern District of California San Francisco Division, No. 3:17-md-02777-EMC, May 16, 2018, ¶¶ 255–257; Third Amended Class Action Complaint, *In re MyFord Touch Consumer Litigation,* United States District Court for the Northern District of California San Francisco Division, No. 13-cv-3072-EMC, October 13, 2015, ¶¶ 323, 359, 373; First Amended Class Action Complaint for Damages, *Oula Zakaria v. Gerber Products Co.,* United States District Court for the Northern District of California, No. 2:15-cv-0200-JAK, February 27, 2015, ¶ 91.
4. Diamond, S. S. (2011), "Reference Guide on Survey Research", in *Reference Manual on Scientific Evidence 3rd Edition*, Washington, DC: The National Academies Press, 359–424 at p. 366.

5. Peter, J. P., and J. C. Olson (2010), "Affect and Cognition and Marketing Strategy", in *Consumer Behavior and Marketing Strategy*, New York, NY: McGraw-Hill, 36–65.
6. Peter, J. P., and J. C. Olson (2010), "Affect and Cognition and Marketing Strategy", in *Consumer Behavior and Marketing Strategy*, New York: McGraw-Hill, 36–65.
7. Winer, R. S., and R. Dhar (2011), "Analyzing Consumer Behavior", in *Marketing Management*, Upper Saddle River, NJ: Pearson Education, Inc., 87–123.
8. *See*, for example, Mitchell, A. and J. Olson (1981), "Are Product Attribute Beliefs the Only Mediator of Advertising Effects on Brand Attitude?" *Journal of Marketing Research* 18, no. 3, 318–332; Mackenzie, S. (1986), "The Role of Attention in Mediating the Effect of Advertising on Attribute Importance", *Journal of Consumer Research* 13, no. 2, 174–195; Krishnamurthi, L. and S.P. Raj (1985), "The Effect of Advertising on Consumer Price Sensitivity", *Journal of Marketing Research* 22, no. 2, 119–129; Ford, G., D. Smith, and J. Swasy (1990), "Consumer Skepticism of Advertising Claims: Testing Hypotheses from Economics of Information", *Journal of Consumer Research* 16, no. 4, 433–441.
9. *See*, for example, conjoint analysis has been proposed or implemented in recent product liability class actions in the auto industry (*In re GM Ignition Switch MDL Litigation*, *In re FCA EcoDiesel Litigation*, *Callaway et al. v. Mercedes-Benz*, *In re MyFord Touch Consumer Litigation*, and *Flynn v. FCA US LLC*), in the food industry (*Oula Zakaria v. Gerber Products Co.* and *Morales v. Kraft Foods Group Inc.*), and in the consumer electronics industry (*Davidson v. Apple Inc.*).
10. *See*, for example, Order Granting in part and Denying in part Defendants' Motions for Summary Judgement and Plaintiffs' Motion to Certify Class, *Flynn v. FCA US LLC*, United States District Court for the Southern District of Illinois, No. 15-CV-0855-MJR-DGW, July 5, 2018.
11. For example, in the case *Morales v. Kraft Foods Group Inc.*, the plaintiff expert proposed a conjoint analysis during the class certification stage and implemented the conjoint analysis after class certification was granted. (In Chambers) Order Re Plaintiff's Motion for Class Certification (DKT. 47), *Claudia Morales, et al. v. Kraft Foods Group., Inc., et al.*, United States District Court for the Central District for California, No. LACV1404387JAKPJWX, June 23, 2015; (In Chambers) Order Re Defendant's Motion to Exclude Plaintiff's Survey and Expert Testimony of Dr. Anand V. Bodapati (Redacted DKT. 284, Unsealed DKT. 297); Defendants' Motion for Decertification (Redacted DKT. 285, Unsealed DKT. 294); Defendants' Motion for Partial Summary Judgement (Redacted DKT. 286, Unsealed DKT. 295), *Claudia Morales, et al. v. Kraft Foods Group., Inc., et al.*, United States District Court for the Central District of California, No.LACV1404387JAKPJWX, June 9, 2017. Ultimately, the Court decertified the class in this case.
12. Rao, V. R., *Applied Conjoint Analysis*, New York, NY: Springer.
13. This form of conjoint analysis is known as Choice-Based Conjoint (or CBC).
14. Ben-Akiva, M., D. McFadden, and K. Train (2018), Working Paper, "*Foundations of Stated Preference Elicitation – Consumer Behavior and Choice Based Conjoint Analysis*", 1–144 at pp. 92–93.
15. Ben-Akiva, M., D. McFadden, and K. Train (2018), Working Paper, "*Foundations of Stated Preference Elicitation – Consumer Behavior and Choice Based Conjoint Analysis*", 1–144 at p. 9.
16. Allenby, G., J. Brazell, J. Howell, and P. Rossi (2013), "Using Conjoint Analysis to Determine the Market Value of Product Features", *Proceedings of the Sawtooth Software Conference*, October 2013, p. 342.
17. Allenby, G., J. Brazell, J. Howell, and P. Rossi (2013), "Using Conjoint Analysis to Determine the Market Value of Product Features", *Proceedings of the Sawtooth Software Conference*, October 2013, p. 342.
18. Order Denying Plaintiffs' Motions for Class Certification Pursuant to federal Rules of Civil Procedure 23(b)(3) or 23(c)(4) [73,74], *Saavedra v. Eli Lilly & Co.*, United States District Court for the Central District of California, No. 2:12-CV-9366-SVW, Dec. 18, 2014, p. 5.
19. (In Chambers) Order Re Defendant's Motion to Exclude Plaintiff's Survey and Expert Testimony of Dr. Anand V. Bodapati (Redacted DKT. 284, Unsealed DKT. 297); Defendants' Motion for Decertification (Redacted DKT. 285, Unsealed DKT. 294); Defendants' Motion for Partial Summary Judgement (Redacted DKT. 286, Unsealed DKT. 295), *Claudia Morales, et al. v. Kraft Foods Group., Inc., et al.*, United States District Court for the Central District of California, No. LACV1404387JAKPJWX, June 9, 2017, pp. 28-29.
20. Order Granting in Part and Denying in Part Defendant's Motion for Summary Judgement, *In re MyFord Touch Consumer Litigation*, United States District Court for the Northern District of California, Case No. 13-cv-03072-EMC, February 14, 2018.
21. For example, "Choice-Based Conjoint" is a popular type of conjoint that can estimate individual-level preferences and willingness to pay. Rao, V. R., *Applied Conjoint Analysis*, New York, NY: Springer, pp. 127–183.
22. "One of the first steps in designing a survey or in deciding whether an existing survey is relevant is to identify the target population (or universe). The target population consists of all elements (i.e., individuals or other units) whose characteristics or perceptions the survey is intended to represent." Diamond, S. S. (2011), "Reference Guide on Survey Research", in *Reference Manual on Scientific Evidence 3rd Edition*, Washington, DC: The National Academies Press, 359–424 at p. 376.
23. "[S]election of attributes and levels is a very crucial step in the design of conjoint studies … The scientific aspects arise from an understanding of the consumer's choice process, more specifically salient attributes involved in the choice of an alternative by a majority of target consumers." Rao, V. R., *Applied Conjoint Analysis*, New York, NY: Springer, p. 43.
24. Ben-Akiva, M., D. McFadden, and K. Train (2018), Working Paper, "*Foundations of Stated Preference Elicitation – Consumer Behavior and Choice Based Conjoint Analysis*", 1–144 at p. 11.
25. *See*, for example, Schkade, D. A. and D. Kahneman (1998), "Does Living in California Make People Happy? A Focusing Illusion in Judgments of Life Satisfaction", *Psychological Science*, 9, 340–346; Kahneman, D., *et al*. (2006), "Would You Be Happier If You Were Richer? A Focusing Illusion", *Science*, 312, 1908–1910.
26. Dr. Shari Diamond's *Reference Guide on Survey Research* states that: "When unclear questions are included in a survey, they may threaten the validity of the survey by systematically distorting responses if respondents are misled in a particular direction, or by inflating random error if respondents guess because they do not understand the question. If the crucial question is sufficiently ambiguous or unclear, it may be the basis for rejecting the survey." Diamond, S. S. (2011), "Reference Guide on Survey Research", in *Reference Manual on Scientific Evidence 3rd Edition*, Washington, DC: The National Academies Press, 359–424 at p. 388.
27. "[T]he wording of a question … can be leading or non-leading, and the degree of suggestiveness of each question must be considered in evaluating the objectivity of a survey." Diamond, S. S. (2011), "Reference Guide on Survey

Research", in *Reference Manual on Scientific Evidence*, 359–424 at p. 393. "[I]n assessing the validity of a survey, the judge should take into account the following factors: whether the questions asked were … not leading." Federal Judicial Center (2004), *Manual for Complex Litigation, Fourth Edition*, S. Marcus *et al*. eds., Washington, DC: Federal Judicial Center, p. 103.

28. Neuendorf, K. (2016), *The Content Analysis Guidebook*, Second Edition, Los Angeles, CA: Sage Publications, pp. 1–3; Gross, B. L., and J. N. Sheth (1989), "Time-Oriented Advertising: A Content Analysis of United States Magazine Advertising, 1890-1988", *Journal of Marketing* 53, no. 4, 76–83.
29. Tichy, L.K. and A. Shakotko, "Litigators, Wrangle That Data With Content Analysis", *Law360*, (November 2017).
30. Tichy, L.K. and A. Shakotko, "Litigators, Wrangle That Data With Content Analysis", *Law360*, (November 2017).
31. Tichy, L.K. and A. Shakotko, "Litigators, Wrangle That Data With Content Analysis", *Law360*, (November 2017); *Beef Products Inc. v. American Broadcasting Companies Inc.*, No. 12-cv-292, South Dakota Circuit Court, First Circuit, Union County.
32. *See*, for example, Woolridge, J.M., *Introductory Econometrics: A Modern Approach*, Fourth Edition, Mason, OH; South-Western Cengage Learning, at pp. 450–454.
33. Abadie, A., A. Diamond and J. Hainmueller (2010), "Synthetic Control Methods for Comparative Case Studies: Estimating the Effect of California's Tobacco Control Program", *Journal of the American Statistical Association* 105, no. 490, 493–505 at p. 493. *See also*, Card, D. and A. B. Krueger (1994), "Minimum Wages and Employment: A Case Study of the Fast-Food Industry in New Jersey and Pennsylvania", *The American Economic Review* 84, no. 4, 772–793.
34. Abadie, A., A. Diamond and J. Hainmueller (2010), "Synthetic Control Methods for Comparative Case Studies: Estimating the Effect of California's Tobacco Control Program", *Journal of the American Statistical Association* 105, no. 490 493–505.
35. *See*, for example, de Haan, J. and E. Diewert (2013), "Hedonic Regression Methods", in OECD, *et al., Handbook on Residential Property Price Indices*, Eurostat, Luxembourg.
36. Greene, W. H. (2012), *Econometric Analysis*, Seventh Edition, New Jersey: Pearson, pp. 96–97; de Haan, J. and E. Diewert (2013), "Hedonic Regression Methods", in OECD, *et al., Handbook on Residential Property Price Indices*, Eurostat, Luxembourg, p. 51.

Note

The views expressed in this chapter are solely those of the authors, who are responsible for the content, and do not necessarily represent the views of Cornerstone Research.

Samid Hussain, Ph.D.
Cornerstone Research
599 Lexington Avenue
40th Floor
New York, NY 10022-7642
USA

Tel: +1 212 605 5320
Email: shussain@cornerstone.com
URL: www.cornerstone.com

Samid Hussain heads the consumer fraud and product liability practice at Cornerstone Research. He specialises in analysing economic, marketing, and statistical (econometrics) issues in competition, consumer fraud, product liability, data privacy & breach, antitrust, life sciences & healthcare, breach of contract, and intellectual property matters. Dr. Hussain consults on economic and marketing issues related to class actions, including liability, class certification, and damages. He has also conducted and applied survey analyses in complex market settings. Dr. Hussain has experience in a variety of industries, including automobiles, high technology, oil and gas, airlines, telecommunications, food & beverage, genetically modified crops, and herbicides. He has published articles on class certification and damages issues and taught courses as a visiting lecturer at Stanford University and instructor at Cornell University.

Vildan Altuglu, Ph.D.
Cornerstone Research
599 Lexington Avenue
40th Floor
New York, NY 10022-7642
USA

Tel: +1 212 605 5006
Email: valtuglu@cornerstone.com
URL: www.cornerstone.com

Vildan Altuglu applies economic analysis and marketing research techniques to matters involving product liability, product misrepresentation, false advertising, antitrust, intellectual property, and general business litigation. She is a leader of the firm's consumer fraud and product liability practice. Dr. Altuglu has expertise addressing class certification and liability issues using economic, marketing, and consumer behaviour data. She has experience in cases involving data breaches and allegations of unauthorised access to personally identifying data. Dr. Altuglu's industry experience includes automobiles, consumer financial products, consumer packaged goods, technology products, and pharmaceuticals.

Additional Authors

Matteo Li Bergolis, Ph.D. mlibergolis@cornerstone.com

Matteo Li Bergolis focuses on economic, marketing, and statistical matters related to product liability, data privacy, and antitrust litigation. Dr. Li Bergolis has expertise applying sophisticated econometric analyses and survey methods to assess class certification, liability, and damages issues. Dr. Li Bergolis has led teams supporting experts in several high-profile cases involving allegations of product defect, false advertising, data privacy violation, and price fixing.

Andrea Cardani, M.B.A. acardani@cornerstone.com

Andrea Cardani has over a decade of experience providing economic and financial analysis and expert support in all phases of commercial litigation. Mr. Cardani specialises in international arbitration cases involving valuation and damages and in class certification issues related to consumer fraud and product liability. Mr. Cardani's industry experience includes agriculture, automotive, computer software, consumer products, energy, financial markets and services, mining, oil and gas, pharmaceuticals, real estate, semiconductors, and transportation services. He was retained as a testifying expert in a high-stakes ICC arbitration related to an oil project in Central America.

CORNERSTONE RESEARCH

Cornerstone Research provides economic and financial consulting and expert testimony in all phases of complex litigation and regulatory proceedings. The firm works with an extensive network of prominent faculty and industry practitioners to identify the best-qualified expert for each assignment. Cornerstone Research has earned a reputation for consistent high quality and effectiveness by delivering rigorous, state-of-the-art analysis for 30 years. The firm has 700 staff and offices in Boston, Chicago, London, Los Angeles, New York, San Francisco, Silicon Valley, and Washington.

The Refinement of Regulatory and Liability Issues Concerning Autonomous Motor Vehicles

Francis P. Manchisi

Ernest V. Goodwin

Wilson, Elser, Moskowitz, Edelman & Dicker LLP

The autonomous motor vehicle industry is growing exponentially. The automotive industry, manufacturers and governments are continuing to refine the development and implementation of autonomous motor vehicles to maximise efficiency and safety. While these technological advancements will offer numerous benefits, they will also expose manufacturers, distributors, and insurers to new and potentially greater product liability risks. It is likely that these advancements will reshape motor vehicle liability jurisprudence and the insurance industry. Moreover, any problems with the operation of autonomous motor vehicles will be subjected to increased public and media scrutiny. Accordingly, it is vital to ensure that the implementation of autonomous motor vehicles is efficient, safe, and as seamless as possible. This chapter discusses the regulation, innovation, risk, and implementation of autonomous motor vehicles.

Current iterations of motor vehicles continue to be increasingly safer than their predecessors. Even with the incorporation of seat belts, airbags, mirrors, indicator lights, all-wheel drive, anti-lock brakes, children's car seats, Bluetooth, power steering, and other features that now are taken for granted, there are still a large number of motor vehicle accidents every year. In 2017, motor vehicle accidents were responsible for the deaths of 37,133 people in the United States. *See Automated Vehicles 3.0 – Preparing for the Future of Transportation*, U.S. Department of Transportation and NHTSA (October 2018) (https://www.transportation.gov/sites/dot.gov/files/docs/policy-initiatives/automated-vehicles/320711/preparing-future-transportation-automated-vehicle-30.pdf). Of all serious motor vehicle crashes, 94 per cent involve driver-related factors, such as impaired driving, distraction, and speeding or illegal manoeuvres. *See Automated Vehicles 3.0 – Preparing for the Future of Transportation*, U.S. Department of Transportation and NHTSA (October 2018) (https://www.transportation.gov/sites/dot.gov/files/docs/policy-initiatives/automated-vehicles/320711/preparing-future-transportation-automated-vehicle-30.pdf). In 2017, nearly 11,000 fatalities involved drinking and driving. *See Automated Vehicles 3.0 – Preparing for the Future of Transportation*, U.S. Department of Transportation and NHTSA (October 2018) (https://www.transportation.gov/sites/dot.gov/files/docs/policy-initiatives/automated-vehicles/320711/preparing-future-transportation-automated-vehicle-30.pdf). Speeding was a factor in nearly 10,000 highway fatalities. Nearly 3,500 fatal crashes involve distracted drivers. 5,977 pedestrians were killed by motor vehicles in 2017. *See Automated Vehicles 3.0 – Preparing for the Future of Transportation*, U.S. Department of Transportation and NHTSA (October 2018) (https://www.transportation.gov/sites/dot.gov/files/docs/policy-initiatives/automated-vehicles/320711/preparing-future-transportation-automated-vehicle-30.pdf).

Autonomous vehicles that accurately detect, recognise, anticipate, and respond to the movements of all transportation users can lead to breakthrough gains in transportation safety. Unlike human drivers, autonomous motor vehicles are not prone to distraction, fatigue, or impaired driving, which contribute to a significant portion of transportation fatalities. Autonomous motor vehicle technologies that are integrated carefully into motor vehicles can help vehicle operators detect and avoid other vehicles, motorcyclists, pedestrians, bicyclists, and other vulnerable users on roadways, thereby increasing safety across the transportation system. Fully realising the life-saving potential of autonomous motor vehicles, however, will require careful risk management as new technologies are introduced and adopted across the transportation system.

Legislative Issues

Federal and State Framework

The traditional roles of the federal government, state, and local governments, and private industry are theoretically well-suited for addressing autonomous motor vehicles. The federal government is responsible for regulating the safety performance of vehicles and vehicle equipment, and commercial operation in interstate commerce. States and local governments regulate the licensing of drivers, establishing rules of the road, and formulating policy in tort liability and insurance. Private industry is the primary source of transportation research investment and commercial technology development.

The United States' unique legal and legislative framework, however, is still an issue that the full implementation of autonomous motor vehicles needs to navigate. The U.S. system comprises 50 states, each 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 in 2016, and revised sets in 2017 and 2018. NHTSA hopes that they bring more uniformity to the manufacture of autonomous vehicles and has stated that it will liaise with foreign agencies to foster development and innovation.

Some state governments have enacted permissive regulations for autonomous motor vehicles to encourage technology and motor vehicle companies to create testing programmes within their states. Since 2012, at least 41 states and Washington, D.C. have considered

legislation related to autonomous motor vehicles. Twenty-nine states – Alabama, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Maine, Michigan, Mississippi, Nebraska, New York, Nevada, North Carolina, North Dakota, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Vermont, Washington and Wisconsin – and Washington D.C. have enacted legislation related to autonomous motor vehicles. *See Autonomous Vehicles – Self-Driving Vehicles Enacted Legislation*, National Conference of State Legislatures (March 19, 2019) (http://www.ncsl.org/research/transportation/autonomous-vehicles-self-driving-vehicles-enacted-legislation.aspx). Moreover, governors in Arizona, Delaware, Hawaii, Idaho, Illinois, Maine, Massachusetts, Minnesota, Ohio, Washington, and Wisconsin have issued executive orders related to autonomous motor vehicles. These laws vary in scope from comparatively wide-open schemes in Arizona to stricter laws in Nevada, a state that requires two operators in an autonomous vehicle during a test on public roads.

NHTSA – Automated Vehicles 3.0 – Preparing for the Future of Transportation

In October 2018, the National Highway Traffic Safety Administration ("NHTSA") released a new version of its guidance for autonomous motor vehicles in the United States. *See Automated Vehicles 3.0 – Preparing for the Future of Transportation*, U.S. Department of Transportation and NHTSA (October 2018) (https://www.transportation.gov/sites/dot.gov/files/docs/policy-initiatives/automated-vehicles/320711/preparing-future-transportation-automated-vehicle-30.pdf). The Federal guidance for autonomous motor vehicles advances the U.S. Department of Transportation's commitment to supporting the safe integration of automation into the broad multimodal surface transportation system. "Preparing for the Future of Transportation 3.0" builds upon, but does not replace, the voluntary guidance provided by the U.S. Department of Transportation in "Automated Driving Systems 2.0: A Vision for Safety". *See Automated Driving Systems – A Vision for Safety 2.0*, U.S. Department of Transportation and NHTSA (September 2017) (https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/13069a-ads2.0_090617_v9a_tag.pdf). In "A Vision for Safety 2.0", Elaine Chao, the Secretary of the Department of Transportation ("DOT"), noted five times in her one page executive summary that it was only "voluntary guidance".

"A Vision for Safety 2.0" called for industry, state and local governments, safety and mobility advocates, and the public to assist with the deployment of autonomous motor vehicles and technologies. The DOT notes that the new policy builds on the previous policy and incorporates feedback received through public comments and congressional hearings. The DOT states that the new policy "paves the way for the safe deployment of advanced driver assistance technologies by providing voluntary guidance that encourages best practices and prioritises safety". *See U.S. DOT releases new Automated Driving Systems guidance*, United States Department of Transportation – NHTSA, (September 12, 2017) (https://www.nhtsa.gov/press-releases/us-dot-releases-new-automated-driving-systems-guidance).

"Preparing for the Future of Transportation: Automated Vehicles 3.0" incorporates the results of stakeholder engagement to provide updated voluntary guidance and policy considerations for a range of industry sectors, including manufacturers, technology developers, infrastructure owners and operators, commercial motor carriers, bus transit, and state and local governments.

The guidance supports the safe development of autonomous motor vehicles by:

- Affirming the approach outlined in *A Vision for Safety 2.0* and encourages automated driving system developers to make their Voluntary Self-Assessments public to increase transparency and confidence in the technology.
- Provides considerations and best practices for state and local governments to support the safe and effective testing and operation of automation technologies.
- Supports the development of voluntary technical standards and approaches as an effective non-regulatory means to advance the integration of automation technologies into the transportation system.
- Describes an illustrative framework of safety risk management states along the path to full commercial integration of automated vehicles. This framework promotes the benefits of safe deployment while managing risk and provides clarity to the public regarding the distinctions between various stages of testing and full deployment.
- Reducing policy uncertainty and clarifying roles.
- Outlining a process for working with DOT as technology evolves.

The new guidance provides several updates to the DOT's initiatives relating to autonomous motor vehicles by:

- Stating that the DOT will interpret and adapt the definitions of "driver" and "operator" as appropriate to recognise that such terms do not refer exclusively to a human, but may include an automated system.
- Recognising that given the rapid increase in automated vehicle testing activities in many locations, there is no need for DOT to favour particular locations or to pick winners and losers. Therefore, the DOT no longer recognises the designations of 10 Automated Vehicle Proving Grounds.
- Urging states and localities to work to remove barriers – such as unnecessary and incompatible regulations – to autonomous vehicle technologies and to support interoperability.
- Affirming DOT's authority to establish motor vehicle safety standards that allow for innovative autonomous vehicle designs – such as vehicles without steering wheels, pedals, or mirrors – and notes that such an approach may require a more fundamental revamping of the NHTSA approach to safety standards for application to autonomous vehicles.
- Reaffirming DOT's reliance on a self-certification approach, rather than type approval, as the way to balance and promote safety and innovation.
- Clarifying that rather than requiring a one-size-fits-all approach, the Federal Transit Administration will provide transit agencies with tailored technical assistance as they develop an appropriate safety management system approach to ensuring safe testing and deployment of automated transit bus systems.
- Announcing a study of the workforce impacts of autonomous motor vehicles, in collaboration with DOT, U.S. Department of Labor, U.S. Department of Commerce, and the U.S. Department of Health and Human Services.

"Preparing for the Future of Transportation: Automated Vehicles 3.0" also announced several rulemakings and other actions being taken in the future by the DOT's operating administrations, including:

1. The NHTSA will request public comment on a proposal to streamline and modernise the procedures it will follow when processing and deciding exemption petitions.

2. The Federal Motor Carrier Safety Administration will initiate an Advance Notice of Proposed Rulemaking to address automated vehicles, particularly to identify regulatory gaps, including in the areas of inspection, repair, and maintenance for autonomous driving systems.
3. The Federal Highway Administration plans to update the 2009 Manual on Uniform Traffic Control Devices, taking into consideration new connected and automated vehicle technologies.
4. The Federal Railroad Administration is initiating research to develop and demonstrate a concept of operations, including system requirements, for the use of automated and connected vehicles to improve safety of highway-rail crossings.
5. The Maritime Administration and FMCSA are evaluating the regulatory and economic feasibility of using automated truck queueing as a technology solution to truck staging, access, and parking issues at ports.
6. The Pipelines and Hazardous Materials Administration is researching the ability to enable the digital transmission of information to first responders before they arrive at an incident that involves hazardous materials.
7. The Federal Transit Administration has published a five-year research plan on automating bus transit.

In a notable part of its most recent guidance, the DOT stated that through NHTSA, it intends to reconsider the necessity and appropriateness of its current safety standards as applied to autonomous motor vehicles. *See Automated Vehicles 3.0 – Preparing for the Future of Transportation*, U.S. Department of Transportation and NHTSA (October 2018) (https://www.transportation.gov/sites/dot.gov/files/docs/policy-initiatives/automated-vehicles/320711/preparing-future-transportation-automated-vehicle-30.pdf). NHTSA is considering changes to particular safety standards to accommodate autonomous motor vehicle technologies and the possibility of setting exceptions to certain standards – that are relevant only when human drivers are present – or autonomous motor vehicles. Going forward, NHTSA may also consider a more fundamental revamping of its approach to safety standards for application to autonomous motor vehicles. *See Automated Vehicles 3.0 – Preparing for the Future of Transportation*, U.S. Department of Transportation and NHTSA (October 2018) (https://www.transportation.gov/sites/dot.gov/files/docs/policy-initiatives/automated-vehicles/320711/preparing-future-transportation-automated-vehicle-30.pdf). The DOT believes that reliance on a self-certification approach, instead of type approval, more appropriately balances and promotes safety and innovation. *See Automated Vehicles 3.0 – Preparing for the Future of Transportation*, U.S. Department of Transportation and NHTSA (October 2018) (https://www.transportation.gov/sites/dot.gov/files/docs/policy-initiatives/automated-vehicles/320711/preparing-future-transportation-automated-vehicle-30.pdf). Notably, the DOT notes that it "will continue to advance this approach with the international community". *See Automated Vehicles 3.0 – Preparing for the Future of Transportation*, U.S. Department of Transportation and NHTSA (October 2018) (https://www.transportation.gov/sites/dot.gov/files/docs/policy-initiatives/automated-vehicles/320711/preparing-future-transportation-automated-vehicle-30.pdf).

NHTSA's current statutory authority to establish motor vehicle safety standards is sufficiently flexible to accommodate the design and performance of different autonomous motor vehicle concepts in new vehicle configurations. NHTSA correctly recognises that the accelerating pace of technological change, especially in the development of software used in autonomous motor vehicles, likely requires a new approach to the formulation of the Federal Motor Vehicle Safety Standards. The pace of innovation in autonomous motor vehicle technologies is incompatible with lengthy rulemaking proceedings and highly prescriptive and feature-specific or design-specific safety standards. Future motor vehicle safety standards will arguably need to be more flexible and responsive, technology-neutral, and performance-oriented to accommodate rapid technological innovation. They may incorporate simpler and more general requirements designed to validate that an autonomous motor vehicle can safely navigate the real-world roadway environment, including unpredictable hazards, obstacles, and interactions with other vehicles and pedestrians who may not always adhere to the traffic laws or follow expected patterns of behaviour.

Best Practices for State and Local Governments

State and local governments hold clearly defined roles in ensuring the safety and mobility of road users in their jurisdictions. They are responsible for licensing human drivers, registering motor vehicles, enacting and enforcing traffic laws, conducting safety inspections, and regulating motor vehicle insurance and liability. They are also responsible for planning, building, managing, and operating transit and the roadway infrastructure. Many of those roles may not change significantly with the deployment of autonomous motor vehicles. There are many ways these governments can prepare for automated vehicles. They can review laws and regulations that may create barriers to testing and deploying autonomous motor vehicles. They can also adapt policies and procedures, such as licensing and registration, to account for autonomous motor vehicles. State and local governments can also assess infrastructure elements, such as road markings and signage, so that they are conducive to the operation of autonomous motor vehicles. They can provide guidance, information, and training to prepare the transportation workforce and the general public.

State legislatures should engage the DOT on legislative technical assistance. Unnecessary or overly prescriptive state requirements could create unintended barriers for the testing, deployment, and operations of advanced vehicle safety technologies. They should also adopt terminology defined through voluntary technical standards. State legislatures should use terminology already being developed through voluntary, consensus-based, technical standards.

States should assess roadway readiness for autonomous motor vehicles. These assessments could help infrastructure for autonomous motor vehicles, while improving safety for drivers in motor vehicles that do not currently have autonomous features. Autonomous motor vehicle developers are designing their technologies with the assumption that these technologies will need to function with existing infrastructure. There is general agreement that greater uniformity and quality of road markings, signage, and pavement condition would be beneficial for both human drivers and autonomous motor vehicles.

States should also consider minimum requirements for test drivers who operate test vehicles at different automation levels. States should coordinate and collaborate with a broad and diverse set of stakeholders when developing and defining jurisdictional guidelines for safe testing and deployment of autonomous motor vehicles.

Infrastructure owners and operators should: support safe testing and operations of autonomous motor vehicles on public roadways; learn from testing and pilots to support highway system readiness; and identify data and opportunities to exchange data.

Local governments control a substantial part of the United States' roads and parking infrastructure. They also have substantial control and/or influence over land use via zoning and permitting. In the

process of implementing the use of autonomous motor vehicles, local governments should: facilitate safe testing and operation of autonomous motor vehicles on local streets; understand the opportunities that autonomous motor vehicles provide; consider how land use, including curb space and parking spaces will be affected; and engage with citizens regarding the implementation of autonomous motor vehicles.

States and local governments must similarly be concerned with prioritising digital infrastructure and cyber security. To mitigate against potential cyber security threats, state and local governments should have an effective and flexible security programme in place to assess and manage risk, including evaluating technology, key facilities, engaged personnel, and security processes.

Private Sector

In *Automated Vehicles 3.0 – Preparing for the Future of Transportation*, the DOT places a lot of responsibility for the innovation and implementation of autonomous motor vehicles with the private sector. Accordingly, the private sector is critical to advancing the development, testing, and commercialisation of autonomous motor vehicles. In addition to developing and commercialising automation technology, the private sector also should play a critical role in promoting consumer acceptance in two distinct ways. First, companies developing and deploying automation technology need to be transparent about vehicle safety performance. Second, companies should engage with consumers through public education campaigns. The exchange of information between the public and private sector is also critical for helping policymakers understand the capabilities and limitations of these new technologies, while ensuring that the private sector understands the priorities of policymakers and the issues they face.

A Vision for Safety 2.0 provided voluntary guidance to stakeholders regarding the design, testing, and safe deployment of autonomous motor vehicles. It identified 12 safety elements that autonomous motor vehicles should consider when developing and testing their technologies: 1) system safety; 2) operational design domain; 3) object and event detection and response; 4) fallback (minimal risk condition); 5) validation methods; 6) human machine interface; 7) vehicle cyber security; 8) crashworthiness; 9) post-crash automated driving system behaviour; 10) data recording; 11) consumer education and training; and 12) federal, state, and local laws. *See Automated Driving Systems – A Vision for Safety 2.0*, U.S. Department of Transportation and NHTSA (September 2017) (https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/13069a-ads2.0_090617_v9a_tag.pdf). *A Vision for Safety 2.0* encouraged private sector companies to submit Voluntary Safety Self-Assessments (VSSA) to the DOT. The VSSAs are intended to demonstrate to the public that entities are considering the safety aspects of autonomous motor vehicles and communicating and collaborating with the DOT. They are also meant to encourage the self-establishment of industry norms and build public trust. The DOT encourages entities to make their VSSAs public to promote transparency and to demonstrate that safety considerations are built into the autonomous motor vehicles' designs and also tested on roads. Following the guidance in *A Vision for Safety 2.0*, the following companies have voluntarily shared their VSSAs with the DOT: Apple; AutoX; Ford; GM; Mercedes Benz; Navya; Nuro; Nvidia; Starsky Robotics; Uber; Waymo; and Zoox. *See* https://www.nhtsa.gov/automated-driving-systems/voluntary-safety-self-assessment.

Risk Management Factors for Manufacturers to Consider

Any problems with the operation and/or use of an autonomous motor vehicle would be a setback to adoption of the technology. The public and media coverage will likely be extensive as technology evolves from experimental to a consumer product. Therefore, from a risk management perspective, manufacturers should consider, *inter alia*:

1) creating simple and conclusive schemes to record when the driver overrides the autonomous motor vehicle computer;
2) reputational risk insurance coverage as media focus on autonomous technology grows;
3) a disabling function as a response to any attempts to alter or enhance the software;
4) requiring hold harmless, defence, indemnification, and additional insured language on all contracts with downstream vendors and sub-contractors;
5) clearly defining maintenance procedures to be followed by the operator. If the operating system detects a problem that is not addressed by the owner, it should disable autonomous functionality to prevent potential loss;
6) considering all possible surface transportation conditions and different road landscapes;
7) working with all potential user groups to incorporate universal design principles;
8) anticipating human factors and driver engagement issues;
9) contributing to the development of voluntary, consensus-based, and performance-oriented technical standards;
10) adopting cyber security best practices;
11) delineating which entities/vendors/component part manufacturers own proprietary information, data, liability, risk, and revenue in the manufacturing and design process; and
12) preventing the moral hazard that arises when the operator has little or no exposure for a loss by developing an insurance product that includes both the manufacturer and the operator on the policy in order to align the financial interests of the operator and the autonomous motor vehicle manufacturer.

Best Practices for Private Entities Implementing Autonomous Motor Vehicles

In addition to meeting any regulatory or statutory requirements, the DOT envisions that entities testing and eventually deploying autonomous motor vehicles will employ a mixture of industry best practices, consensus standards, and voluntary guidance to manage safety risks along the different stages of technology development. *See Automated Vehicles 3.0 – Preparing for the Future of Transportation*, U.S. Department of Transportation and NHTSA (October 2018) (https://www.transportation.gov/sites/dot.gov/files/docs/policy-initiatives/automated-vehicles/320711/preparing-future-transportation-automated-vehicle-30.pdf).

Collaboration will be needed among manufacturers, technology developers, infrastructure owners and operators, and relevant government agencies to establish protocols that will help to advance safe operations in these testing environments.

Development and Early Stage Road Testing

Development and early stage road testing is the first safety risk management stage in the implementation of autonomous motor

vehicles. Significant engineering and safety analysis are performed prior to on-road testing with a prototype autonomous motor vehicle to understand safety risks and implement mitigation strategies. The primary purpose of this stage is to further develop the technology (software and hardware). There are many existing industry standards that guide general technology development. This stage can be characterised by these general characteristics:

- The system would generally be characterised as a prototype that already passed laboratory and/or closed-course testing. The hardware and the vehicle platform may comprise development or rapid prototyping-level equipment.
- Autonomous motor vehicle use cases and associated autonomous functions are identified and implemented, and requisite software validation and verification are performed in controlled environments prior to this stage. The primary purpose of this stage of road testing is to validate the completeness of use cases and to verify that implemented software can perform associated functions.
- Controlled environment (track, simulation, etc.) testing and software development are continuing alongside autonomous motor vehicle prototype road testing. Known use cases are being tested in controlled environments and new use cases identified in road testing are being evaluated and stored.
- Development of use cases could include initial assessments of a broad range of roadway characteristics (e.g., lane markings, signage) and operational scenarios (e.g., work zones, road weather) to inform autonomous motor vehicle performance in the roadway environment.
- Additional software development is taking place in failure handling, crash imminent scenario handling, and edge case handling.
- Safety drivers serve as the main risk mitigation mechanism at this stage. Safety-driver vigilance and skills are critical to ensuring safety of road testing and identifying new scenarios of interest.
- Some safety items (such as cyber security and human-machine interface) may be addressed in alternative ways when compared to production systems.
- Usually, in addition to a safety driver, an employee engaged in the autonomous motor vehicle function/software development track is also present in the vehicle. Software changes can happen frequently (both for safety-critical issues and other reasons) but are tracked and periodically harmonised.
- Members of the public are not in autonomous motor vehicle prototype vehicles during early stage road testing.

It is important to note that the stage of testing and deployment of an autonomous motor vehicle in one facet does not adequately represent the maturity of all autonomous motor vehicle development activities an entity may be pursuing. For example, an entity may be at a "limited deployment stage" in one specific area giving limited rides to members of the public (e.g., daytime-only, less than 35 miles per hour, no precipitation, on a few streets in a metropolitan area). However, simultaneously that same entity may be developing its technologies to advance its autonomous motor vehicle capabilities and expand its capabilities elsewhere (e.g., to include nighttime, higher speeds, precipitation, or larger or different geographical areas).

Expanded Autonomous Motor Vehicle Testing

Once the development progresses and specifications and software components are validated to be generally complete, software handling of non-nominal cases is integrated into an autonomous motor vehicle. The primary purpose of this stage of testing is to build statistical confidence in matured software and hardware within the intended operational environment and observe system failures, safety driver subjective feedback, and execution of fail-safe/fail-operational system behaviours. This stage can be characterised by these general attributes:

- The autonomous motor vehicle has matured both in terms of hardware and software. Information necessary to establish a safety self-assessment should be available and reasonably stable.
- Targeted operational design domain is more clearly identified and near fully specified. This could include an understanding of how the autonomous motor vehicle interprets the standard roadway environment, such as lane markings, signage, varying traffic laws, dynamic roadway conditions, and other users.
- The functional safety approach has been carried out; safety goals are identified and risk management controls implemented.
- Autonomous motor vehicle use cases are validated to be nearly complete. Implemented functions are validated and verified to meet engineering requirements in both controlled and on-road environments.
- Most elements of the autonomous – such as fallback (minimal risk condition) mechanisms – are identified and implemented. Safety drivers are still in the loop, but they are expected to serve as the secondary risk mitigation strategy.
- Depending on the vehicle platform, some safety items (such as cyber security and human-machine interface) may still be addressed in alternative ways.
- The safety driver may be the only person in the vehicle. Time between subsequent safety driver actions may be extending. Ensuring that safety drivers can maintain their vigilance in reduced workload is important.
- Members of the public are still not in ADS prototype vehicles during expanded road testing.

Advancing an autonomous motor vehicle from prototyping stages to production release involves numerous development objectives. These include the ability for the autonomous motor vehicle to perform nominal driving functions in known use cases, perform crash-avoidance manoeuvres, revert to a safe state when there are identified system and sensor failures, and react reasonably safely in edge cases. On-road testing cannot be expected to address all aspects of testing needs toward deployment. On-road testing is an important part of the overall development process in identifying and validating the completeness of use cases, gaining statistical confidence in a system's ability to handle use cases, and identifying edge cases and otherwise interesting/difficult cases, as well as public perceptions and expectations. However, once a new scenario of interest is identified in road-testing, it is usually added to a library and re-tested many times in controlled environments (simulation, track, hardware-in-the-loop, software-in-the-loop, etc.) and integrated as part of each software update release readiness assessment.

Limited to Full Deployment

Limited autonomous motor vehicle deployment is similar to what the public understands as demonstrations. Full deployment of autonomous motor vehicles represents a system that is able to, for example, operate commercially and widely engage with the public. The main purpose of this stage is to reach statistical confidence in the software for the intended operational environment, validate underlying safety assumptions, gather user and public feedback, and

identify fine-tuning opportunities in user compatibility areas. This stage can be characterised by these general characteristics:

- Complete engineering requirements for autonomous motor vehicles are specified by the entity developing the technology, and internally documented. Engineering design reviews are performed and documented.
- The operational design domain is specified clearly, and autonomous motor vehicle operation only takes place within that operational design domain. Relevant operational design domain elements are monitored to ensure full coverage. Any operational design domain expansions go through requisite validation and verification processes, are documented, and are appropriately communicated when applied as a software update in deployed units.
- Near-full software, hardware, system failure validation, and verification processes have been carried out with near production hardware.
- The software is stable. Software changes are centrally managed at the fleet level. Any major change goes through new release readiness testing.
- Nearly all elements of the autonomous motor vehicle system are identified and implemented. Safety drivers (including remote safety drivers) may still be used, but their roles are limited and may eventually be eliminated. Risk-based assessments are performed to assure safety of these approaches.
- Safety and key performance indicators are set and monitored.
- All safety items (including cyber security and human-machine interface) are addressed.
- Members of the public are allowed in autonomous motor vehicles on public roads, initially on a limited basis.
- Systems move toward full operation by being offered for sale, lease, or rent (to include free ride-sharing) or otherwise engaged in commerce in the form of the transport of goods or passengers.
- In specified deployment areas, law enforcement, first responders, and relevant state and local agencies know of operational protocols and administrative procedures following a crash or other roadway event related to an autonomous motor vehicle.

As autonomous motor vehicle developers progress through the development stages, they should engage with the DOT and the autonomous motor vehicle stakeholder community. While there will obviously be concerns with sharing potentially proprietary information and/or data, a collaborative effort will likely aid the development process, prioritise safety and manage risks.

Conclusion

Federal and state legislatures will enact legislation dictating policies and laws regarding the development and implementation of autonomous motor vehicles while the use of these vehicles continues to increase exponentially. However, the most recent guidance from the DOT explicitly states that it is looking to the private sector to innovate and shape the market. The increase in autonomous motor vehicles will change profoundly the safety of driving and the attendant costs. Any issues with the operation of autonomous motor vehicles will be subjected to increased scrutiny. Accordingly, it is vital to ensure that the implementation of autonomous motor vehicles is efficient, safe, and as seamless as possible.

Francis P. Manchisi

Wilson, Elser, Moskowitz, Edelman & Dicker LLP
150 East 42nd Street
New York, NY 10017
USA

Tel: +1 212 490 3000
Email: francis.manchisi@wilsonelser.com>
URL: www.wilsonelser.com

Francis Manchisi is a partner in Wilson Elser's New York Metro offices. He focuses his practice on the defence of domestic and foreign manufacturers and insurance carriers. Frank, who has practised at Wilson Elser throughout his career, helped build and now leads the firm's highly regarded Product Liability, Prevention & Government Compliance practice. Frank also served on the firm's Executive Committee for five years. For more than 25 years, Frank has served as national product liability counsel to manufacturers of boats and boat components. He also currently serves as national counsel to a variety of manufacturers both in the US and abroad. Frank also frequently is retained by insurance carriers based in Finland, Sweden, Denmark and Norway to represent their insured manufacturers in US lawsuits involving products made in Europe and sold in the United States.

Ernest V. Goodwin

Wilson, Elser, Moskowitz, Edelman & Dicker LLP
150 East 42nd Street
New York, NY 10017
USA

Tel: +1 212 490 3000
Email: ernest.goodwin@wilsonelser.com
URL: www.wilsonelser.com

Ernest Goodwin is a partner in Wilson Elser's New York Metro offices. He focuses his practice on product liability, specifically the defense of domestic and foreign manufacturers, distributors, and retailers in the United States, Canada, and Europe. Ernie also provides clients with innovative and timely strategic counsel to help them make better-informed decisions, resolve complex legal challenges, and achieve specific business goals. In addition, he also has experience in the defence of manufacturers, distributors, and retailers of industrial products and equipment, and defended corporations in construction, labour and employment, securities and commercial matters. Ernie also represents manufacturers in litigations and pre-suit investigations in claims involving property damage arising out of fires and liquid leaks. Ernie prides himself on being responsive to clients and colleagues, regardless of the day or time, and thinks outside the box and in terms of the big picture when defending a claim or lawsuit.

WILSON ELSER
WILSON ELSER MOSKOWITZ EDELMAN & DICKER LLP

Wilson Elser, a full-service and leading defence litigation law firm (www.wilsonelser.com), serves its clients with nearly 800 attorneys in 31 offices in the United States and one in London. Founded in 1978, it ranks among the top 200 law firms identified by *The American Lawyer* and is included in the top 50 of *The National Law Journal's* survey of the nation's largest law firms. Wilson Elser serves a growing, loyal base of clients with innovative thinking and an in-depth understanding of their respective businesses. The firm is also a founding member of Legalign Global™, a premier international network of separate and independent insurance-related law firms formed to meet the legal needs of the growing multinational insurance market. Member firms include BLD Bach Langheid Dallmayr, DAC Beachcroft and Wotton + Kearney.

Criminal Liability for Defective Products

Howard Watson

Herbert Smith Freehills LLP

Tony Dempster

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 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.

Impact of Brexit

The GPSR are part of UK law (albeit their purpose is to implement EU law) and will therefore remain in force after the UK leaves the EU. However, various aspects of the GPSR are tied into the EU-wide system of product safety regulation that may or may not be recognised in the UK post-Brexit. For example, when defining the concept of a 'safe product' the GPSR refer to applicable European standards (as well as UK standards). The GPSR also refer to the UK government using the EU RAPEX system to notify governments of other member states of products that pose a serious risk. Parliament has passed a statutory instrument amending the GPSR to remove these references to EU-level regulation. These amendments will automatically come into force in the event that the UK leaves the EU in a 'no deal scenario' (i.e. without a withdrawal agreement having been finalised and without any transitional period). In the event that there is a withdrawal agreement, it is anticipated that decisions on issues such as the UK's continuing recognition of European standards and participation in the RAPEX system will be taken during the transitional period.

Changes to EU 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, be retained after the UK leaves (potentially subject to amendments of the kind that have already been passed in relation to the GPSR to remove certain references to EU-wide regulation). If, on the other hand, the new Regulation 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). As noted above, the reference to European standards will be removed in the event that the UK leaves the EU without a withdrawal agreement.

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). Again, the references to CE marking will be removed and replaced with reference to a new UK system of marking ("**UKCA**") in the event of a no-deal Brexit.

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. The UK will not automatically continue to participate in RAPEX after it leaves the EU. There have been suggestions that the UK may seek to remain part of RAPEX (whether as a full participant or in some other way). It is likely that this will be considered further during the transitional period that would follow a withdrawal agreement being finalised. If, on the other hand, the UK leaves the EU without a deal, it will cease to be part of RAPEX (albeit some mechanism for ongoing participation could be agreed at a later date).

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.

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 largely 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. As explained above, it remains to be seen whether or not the UK will continue to participate in the RAPEX system after it leaves the EU.

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;
- the requirement to adopt appropriate 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; and
  - to take appropriate action to address any safety issue it becomes aware of (including withdrawal and/or recall of products). In 2018 the Government published a new Code of Practice ("*Supporting Better Product Recalls*") which includes guidance on the type of measures that a company should have in place to enable it to effectively withdraw/recall products where necessary. This includes, in particular, an expectation that companies will have a written Product Safety Incident Plan. Such a plan is expected to include, amongst other things: (i) information on product and customer traceability; (ii) a plan for monitoring product safety; (iii) a plan for notification of the relevant authorities; (iv) a risk assessment procedure; and (v) a mechanism for deciding upon appropriate corrective action.

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 that documentation 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, 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, then 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 punishable with a fine.

The Consumer Protection Act 1987

The Consumer Protection Act 1987 ("**CPA**") gives effect to the European Product Liability Directive (1985/374/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. 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).

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 CPA also creates a no-fault liability regime under which individuals who have suffered personal injury or property damage caused by a defective product can seek compensation from the manufacturer (and, potentially, other entities deemed to be responsible for the product). This forms part of the civil law applicable to product liability claims and is therefore outside the scope of this article which focuses on the criminal/regulatory regime.

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. Corporate Manslaughter is a statutory offence that 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 11 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 and/or 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 (for example, 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*", commentary in the guidelines, and in the judgments in which the guidelines have been applied, 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.
- 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 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.

Acknowledgment

The authors would like to acknowledge the assistance of David Bennett, Senior Associate in the litigation and arbitration division at Herbert Smith Freehills LLP, in preparing this article.

Howard Watson

Herbert Smith Freehills LLP
Exchange House
Primrose Street
London EC2A 2EG
United Kingdom

Tel: +44 20 7466 2088
Fax: +44 20 7374 0888
Email: howard.watson@hsf.com
URL: www.herbertsmithfreehills.com

Howard is a partner in the litigation and arbitration division specialising in product liability, health and safety and large personal injury claims.

He advises clients in relation to their civil and criminal liabilities arising from dangerous or defective products and has been involved in many high-profile product recalls and product safety related issues. As well as advising in relation to civil claims for damages, he also handles regulatory investigations and prosecutions.

In addition, he is experienced in the conduct of group litigation and over recent years has been involved in high-profile product liability claims involving organophosphates, RF radiation, deep vein thrombosis, the Scania group action and Thalidomide.

Tony Dempster

Herbert Smith Freehills LLP
Exchange House
Primrose Street
London EC2A 2EG
United Kingdom

Tel: +44 20 7466 2340
Fax: +44 20 7374 0888
Email: anthony.dempster@hsf.com
URL: www.herbertsmithfreehills.com

Tony is a partner in the contentious insurance and reinsurance group of Herbert Smith Freehills where he became a partner in 1994. He has a broad practice covering the full range of contentious insurance and reinsurance work. This includes advising on coverage issues and policy disputes involving all types of insurance and reinsurance contracts, in particular property/business interruption, public/product liability, professional indemnity, contractors all risks and directors and officers policies, as well as facultative and treaty reinsurances. In addition, he handles a wide range of general commercial disputes and has particular expertise in product recall/liability and environmental claims. He is also very experienced in managing overseas litigation, in particular in Continental Europe and USA, often involving disputes on conflicts of law and jurisdiction. Tony is the Honorary Solicitor to the Chartered Institute of Loss Adjusters and member of the British Insurance Law Association.

The Practicalities of Managing a Global Recall

Richard Matthews

Fabian Volz

Eversheds Sutherland

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 technological, political and regulatory landscape which impact upon this area:

Supply chain dynamics

The pace of technological change in many sectors, combined with a drive to push down costs, is resulting in a significant shift in global supply chains. Increasingly, multiple global brands are sourcing technology from the same leading suppliers so as to ensure that their customers have the latest technology at the best price. At the same time, the cost of new technologies has led producers to rely increasingly on modular strategies where common elements are included in multiple models/brands of product. The result, seen repeatedly in recent global recalls over recent years, is a 'ripple effect' in which safety concerns arising in relation to a single supplier generate a vast tide of recalls across multiple brands around the world.

In this context, the protracted series of recalls by carmakers across the globe from 2013–18 following safety concerns over Takata airbag components, might be seen as a harbinger of things to come. To date, the safety issue identified in components manufactured by Takata, which held 20% of the global airbag market, has resulted in the recall of in excess of 70 million inflators across the globe affecting more than 30 automotive brands and leading to a $1 billion settlement with regulators following criminal charges in the US. Recalls on this scale, and spread so widely across an industry, have thankfully been few and far between to date. However, the continuing evolution of supply chain models may make them a common occurrence.

It is not only this shift in supply chain structures which is driving a growth in recall risks. Competitive pressure from both industry incumbents and disruptive, innovative start-ups forces ever faster speed-to market. This pressure to reach the market first leaves less time for research and development work and increases cost pressures at a time when the complexity of technology is increasing at a rate never seen before. In many cases, technological advances may ultimately serve to reduce the overall safety risk posed by products. At the same time, however, there is a real risk that the strain put on quality control systems having to address ever more complex issues with tighter timescales and leaner budgets serves to propagate the very product safety crises which the technologies are designed to prevent.

Shifting the burden to business

Alongside the challenge of accelerating technological change, concerns over the risk of adverse publicity, as well as growing regulatory pressure, have been driving an increased focus by businesses on ensuring strict compliance with regulations, even in the absence of evidence of a specific safety risk. The recent 'dieselgate' debacle affecting the car industry demonstrates how increasingly, even if a product has been marketed for years without any complaints, and bears the requisite conformance markings, questions can still be raised over its conformance or safety, 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 content, or the perceived spirit, of the latest regulatory standards. The onus is increasingly shifted onto manufacturers to demonstrate that all of the components are within specification and operate and interact safely. 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 raise 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. Recent high-profile and large-scale recalls of domestic appliances have increased pressure on national regulators to take a more proactive stance in monitoring the response of business to safety incidents. This is beginning to translate into government action: in January 2018 the UK Government, faced with criticism over a lack of co-ordination from localised Trading Standards

offices charged with overseeing product safety issues, announced the creation of a new body, the Office for Product Safety and Standards ('OPSS') to advise on and co-ordinate action on product safety. The OPSS has issued a code of practice on consumer product safety-related recalls.

The influence of Global Politics

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 EU 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, 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 US arrangements or seek to maintain a system which reflects the EU approach.

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 root cause 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://ec.europa.eu/DocsRoom/documents/17107).
- 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.

Whilst governments are increasingly proactive in issuing guidance on the management of recalls (in March 2018, for example, the OPSS issued the UK's first ever government-backed Code of Practice for product safety recalls, PAS7100), 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 (as faced by Vauxhall/Opel Zafira owners in Europe in 2016).

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 negative publicity 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), the Electromagnetic Compatibility Directive (2014/30/EU) and the Construction Products Regulation (305/2011) 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 some years on, it remains to be seen what impact this will have on the approach of both 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 strategies. 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.

Within the European Economic Area, the "Product Safety Business Alert Gateway" (formerly referred to as "GPSD Business Application" online procedure) has been available since 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 Alert" with informal meetings or other communications 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 benefiting from some degree of 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 2,201 in 2017, 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 latest RAPEX Annual Report showed that all 31 participating countries save for Liechtenstein sent notifications through the RAPEX system in 2017, but six countries (Hungary, Germany, Spain, France Bulgaria and the UK) accounted for over 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 the long-running Takata airbag recalls referred to above.

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 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 publicly 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 nearly 20 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 monitor the situation so that they are aware of any future claims they may face. Learning from their American colleagues, claimant lawyers in Europe are increasingly seeking to use the press and social media 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 can use their own social media presence 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 offurther 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 their proposed strategy. The solution should be acceptable to the public, to regulators and to the company's 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, but 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 US CPSC is somewhat ahead of the EU in promoting the use of social media to communicate product safety alerts, and 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.

Advances in connected technologies can provide businesses with powerful new tools to manage product safety risk: towards the end of its recent recall campaign to address fire risks identified with its Note 7 phone, Samsung took the bold decision to launch a 'bricking app' to limit the ability of the few remaining affected phones to charge so as to remove them from the market. Whilst such approaches may provide a highly effective mechanism for neutralising the risk, they clearly cannot be taken lightly: producers will need to carefully balance the benefits against the risks which might arise for users from being unable to use their device – perhaps explaining reports that Samsung's apps merely restricted charging to 30 per cent rather than fully disabling the phones.

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 choose to deal direct with end users; for example, arranging a direct product exchange rather than expecting consumers 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.

The increasing prevalence of electronic payments and the growth of connected products are improving the prospects of identifying and contacting purchasers or users of affected product. Nevertheless, it remains the case that 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 have been considered but the current varied patchwork of approaches seems unlikely to change in the near future.

Finally, the threats arising from product crises extend beyond court actions. Increasingly, company executives find themselves the target of prosecutions following product safety or compliance incidents. Following the recent vehicle emissions scandals a former CEO of a car manufacturer and four other former executives have

been charged with fraud by German prosecutors and face the threat of jail terms if found guilty. Even where prosecutions are not advanced against executives, they increasingly 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 lawyers 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. Consideration should be given to the role of legal privilege (discussed further below); however, 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.

Acknowledgment

The authors would like to acknowledge the contribution of Peter Shervington, Principal Associate at Eversheds Sutherland. Peter is a specialist in product liability and product risk management with considerable experience handling product liability issues, crisis management and supply chain disputes arising from alleged product defects. Peter acts for a wide range of major industrial clients including automotive OEMs and Tier 1/Tier 2 suppliers, pharmaceutical and medical devices manufacturers and tech businesses. He is recognised by *The Legal 500* for his product liability work, is a regular conference speaker and has provided training to many businesses on practical steps to manage product liability risk.

Email: petershervington@eversheds-sutherland.com.

Richard Matthews

Eversheds Sutherland (International) LLP
1 Wood Street
London EC2V 7WS
United Kingdom

Tel: +44 845 498 4372
Fax: +44 845 498 4994
Email: richardmatthews@eversheds-sutherland.com
URL: www.eversheds-sutherland.com

Richard heads Eversheds Sutherland's Product Liability Group.

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 a leading tyre manufacturer in multi-party proceedings arising out of a fatality in a road traffic accident, 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.

Richard is a named product liability expert in the UK legal directories and identified as one of the "World's Leading Product Liability Lawyers".

Fabian Volz

Eversheds Sutherland (Germany) LLP
Brienner Strasse 12
80333 München
Germany

Tel: +49 895 456 5391
Fax: +49 895 456 5158
Email: fabianvolz@eversheds-sutherland.com
URL: www.eversheds-sutherland.com

Fabian heads Eversheds Sutherland's German insurance and product liability practice.

He has more than 20 years of national and international experience. His focus is in the automotive, supplier and electrical/electronic industry, as well as in the pharmaceutical and medical devices sector. He is also regularly instructed by insurers.

Fabian specialises in international product recalls and all aspects of product safety compliance, such as the implementation of European standards, compliance with pre- and post-marketing obligations on the part of manufacturers and distributors of consumer products, and advice on preventing product liability claims. He also has long-standing experience in litigation and arbitration, as well as in alternative dispute resolution.

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 is recognised for Dispute Resolution by *The Legal 500 Germany 2018* and *JUVE Handbook 2018*. He is nominated as a leading lawyer for product liability in Germany by the Legal Media Group "Guide to the World's Leading Lawyers". In 2018, Fabian received the "Acritas Star Lawyer" award from the leading international legal research company Acritas based on clients' praise for his matter handling and customer focus.

EVERSHEDS SUTHERLAND

Eversheds Sutherland is one of the world's largest law firms with more than 2,300 lawyers located in 67 offices in 34 countries. Recognised by Acritas as a Global Elite Law Firm, we regularly advise on billion-dollar deals and high-profile cases on behalf of the world's most powerful corporations and financial institutions. In an era of increasing globalisation, we are unique in our multi-jurisdictional project management approach and commitment to seamless service delivery across our international offices.

United by a shared vision, values and understanding of what our clients really want, our lawyers provide top-quality legal advice whether they are operating locally or across borders from our bases in Europe, the US, Middle East, Asia and Africa.

Product Liability in Asia

David Goh

Bindu Janardhanan

Squire Patton Boggs

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 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 production 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 the 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, 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 manufacturers 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 addresses 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 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.

David Goh

Squire Patton Boggs
29th Floor, Edinburgh Tower, The Landmark
15 Queen's Road Central
Hong Kong SAR

Tel: +852 2511 1040
Email: david.goh@squirepb.com
URL: www.squirepattonboggs.com

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.

Bindu Janardhanan

Squire Patton Boggs
29th Floor, Edinburgh Tower, The Landmark
15 Queen's Road Central
Hong Kong SAR

Tel: +852 2511 1040
Email: bindu.janardhanan@squirepb.com
URL: www.squirepattonboggs.com

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.

SQUIRE PATTON BOGGS

Squire Patton Boggs provides clients with unique insight at the point where law, business and government meet, giving them a voice, supporting their ambitions and achieving successful outcomes.

Squire Patton Boggs has grown to become one of the world's strongest law firms through a unique mix of organic growth to match our clients' needs plus astute combinations to bring additional local insight, skills and opportunities.

Today, Squire Patton Boggs has a global team of more than 2,600 including more than 1,500 partners and lawyers.

Chapter 8

Australia

Colin Loveday

Andrew Morrison

Clayton Utz

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 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

Claims against Australian regulators are not common and present particular challenges for aggrieved claimants. In part, this reflects the availability of statutory immunities and protections for regulators in the discharge of their mandated functions. In part, it reflects the current state of the debate concerning the viability of claims predicated on a decision by a regulator not to act in relation to a particular issue (typically described as *nonfeasance* claims) and those involving action by a regulator which is said to have been beyond power (*ultra vires*) or to have resulted in the failed discharge of power/duty (*misfeasance*). The former remains an area where claimants find it very difficult to attract any assistance from Australian courts. The latter claim may potentially offer better prospects, but care is required not to assume that Australian courts are easily satisfied that, in the discharge of their statutory authority, a regulator will thereby be held to owe claimants a duty of care in that process or have breached any such duty. A useful authority in this regard is the decision of *Beach JA in Regent Holdings v State of Victoria* [2013] VSC 601, in which abalone farmers sued the State for an alleged failure to prevent or adequately limit the escape of a devastating virus from farmed abalone pens into the wild abalone population across coastal Victoria. While the relevant authority had power to intervene, and had done so, the Court held in favour of the State on duty of care (there was none), causation and damages. There was no appeal and the underlying class action was settled on that basis.

1.5 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.

1.6 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, in order 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 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

Lawyers and representative bodies may advertise for claims in Australia subject to applicable professional conduct rules, which vary across each Australian State and Territory.

By way of example, in New South Wales (Australia's most populated State), lawyers or principals of a law practice can publish advertisements in accordance with the applicable professional conduct rules. In New South Wales, the applicable conduct rules are the *Australian Solicitors' Conduct Rules* (2015), approved pursuant to the *Legal Profession Uniform Law*. Rule 36 relates to the advertising of legal claims. These conduct rules stipulate that any advertisement in relation to a solicitor or law practice must not be false, misleading or deceptive (or likely to mislead or deceive), offensive or otherwise prohibited by law (Rule 36.1). Lawyers must also ensure that any advertisements published do not convey a false, misleading or deceptive impression of specialist expertise (Rule 36.2). A failure to comply with these conduct rules may result in a finding of unsatisfactory professional conduct or professional misconduct against those involved.

Advertising for legal services or claims is most commonly engaged in by lawyers and legal practices in the personal injury space. In some Australian States and Territories, this area of legal services advertising is further restricted. For example, in Queensland, advertising for personal injury legal services is limited to publication of a statement (by an "allowable publication method" defined in s 65 of the *Personal Injuries Proceedings Act 2002* (Qld)) that includes only the name and contact details of the practitioner or law practice of which the practitioner is a member, together with information as to any area of practice or speciality of the practitioner or law practice (*Personal Injuries Proceedings Act 2002* (Qld) s 66).

4.6 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.

4.7 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.

4.8 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.

4.9 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.

4.10 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.

4.11 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.

4.12 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.

4.13 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 which 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 a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

Australia continues to have a very active product liability litigation environment. This is due in part to Australia's consumer product regulator ("ACCC") playing an influential role in product safety compliance and in product liability claims. There continues to be a strong interplay between the ACCC's enforcement activity and claims for compensation by consumers against manufacturers for alleged breaches of the ACL. More often than not, these claims are brought by way of a class action.

In the past 12 months, Australia has witnessed the commencement of multiple class actions concerning diesel motor emissions issues and multiple class actions in respect of Takata airbags, to name just a few. A number of other product liability class actions in other industry sectors are also before the courts.

In addition, the ACCC has been extremely diligent in its overview of product recalls.

Colin Loveday

Clayton Utz
Level 15, 1 Bligh Street
Sydney NSW 2000
Australia

Tel: +61 2 9353 4193
Email: cloveday@claytonutz.com
URL: www.claytonutz.com

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.

Andrew Morrison

Clayton Utz
Level 18, 333 Collins Street
Melbourne VIC 3000
Australia

Tel: +61 3 9386 6537
Email: amorrison@claytonutz.com
URL: www.claytonutz.com

Andrew Morrison 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

Sérgio Pinheiro Marçal

Pinheiro Neto Advogados

Laura Beatriz de Souza Morganti

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 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

No. According to several court precedents, the regulatory authorities cannot be held liable for a defective/faulty product.

1.5 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.

1.6 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 to 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 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 their 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 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

No. There are legal provisions which prohibit the use of marketing for the dissemination of legal services for the specific purpose of attracting clients.

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

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

4.7 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.

4.8 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 appeal: (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).

4.9 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.

4.10 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.

4.11 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.

4.12 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.

4.13 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 included 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 than 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 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 exclusively 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 exclusively 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 a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

The Brazilian model for recalling the very harmful and hazardous products or services is different from the American model, in which the risk classification is a determining factor for the recall. Although the legal rules that determine the procedures to be adopted by the suppliers who have to make a recall of their products is from 2012, it is anachronistic. In view of that, the Brazilian Ministry of Justice recently announced a public consultation for the update of consumer products recall. It is an important initiative that seeks for the improvement of product recall effectiveness.

Lastly, the discussions about the use of new technologies and artificial intelligence are not yet effective in Brazil, and there are no precedents thereof.

Sérgio Pinheiro Marçal
Pinheiro Neto Advogados
Rua Hungria, 1100
São Paulo
Brazil

Tel: +55 11 3247 8577
Email: smarcal@pn.com.br
URL: www.pinheironeto.com.br

Partner in the Litigation Department at the law firm Pinheiro Neto Advogados since 1996. He is a former Chairman of the São Paulo Lawyers Association ("AASP").

He is highly recommended as a product liability law practitioner by *Chambers and Partners*, *Who's Who Legal*, *Best Lawyers* and *Euromoney World Leading Lawyers*. He has also been repeatedly named a "most admired attorney" in consumer and product liability practice by Brazilian magazine Análise Advocacia.

Languages: Portuguese and English.

Laura Beatriz de Souza Morganti
Pinheiro Neto Advogados
Rua Hungria, 1100
São Paulo
Brazil

Tel: +55 11 3247 8745
Email: lmorganti@pn.com.br
URL: www.pinheironeto.com.br

Counsel in the Litigation Department at the law firm Pinheiro Neto Advogados, where she has been working as an associate since 1998.

Areas of expertise: consumer law; product liability; class actions; civil litigation; tort and contractual liability; commercial disputes from agribusiness; and regulatory aspects involving production and sale of agrochemicals.

Member of the Brazilian Institute of Studies of Competition, Consumer Affairs and International Trade ("IBRAC").

Languages: Portuguese, English and Spanish.

PINHEIRONETO
ADVOGADOS

Pinheiro Neto Advogados is a Brazilian, independent, full-service firm specialising in multi-disciplinary deals and in translating the Brazilian legal environment for the benefit of local and foreign clients. Founded in 1942, Pinheiro Neto Advogados was one of the first Brazilian law firms to serve foreign clients as well as the first Brazilian law firm to specialise in corporate clients. With clients in almost 60 countries, the firm was recognised in 2014 by the Brazilian government as the number one exporter of legal services from Brazil. The firm advises and represents both local and international clients in a broad range of sectors, including automotive, banking and financial services, construction and materials, energy and natural resources, environment and waste management, health care, oil and gas, real estate and technology.

Canada

Nicole Henderson

Jessica Lam

Blake, Cassels & Graydon LLP

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 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

At common law, any liability against a regulator for a defective product would generally be founded in negligence. Canadian courts have been reluctant to find that regulators owe any private duty of care to individuals that may be affected by a defective product, while not foreclosing the possibility that such a duty may be recognised in an appropriate case. To establish a private duty of care, the plaintiff would usually need to show that it had some relationship with the regulator that is distinct from and more close and direct than the relationship between the regulator and the larger public. This could include circumstances where the regulator has made specific representations to the plaintiff or had some specific knowledge about the danger associated with a product.

In some cases, the relevant statutory scheme may provide immunity to the regulator.

1.5 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).

1.6 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 in 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. Generally, the scope of the duty to warn will depend on the level of risk associated with the ordinary use of the product and the likelihood that such risk will occur. For example, Canadian courts have held that manufacturers of products that are ingested or otherwise placed in the body, have a heavy onus to provide clear, complete and current information concerning the dangers inherent in the ordinary use of their product.

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 has 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 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.

Canada does not have any regime akin to the US Multi-District Litigation (MDL) procedure to manage large numbers of individual claims. 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.

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 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

While lawyers in Canada may advertise for claims, the law societies' codes of conduct generally require that any marketing be demonstrably true, accurate and verifiable, and that the marketing does not mislead, confuse or deceive members of the public. In recent years, there has been an increase in advertising by personal injury class action lawyers, which has resulted in an increase in claims in some areas, particularly mass tort cases.

4.6 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.

4.7 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. Some provinces also 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.

4.8 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.

4.9 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 and impartial expert, and it must not violate any exclusionary evidence rules. Novel scientific evidence is subject to special scrutiny to determine its necessity and reliability.

4.10 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.

Fact witness and experts are generally subject to cross-examination on affidavits filed on pre-trial motions (e.g. for summary judgment or class action certification).

4.11 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 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 purpose, 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.

4.12 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 to 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.

4.13 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$375,000. 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. In class actions involving personal injury, any settlement must receive the consent or approval of the relevant provincial health insurer in accordance with that province's subrogation legislation. Some provincial health insurers have become more involved in class action litigation in recent years.

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?

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

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 an increasing 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 a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

With the recent legalisation of cannabis in Canada, there has been some new case law involving product liability claims against cannabis companies. In 2018, a Nova Scotia court certified the first cannabis product liability class action in Canada. A medical cannabis producer had issued a voluntary recall of a number of its products, after some of the products were found to contain traces of pesticides that were not authorised for use on cannabis plants. The plaintiff alleged that she suffered various adverse health consequences as a result of consuming the recalled cannabis. The court certified several common issues relating to negligent distribution, marketing, and sale of the recalled cannabis, as well as those relating to breach of consumer protection legislation, sale of goods legislation, breach of contract, and unjust enrichment. Other similar class actions have recently been commenced against cannabis companies in Canada.

Nicole Henderson

Blake, Cassels & Graydon LLP
199 Bay Street, Suite 4000
Commerce Court West
Toronto, ON M5L 1A9
Canada

Tel: +1 416 863 2399
Email: nicole.henderson@blakes.com
URL: www.blakes.com

Nicole is a Partner in the Blakes Litigation & Dispute Resolution group. Her practice focuses on class actions, particularly in the areas of product liability and privacy. She also practises public law, including constitutional, freedom of information, administrative, and regulatory law. 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 an integral part 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 in damages, alleging negligent design, testing and warning.

Prior to joining Blakes, Nicole clerked at the Federal Court of Appeal.

Jessica Lam

Blake, Cassels & Graydon LLP
199 Bay Street, Suite 4000
Commerce Court West
Toronto, ON M5L 1A9
Canada

Tel: +1 416 863 5847
Email: jessica.lam@blakes.com
URL: www.blakes.com

Jessica is an Associate in the Blakes Litigation & Dispute Resolution group. Jessica has a diverse litigation practice with a focus on product liability and class action matters, which often involve complex scientific and medical evidence.

Jessica has also been involved in matters involving contract law, administrative law, media law, privacy law and constitutional law, and has appeared as counsel before various levels of courts.

Blakes
CANADIAN LAWYERS

As one of Canada's top business law firms, Blake, Cassels & Graydon LLP (Blakes) provides exceptional legal services to leading businesses in Canada and around the world. We focus on building long-term relationships with clients. We do this by providing unparalleled client service and the highest standard of legal advice, always informed by the business context. Our Product Liability team is widely regarded as one of the top practices in the country and we are the only firm recognised in Band 1 for Product Liability Defence by *Chambers Canada: Canada's Leading Lawyers for Business 2019*. We are frequently retained as counsel to guide clients through the interrelated regulatory and litigation issues that arise throughout a product's lifecycle, from early product assessment, claims prevention and compliance to tailored risk and reputation management strategies, and defence of claims.

China

Kelly Liu

Wu Di

Squire Patton Boggs

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 a danger to personal or property safety caused by the defective product, a plaintiff 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 plaintiff must choose one or the other. Once the plaintiff 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 plaintiff 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. Most courts tend to hold the opinion that it also covers the damaged product itself; however, due to 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 of 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 should pay for the funeral, 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 plaintiff, the liable party shall be responsible for restoring or compensating for it; if the plaintiff 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 in such situation, the Supreme Court of the People's Republic of China, which interprets the Tort Law of the People's Republic of China ("Tort Law"), holds the opinion that the maximum amount of punitive compensation shall not be limited by a fixed standard or a specific value. Instead, the courts shall exert their discretions on this issue based on the specific facts of each case, and the following factors shall normally be taken into account when determining the amount of punitive compensation: the motive of the infringers conducting the infringements; duration of infringement; whether the infringers intend to conceal their illegal acts; the infringers' responses to the opinions from consumers or social organisations; financial status of the infringers; criminal or administrative penalties the infringers have received; the infringers' gains obtained from their infringement; actual losses incurred by the victims; social influences of the cases; and so on.

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 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

No authority will be found liable, although a specific officer might be charged with dereliction of duty, the taking of a bribe and other crimes.

1.5 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 a 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.

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

Criminal sanctions also apply to the supply of defective products. Article 146 of China Criminal law provides that where a producer or seller passes a defective product off as a high-quality one, if the sum obtained through sale exceeds 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. Whoever produces electrical appliances, pressure containers, inflammable or explosive products or any other products that are not up to the national or trade standards for safeguarding personal or property safety or knowingly sells such products, thereby causing serious consequences, shall be sentenced to fixed-term imprisonment of not more than five years and shall also be fined not less than half, but not more than two times, the amount of earnings from sales; if the consequences are especially serious, he shall be sentenced to fixed-term imprisonment of not less than five years and shall also be fined not less than half but not more than two times the amount of earnings from sales.

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 plaintiff bears the burden of proving defect and damages and the causation between the two, while the seller/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 plaintiff. Only a few courts in major cities like Beijing, Shanghai, and Guangzhou have 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 a lack of consistency in court decisions in the 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 plaintiff can show that the defendant wrongly exposed the plaintiff 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 plaintiff 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 plaintiff 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"), the Tort 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 statute of limitations for the action has expired, or it has been 10 years since the product was first delivered to the consumer.
- Jurisdiction opposition.
- The plaintiff 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, plaintiffs can still re-litigate the same. However, the court can directly confirm the facts unless the plaintiff 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 plaintiff, 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 plaintiff'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 plaintiff'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 include people's jurors randomly drafted from a pool. If a summary procedure is applied, there will only be one judge handling the case. However, people's jurors are not equivalent with or similar to the jurors of the common law 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 technical issues, the court has the authority to appoint specialists for the verification of evidence. As for expert witnesses, a party needs to apply to the court and the court will decide whether to approve the application. The expert witness can provide his professional opinion and written verification reports to support the arguments of the party who invited the person with professional 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 are no specific rules for class action procedures regarding product liability claims in China. However, in China, there is a framework of "collective action procedure" under the current Civil Procedure Law of the People's Republic of China ("Civil Procedure Law"), which provides the possibility of filing a joint action while "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 to the legitimate rights and interests of groups of 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 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

There are a host of so-called "professional counterfeit hunters" in China who constantly seek for defective and flawed products in the markets, advertise for claims from other common consumers, and organise lawsuits in different areas of China. They are mostly focused on food products, drug products, and household appliances. Motor vehicles are not their main targets at present.

4.6 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 the receipt of the pleading. The court shall then deliver a copy of the pleading to the defendant within five days after the pleading is filed; the defendant shall file a statement of defence within 15 days of receiving the copy of the pleading, which shall be delivered to the plaintiff by the court within five days from the receipt of the defendant's defence. Failure by the defendant to submit a defence will not affect the hearing of the case by the court.

4.7 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 must decide the matters of both law and fact during the same procedure.

4.8 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. Also, any party can file a retrial application against the legally effective judgment with the supervision court.

4.9 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 it is deemed necessary to verify a technical issue; a party can also file for such a procedure. The technical opinion is also 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 an application. Once the court approves the application of the plaintiff or the defendant (the defendant can also submit such application and the burden of proof will be transferred to them), it will suspend the trial 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 technical issues in the lawsuit.

4.10 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 is currently accepted only upon justifiable reasons that are provided to and approved by the courts. In general, factual or expert witnesses are required to testify during the court hearing.

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 acceptable evidence by the court.

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

Under Article 37 of Several Provisions of the Supreme People's Court on Evidence in Civil Proceedings, after the expiration of the time limit for evidence submission, the court may organise evidence exchange prior to the trial when: there is an application for evidence exchange by either party; or the court believes evidence exchange is necessary.

4.12 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 file arbitration instead of a lawsuit for the matters, subject to the scope of the arbitration clause and the Arbitration Law of China.

Actually, mediation is also an alternative dispute resolution in China under the law. In practice, the court tends to push for settlement 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.

4.13 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 if the plaintiff is not domiciled in China, as long as the infringement was committed in China or the consequence of the infringement also took place in China.

Therefore, even if the distributor or manufacturer is not domiciled in China, it can be sued as a defendant in a product liability case in the courts of China.

5 Time Limits

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

Yes, there are statutes of limitations 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 general statute of limitations is three years under the Basic Principles of Civil Law promulgated in October 2017. However, product liability actions are usually subject to special time limits.

The limitation of action based on the cause of selling defective products was first established 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 plaintiff knew or should have known that its rights were impaired. The right of the 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 warranty period 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 three-year limitation period in product liability lawsuits does not vary depending on whether the product liability is fault-based or strict liability. The age or condition of the plaintiff does not affect the calculation of the time limits.

In accordance with the Basic 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 on which the plaintiff should have known that their rights were damaged, issues of concealment or fraud could change the calculation of the time limit. In practice, however, such cases are rare.

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 under the Tort Law, and there are cases where the claims include court orders to recall the involved products, so far it is not known that any court has issued a judgment to initiate 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 to the product itself, the Product Quality Law expressly excluded it, while the wording used in the Tort Law very generally refers to "injury or damage of others". However, the Tort Law was enacted later than the Product Quality Law, and when the Sub-Committee of Legislative Affairs of the Standing Committee of the National People's Congress explains the Tort Law, it holds the opinion that damage to the product itself is recoverable in a product liability claim. In practice, most courts follow this explanation. Other types of recoverable damage usually 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?

As to whether product liability covers the damage to the product, if the defect endangers another person's property or personal safety, the plaintiff can request for any defects to be removed, any dangers to be eliminated, or any other appropriate actions to be taken, but costs such as medical monitoring cannot be recovered. Further, if the plaintiff is also the consumer, it may consider filing a claim against the operator to stop selling the product or providing the service, or even recall the products with potential malfunction, under the Consumer Protection Law.

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

Yes, under 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 statutory 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 in civil lawsuits. The decision to settle is completely with the 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?

There is no equivalent 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 plaintiff is the prevailing party, it can recover the court fees from the losing party. As to verification costs, it is the applicant who bears the costs and the party inviting the expert assessor who pays the associated costs. If the product liability case arose as a result of personal injury, the plaintiff might recover the attorneys' fees.

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

Yes, legal aid is available 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 receive funding for product liability disputes.

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

In China, legal aid is receiving **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 equivalent 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 provided in Article 101 of China Civil Procedure law that: "[w]here the lawful rights and interests of an interested party will be irreparably 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. However, once the court accepts 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 applies a preservation measure; the people's court shall revoke the preservation.

8 Updates

8.1 Please provide a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

The so-called "professional extortioner for fraud-fighting" in China has been trolling businesses in China for quite some time. The

Consumer Protection Law and the Food Safety Law of China, as well as the courts, are usually very protective over the consumers/plaintiffs. These professional extortioners take advantage of the system and look for minor mistakes or omissions made by the manufacturers to launch their attacks. Businesses in the food industry are particularly vulnerable to the claims of misrepresented food ingredients or mistakenly placed logos as it is usually easier to spot the omissions and the Food Safety Law provides tenfold damage, making extorting activities even more lucrative compared to the treble damage provided by the Consumer Protection Law. The professional extortioners usually target manufacturers and sellers with good reputations to find deep pockets and make it easier to get a higher settlement amount. The Supreme Court has clarified, under Article 3 of the Judicial Interpretation on the Trial of Dispute Cases Relating to Food and Drugs, "where the buyer claims rights against producer and seller and the producer and seller defend on the grounds that the buyer purchases food or drugs while having the knowledge of a quality issue in a dispute relating to food or drugs, the people's court shall not support the defence of the producer and seller". In practice it is quite a challenge for the defendants to establish the "knowledge of quality issue" of the plaintiff; however, it is already a significant improvement in keeping the extortioners at bay. As the "professional extortioners" also create problems for other businesses, including car manufacturers, it is good to learn that the Supreme Court is now aiming to contain the extortioners in other industries by issuing judicial interpretations as shown in an official reply to the State Administration of Industry and Commerce in May 2017. In addition to market disruption, the Supreme Court also deems these extortion activities as a waste of judicial resources. It will be interesting to see what solution the Supreme Court will adopt to improve the situation.

In the past, car owners generally would adopt the improvement measures suggested by the manufacturers in the recall notices, but we are seeing the trend that more and more car owners choose to file lawsuits against the manufacturers when they are not satisfied with the recall notices. For example, as to the water soaking issue, some car owners started to complain in 2017, the manufacturer implemented the recall which promised to remove the unnecessary drain valve for the intake line for vehicles in the range for free and install a baffle at the air inlet to prevent excess water from entering the intake line. However, 48 car owners were dissatisfied with the recall measures and chose to hold a lawsuit against the manufacturer. The court appointed a verification institution to conduct a forensic appraisal, and its opinion was that the recall measure of removing the unnecessary drain valve for the intake line for vehicles in the range was unreasonable. The manufacturer did not agree with this appraisal opinion and applied for a foreign expert to appear in court to cross-examine the hearing, and also submitted a re-appraisal application. The lawsuit is still pending, but with the negative appraisal opinion, it is a huge challenge for the manufacturer to defend its recall measure and products.

Kelly Liu

Squire Patton Boggs
25th Floor, North Tower
Suite 2501 Beijing Kerry Centre
1 Guanghua Road Chaoyang District
Beijing 100020
China

Tel: *+86 10 6589 3782*
Email: *kelly.liu@squirepb.com*
URL: *www.squirepattonboggs.com*

Kelly Liu has more than 14 years' experience as legal professional. Since 2005, she has worked for a foreign-related intellectual property agency, a German law firm's Shanghai office, and a US chemical company. She is currently a partner of Squire Patton Boggs (US) LLP, Beijing Office, and the person in charge of the product liability field. She mainly engages in automotive product liability, data compliance, intellectual property, including litigation and non-litigation. She has a wealth of negotiating experience and skills, especially for high-risk cases.

Wu Di

Squire Patton Boggs
25th Floor, North Tower
Suite 2501 Beijing Kerry Centre
1 Guanghua Road Chaoyang District
Beijing 100020
China

Tel: *+86 10 6589 3784*
Email: *di.wu@squirepb.com*
URL: *www.squirepattonboggs.com*

Wu Di focuses his practice on the defence of product liability in the automotive industry. He has rich experience in defending product manufacturers and distributors in individual product liability actions involving injuries and wrongful death claims.

SQUIRE PATTON BOGGS

Squire Patton Boggs provides clients with unique insight at the point where law, business and government meet, giving them a voice, supporting their ambitions and achieving successful outcomes.

Squire Patton Boggs has grown to become one of the world's strongest law firms through a unique mix of organic growth to match our clients' needs plus astute combinations to bring additional local insight, skills and opportunities.

Today, Squire Patton Boggs has a global team of more than 2,600, including more than 1,500 partners and lawyers.

Chapter 12

England & Wales

Michael Spencer QC

Adela Williams

Arnold & Porter

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 arising from a 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 risk-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). The approach to defect in *Wilkes* was followed in another case involving allegedly defective hip prostheses: *Gee & Others v DePuy International Limited* [2018] EWHC 1208 (QB). 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 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 in circumstances where 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, but this 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. However, a new EU Commission proposal for a Directive providing for collective redress actions in cases of breach of EU consumer protection legislation was published on 11 April 2018. See question 4.4, below.

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

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 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

In England and Wales, a public body charged with exercising a regulatory function in relation to public welfare may be liable for breach of statutory duty if a right to sue for breach of statutory duty is included or may be inferred from the relevant legislation. In limited circumstances, a regulatory body may be liable in negligence for the careless performance of its statutory duty. However, while a claim is possible in principle, the courts are generally reluctant to find that a duty of care arises (*X v Bedfordshire CC* [1995] 2 A.C. 633).

That situation may change, at least in relation to notified bodies and their responsibilities under the Medical Devices Directive (Directive 93/24/EEC), following the decision of the CJEU in Case *C-219/15 Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH*. In that case, which involved faulty breast implants, the CJEU confirmed that the functions of notified bodies are intended "to protect the end users of medical devices", and stated that, where there is evidence that a device is not in compliance with EU standards, notified bodies are required to "take all the steps necessary" to ensure that they meet their obligations to ensure the device is in conformity with the directive. Whether a notified body may be found liable in respect of injury caused by a defective device is, however, determined by national law. Finally, it should be noted that the EU Medical Devices Regulation, which will become applicable from 2020, provides greater specificity surrounding the obligations of notified bodies and seems likely to increase their accountability in cases where defective devices result in injury to patients. The implications of the new Regulation, after the UK leaves the EU, are currently uncertain.

1.5 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.

1.6 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. This continues to be applied in most cases, for example in the recent case of *Claire Busby v Berkshire Bed Co. Ltd* [2018] EWHC 2976 (QB) in which the court rejected a claim after the claimant sustained tetraplegia following a fall from a bed. Although the bed was not of satisfactory quality as it had two feet missing, the missing feet had not caused or materially contributed to the claimant's fall. 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 in fact 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 that 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 required to provide patient information leaflets with their medicines unless the warnings and information can be included 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 shown 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 scope of the defence has been controversial and the correct transposition of the wording of the Product Liability Directive into UK law was challenged by the European Commission, although the European Court of Justice concluded that the Commission had failed to make its case that UK implementation of the defence was incorrect (*Commission v United Kingdom* (Case C-300/95)).

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* and *Gee v DePuy International* cases 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 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, although this may change as a result of a recently published EU proposal for a Directive providing for collective redress in respect of infringements of consumer legislation (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, the European Commission has recently (11 April 2018) published a proposal for a Directive that would allow qualified entities, which represent the collective interest of consumers, to bring representative actions against infringements of provisions of EU law, seeking remedies as available under national laws. The draft legislation is proposed to apply to breaches of some EU pharmaceuticals legislation (Articles 86 to 100 of Directive 2001/83/EC relating to advertising and promotion). Recent European Parliament amendments to the draft Directive propose that the collective redress provisions should also apply to breaches of the following: Regulation (EC) No. 726/2004 on the centralised procedure for marketing authorisations; cosmetics legislation; and general product safety legislation. The draft legislation also refers to the Product Liability Directive, although it is not clear how it is meant to apply to this. It remains to be seen what form the final Directive will take and whether it will be implemented in the UK after the UK leaves the EU. However, representative actions may already be brought in England and Wales on behalf of consumers seeking damages for infringement of competition law.

4.5 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

Solicitors in England & Wales are permitted to advertise for claims, as long as their activities comply with the publicity rules published by the Solicitors Regulation Authority (SRA). Barristers in England & Wales are unable to initiate litigation on behalf of clients, and in contentious (as opposed to advisory) matters are usually required to be instructed by a solicitor. Consequently, for them, advertising for claims would be unproductive and is not practised.

In summary, advertising must be accurate and not misleading, and not likely to diminish the trust the public places in the legal professional and in the provision of legal services. Publicity relating to charges must be clear. Lawyers may not make unsolicited approaches in person or by telephone to members of the public. Publicity material must include appropriate contact details and information about the lawyer's regulated status, and must not mislead concerning the professional status of any manager or employee.

The inability of claimant lawyers to make unsolicited approaches to members of the public was in the past circumvented by claims management companies who proactively contact individuals and gather potential claims which they would then refer on to lawyers, in exchange for a referral fee. Such referral fees were banned by s.56 of the Legal Aid, Sentencing and Punishment of Offenders Act 2012 (LASPO), which prevents a "regulated person" paying or being paid for a referral of prescribed legal business and also prevents them being paid for arranging for another person to provide services to their client. The ban, coupled with other changes which make the litigation environment less favourable for claimant personal injury lawyers, has likely reduced the total number of such claims, although this is difficult to quantify.

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

Timing depends on the complexity of the case and the value of the claim. According to the Civil Justice Statistics Quarterly for January to March 2018, 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 57 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.

4.7 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 may order the trial of preliminary issues of law and fact in separate proceedings prior to the main trial, and may 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.

4.8 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 at 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.

4.9 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 may 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.

4.10 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 unable to attend court as a result of illness.

4.11 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 under way. 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.

A revised disclosure regime which seeks to limit disclosure is the subject of an ongoing pilot scheme in some business and property courts. The key feature of the proposed new disclosure rules is that there will be no automatic entitlement to search based 'standard disclosure'. Instead, 'basic disclosure', limited to the key documents on which a party has relied and those that are necessary to enable the other parties to understand the case they have to meet, will usually be provided with the statement of case (pleading). At this stage, a party will be required to state whether it intends to seek "extended disclosure". The pilot scheme is planned to last for some two years and, if successful, may be applied more generally.

4.12 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). Courts have refused to award costs to a successful party where they unreasonably refused to mediate (*Dunnett v Railtrack plc* [2002] EWCA Civ 303), and awarded indemnity costs against an unsuccessful party (*ICI Ltd v Merit Merrell Technology Ltd* [2018] EWHC 1577 (TCC)), although it has also been held that complex questions of law might make a case unsuitable for mediation and, if there is no realistic prospect of a successful outcome, it may not be unreasonable to decline to mediate (*Gore v Naheed* [2017] EWCA 369).

4.13 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". It remains to be seen to what extent existing EU provisions will continue to apply to England and Wales after the UK leaves the EU.

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). The Court found that parent company control had been present in *Lungowe and Ors. v Vedanta Resources Plc and Konkola Copper Mines Plc* [2017] EWCA Civ 1528, allowing the claim to proceed in England and Wales. However, the extent to which parent companies may be liable for the acts and omissions of their overseas subsidiaries was further clarified in *His Royal Highness Okpabi v Royal Dutch Shell Plc* [2018] EWCA Civ 191: issuing mandatory policies across a group may not be enough to establish a duty of care in the absence of evidence of more direct and substantial control of the operations of the subsidiary.

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 Remedies

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).

Personal injury can include a physical change making the sufferer appreciably worse off in terms of their health or capability, even if that change is hidden and symptomless: in *Dryden & Ors v Johnson Matthey Plc* [2018] UKSC 18, the Supreme Court held that this applied to individuals who had been sensitised to platinum salts and produced a particular type of antibody which meant that they were likely to have an allergic reaction involving physical symptoms if their exposure to platinum salts continued (*Grieves v FT Everard & Sons Ltd* [2007] UKHL 39 distinguished: sensitisation was a harmful physiological change, unlike pleural plaques).

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.

Straightforward smaller personal injury claims (up to a value of £25,000) are now required to be commenced via claims portals under protocols which provide for recovery of only fixed costs if a claim is resolved under the protocol.

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 abolished 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 (ATE) 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, although in *Sandra Bailey & Others v GlaxoSmithKline UK Limited* [2017] EWHC 3195 (QB) the cap was held not to apply and it was confirmed that it was within the court's discretion to order security in excess of the funding 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).

The Government has recently proposed that a regime of fixed recoverable costs be introduced for all civil claims up to a value of £100,000, excluding clinical negligence cases and claims in the business and property courts.

8 Updates

8.1 Please provide a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

See above. The key developments over the past year have been procedural. The changes to disclosure obligations, currently being trialled in a pilot scheme, could have substantial implications for the costs associated with litigation including in relation to product liability claims, as could the proposed extension to the fixed recoverable costs. The proposed Directive permitting collective redress actions could alter the litigation landscape in the EU if enacted; in these circumstances, the UK's response in the context of Brexit could be important in determining whether the UK is seen as an attractive forum for such litigation in the future.

To date there has been little experience reported in relation to the way that the courts are approaching questions of product liability in the context of new technologies such as artificial intelligence (AI). It seems that what is truly new about such technologies are the aspects of autonomy and self-learning. In other words, an algorithm could develop and take decisions, including operating machinery or manipulating data in ways that cause harm, but which are not foreseeable nor conditioned by any human operator. Some commentators, including several in the context of a House of Lords Select Committee on Artificial Intelligence report (HL Paper 100) published on 16 April 2018, consider that such developments will challenge the underlying basis of legal obligations according to present concepts of private law (whether contractual or tortious). Others take the view that existing liability mechanisms are likely to be adequate to the task. Suggestions have been made for alternative insurance arrangements applicable to e.g. driverless cars and drones, but in general no specific case has been made as to why existing mechanisms for legal liability and redress might not cope with products and systems that incorporate AI, just as they have coped to date with other complex and technologically advanced products.

Michael Spencer QC

Barrister (retired from practice in January 2018)

Email: spencer@crownofficechambers.com

Called to the Bar: 1970; Queens Counsel: 1989. He read Law at Oxford. M.A. (Oxon). Profumo Scholarship, Inner Temple. Recorder 1987 - 2007. Deputy High Court Judge 1997 – 2007.

Professional Affiliations: Professional Negligence Bar Association, London Common Law and Commercial Bar Association, Midland Circuit.

Practice: Product liability and regulatory work. He has been regularly instructed on behalf of manufacturers in the pharmaceutical industry on drug claims, and in the group litigation which arises out of such actions. Past cases have included the recent successful defence of DePuy International in respect of litigation relating to metal on metal hip prostheses, Opren (Benoxaprofen), whooping cough vaccine, benzodiazepines, MMR vaccine, thrombogenicity of 3rd generation oral contraceptives, claims relating to blood products and to alleged birth defects relating to maternal use of sodium valproate, as well as the recent successful defence of DePuy International in respect of litigation relating to metal on metal hip prostheses. He has also been instructed in respect of clinical negligence claims brought against health authorities, and on behalf of health authorities in respect of Health and Safety prosecutions arising out of hospital accidents. He has acted in various public inquiries, including those into legionnaire's disease and the Clapham railway disaster, and the Southall Rail Accident Inquiry and the Bexley Derailment Arbitration. He represented the Department of Trade and Industry in respect of 600,000 claims brought by miners against British Coal for damages relating to chronic obstructive pulmonary disease, and in respect of claims by the DTI against contractors for contribution to such damages.

Publications: Author of chapters on confidentiality and product liability in Powers & Harris on Clinical Negligence. Contributor to *Doctors, Patients and the Law* (Blackwell Scientific Publications). Joint Editor of O'Grady, Dodds-Smith, Walsh and Spencer on *Medicines, Medical Devices and The Law*.

Adela Williams

Arnold & Porter
Tower 42, 25 Old Broad Street
London EC2N 1HQ
United Kingdom

Tel: +44 20 7786 6115
Fax: +44 20 7786 6299
Email: Adela.Williams@arnoldporter.com
URL: www.arnoldporter.com

Adela Williams is a partner in the London office of Arnold & Porter, specialising in product liability litigation (unitary actions and group litigation), principally involving life sciences clients and including claims involving unlicensed medical products in the research context as well as marketed products. Such litigation has often involved co-ordinating proceedings within the EU and advising on forum and other jurisdictional issues. Past cases include the fetal anticonvulsant litigation and the successful defence of group litigation involving more than 100 claims relating to the "third generation" oral contraceptive pill on behalf of two of the defendant manufacturers.

She also advises clients in relation to the regulation of medicinal products, medical devices, foods and cosmetics in the EU and acts on their behalf in litigation arising from the decisions of regulatory bodies.

She is an Assistant Coroner.

Arnold & Porter

Arnold & Porter is an international law firm with over 1,000 attorneys in 16 offices in the US, London, Brussels, Frankfurt, Shanghai and Seoul. 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.

Please contact Ian Dodds-Smith, Dr. Adela Williams or Tom Fox in the London Office for UK or EU product liability enquiries, and Anand Agneshwar in the New York Office for US enquiries.

Chapter 13

France

Carole Sportes

Valérie Ravit

Squire Patton Boggs

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 for 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 (Article 1641 of the FCC) owed by the seller to the buyer.
  - In matters between consumers and professionals, Article L. 217-4 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 (Article 1245-5 of the FCC). The distributor who affixes his name, trade mark or any other distinguishing sign on the product, 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 (Article 1245-6 of the FCC).

1.4 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

L'ANSM, the French National Agency for Medicines and Health Products Safety, conducts assessment of healthcare products and acts as a decision-making body in the field of sanitary regulation (Article L. 5311-1 of the Public Health Code) under the supervision

of the Ministry of Health. Its Director General makes decisions on behalf of the French State (Article L. 5322-2 of the Public Health Code).

Therefore, the French State's liability can be triggered by the actions or inactions of the French National Agency for Medicines and Health Products Safety as, for instance, when this authority failed to revoke the marketing authorisation of a defective product (Council of State, 9 November 2016, n°393902).

The French State's liability may be excluded or limited in case of a fault committed by a private party subject to State control (in the abovementioned case, the producer) or to the control of an authority acting on behalf of the State. However, the fault of a public or private party with whom the State collaborates closely for implementing a public service mission cannot exonerate the State from its liability (*Conseil d'Etat*, 9 November 2016, n°393926, Paris Administrative Court of Appeal, 4 August 2017 No16PA00157, 16PA03634).

1.5 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. 421-3 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 (Article L. 521-7 of the Consumer Code).

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

1.6 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 *mens rea* 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 substance**s. 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.

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 held in an action involving the liability of the producer of a vaccine due to an alleged defect in that vaccine, the ECJ stated, on 21 June 2017, that:

- The Court may use serious, specific and consistent evidence enabling it to conclude that there is a defect in the vaccine and that there is a causal link between that defect and that disease. National courts must, however, ensure that their specific application of those evidentiary rules does not result in the burden of proof introduced by Article 4 being disregarded or the effectiveness of the system of liability introduced by that directive being undermined.
- The ECJ then considered that the national Courts cannot use predetermined causation-related factual evidence which would result in the burden of proof being disregarded.

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 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 the 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 products (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, however, the French Supreme Court has not ruled on that question.

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 5° 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 in 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.

Class actions are also available in the environmental sector (Article L. 142-2 of the French Environmental Code), in the equal opportunity sector (Law No. 2016-1547 of 18 November 2016) and in the data protection sector (Law No. 2018-493, and ordonnance No. 2018-1125 dated December 13, 2018).

- 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 L. 141-1 of the French Environmental Code).

- Equal opportunity sector:

Law No. 2016-1547 of 18 November 2016 introduced class actions in the anti-discrimination 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 grounds 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 introduced class actions for data protection. Such action has been modified by Law No. 2018-493, and ordonnance No. 2018-1125 dated 13 December

2018; under this new regime, an action can be brought when several natural person are in a similar situation and suffer from damages resulting from a breach of EU Regulation 2016/679 or of French law "Informatic and Liberties" by a person in charge of handling personal data or a sub-contractor.

Under the new law, the claimants can now claim either an injunction or seek the liability of the breaching party to obtain compensation for material damages or moral damages.

The liability can only be sought if the cause of the damages occurred after 24 May 2018.

This action is open to associations which bylaws provide that the purpose of the association is the protection of privacy and personal data which have been registered for at least five years. 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 bylaws.

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 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

Advertisements for claims can be construed as defamatory or as a violation of the presumption of innocence.

Moreover, under article 10 of the rules of professional conduct, lawyers must comply with ethical rules when advertising their services. Lawyers' advertisements are not like other commercial advertisement, they must be loyal and sincere.

However, once the liability of the producer is established in a class action, courts must provide for advertisement of the judgment in their decision. The burden is on the producer who must inform consumers that they can opt in to the class action.

Under French law, the class is determined during the judgment on liability. Accordingly, advertising will impact the final number of claims.

4.6 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 a further 18 months for the recourse before the *Cour de Cassation*.

Several emergency procedures are also available, such as interim relief and fixed-date proceedings.

4.7 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.

4.8 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.

4.9 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.

4.10 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.

4.11 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.

4.12 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.

4.13 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?

French law has strictly implemented the time limits of articles 10 and 11 of the European Directive 85/374/EEC regarding liability for defective products.

Article 1245-15 of the FCC provides that the liability of the producer is extinguished upon the expiry of a period of 10 years from the date on which the producer put into circulation the actual product which caused the damage.

Article 1245-16 of the FCC provides that a limitation period of three years applies to proceedings for the recovery of damages from defective products which begins to run from the day on which the plaintiff became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer.

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 2224 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.

Regarding liability for latent defect, Article 1648 of the FCC provides that the two-year statute of limitations starts running from the discovery of the defect.

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 recoverable damages. 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?

Strictly contingent fee arrangements are forbidden under French law.

Written fee arrangements containing both a fixed and a contingent fee are, however, permitted when the calculation is set out in advance.

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

Third party funding is not 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 a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

- On 12 February 2019, the European Parliament released a resolution on a comprehensive European industrial policy on artificial intelligence and robotics (2018/2088(INI)).

  According to this resolution, "existing rules and processes ought to be reviewed, and if necessary modified, to account for artificial intelligence and robotics". The Parliament commends the initiative "to create the Expert Group on Liability and New Technologies with the aim of providing the EU with expertise on the applicability of the Product Liability Directive to traditional products, new technologies and new societal challenges" but "[r]egrets […] that no legislative proposal was put forward during this legislature, thereby delaying the update of the liability rules at EU level and threatening the legal certainty across the EU in this area for both traders and consumers".

  Accordingly, changes are to be expected in the coming years regarding product liability at the European level.
- A draft bill relating to the French tortious liability regime was issued on 13 March 2017. The legislative process has been put on hold but should resume by the end of 2019.

Carole Sportes
Squire Patton Boggs
7 rue du Général Foy
75008 Paris
France

Tel: +33 15383 7400
Email: carole.sportes@squirepb.com
URL: www.squirepattonboggs.com

Carole Sportes, Managing Partner of the Squire Patton Boggs' Paris office, heads its international dispute resolution department.

Carole Sportes specialises in the areas of insurance, aviation and in product liability litigation. She acts for major pharmaceutical companies, international insurers and air carriers.

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 during 10 years to the development of a French boutique law firm before joining Squire Patton Boggs in January 2015.

Carole's clients are sensitive to her extensive experience in handling mass tort litigation and correlative ability to craft and ensure coherent strategy of defence in multi-district litigations. She is also well regarded as to her ability in dealing with technical and complex matters.

Valérie Ravit
Squire Patton Boggs
7 rue du Général Foy
75008 Paris
France

Tel: +33 15383 7400
Email: valerie.ravit@squirepb.com
URL: www.squirepattonboggs.com

Valérie Ravit is a partner within the dispute resolution department of Squire Patton Boggs in Paris. Her activity is focused in the areas of insurance and reinsurance, industrial risks, environmental liability and product liability, especially for health products.

Valérie advises leading insurance companies on their policy wording. She intervenes both as coverage counsel and defence counsel. She is also involved in reinsurance litigation.

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 Life Sciences, Aerospace & Defence, Energy, Automotive and Diversified Industrials, Chemicals, Marketing Services.

Germany

Michael Molitoris

Dr. Juan Carlos Dastis

Noerr LLP

1 Liability Systems

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

There are two systems of product liability in Germany: tort law; and the Product Liability Act.

The tort law provisions applicable to damages resulting from the supply of products have been in place since the German Civil Code came into force in 1900. However, the beginning of German product liability law is usually traced back to a landmark case by the German Federal Court of Justice some 50 years ago. Although German tort law in general is fault based, in this seminal ruling, the German Federal Court of Justice supported product users by reversing the burden of proof with regards to fault. Since then, the German Federal Court of Justice has kept on developing this branch of law to this day.

The second pillar of product liability in Germany is the Product Liability Act, which entered into force on 1 January 1990. This Act had become necessary in order to implement the European Product Liability Directive from 1985. If a product causes a person's death, injury to his body or damage to his health, or damage to an item of property, the producer of the product has an obligation to compensate the injured person for the resulting damage. Liability under the Product Liability Act is strict.

Contractual liability might play a role if the aggrieved party happens to be in a contractual relation with the producer. Contractual liability is neither excluded by tort law nor by the Product Liability Act.

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.

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

The manufacturer is liable for his negligence under tort law and under the Product Liability Act (see question 1.1 above).

Under certain circumstances, an importer might be regarded as a manufacturer and therefore be liable regardless of his own negligence (sec. 4 (2) Product Liability Act).

The distributor (and/or the retail supplier) might be liable; however, only if the producer of the product cannot be identified (sec. 4 (3) Product Liability Act). Liability might also arise if the product presents the distributor as its producer (sec. 4 (1) Product Liability Act).

Apart from that, the legal responsibility of the importer, the distributor and the retail supplier based on tort for a defect of the final product is rather limited. In general, they are liable for the specific activities of their own task and role (e.g. defects resulting from transport or storage).

1.4 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

In the case of products requiring certification or monitoring by law, there are usually three parties with different spheres of responsibility: the manufacturer; the privately organised certification or monitoring body (e.g. TÜV or ZÜS); and the regulatory authority. The state authority, which cannot circumvent its responsibility through privatisation, is responsible for supervising both the manufacturer and the private certification or monitoring body. However, due to the subsidiarity of official liability under German law and the predominant responsibility of the manufacturer, state liability has only been considered in a few exceptional cases.

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

The manufacturer's responsibility for the product does not end after the product is placed on the market; products placed on the market must be monitored so that the manufacturer is able to prevent potential hazards that may be caused by the product. If a warning is not sufficient, the manufacturer may also be obliged to withdraw the dangerous products from the market as effectively as possible. If he fails to do so, the manufacturer may face claims for damages from the affected product users.

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

Supplying a defective product in Germany may lead to criminal

sanctions against the manufacturer. If the manufacturer is a company, the criminal responsibility for the product usually lies with the managing director or executive employees, who can be held responsible for the misconduct of the company. It should be noted that there is no criminal law for corporations in Germany.

Typical offences in connection with the supply of defective products are – in case of personal injuries – (negligent) bodily harm and manslaughter, the legal examination of which regularly poses difficult questions. Beyond the scope of general criminal law, there is a large number of regulations (e.g. food and pharmaceutical law, the Atomic Energy Act, detergents law, etc.) which establish criminal sanctions for product manufacturers. These regulations often penalise certain types of behaviour (e.g. placing certain food on the market) without requiring the occurrence of any damage, leading to very extensive criminal product liability.

2 Causation

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

Under the Product Liability Act, the claimant has the burden of proving defect, damage and causation (for the Product Liability Act, *cf.* sec. 1 (4) Product Liability Act). Liability under the Product Liability Act is strict, so the claimant does not have to prove fault. In tort law, the claimant also has the burden of proving fault. However, the burden of proof with regards to fault is reversed.

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 must establish causation between the damage and the product. Causation must be proven beyond reasonable doubt. Only in exceptional cases is it possible to ease the burden of proof for the claimant.

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

If it cannot be established which of several possible producers manufactured the defective product, none of the possible producers is liable. Under German law, it is crucial to establish a causal link between the product by a particular producer and the damage of the claimant. Accordingly, the concept of market-share liability is contrary to German 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?

Even if the product itself is flawless, a producer might be liable if a damage occurs that could have been prevented by appropriate advice or warnings. In general, the producer must instruct the product user directly. However, the producer may make use of intermediaries in the chain of supply to comply with his information duties.

These principles also apply in pharmaceutical law. In general, pharmaceutical companies are obliged to communicate directly with potential users, e.g. by providing a package information leaflet. The "learned intermediary theory" is alien to German law.

3 Defences and Estoppel

3.1 What defences, if any, are available?

General product liability under sec. 823 (1) of the German Civil Code allows the producer to defend himself by arguing compliance with legal duties. Sec. 1 (2) and (3) Product Liability Act provides a list of explicit defences. These are *inter alia* that the defect is due to compliance of the product with mandatory regulations at the time when the producer placed the product on the market, or that the state of scientific and technical knowledge was not such as to enable the defect to be discovered.

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

Under sec. 823 (1) of the German Civil Code, the producer is not liable for development risks which could not be detected by a reasonable producer at the time of supply. The state of scientific and technical knowledge at that point is applied as yardstick. Such non-detectability is favourable for the producer, hence he bears the burden of proof as soon as the claimant proved a defect at the time of supply.

The state of the art/development risk defence also applies under sec. 1 (2) (5) of the German Product Liability Act (see above), just like the defence of the fault/defect not being discoverable under the state of scientific and technical knowledge at the time of supply. Sec. 1 (4) (2) of the German Product Liability Act places the burden of proof for the non-discoverability of the fault/defect on the producer, in case of dispute.

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

The compliance with regulatory and/or statutory requirements is an indicator for the compliance of the producer's legal duties under general liability law (sec. 823 (1) German Civil Code). However, those requirements are considered to be a minimum standard.

The defence under sec. 1 (2) (4) of the German Product Liability Act is limited to cases where the regulatory/statutory requirements obliged the producer to manufacture the product in a way which inevitably led to the defect. Except for this narrow provision, the special product liability law also contains no defence based on compliance with regulatory and/or statutory requirements.

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

If a final judgment has already been rendered in one case, the matter is *res judicata* and binding on the parties of this case. However, this binding force does not apply to 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?

Defendants can seek contribution or indemnity by a third party via joint and several liability, sec. 840 (1) of the German Civil Code and sec. 5 of the German Product Liability Act, respectively. By sending a third-party notice under sec. 72 and sec. 73 of the German Code of Civil Procedure, the defendant can assure that the third party is bound to the outcome of the litigation between the claimant and defendant, sec. 74 (3) and sec. 68 of the German Code of Civil Procedure. The subsequent proceedings must be brought considering the general statute of limitations for the claims against the third party. There is no specific time limit tying the subsequent proceedings to the claimant's proceedings against the defendant.

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

The general law on damages allows the defendant to allege the claimant's contributory negligence both for the occurrence as well as the extent of the damage, sec. 254 German Civil Code. This will reduce the damages owed to a claimant accordingly. Sec. 6 (1) German Product Liability Act refers to sec. 254 German Civil Code, assuring its applicability.

4 Procedure

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

In Germany, civil cases are decided by judges; there is no trial by jury. However, chambers for commercial matters consist of a judge and two lay judges with a commercial background.

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

Yes, the court can appoint (technical) experts to assist with the taking of evidence.

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

Until very recently, class actions were alien to the German judicial system. On 1 November 2018, a new statute on model declaratory actions was implemented. The claim must be brought by a representative body. The consumers can join this action by enrolling in a claims register.

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

In fact, claims must be brought by a representative body, namely qualified consumer protection associations. To file a suit, this body must present 10 aggrieved consumers. Subsequently, if at least 50 consumers enrol in the claims register within two months, the model declaratory action is admitted.

4.5 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

In general, the legal professional code provides for an advertising ban. However, in recent years this ban has been relaxed by case-law. Notwithstanding, advertising is not yet of any great importance in Germany.

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

This depends on the procedure chosen by the court. The judge has a choice between preliminary written proceedings or an early first hearing. In complex product liability cases, the judge will usually opt for written proceedings, allowing for the exchange of several submissions. According to recent studies, it takes on average 4.8 months at local courts (*Amtsgericht*) and 8.7 months at district courts (*Landgericht*) until a judgment is rendered.

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

The courts can try preliminary issues. In practice, however, this is only rarely the case.

4.8 What appeal options are available?

Sec. 511 of the German Code of Civil Procedure provides for an appeal against first instance judgments, in which new facts might be admitted. Judgments following that second instance can be appealed under sec. 542 of the German Code of Civil Procedure. In this third instance, only legal errors are considered. Court decisions which do not constitute judgments can be appealed under sec. 567 of the German Code of Civil Procedure if there is a specific provision granting such challenge.

4.9 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 following the provisions under sec. 402-414 of the German Code of Civil Procedure.

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

Neither factual nor expert witnesses are required to present themselves for pre-trial deposition. There are no provisions for the exchange of witness statements prior to trial. If an expert submits a written report, it is sent to the court which in turn forwards it to the parties.

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

In Germany, the burden of proof lies with the party who benefits from the facts to be proven. In general, the other party is under no obligation to disclose (documentary) evidence. In particular, there is no discovery.

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

In product liability cases, parties are not required to pursue alternative methods of dispute resolution before bringing proceedings. However, if the parties want to avoid litigation, there are several methods of alternative dispute resolution available.

4.13 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 not domiciled in the German jurisdiction have the same access to German courts as claimants domiciled in Germany. They can be brought within the jurisdiction of a German court as defendants if the court's forum under sec. 12-37 of the German Code of Civil Procedure is pertinent. However, the court can only serve the statement of claim and other writs if public international law, e.g. diplomatic channels, provide a way.

5 Time Limits

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

Yes. It should be noted that time limits in German law are a question not of procedural law but of substantive law and provided for in the Civil Code.

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

The general limitation period is three years and begins at the end of the year in which the claim arose, the creditor became aware of the circumstances giving rise to the claim and of the identity of the debtor. However, there are important deviations under the Product Liability Act (sec. 12), in particular with regards to the beginning.

There are also certain maximum limitation periods which apply irrespective of knowledge of the creditor. The general maximum limitation period is 10 years from the date when the claim arose. A maximum period of 30 years applies to certain damage and inheritance claims. For certain claims, specific limitation periods apply, especially for warranty claims and damage claims based on defects in a product or works. The running of the limitation period may be inhibited by conducting negotiations on the circumstances giving rise to the claim, or by initiating legal procedures including alternative dispute resolution.

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

Fraud is particularly relevant for contractual liability (sec. 438 (3) Civil Code).

6 Remedies

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

Monetary compensation is the standard remedy in product liability cases. A declaratory relief is admissible if the claimant wants to establish an obligation to pay compensation for future damages. Injunctive reliefs are also possible. The injunction order might oblige the defendant to recall goods which have already been put into circulation.

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

In general, damages to property, bodily injuries and mental damages (as part of health impairment) are recoverable. However, the product itself is not protected. In case of damage to property, the claim of damages is limited by three additional requirements: 1) only damages to items other than the defective product itself can be compensated; 2) the other item has to be meant for private use and

consumption; and 3) has to be mainly used for the latter. It should be noted that an end product, which is damaged by a defective, functionally delimitable component, may be a different item in the sense of product liability 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?

In general, medical monitoring costs are not recoverable.

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

The concept of punitive damages is alien to 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?

Under sec. 10 of the Product Liability Act, liability is limited to the amount of 85 million Euros in case that bodily injuries were caused by the same product. This is a substantial difference to tort law, where liability is unlimited.

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, court approval is required for a settlement resulting from the new model declaratory action (see question 4.3 above).

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

If the wronged party was compensated by the manufacturer/producer, the authorities which paid for social reasons can reclaim their payments as the producer/manufacturer is primarily liable as the immediate person responsible.

7 Costs / Funding

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

In principle, the Loser-Pays Principle applies (sec. 91 German Procedural Code), according to which the losing party must pay all costs of the successful party, including the court fees and other incidental expenses, as well as their own legal costs of bringing the proceedings.

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

Yes, it is.

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

The party must make an application to the trial court. In this application, the party must submit a statement about the personal and economic circumstances. Moreover, the claim must have a prospect of success, which means, the court has to find the legal arguments convincing.

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

The German law does not allow for contingency fees, with few exceptions. For example, a contingency fee is permissible, if the applicant (who is not eligible for legal aid) would be otherwise prevented from asserting his rights for purely economic reasons.

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

Litigation funding by a third party funder is not prohibited in Germany and has become more common in recent years. The most important case of third party funding in Germany is a legal expense insurance, which is regulated by the Insurance Act. In this case, the client has a right to exemption for legal costs against his insurer, but only for the statutory fees.

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 costs depend on the value of the claim, which is determined by the court. Therefore, a lack of control for the court exists only if lawyer and client agree on billing on an hourly basis, which is often the case.

8 Updates

8.1 Please provide a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

The most recent development which will have a major impact on Product Liability Law in Germany is the introduction of a class action. The new statute on model declaratory actions is designed to make it easier for consumers to enforce their rights, without having to bear the financial risk that comes with a trial. The first such action has already attracted over 400,000 consumers. However, it remains to be seen whether this "one for all lawsuit" will actually improve the position of consumers. Another model declaratory action has been dismissed as inadmissible on the ground that the consumer protection association did not comply with the standards for representative bodies.

Michael Molitoris

Noerr
Brienner Straße 28
80333 Muenchen
Germany

Tel: +49 89 28628146
Email: Michael.Molitoris@noerr.com
URL: www.noerr.com

Michael Molitoris is partner in the Munich office of Noerr. He has extensive practical experience handling complex German and international litigation and arbitration cases, especially in the fields of commercial disputes/damage claims, product liability, tort law, insurance and reinsurance law, banking law, and white-collar crime.

Michael gained comprehensive experience working on a wide range of litigation and arbitration cases, mostly representing a party but also frequently acting as arbitrator. His work includes civil litigation as well as defence work in criminal proceedings representing German and foreign manufacturers from different industries, banks, and insurance companies. He has been involved in many transnational cases, including litigation/arbitration between parties in the US, UK, Japan, the Russian Federation, Brazil, France, Poland, Hong Kong, Singapore, Switzerland, Austria, and Germany.

Michael is a member of Deutsche Institution für Schiedsgerichtsbarkeit (DIS) (German Institution for Arbitration), International Association of Defence Counsel (IADC), and International Bar Association (IBA). He is former chair and a former member of the board of directors of Lex Mundi.

Michael speaks at many conferences covering the fields of international litigation and arbitration, product liability, and white-collar crime and has published extensively on these topics.

Best Lawyers 2019 counts him among the "Best Lawyers Germany" for arbitration and mediation, litigation, and product liability. *Chambers Global 2019* and *Chambers Europe 2019* recommend him as leading lawyer for litigation. Furthermore, JUVE Handbook 2018/2019 recommends him for dispute resolution, litigation, arbitration/mediation as well as product liability.

Dr. Juan Carlos Dastis

Noerr
Brienner Straße 28
80333 Muenchen
Germany

Tel: +49 89 28628514
Email: JuanCarlos.Dastis@noerr.com
URL: www.noerr.com

Juan Carlos Dastis is an associate in the Munich office of Noerr and member of the firm's litigation, arbitration, and ADR practice group. He has broad practical experience in German and international litigation and arbitration, particularly in commercial disputes, general civil law, private international law, as well as international civil procedure.

Carlos had already set the course towards this international focus during his legal education in Hamburg, London, Cambridge, and Oxford. This background and his recent casework in in the fields of Commercial Disputes, Damage Claims and Product Liability equip him with outstanding skills in national and international litigation and arbitration, satisfying numerous clients so far.

Carlos is a member of the Munich Bar and lecturer at Ludwig Maximilian University of Munich (LMU). Carlos has published extensively in the field of commercial law. The majority of his papers deal with sales law, while his most recent publication on collective redress in Germany and Europe is equally noteworthy. His doctorate on buyer's right of withdrawal in European private law at the Max Planck Institute for Comparative and International Private Law in Hamburg was sponsored by the German Economy Foundation. He was granted the Gunther Elbing Award 2018 for strengthening the link between science and practice.

Noerr

Noerr is one of the top European law firms with 500 professionals in Germany, Europe, and the US. They deliver real value to clients by devising and handling the right solutions for complex and sophisticated legal matters. The Noerr difference is a unique combination of legal excellence, creative thinking, international experience, and in-depth industry knowledge.

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 and 2018 (by Laws 3587/2007 and 4512/2018, respectively).

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 follows 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 and Law 4177/2013 (Rules Regulating the Market of Products and the Provision of Services) (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 see also below under question 1.4.

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 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

The potential liability of a regulatory authority falls within the legal frame of the state's and state entities' liability (articles 104-106 of GCC's Introductory Law), requiring an unlawful act or omission at the exercise of their duties and being regulated by the general provisions of the GCC regarding legal entities; an exception applies where a general public interest supersedes. A joint liability of the state/state entity and the particular person acted in breach of the law is established.

1.5 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. Producers must also 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.

1.6 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).

It is noted that before the 2018 revision of the Consumers' Law (see below under question 8.1), the definition of "consumer" was extremely broad, including any natural or legal person or entity without legal personality that was the end recipient and user of products or services, as well as any guarantor in favour of a "consumer" (but not for a business activity) (previous article 1, para. 4a of the Consumers' Law); moreover, such definition had been further expanded by case law to cover persons that used the products or services not only for private use but also for business use. As of 18.3.2018, this extended definition was narrowed and "consumer" is considered any natural person acting for purposes not falling within a commercial, business, handcraft or freelance activity (new article 1a, para. 1 of the Consumers' Law).

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, as 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 also administrative and criminal (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 (subject 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 of 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 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

Lawyers may not advertise for claims in any case. Representative bodies may do so, provided their public announcements are true, accurate and not misleading, otherwise administrative sanctions may be imposed on them and may result in their deletion from the registrar of the consumers associations (article 10, paras. 26-28 of the Consumers' Law); however, such advertising occurs rather rarely, and it does not materially affect relevant claims brought.

4.6 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), and has been in force since 1 January 2016. Under the new regime, the hearing is purported to take place around six to seven (6–7) months after the filing of a lawsuit (articles 215 and 237 of GCCP) but that time frame is in practice prolonged.

4.7 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 the court's jurisdiction or competence, and these 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.

4.8 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.

4.9 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.

4.10 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.

4.11 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).

4.12 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, as a rule) 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). By Law 4512/2018, mandatory mediation was introduced for certain disputes, although not including product liability/safety claims (see below under question 8.1).

Further, the 2013 EU legislation on alternative dispute resolution ("ADR") applies to Greece; specifically, Ministerial Decision No. 70330/30.6.2015 implemented the ADR Directive 2013/11/EU and set supplementary rules for the application of the 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.

4.13 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 especially 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 the Consumers' Law, a three (3)-year limitation period applies to proceedings for the recovery of damages, while the right to initiate proceedings against the producer is extinguished upon the expiry of a ten (10)-year period from the date the producer put the product into circulation. The age or condition of the claimant does not affect the calculation of the time limits, 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 the Consumers' Law, the types of damage that are recoverable are: a) damages caused by death or by personal injury to anyone; and b) damage or destruction caused 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 (especially articles 540–543 of GCC): a) the 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. However, in collective claims, the way the amount for moral damages awarded is calculated and the effect of the relevant decision (see above under questions 3.4 and 6.1) brings it closer to a pecuniary sentence, a so-called "civil sanction" imposed on the producer (article 10, paras 16.b and 20 of the Consumers' Law). It is noted that by the latest revision (see below under question 8.1), the obligation to allocate 20% of the moral damages awarded to the General Consumers' Secretariat so that same are invested for the promotion of policies regarding consumers' protection, was abolished (article 10, para 22 of the Consumers' 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?

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 (articles 209–214 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). Another alternative introduced in 2012 and titled "judicial intervention" is actually 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 (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. The 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. Low-income citizens are those with an annual familial income not exceeding 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 that 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 a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

a) The Consumers' Law has been amended several times. The first set of 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, para. 30 of Consumers' Law).

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 and article 13b of Consumers' Law).

Lastly, in 2018 the Consumers' Law was again extensively revised and also codified into a new text (in force as of 18.3.2018). Regarding product liability rules, a) material change was made to the definition of "consumer" that was narrowed; other basic changes regard b) the regulatory authorities and their enforcement duties, c) the funding of consumers' associations, and d) the administrative proceedings and sanctions imposed (articles 1a.1, 7, 10, 13a and 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 various amendments to the Civil Procedural Rules of 2011–2015 (see above under question 6.6).

This trend is broader in Greek law (see above under question 4.11) and within the same frame one may also note a) Law 3898/2010 which implemented Directive 2008/52/EC "on certain aspects of mediation in civil and commercial matters", and b) Law 4512/2018 which introduced extensive provisions on mediation in civil and commercial matters, including a list of disputes with mediation being mandatory before they are litigated (e.g. for car accidents, among owners of flats, for professionals' fees); however, the constitutionality of such compulsory mediation was questioned (Opinion No 34/2018 of the Supreme Court's Administrative Plenary Session) and for the time being the effect of the relevant provisions has been suspended until 16.9.2019 (article 19 of Law 4566/2018).

Thus far, application of ADR remains limited.

c) Dealing by the Greek courts of issues related to new technologies and artificial intelligence remains primitive.

Dimitris Emvalomenos
Bahas, Gramatidis & Partners
26 Filellinon Street
105 58 Athens
Greece

Tel: *+30 210 3318 170*
Fax: *+30 210 3318 171*
Email: *d.emvalomenos@bahagram.com*
URL: *www.bahagram.com*

Qualified: Athens, 1987.

Degrees: LL.M., University of London, Queen Mary College, 1988; and LL.B., University of Athens Law School, 1987.

Areas of practice: Corporate, Commercial, Product Liability, Consumer Law, Competition, Network Contracts, M&As.

Career to date: 2002, Partner, Bahas, Gramatidis & Partners, Athens, Greece. 1990, Partner, Bahas, Gramatidis & Associates, Athens, Greece. 1989, Lawyer, Zepos & Zepos Law Firm, Athens, Greece. 1987, Lawyer, Morland Navigation Company, London, UK.

Professional associations/memberships: Piraeus Bar. Greek Commercial Lawyers' Association, Athens. Competition Law Partnership, Athens. Greek Association for Arbitration, Athens. Greek Association of Law and Economics, Athens. Greek Association for Financial Law, Athens. IBA (SBL Committees C, L, M, S). European Justice Forum (EJF), Brussels (www.europeanjusticeforum.org): correspondent for Greece. DRI Europe (www.drieurope.org) (P/L, Competition, Business Transactions): Country Chair – Greece. IADC (www.iadclaw.org).

Publications: Dimitris Emvalomenos is the author of numerous articles – please see his biography on the Bahas, Gramatidis & Partners website.

Languages: Greek and English.

Additional information: Married, with three children.

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 the 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

Bindu Janardhanan

Squire Patton Boggs

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 of failure to comply with the terms of the contracts, or breach of statutory duty (such as under the Sales 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 legislations regarding product liability include the Consumer Goods Safety Ordinance (Chapter 456 of the Laws of Hong Kong), Control of Exemption Clauses Ordinance (Chapter 71 of the Laws of Hong Kong), Sale of Goods Ordinance, Toys and Children's Products Safety Ordinance (Chapter 424 of the Laws of Hong Kong), Pharmacy and Poisons Ordinance (Chapter 138 of the Laws of Hong Kong), and Dangerous Goods Ordinance (Chapter 295 of the Laws of Hong Kong), which considerably improve the position of consumers.

As Hong Kong adopts a common law system, product liability is also governed by case laws, both in the civil and criminal aspects.

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

The state does not operate any schemes of compensation for any particular product.

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 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

No. Although there are regulatory bodies for different types of products, there is no provisions in the laws, which make the authorities liable for a defective/faulty product. For example, the Pharmacy and Poisons Board serves the function of upholding the Pharmacy and Poison Ordinance (Chapter 138 of the Laws of Hong Kong), but there is no such law that the Board will be held liable for any product liability. Take also the Commissioner of Customs and Excise as an example: the Commissioner has the power to give orders under the Consumer Goods Safety Ordinance (Chapter 456 of the laws of Hong Kong); however, the Commission bears no liability for any defective/faulty products.

1.5 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.

1.6 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 onus of proving fault/defect and damage lies on the claimant. In a civil case, a party must prove a fact in issue on a "balance of probabilities", which means that the claimant's evidence must prove that it is more probable than not that the fault/defect occurred and the damage suffered is due to the fault/defect.

However, it is open to the claimant to invoke the doctrine of *res ipsa loquitur*, which is a doctrine in common law of torts that infers negligence from the nature of the accident/injury when there is no direct evidence of fault/defect. The claimant has to prove: (1) the injury would not have occurred 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. However, in practice, the application of this doctrine is very narrow.

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. The factual causation "but-for" test is applied. The claimant must prove that "but for" the defect, he/she would not have sustained the injury or damage.

As for the causation in law, it must be proved that the injury or damage incurred is not too remote a consequence of the defect.

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, as it will only be one of the factors that courts use to determine if the defendant's act materially caused the damage/injury, 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 laws impose an 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 one that is foreseeable, and that even if it had taken all reasonable care, the defect would 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 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 fault/defect was discoverable once the manufacturer successfully raises the 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 damage that party is held liable to pay to the claimant.

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?

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 court experts under 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 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

Advertisements by solicitors and barristers for claims in Hong Kong are governed by the Solicitors' Practice Promotion Code of the Law Society of Hong Kong, and the Code of Conduct of the Hong Kong Bar Association. Advertisements are allowed as long as they are

decent, legal, honest and truthful. However, both Codes have a list of limitations, such as advertisements which set out a solicitor's or firm's success rate or which are likely to mislead or deceive. Promotions usually take the form of advertisements and interviews in newspapers, on television and on the exterior of public transport. Promotions by solicitors are more frequently seen than those by barristers. Currently, there is no data on direct correlation between the promotions and the number and type of claims.

4.6 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.

4.7 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.

4.8 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.

4.9 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.

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

Under Order 39, rule 1 of the Rules of the High Court (Chapter 4A of the Laws of Hong Kong), the counsel for the claimant can order that the Defendant's witness be examined before the Trial by the examiner of the court.

Witness statements and expert reports are generally exchanged prior to trial. Factual expert witnesses may be required to present themselves at the hearing or trial if any parties cross-examine them on their statements or report.

4.11 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 question in the action. It is possible to apply for discovery before commencement of proceedings, but usually discovery is not done after the pleadings have closed. Discovery may continue up to trial.

4.12 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.

4.13 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 company), is domiciled overseas and has no real presence in Hong Kong, upon 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 in 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 limit depends on the cause of action. A civil action for breach of a commercial contract must be instituted within six years from the date on which the breach of contract happened (section 4(1)(a) of the Limitation Ordinance, Cap. 347 of the Laws of Hong Kong). In respect of a claim which causes personal injuries, the time limit is three years (section 27(4) of the Limitation Ordinance). Action for employees' compensation/work-related injuries must be brought within two years from the date of the accident that causes the injury (section 14(1) of the Employees' Compensation Ordinance, Cap. 282). The time limits set out in the Limitation Ordinance can only be extended in exceptional circumstances, such as where the plaintiff was mentally incapacitated for a certain period or the action is based upon the fraud of the defendant.

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.

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.

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.

6.3 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 must be proved. 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 not necessary. 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 the laws of Hong Kong.

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 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 a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

In Hong Kong, there is no explicit laws governing product liability. There have been no prominent changes as to the relevant statutes in Hong Kong that are relevant to consumer protection.

There have been cases concerning beauty products or administration of beauty products. In *HKSAR v Chow Heung Wing Stephen* [2018] HKCFI 60, which involved cytokine-induced killer ("CIK") blood product to patients, which caused the death of the patient. Although the case concerns more gross negligence than product liability (para. 49 of the judgment), there is indeed a need for advancement of the regulations on beauty products and the administration of beauty products.

David Goh

Squire Patton Boggs
29th Floor, Edinburgh Tower, The Landmark
15 Queen's Road Central
Hong Kong SAR

Tel: +852 2509 9977 / +852 2103 0350
Email: david.goh@squirepb.com
URL: www.squirepattonboggs.com

David Goh mainly handles large, complex and international commercial disputes and product liability. He also advises clients on regulatory matters, compliance and anti-bribery/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.

Bindu Janardhanan

Squire Patton Boggs
29th Floor, Edinburgh Tower, The Landmark
15 Queen's Road Central
Hong Kong SAR

Tel: +852 2509 9977 / +852 2103 0351
Email: bindu.janardhanan@squirepb.com
URL: www.squirepattonboggs.com

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 clients in 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.

SQUIRE PATTON BOGGS

We have been established in Hong Kong for more than 15 years. Our office is licensed in Hong Kong and can provide clients with a full range of legal support and advisory services. We currently represent multinational clients as well as clients based in the US and Europe with business operations in the Asia region.

The Hong Kong office is one of the few international legal practices that can provide comprehensive local, US and international tax advice. In addition, we advise international, local and China-based enterprises on their merger and acquisition transactions, capital market transactions, joint ventures, international business law matters, outbound investment issues and in dispute resolution.

The Hong Kong office has a diverse client base, ranging from individual clients to private enterprises, multinational corporations and governmental agencies in Hong Kong and other countries and territories in the region, including mainland China.

Chapter 17

India

Vivek Bajaj

Sonakshi Sharma

AZB & Partners

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 term 'product liability' has not been defined under any Indian statute. However, in accordance with the evolving jurisprudence around product liability claims in India, the term has generally been understood to mean the liability of any or all parties that form a part of the manufacturing and supply chain of a product, arising from any defect in the product and consequent loss or injury caused by the defective product.

In India, there is no one specific statute or law providing the entire legal framework for product liability claims. There exist multiple general and sector-specific laws that form part of the legal framework governing product liability in India which, in certain instances, may overlap depending on the sector and facts of the case.

Briefly, the substantive civil laws that relate to product liability in India are:

a. the Sale of Goods Act, 1930 (**SGA**);

b. the Consumer Protection Act, 1986 (**CPA**); and

c. the Indian Contract Act, 1872 (the **Contract Act**).

Liability with respect to defective products is typically linked to the damage caused, and in most product liability claims, there is always an element of a contractual relationship between the parties.

The SGA governs the relationship of a seller and buyer of movable goods in India. The SGA specifically provides for implied conditions or warranties undertaken by the seller with respect to fitness and merchantable quality of the product sold; and that there is an implied warranty for the goods sold to be free from defects. A breach of such an implied warranty entitles the purchaser the right to sue for damages. In product liability cases that are also contractual breaches, apportionment of liability is ordinarily contractually driven and may be joint or several (or both) depending on the provisions of the contract and the facts and circumstances of the case. By virtue of contractual arrangements, parties are permitted to exclude liability for indirect losses even if they were aware of such losses when they made the contract.

The CPA in a sense codifies the principles of product liability with respect to sale or supply of defective products to consumers. However, redressal under the CPA is only available to aggrieved parties who fall under the statutory definition of a 'consumer', which includes persons who have purchased or hired goods or services for consideration and does not extend to purchase for resale or commercial purposes. Aggrieved parties not being a 'consumer' under the CPA would be required to seek alternate methods of grievance redressal through civil suit or under contractual liability.

Further, as India is a common law country, courts are influenced by principles of justice, equity and good conscience, and principles of tort law. Courts have developed principles of fault-based liability such as negligence, and principles of strict liability, although the codification of these principles under the CPA has restricted the development of jurisprudence on strict liability under principles of tort law with respect to product liability claims in India.

The provisions of the Indian Penal Code, 1860 (**IPC**), such as those relating to criminal negligence, fraud and cheating, may apply in cases of defective products supplied if criminal intent is ascribed to the acts of the manufacturers or suppliers.

There are also regulations, such as the Bureau of Indian Standards Act 2016 (**BIS Act**), which set out mandatory and voluntary standards and specifications applicable to products across different sectors and industries. If any goods or articles do not conform to a mandatory standard, the regulatory authority under the BIS Act has the power to issue directions to stop the supply and sale, and may recall the non-conforming goods or articles. The BIS Act also provides for penal consequences, including fines and imprisonment for non-conformance, including non-conformance to prescribed standards.

In addition to the foregoing, specific areas such as the food, pharmaceuticals, automotive and electronics industries have specific laws that govern and regulate product standards, product safety and liability in these sectors, which also prescribe penalties that may be imposed for breach of statutory obligations.

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

The state does not operate 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?

In cases of defective products that are also contractual breaches, apportionment of liability is ordinarily contractually driven and may be joint or several between the manufacturer and seller (or both)

depending on the provisions of the contract and the facts and circumstances of the case. Usually, the warranty with respect to the product is typically provided by the manufacturer alone which is passed on by the seller/retailer to the consumer, thereby creating privity of contract between the manufacturer and the consumer.

In cases of tort, the Indian courts recognise the principle of joint and several liability and multiple parties may be held jointly liable in respect of any tortious claim by an affected person in the event that (1) the parties have, acting in concert, committed a wrongful act resulting in loss or damage to the affected person, or (2) when not acting in concert, have, by their individual wrongful acts, caused loss or damage to the affected person. In exceptional cases, courts have apportioned the liability between multiple tortfeasors on the basis of material evidence available on record, indicating the degree of liability of each tortfeasor.

Further, in consumer complaints under the CPA, the principle of joint and several liability has been upheld and the manufacturer (on account of the warranty provided) and dealer (being the seller or distributor) have been held to be jointly and severally liable for sale of defective products.

1.4 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

While regulatory authorities prescribe compliance standards and implement enforcement of legislation, there is no statutory liability against a regulatory authority with respect to a defective or faulty product.

1.5 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 one designated regulatory body that governs product safety reporting or recalls in India; however, sector-specific statutes do envisage and provide for recall procedures for defective products.

Recall under the BIS Act:

If the BIS is convinced that goods or articles bearing standard marks do not conform to the requirements of the relevant standard, the BIS has the power to direct the certified body or licence holder or its representative to stop the supply and sale, and may recall the non-conforming goods or articles. The BIS Act also provides for penal consequences, including fines and imprisonment for non-conformance with prescribed standards and other acts of non-compliance.

Recall under Drugs and Cosmetics Act 1940 read with the Medical Devices Rules 2017 (the **Drugs Act**):

Manufacturers or distributors that obtain licences for the manufacture and distribution of drugs and medical devices are required to adhere to a number of conditions, including the recall of devices that do not meet specified standards. The relevant licensing authority also has the power to order recall of devices that do not conform to the prescribed standards. In addition, the rules framed under the Drugs Act impose a general obligation on manufactures or authorised agents to (1) recall drugs and medical devices (manufactured or imported) that are likely to pose a risk to users' health, indicating reasons for the recall, and (2) inform the competent authority of the relevant details. Contravention of the provisions could result in penal consequences, including fines, imprisonment, cancellation, suspension or debarment of the licence holder.

Recall under the Food Safety and Standards Act 2006 (**FSSA**):

The Food Safety and Standards (Food Recall Procedure) Regulations 2017 (the Food Recall Regulations) framed under the FSSA, contain detailed provisions and procedures for the removal of food that is unsafe, including by way of recalls, and require all food business operators (FBOs) engaged in the manufacture, import or wholesale supply of food to have an up-to-date recall plan. The Food Authority is required to monitor the progress of a recall and assess the effectiveness of the action taken by the FBOs. Under the provisions of the Food Recall Regulations, the Food Authority can (1) ensure removal of food under recall from all stages of the food chain, (2) disseminate information to the consumers concerned and customers, and (3) retrieve, destroy or reprocess food under recall. Prior to the notification of the Food Recall Regulations, the Food Authority has used its inherent powers under the FSSA to recall defective or unsafe food.

Recall under the Motor Vehicles Act 1988 (**MVA**):

The MVA does not provide for the recall of automobiles in India. Despite this lack of statutory or regulatory guidance, product recalls do occur frequently in the automobile industry and are usually voluntary strategic actions to limit potential liability due to defective products. The Voluntary Code of Vehicle Recall dated July 2012 issued by the Society of Indian Automobile Manufacturers, although does not mandate a recall, contains guidelines for a voluntary recall of vehicles containing safety defects.

Recall under the CPA:

Consumer fora established under the CPA can order a manufacturer or seller or distributor to withdraw hazardous goods from being offered for sale. Failure to comply with an order passed by a consumer forum can have penal consequences, such as a fine or imprisonment.

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

Sector-specific statutes, such as the FSSA and Drugs Act, prescribe penalties (which include imprisonment and fine) for manufacturing and supplying defective products. For example, under the FSSA, the manufacture, storage, sale, distribution or import of food that is unsafe for human consumption by any person is punishable by imprisonment as well as a fine, and the extent of both shall be proportionate to the injury caused. Further, the BIS Act also provides for penalties (which include imprisonment and fine) that may be imposed for manufacture, import, supply and distribution of goods non-conforming of prescribed standards.

Further, if criminal intent can be attributed to the offence committed, the breaching party can be held liable on various degrees under the IPC.

2 Causation

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

In India, the aggrieved party bears the burden of proof, in a claim under contract or tort. Under the Indian Evidence Act, 1872, liability to prove the existence of facts is upon the person asserting those facts, i.e. the claimant/plaintiff. Any party seeking the court's intervention as to enforcement of its legal rights must prove the facts that establish and substantiate its claim.

In a criminal case involving product liability or product defect, the burden of proof generally lies on the prosecution, except where statutes provide otherwise. Statutes such as the Drugs Act (as applicable in some Indian states) and the FSSA, in certain circumstances, create a presumption of an offence or violation and, therefore, in such cases, the burden of proof is on the person charged with an offence to prove that the offence was not committed.

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 claims relating to defects in products, depending on the factual circumstances, the aggrieved party should have suffered a loss to claim damages from the breaching party. In some cases, however, the manufacturer or importer will be liable to rectify the defect, replace the defective part or product or pay compensation if such rectification or replacement is not possible, without actual loss having being suffered by every claimant, if a product defect has been admitted by such manufacturer or importer. Although judicial precedents are lacking on this aspect, we believe that a claimant will not be entitled to damages on account of merely being exposed to an increased risk known to be associated with a defective product.

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

In India, consumer products/packaged commodities are required to mandatorily specify details of the manufacturer and, if applicable, the importer. Therefore, it is unlikely that a claimant cannot establish the manufacturer of a defective product. In any event, such instances (i.e., it is not possible to establish which of several possible producers manufactured the defective product) have not been tested in the Indian scenario and the legal position on this has yet to evolve.

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?

Mandatory labelling requirements typically include specifications of use and statutory warnings of the product. There is no separate requirement to specify or provide warnings, and the obligation for appropriate labelling is independent of the intermediary's knowledge. The principle of 'learned intermediary' discharging the duty owed by the manufacturer to the ultimate consumer is not generally applied in the Indian context.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The defence typically available to manufacturers, distributors or sellers in product liability claims include the following:

a) the product being compliant with requisite statutory standards;

b) the product not being 'defective', and if the claim is under the CPA, then the 'defect' not falling within the prescribed definition under the CPA;

c) if the claim is under the CPA, then the purchaser of the product is not a 'consumer' as defined under the CPA;

d) loss or injury is owing to negligence or misuse by the consumer or buyer, including contributory negligence;

e) the consumer or buyer had examined the goods prior to purchase and accepted it, being satisfied of its quality or specification; or

f) contractually agreed disclaimers or limitations on warranties in terms of scope, period, recourse and amount.

In addition to the foregoing, defendants (such as manufacturers, distributors or sellers) could also contend that a civil action or complaint is barred by limitation in case of belated actions.

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

There is no state of the art/development risk defence available to a manufacturer in India.

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?

Demonstrating compliance with regulatory and/or statutory requirements, prescribed standards, licensing requirements, etc., although might assist in mitigating liability, are not always an absolute shield to absolve the manufacturer from all liability in relation to a defective product.

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

The cause of action and type of damage dictate liability of the breaching party to a claimant. Different claimants can initiate

separate litigations for their cause of action and damage against the same breaching party. Different claimants bringing in different claims for their respective cause of action does not amount to 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?

In cases of composite negligence, an aggrieved party is entitled to recover damages from any or all of the negligent tortfeasors. That said, Indian courts have held that a tortfeasor proceeded against has the remedy to sue the other tortfeasors to recover contribution amounts to the extent of their liability. However, such proceedings are not evidenced as much in product liability claims. Further, in cases of back-to-back indemnity agreements between the breaching party and third party for contractual liability, the breaching party may claim indemnity from the third party in subsequent proceedings, provided that the loss has been suffered by the breaching party.

Limitation on the filing of suits in India is governed by the Limitation Act, 1963 (**Limitation Act**). The period of limitation for a civil proceeding for monetary compensation on account of a contractual breach is three years from the date on which the breach occurs.

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

Indian courts have recognised the principle of contributory negligence, i.e. the person who has suffered damage is also guilty of some negligence and has contributed towards the damage. However, where the defendant's negligence makes the plaintiff less circumspective, the plaintiff has not been held guilty of contributory negligence.

4 Procedure

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

Cases are adjudicated by judges as the jury system was abolished in India in 1974.

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)?

Indian courts cannot appoint technical experts to sit as assessors with the judges. However, the opinions of experts are admissible as evidence, and typically parties rely on such opinions for substantiating their claims.

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

Under the Code of Civil Procedure 1908 (**CPC**), two or more plaintiffs have the right to aggregate their claims in a suit against one defendant, even if their causes of actions are separate and distinct, in the event that the right to obtain relief arises out of the same act, transaction, or series of acts or transactions, and the causes of action are of such a nature that if separate suits were filed by the plaintiffs, common questions of law or fact would arise. The CPA also recognises the right of one or more consumers or a voluntary consumer association to file a complaint against a single manufacturer, dealer, distributor, etc. on behalf of, or for the benefit of, numerous consumers having the same interest.

The plaintiffs or the complainants are required to obtain prior permission from the relevant court or forum for adjudication of disputes under the CPC or CPA before instituting such class action proceedings.

The CPC also allows one or more persons to file a suit against the opposing party on behalf of, or for the benefit of, numerous persons having the same interest in the suit, with the prior permission of the court in which the suit is required to be instituted. In this regard, interest is said to be similar or common when the plaintiffs have a common grievance against the defendant and the relief sought is in its nature beneficial to all persons interested in the suit. Additionally, the CPA provides the district, state and national fora the power to grant relief to several consumers who are unidentifiable. This power is typically exercised in the event of loss or injury being suffered by a large number of consumers as a result of defective goods or services, and where the consumers cannot easily be identified. The CPA also permits the Indian Central Government or State Government to file a complaint before a district, state, and national forum, either in its individual capacity or as a representative of interests of the consumers in general.

Class action claims in product liability cases have not been very common in India. Although, with increasing access to technology and connectivity, these have become a known phenomenon and have been gaining momentum in recent times.

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

As discussed above, claims may be brought by a representative body such as a voluntary consumer association, with prior permission from the relevant court or forum for adjudication of disputes under the CPC or CPA.

4.5 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

The Bar Council of India, which is the regulatory body for the legal profession, does not permit lawyers to solicit work, and therefore lawyers are not permitted to advertise for claims. However, there are no prohibitions on representative bodies from advertising for claims, and these are not very infrequent in the Indian scenario. In the recent instance of the Johnson & Johnson (**J&J**) faulty hip implant, the government published notices on its website inviting all

patients who had received the hip implant to file a claim in case they had suffered any injury due to the implant.

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

Due to the backlog of cases pending before the Indian courts, a suit would reach the trial stage within six to 12 months, provided that requisite notices have been served and the prescribed procedure has been complied with. Most product liability claims are, however, initiated under the CPA, which also prescribes timelines that are required to be followed by the dispute resolution fora. The fora must endeavour to decide a complaint within a period of three months from the date of receipt of 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.

4.7 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, Indian courts do adjudicate upon preliminary issues regarding the maintainability of the claim, usually restricted to questions of law and not fact. Findings on such preliminary matters generally determine progress of the case.

As discussed earlier, the jury system is not present in India, and therefore all issues are determined by judges.

4.8 What appeal options are available?

Generally, the Indian courts hierarchy has district courts, high courts (with jurisdiction over states of the country) and the apex court, i.e. the Supreme Court of India. Appeals from district courts would lie before the high court, and thereafter the Supreme Court, depending upon factors such as the nature of claim, pecuniary jurisdiction, etc. District courts typically have original jurisdiction except in certain cities where the High Court of the city has original jurisdiction, and appeals in such cases usually lie before a larger bench of judges of the same High Court. Specific statutes also provide for appeal procedures from cases before tribunals/other quasi-judicial bodies formulated under the statute, to either an appellate tribunal and/or the High Court, and Apex Court.

4.9 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?

Under Indian civil law, experts may be appointed by the court when it is necessary to form an opinion based on a technical or scientific issue. Expert opinions may be relied on by the parties to a suit or proceeding. The Evidence Act sets out the circumstances in which a court can rely on experts and these include instances when the court has to form an opinion on foreign law, science, art and handwriting. Indian criminal courts are also vested with the power to summon, examine and receive evidence from experts, including receiving reports from certain governmental scientific experts under the provisions of the Criminal Procedure Code 1973. Further, under the CPA, the consumer courts have the power to appoint experts to examine defective products manufactured, sold or distributed in the event that the defect cannot be determined without proper analysis or testing of the goods.

The courts are not bound by the evidence or opinions of the experts and have discretion to admit this evidence or derive their own conclusions based on these opinions.

4.10 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 is not a practice in India and, therefore, factual or expert witnesses are not required to present themselves for such depositions.

4.11 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 prior to commencement of court proceedings or as a pre-trial procedure.

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

Alternate dispute resolution (**ADR**) mechanisms such as arbitration and mediation are gaining popularity and generally adopted as a first step towards dispute resolution between parties. However, ADR mechanisms are not mandated under Indian law. That said, a recent amendment to the Commercial Courts Act (which seeks to streamline and fast-track commercial disputes) makes pre-institution mediation mandatory in all cases where the parties do not require immediate intervention by courts.

4.13 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?

Claims can be instituted in India by or against a foreign party, if the cause of action of such proceeding arises in India.

5 Time Limits

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

Limitation on filing of suits in India is governed by the Limitation Act. Specific statutes may also prescribe particular limitation periods for claims instituted under such 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?

The period of limitation for a civil proceeding for monetary compensation on account of a contractual breach is three years from the date on which the breach occurs.

The CPA provides for a limitation period of two years from the date of the cause of action; however, the CPA gives the consumer court the discretion to entertain complaints filed beyond the limitation period if it is satisfied with the reasons for the delay.

The FSSA states that cognizance shall not be taken of any offence after a period of one year from its commission, but this may be extended up to three years with the approval in writing of the Commissioner of Food Safety.

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

Under the Limitation Act, where a claim is based upon fraud of the defendant or its agent or where any documents necessary to establish the right of the plaintiff or applicant have been fraudulently concealed from him, the period of limitation begins after the plaintiff or applicant 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?

The general law of economic damages in the Indian context is covered under the SGA, Contract Act, CPA and tort law. The Contract Act provides for the payment of damages or compensation by the defaulting party to the aggrieved party for any loss or damage that arose as a natural consequence of a breach; or that the parties were aware, at the time of entering into the contract, would possibly result from a breach. In this context, the Contract Act does not allow damages for remote, indirect or incidental loss.

The Indian courts have broad powers to pass interim orders prior to a full trial and at any time during the legal proceedings when considered necessary and proper in light of the facts and circumstances of the case. Further, Indian courts are empowered to pass interim orders to prevent damage, alienation, removal or disposition of property or otherwise causing injury to the plaintiff in relation to any property in dispute in the suit. The courts are also able to pass an interim order attaching the assets of a defendant or requiring it to furnish security in certain circumstances.

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

In India, law has categorised damages as 'direct damage' or 'indirect damage'; 'consequential damage' or 'remote damage' (the test is whether certain damage suffered by the aggrieved party was a foreseeable consequence of an act or omission on the part of the breaching party); and 'punitive or exemplary damage'.

The damages which can be awarded in an action based on tort may be contemptuous, nominal, ordinary or exemplary. The primary object of award of damages is to compensate the aggrieved party for the harm suffered, while the secondary object is to punish the breaching party for its conduct in inflicting such harm. The secondary object is achieved in certain cases by awarding, in addition to compensatory damages, damages which are termed as exemplary, punitive, vindictive or retributory damages. In awarding punitive or exemplary damages, the emphasis is not on the injury caused, but on the defendant and its conduct. There is, however, reluctance of Indian courts to award considerably significant amounts of exemplary or punitive damages in claims under tort law.

Further, damages under contract may be either liquidated or unliquidated. Liquidated damages are those that have been agreed upon and fixed by the parties in anticipation of a breach, whereas unliquidated damages must be assessed and quantified. However, the Contract Act does not contemplate grant of 'indirect damages' or 'remote damages'.

Indian courts are generally conservative in awarding compensation or damages for tortious liabilities pertaining to mental trauma, distress, and cases where no actual damage is proven. However, damages have been awarded for non-pecuniary losses like pain and suffering consequential to injury inflicted on the plaintiff with compensation varying depending on the intensity of the pain and suffering borne by the plaintiff. The courts have also been generous (by Indian standards) in awarding damages for mental agony arising from, *inter alia*, cases involving negligence. A reduction in life expectancy is another non-pecuniary loss for which courts have awarded damages in cases where normal life expectancy has been shortened as a result of the injury sustained. Given the difficulties involved in assessing such damages, courts tend to award only very moderate sums. Indian courts are reluctant to grant damages for mental agony in the absence of compelling reasons in case of property damage, and where such damages are granted, the quantum of damages is nominal.

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 circumstances where the product is admittedly defective, such as in the case of faulty medical devices which have been implanted in humans, the compensation awarded to the aggrieved party would take into account the cost of medical monitoring. That said, these are not claims commonly seen in the Indian scenario.

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

In contractual disputes, Indian courts do not normally award punitive or exemplary damages, but may do so where elements of fraud, oppression or malice are established. In awarding punitive or exemplary damages, the emphasis is not on the injury caused, but on the breaching party and its conduct.

However, in product liability claims under the principles of tort law, practically there is limited jurisprudence available as aggrieved parties usually seek redressal under the CPA or under the Contract Act. This is also due to reluctance of Indian courts to award considerably significant amounts of exemplary or punitive damages in claims under tort law. The CPA permits awards of punitive damages in circumstances deemed fit by the consumer courts. Damages have been awarded by Indian courts under the CPA in exceptional cases by way of compensation where it has been established that the aggrieved party suffered harassment and extreme pain and suffering as a result of the conduct of the manufacturer, supplier or distributor, pursuant to being notified about the defective product. However, the quantum of damages awarded under the CPA or by a civil court is much lower than and not comparable with punitive damages that are awarded in other developed countries.

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 statutorily mandated maximum limit for damages recoverable from a manufacturer. However, by virtue of contractual arrangements, parties are permitted to exclude liability for indirect losses even if they were aware of such losses when they made the contract. The Contract Act also permits parties to agree on the quantum of liquidated damages payable by the breaching party in case of breach, thereby limiting the quantum of liability of the breaching party under contract law.

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

Typically, terms of voluntary out-of-court settlements (which are not mandated by court) must be recorded in writing and the settlement agreement should be filed in the proceedings before the court for the terms of settlement to be taken on record. Based on the settlement reached, the court will pass a decree. That said, settlement of group/class actions and claims by minors must be made with the prior approval of the court and in accordance with the procedure set out under the CPC.

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?

We have not seen instances of this in India.

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?

Courts may award reasonable court fees, legal costs and other incidental expenses to the successful party. The amount of costs permitted to be recovered is subject to the discretion of the court and may not necessarily equal the actual costs borne by the party.

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

The Legal Services Authorities Act, 1987 (Legal Services Act) establishes authorities at the district, state and national level to provide free legal services to certain classes of people.

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

Under the Legal Services Act, only certain economically and socially weaker classes of persons defined under the Legal Services Act are entitled to free legal services, such as women, children, victims of human trafficking, people with a disability, victims of mass disaster, ethnic violence, natural disasters, socially and economically backward classes, and industrial workmen.

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

The Bar Council of India, which is the regulatory body for lawyers, does not permit lawyers to charge a success fee or contingent fee.

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

The Supreme Court of India recently held in *Bar Council of India v AK Balaji and ors* (AIR 2018 SC 1382) that third party funding/legal financing agreements are not prohibited in India. Practically, the funding is based on commercially agreed terms between the parties.

Additionally, the Consumer Welfare Fund provides financial assistance for expenses on advocacy and class action suits, and applications may be made to it for reimbursement of legal expenses incurred by a complainant or a class of complainants upon completion of a consumer dispute.

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, courts do not exercise control over the costs incurred by parties as courts are conservative in awarding costs to a litigant.

8 Updates

8.1 Please provide a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

Landmark product liability cases are increasingly seen in the Indian scenario under industry-specific statutes such as the FSSA and the Drugs Act. Additionally, owing to limitations of legislative development, and the delay in disposition of pending cases due to systemic problems, the Government of India has intervened in some instances to ensure breaching parties are held accountable and necessary steps are taken in this regard. Significant developments in this field have occurred in the last year through governmental intervention.

In relation to the global emission scandal involving Volkswagen, a public interest litigation case was filed against Volkswagen in India before the National Green Tribunal (**NGT**, which is the forum set up in India for expeditious disposal of cases relating to environmental and conservation-related issues) towards the end of 2015, seeking a ban on sale of its cars in India. The NGT constituted a committee to estimate the quantum of loss caused by Volkswagen, and the committee recommended a fine of about USD 24,500,000. Based on recent press releases, it appears that the NGT has now imposed an enhanced fine of about USD 72,122,500 on Volkswagen to create deterrence, on account of the environmental damage caused.

Six years after the cancellation of J&J's import licence for hip replacement devices that were faulty, J&J has been ordered by the Indian Ministry of Health and Family Welfare (**Ministry of Health**) to pay compensation (approximately ranging between USD 43,000 to USD 178,000) to patients who had received the faulty hip implant. A committee was formed by the Ministry of Health that calculated the compensation payable based on a formula using a person's age and the extent of disability. J&J challenged the committee's decision on grounds of lack of transparency and opportunity to be heard, which remains pending. However, the Supreme Court in a separate petition filed on behalf of a patient affected by the faulty implant chose not to interfere with the committee's proposal on the quantum of compensation, including the manner of computation of the compensation. As a result of the J&J case, an expert subcommittee has been constituted to review and appropriately recommend provisions for compensation in case of faulty devices under the Medical Devices Rules, 2017.

To keep up with changing times and the advancement of technology, legislators and the judiciary are continuously attempting to keep Indian laws updated; however, it remains challenged by the rapid pace at which technology is progressing. In situations where processes are increasingly being automated, such as 3D printing and driverless cars, the existing principles of product liability in India are not sufficiently evolved to identify and apportion liability in cases involving human and machine error. The issue of liability is even less clear in situations where the involvement of a human element is reduced and important decisions are taken by artificial intelligence systems.

Vivek Bajaj

AZB & Partners
7th Floor, Embassy Icon, Infantry Road
Bangalore 560 001
India

Tel: +91 80 4240 0500
Email: vivek.bajaj@azbpartners.com
URL: www.azbpartners.com

Vivek Bajaj is a partner at AZB & Partners' Bangalore office. He has been practising corporate and civil law for over 15 years. The focal areas of his practice are mergers and acquisitions, private equity, commercial law, real estate and product liability in India. Mr. Bajaj has extensive experience in drafting key transaction documents, advising on investment structures and regulatory compliance, and in leading negotiations in relation to mergers and acquisitions and private equity transactions. He actively participates in various seminars and is invited to take part in conferences as a speaker and panellist. Mr. Bajaj has also written articles on various topics, and particularly in relation to product liability regulations in India.

Mr. Bajaj completed his Bachelor of Laws degree in 2000 and began his career at Holla & Holla, a litigation law firm based in Bangalore. He has been with AZB & Partners since 2005.

Sonakshi Sharma

AZB & Partners
7th Floor, Embassy Icon, Infantry Road
Bangalore 560 001
India

Tel: +91 80 4240 0500
Email: sonakshi.sharma@azbpartners.com
URL: www.azbpartners.com

Sonakshi Sharma is an associate at AZB & Partners' Bangalore office. Her primary practice areas include general corporate law, mergers and acquisitions, private equity and real estate law, as well as advising on other regulatory matters. Sonakshi has also advised on multiple matters relating to product liability and product recall in India. Primarily, she has assisted with a variety of corporate transactions involving foreign investment, in relation to which she has also negotiated and drafted key transaction documentation.

Sonakshi received her BA LL.B. (Hons.) from Amity Law School, Delhi (affiliated to Guru Gobind Singh Indraprastha University) in 2014. She subsequently obtained an LL.M. with a specialisation in international business law from the National University of Singapore in 2015, and began her career at AZB & Partners in the same year.

AZB & PARTNERS
ADVOCATES & SOLICITORS

AZB & Partners is a prominent law firm in India. It was founded in 2004 with a clear purpose to provide reliable, practical and full-service advice to clients based on an in-depth knowledge of the legal, regulatory and commercial environment within which our clients operate and a full understanding of their overall business objectives. The firm now has six offices across Mumbai, Delhi, Bangalore and Pune, with a driven team of 400+ lawyers.

The firm has been involved in advising in the field of mergers, acquisitions, joint ventures and general corporate, regulatory practice and securities laws, private equity, capital markets, funds, banking and finance, infrastructure and project finance, real estate, media and entertainment, employment, insurance, intellectual property, taxation, competition law, and litigation and arbitration.

The firm has received wide national and international acclaim within the legal sphere including 'Ranked No. 1' by RSG Top 40 India law firm ranking, 2017.

Chapter 18

Ireland

Tom Hayes

Michael Byrne

Matheson

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 (the "Directive"). The 1991 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 1991 Act, 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. The 2004 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 ("CCPC") 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 CCPC 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 CCPC has also been given the power to order a product recall, as set out in question 1.5 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 remains 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. However, such schemes are *ad hoc*, rather than statutorily required.

It is likely that the Irish Government will establish a Tribunal in 2019 to consider awards of compensation to women who have been affected by cervical cancer screening issues.

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 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

In principle, a regulatory authority could be found liable in tort in respect of a defective/faulty product where the requisite elements of the claim (as outlined in response to question 1.3 above) are established. For example, such a claim might arise on the basis that the regulatory body had knowledge of a defective/faulty product but failed to order the producer of the product to take appropriate action, such as ordering the producer to issue a product recall for example, and in circumstances where the defective/faulty product has then caused harm to the claimant. However, in practice, such claims are difficult to establish against regulatory authorities and the claimant will need to show something akin to "bad faith" on the part of the regulatory authority concerned.

1.5 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 CCPC 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 CCPC 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 CCPC 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 a 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.

1.6 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 CCPC.

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 *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 CCPC 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 CCPC 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 CCPC 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 a 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 has an inherent jurisdiction to hear from such parties as it sees fit. In addition, under new Superior Court rules (the Rules of the Superior Courts (Conduct of Trials) 2016 (SI 254 of 2016)), which recently came into effect, a judge may, either where requested to by the parties or of his own accord, make various directions as to expert evidence, including the appointment of a single joint expert.

Alternatively, the court may appoint a separate person, known as an "assessor" to "*assist the court in understanding or clarifying a matter, or evidence in relation to a matter*". An assessor can be asked to prepare a written report in relation to the subject matter of a dispute. However, as is also the case with parties consulted under the court's inherent jurisdiction, the assessor is there merely to assist the judge make a determination and the findings of any written report are not binding.

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.

However, despite this recommendation, no steps were taken by the legislature and the issue of multi-party litigation is now one of the topics under review by a specialist Review Group established in 2017, at the request of the Irish Government, in the context of a broader review of the Administration of Civil Justice in the Courts of Ireland.

On 4 November 2018, the European Commission published a draft directive which, if implemented, would introduce, for the first time in Ireland, a style of class action litigation by consumers against corporates. The directive proposes a new type of "*representative action, the European way*". This would allow a "*qualified entity*" to take a representative action before a Member State court on behalf of a group of consumers who have been affected by a breach of consumer protection laws and seek redress for the affected group. The consumers concerned would not be parties to the proceedings.

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

Representative and consumer associations will generally lack the necessary *locus standi* to bring such actions, at the present time. However, please see question 4.3 above for recent developments.

4.5 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

As representative bodies cannot generally bring claims on behalf of a number of claimants, no such advertising occurs.

Advertising by solicitors is governed by the Solicitors (Advertising) Regulations 2002 and is subject to strict regulation, particularly with reference to advertising for claims. In particular, solicitors are prohibited from expressly or implicitly referring in advertisements to claims for damages for personal injuries, the possible outcome of any such claim, and the provision of legal services in respect of same. Advertising for claims which are of a non-personal injury nature are also restricted insofar as they bring the profession into disrepute and are perceived to be in bad taste.

Advertising does not materially affect the number or type of claims brought in Ireland.

4.6 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 Personal Injuries Assessment Board (save for certain exceptions). This Personal Injuries Assessment 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 Personal Injuries Assessment Board that they intend to rely upon legal issues to defend their position, the Personal Injuries Assessment 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. Pursuant to the Court of Appeal Act 2014, decisions of the High Court may be appealed to the 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 CCPC 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?

As noted at question 4.2 above, recent changes to the Superior Court Rules allow the court to appoint an expert, known as an "assessor", to assist it in considering technical issues.

The overall objective behind the new Superior Court Rules regarding evidence is to ensure that expert evidence is presented to the court in an efficient manner. Accordingly, these rules allow the court to make various directions in respect of the nature and extent of the evidence to be heard in the proceedings. For example, the rules provide that in commercial, competition, chancery or non-jury cases, expert evidence must be restricted to that which is "*reasonably required to enable the Court to determine the proceedings*".

The parties are also free to appoint their own experts to put forward their opinion as evidence at trial. 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?

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).

The Mediation Act 2017 has introduced a statutory obligation on solicitors to (i) advise clients about the benefits of mediation prior to commencing proceedings, and (ii) make a statutory declaration confirming such advice has been given. If the originating document is not accompanied by the declaration, the court is empowered to adjourn the proceedings to facilitate compliance. As the Mediation Act 2017 only came into force at the beginning of 2018, it is still too early to tell whether it will lead to a material and substantial increase in mediation and a reduction in litigation.

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 of the 2004 Act, 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 previously 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.

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 this 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. Generally, a limitation period of two years applies to personal injuries actions from the date which the plaintiff became aware of, or should reasonably have become aware of, the personal injury.

Interestingly, S.7(2)(a) of the 1991 Act 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 1991 Act 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 Personal Injuries Assessment 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) Act 2017, which came into force on 1 October 2018, has amended the Civil Liability Acts 1961 and 1964 to provide for the award of damages by way of periodic payments order in certain circumstances where a plaintiff has suffered catastrophic injuries. A 'catastrophic injury' is defined as a personal injury which is of such severity that it results in a permanent disability to the person, requiring the person to receive life-long care and assistance in all activities of daily living or a substantial part thereof.

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 CCPC 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 2004 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.

There have been significant recent Supreme Court decisions in the area of third party litigation funding. *Moorview Developments Limited & Ors v. First Active Plc & ors*, a decision of the Supreme Court from July 2018, clarified that the provision of funding by a third party funder with a legitimate interest in the litigation is lawful but such third party funder may be subject to a costs order where the party to the proceedings is not a mark for costs.

However, the Supreme Court has said legislation needs to be urgently enacted to address mounting difficulties with securing access to justice in the civil courts. Recently, in the case of *SPV Osus Limited v. HSBC Institutional Trust Services (Ireland) Limited & Ors* [2018] IESC 44, the Chief Justice of Ireland noted that if a point is reached where it is clear the legislature is making '*no real effort*' to address the problems, the courts may have to fashion a solution.

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 a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

There is an increasing awareness in Ireland of a developing '*claims culture*'. The Irish Government's Personal Injuries Commission in September 2018 reported that compensation for personal injuries in Ireland is on an average of 4.4 times higher than the equivalent compensation in the United Kingdom.

In late December 2018, it was reported that the Irish government is focusing on reforms to the insurance industry to combat issues with compensation by focusing on a recalibration of the Book of Quantum (guidelines for the Irish judiciary for awards in personal injuries matters). The aim of such reform is to ensure that compensatory awards from the Irish courts are regularised.

With specific reference to product liability law, the European Commission has launched an expert group on liability to explore the effects of new and developing products on the implementation of the Directive. The expert group has been tasked with drawing up guidance on the implementation of the Directive but also to provide recommendations to the Commission on required adaptations of the current regime to bring new technologies within the scope of the Directive. It remains to be seen how the Irish courts and indeed, courts at an EU level, will approach issues concerning new technologies and artificial intelligence within the current and any future product liability regime.

Acknowledgment

The authors would like to thank Rebecca Ryan, Partner, and Michael Finn, Partner, for their assistance in the preparation of this chapter.

Tom Hayes
Matheson
70 Sir John Rogerson's Quay
Dublin 2
Ireland

Tel: +353 1 232 2000
Fax: +353 1 232 3333
Email: tom.hayes@matheson.com
URL: www.matheson.com

Tom is Head of the Commercial Litigation and Dispute Resolution Department and head of the Healthcare Group at Matheson. Tom advises a broad range of multinational organisations and healthcare professionals operating in the life sciences, cosmetics and healthcare sector generally. Tom also advises a number of healthcare organisations, hospitals, professionals and their insurers concerning the defence of clinical malpractice litigation in high-value and complex cases. He also represents medical and dental practitioners in defence of complaints before their regulatory bodies, at other statutory inquiries and Inquests.

Education: BA (Hons) Law and Politics.

Michael Byrne
Matheson
70 Sir John Rogerson's Quay
Dublin 2
Ireland

Tel: +353 1 232 2000
Fax: +353 1 232 3333
Email: michael.byrne@matheson.com
URL: www.matheson.com

Michael is a partner in the Commercial Litigation and Dispute Resolution Department at Matheson, where he works in a range of areas including product liability, technology litigation, defamation, regulatory and administrative law. Michael has represented Irish and international companies in a variety of product liability claims, including matters arising from the use of pharmaceuticals and vaccines, mechanical devices, agricultural products and foodstuffs. He also provides advice on regulatory and compliance issues arising for companies trading in Ireland and internationally.

Education: Trinity College Dublin, Bachelor of Laws and German; University of Regensburg, Germany, Master of Laws.

Matheson

Established in 1825 in Dublin, Ireland and with offices in Cork, London, New York, Palo Alto and San Francisco, more than 700 people work across Matheson's six offices, including 96 partners and tax principals and over 470 legal and tax professionals. Matheson services the legal needs of internationally focused companies and financial institutions doing business in and from Ireland. Our clients include over half of the world's 50 largest banks, six of the world's 10 largest asset managers, seven of the top 10 global technology brands and we have advised the majority of the Fortune 100.

Japan

Shinya Tago

Iwata Godo Law Offices

Landry Guesdon

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 party injured by a defective product may still bring a tort claim under the Civil Code. 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 a contract for services), clauses which totally exempt 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 products when there is a latent defect; 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, whereunder the other business operator must provide compensation for all or part of the damage caused by a defect, deliver substitute products without defects or repair the defective products.

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 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 is often 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 PLA or based on tort as explained above.

Article 415 of the Civil Code addresses liability for incomplete performance of obligations, while Article 562, Article 563 and Article 564 govern warranties against latent defects. Also relevant in this context is Article 526 of the Commercial Code, an equivalent provision to Article 566 of the Civil Code, which applies to latent and visible defects in transactions between business operators.

The parties to a contract can be released entirely or partially from their liability under the PLA or tortious/contractual 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 between consumers and business operators. Notwithstanding any special agreement excluding statutory warranties, a seller's liability would not be excluded in case 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 entirely funded by the Government and established under the Preventive Inoculation Law (Law No. 68 of 1948) compensates victims of injuries caused by inoculations. Another scheme, industry-funded and administered by the Pharmaceuticals and Medical Devices Agency (PMDA) under the Act on Pharmaceuticals and Medical Devices (Law No. 192 of 2002) 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 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 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

The PLA does not exclude public bodies from its scope and would apply to public bodies acting as the manufacturer (within the broad meaning of the PLA), although a regulatory authority would rarely act in this capacity. Under the State Compensation Law, when a public official who is in a position to exercise public power has, in the course of performing his duties, illegally inflicted losses on another person, intentionally or negligently, the State or public entity is liable to compensate such losses. When a defect in construction or maintenance of public property has inflicted losses on another person, the State or a public entity is liable to compensate such losses.

1.5 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 (products to be supplied mainly for use by general consumers for their routine everyday activities) regulated by the CPSA.

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.

Under CPSA, a manufacturer/importer must report the occurrence of a "serious product accident" to the competent Minister (Article 35). The competent Minister 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).

1.6 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.
- A damage has occurred and the amount claimed as damages.
- A causal link exists 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 other 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 (Articles 418 and 722) 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:

- 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 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 it very narrowly as knowledge meeting the highest scientific or technical standards then in existence.
- 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 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 (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 where the plaintiff can be shown to have assumed a certain level of risks, and 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) (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 claims 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 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

As per question 4.3, the Japanese class action is virtually useless in this context (to reach out to potential claimants, it is more common and "socially acceptable" to publicise claims through news media coverage rather than through paid advertising; consumer organisations often use victim emergency hotlines and free consultation sessions).

Advertising by lawyers is otherwise permissible but strictly regulated under Regulation No. 44 of 24 March 2000 and related guidelines. Advertising which is false, misleading, exaggerated, illegal or that infringes rules of the national or local bar associations, or impairs the good repute of the profession, is prohibited. There is no media restriction, but the wording, placement and methods are limited (and even more stringently regulated when dealing with ongoing matters).

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

The Law Concerning the Speeding up of Trials enacted in 2003 provides that legal proceedings must be closed within two years. First instance proceedings can last eight months on average but complex cases can take longer 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.

4.7 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).

4.8 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.

4.9 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 the 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.

4.10 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.

4.11 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 before a motion is filed by a party when it is difficult for a party to collect documentary evidence from the other side that would be clearly necessary to prove his case (Article 132-4).

4.12 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: 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.

4.13 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 CCP general forum rules, 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 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 (five years in case of bodily harm or death under Article 724-2) 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.

Under Article 166 of the Civil Code, the right to demand compensation for damages based on liability for fault and liability for defects expires if it is not exercised by the victim or his legal representative within five years from the time when he became aware that he could claim damages in relation thereto. The same applies if 10 years (20 years in case of damages due to bodily harm or death under Article 167) have elapsed after the time when he could claim damages.

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 566, Civil Code). This shall not apply where the seller had knowledge of the defect or had no knowledge of the defect due to his or her gross negligence.

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, 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 can be awarded for monetary and non-monetary damage.

Under the PLA, the manufacturer is liable for damage and injuries to the life, limbs or property of the victim. The manufacturer is not liable when the damage only occurs 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. 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 (Article 415, Article 541, Article 542 and Article 564, 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 or to reduce the price of the defective goods as an alternative to rescinding the sale and purchase contract and making a compensation claim (Articles 562 and 563). 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 a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

An extensive reform of the Civil Code of 1896 has taken place: to produce a more comprehensive and user-friendly version with general principles of law derived from court precedents turned into statute. Amendments adopted in 2017 will enter into force on 1 April 2020 and some of them will affect product liability albeit not drastically.

Although the number of court cases has not increased dramatically, the PLA has helped to establish a more level playing field for plaintiffs and victims of product liability accidents. The development of PL insurance might be one of the reasons. Another reason might be the Japanese legal system itself which is largely based on the German and French civil law models and lacks the main ingredients of a robust plaintiff-driven practice compared with what is available in the US: jury trials; punitive damages; and contingent fee agreements. Severe limitations on pre-trial discovery, high attorneys' fees, costly court filing fees and protracted trials have curbed the expansion of PL litigation. 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. 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 in many industries.

The Japanese government and private sector are making huge investments in artificial intelligence and new technologies as key drivers of future competitiveness. Japan's ambition is to lead the transition from "industry 4.0" to "society 5.0", in which all aspects of society are transformed by new information technologies and systems. The government has issued general policies regarding the use of AI and IoT, and further discussions focusing on legal issues arising from the use of AI systems and machine learning. Some of the challenges are conceptual, such as accountability, how to assign legal responsibility when AI systems cause harm.

Case law is virtually nonexistent, and the following rules remain to be tested before the courts.

- **Civil liability issues**. When AI causes a damage to an AI user or a third party, persons that can be held liable are AI users and manufacturers (broadly interpreted). With respect to AI users, the following issues may arise: should AI be held liable in tort where it causes damage to a third party; and what could be the AI user's liability where AI performs a contract on its own.
- **Tortious liability**. If an AI user is found negligent with respect to AI utilisation, the AI user will be liable for damages (Article 709 of the Civil Code). The traditional concept of negligence does not have to be revisited in this context and the usual definition will apply. For AI users to be negligent, they would need to be able to anticipate the occurrence of specific results arising from AI actions. However, AI systems may perform actions that are unforeseeable to their designers and operators. From this perspective, it is unlikely users will be deemed negligent (although being aware of uncontrollable risks inherent in the black box and still using AI could be negligence in itself). There may still be circumstances under which AI users have a certain duty of care over the actions of AI systems. At least at the early stage of AI introduction, it would not be appropriate to rely on AI systems entirely and AI users would be expected to have minimum monitoring duties.
- **Liability of AI manufacturers**. Manufacturers can be liable for damage caused by a defect in a product under the PLA and if AI is defective, i.e., lacks the safety it should ordinarily provide, the AI manufacturer may be liable under the PLA. No clear view has been established yet as to when AI should be regarded as lacking the safety it should ordinarily provide and the debate goes on.
- **Contractual liability**. In cases where AI systems perform a contract (e.g., by placing automatic orders after checking inventory levels in a warehouse). If AI makes a mistake, e.g., by purchasing unnecessary goods at an outrageous price, should the AI user be liable under such a contract? When the AI user entrusts AI with the execution of a contract, it can be considered that the user expresses his intention to "enter into a contract using AI" with the counterparty. Likewise, the counterparty expresses his intention to "accept a contract offer made by AI". As there is a meeting of the minds between the AI user and his counterparty, the contract is deemed duly made between them. The contract is in principle valid and effective even if a mistake is found in the contract offer made by AI, because the intention of the AI user matches that of the counterparty. A mistake by AI would only render the contract void in exceptional circumstances.

Shinya Tago

Iwata Godo Law Offices
Marunouchi Bldg. 10th floor,
2-4-1 Marunouchi, Chiyoda-ku,
Tokyo 100-6310
Japan

Tel: *+81 3 3214 6205*
Email: *stago@iwatagodo.com*
URL: *www.iwatagodo.com*

Shinya Tago is a Japanese attorney at law, admitted to the New York State Bar Association, partner and Head of the International Practice Committee of Iwata Godo. His practice includes: general commercial litigation; securities litigation; shareholder derivative litigation; arbitration (domestic and international), conciliation and mediation; and tort claims (including product liability disputes).

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.

Landry Guesdon

Iwata Godo Law Offices
Marunouchi Bldg. 10th floor,
2-4-1 Marunouchi, Chiyoda-ku,
Tokyo 100-6310
Japan

Tel: *+81 3 3214 6205*
Email: *lguesdon@iwatagodo@com*
URL: *www.iwatagodo.com*

Landry Guesdon is a Registered Foreign Attorney (Tokyo Bar) and Avocat (Paris Bar), member of the International Practice Committee of Iwata Godo. In Japan since 1997 and with more than 20 years with a Magic Circle firm, Landry Guesdon has extensive experience in mergers and acquisitions, joint ventures and general corporate matters and antitrust spanning numerous industries (pharmaceuticals and medical devices, cosmetics, defence and aerospace, food and agriculture, consumer and retail, general industrials, energy and utilities). Landry Guesdon has received a BA in law from the University of Kent in Canterbury and an LL.M. degree from the University of Paris.

IWATA GODO
Established 1902

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 with about 70 attorneys 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

Tony Dongwook Kang

Yongman Bae

Bae, Kim & Lee LLC

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 had been brought as tort claims under the Civil Code of Korea. However, since 2002, claims can also be brought under the Product Liability Act (Partial Amendments to Act No. 14764 as of April 18, 2017), which gives a plaintiff more flexibility to seek compensation for damages caused by a defective product. 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". 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.

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.

Whereas there is a concurrence of product liability and contractual liability, the plaintiff has to choose one or the other. Consumer fraud statutes appear as articles in different regulations, and whenever the product fails to conform to safety regulations, the plaintiff may raise product liability disputes.

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

In general, in the case of a medicine accident, a victim had claimed damage by applying the Product Liability Act. At the end of 2014, however, an adverse drug reaction damage relief system was introduced, under which a victim was able to be compensated within four months of application for compensation for the side effects of taking medicine without going through a lawsuit. The competent ministry of this system is the Ministry of Food and Drug Safety. However, this system does not apply to side effects from – or intention and gross negligence with respect to – medicines for cancer or special disease or a national vaccination, for which a compensation system has been already in place, and the relevant compensation is paid by the pharmaceutical company.

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

The scope of manufacturers – in other words, responsible entities – is divided into four.

First, manufacturer. A manufacturer is "a person who engages in the business of manufacturing, processing, or importing products" (Item A of Subparagraph 3 of Article 2 of the Product Liability Act). Whether such person indicates itself as a manufacturer by specifying its name on a product does not matter in defining manufacturers.

Second, importer. A person who imports products made in a foreign country also has the same liability for compensation as a manufacturer (Item A of Subparagraph 3 of Article 2 of the Product Liability Act).

Third, manufacturer under indication. A person who indicates that he/she is a manufacturer or importer by putting his/her name, firm name, trademark, or any other discernible sign on a product, or a person who makes a misleading indication that he/she is a manufacturer or importer, is liable for compensation in the same degree as a manufacturer (Item B of Subparagraph 3 of Article 2 of the Product Liability Act). A representative example is an original equipment manufacturer (OEM).

Fourth, supplier (distributor). Even though a person who supplies products is involved in the process of distribution of products, it is difficult for the person to control/manage defects of the products like manufacturers. Therefore, the Product Liability Act prescribes that only when a victim cannot identify a manufacturer, does a supplier have liability complementally under certain satisfied requirements (Paragraph 2 of Article 3 of the Product Liability Act).

1.4 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

The Product Liability Act does not have any regulations that

expressly require a nation's liability for damage for a product. For instance, in a case in Korea where a child suffered suffocation while eating a mini-cup jelly, the child received emergency treatment, but eventually had brain damage due to hypoxia (so-called 'Mini-cup Jelly Suffocation Case'), the court denied the nation's liability for damage (Supreme Court Judgment 2008Da67828 dated November 25, 2010).

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

In Korea, the Framework Act on Consumers works as a basic law for product safety standards. As a general law applying to all consumer goods, the Framework Act on Consumers imposes on the nation the obligation to provide various safety, indication, and advertising standards to be complied with at the time of the manufacture and sale of products, and prescribes a business entity's obligation to report information on product defect and voluntary/compulsory recall.

The nation's obligation to provide safety, indication, and advertising standards under the Framework Act on Consumers is more addressed in the individual statutes related to consumers (including the Food Sanitation Act, the Electrical Appliances Safety Control Act, the Quality Control and Safety Management of Industrial Manufacturer Act, the Motor Vehicle Management Act, and the Pharmaceutical Affairs Act). These statutes regulate product safety standards and recall systems depending on each product item.

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

The Product Liability Act does not have any provisions that expressly provide criminal punishment for product defect. However, Paragraph 1 of Article 50 of the Framework Act on Consumers provides that "if the head of a central administrative agency deems that a business entity causes or might cause any danger or injury to consumers' lives, bodies, or property due to any defect in goods, etc. furnished by the business entity, the head may order the business entity to remove, destroy, or repair such goods, etc., exchange them for other goods, etc., refund their costs, or prohibit the manufacture, import, sale or supply of them, and to repair facilities related to such goods, etc. or take other necessary measures", and Subparagraph 1 of Paragraph 1 of Article 84, the penalty provisions of the same Act, provides that a person who violates Article 50 of the same Act shall be punished by imprisonment with labour for not more than three years or by a fine of not more than KRW 50 million.

2 Causation

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

The Product Liability Act does not have provisions that specify what a victim has to prove in order to require a manufacturer to assume product liability. Usually, general principles under the Civil Act with respect to illegal acts apply thereto. Therefore, with respect to product liability, it is a victim who bears the burden of proof of fault/defect and damage, but in a judicial case, a court has reduced the victim's burden of proof (see question 2.2 below for more details).

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?

According to a judicial precedent, a court has reduced an injured party's burden of proof of the existence of fault and the causation between fault and damage. Specifically, the judicial decision held that: "If the consumer proves that the accident occurred within the area under the manufacturer's exclusive control and proves that such an accident does not usually occur without someone's fault, and as far as the manufacturer may not prove that the accident occurred not from the fault of its product, but from other cause, relaxing the burden of proof by assuming that the product had the defect of not having safety and that the accident occurred resulting from the defect and thus by imposing compensation liability fits the ideal of the damage compensation system, the guiding principle of which is the fair and reasonable sharing of damage." (Supreme Court Judgment 98Da15934 dated February 25, 2000.)

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 Korea. Therefore, a victim has to file a suit against one or more certain 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?

A defect may be found where the manufacturer has failed to warn consumers about the risks associated with the manufacturer, in particular by failing to provide adequate instructions or warnings that can minimise or eliminate foreseeable risks.

There is no principle of "learned intermediary" available in product liability disputes in Korea.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The following defences are available:

- Under the provisions of Article 4 of the Product Liability Act that specify the reasons for exemption from liability, if a person who has liability for damage proves a certain fact, he/she is exempted from the liability for damage. Such certain facts include: (1) the fact that the manufacturer did not supply the product; (2) the fact that the existence of the defect could not be identified by the state of scientific or technical knowledge of the time when the manufacturer supplied the product; (3) the fact that the defect is attributable to the manufacturer who complied with the standard prescribed by any statutes of the time when he/she supplied the product; and (4) in the case of raw materials or components, the fact that the defect is attributable to the design or the instruction on manufacturing by the manufacturer of the product made of the relevant raw materials or components. However, if the person who is liable for damages fails to take appropriate measures to prevent damage caused by the defect, although he/she is either aware of or would have been able to know the existence of such defect after he/she supplied the product, he/she shall not be entitled to any exemption from liability referred to in (2) through (4) (Paragraph 2 of Article 4 of the same Act).
- Paragraph 1 of Article 7 of the Product Liability Act prescribes that "the right of claim for damages under this Act shall be extinguished by the completion of prescription if the injured person or his/her legal representative does not exercise his/her rights within three years from the date on which the injured person or his/her legal representative becomes aware of the damage and the person liable for the damage". Thus, the defence of extinctive prescription may be available.

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 Product Liability Act prescribes that a development risk – in other words, a risk that any imbedded defect may not be identified by the state of scientific or technical knowledge of the time a manufacturer supplies products – falls within the exemption from liability, and imposes the burden of proof on a person who has the liability for damage (Subparagraph 2 of Paragraph 1 of Article 4 of the same Act). The defence of development risk is one of several reasons for exemption from liability for the manufacturer, and therefore, the manufacturer bears the burden of proof.

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

The Product Liability Act prescribes that the manufacturer is exempted from liability "if he/she proves the fact that the defect is attributable to him/her who complied with the standard prescribed by any statutes of the time he/she supplied the product" (Subparagraph 3 of Paragraph 1 of Article 4 of the same Act).

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 plaintiffs 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?

Defendants can claim that the fault/defect was due to the actions of a third party. It is applicable for defendants to seek joint liability for any compensation to the plaintiff, 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?

Yes. Comparative negligence and offset of profit and loss can be acknowledged.

4 Procedure

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

A jury system has not been generally introduced to civil trials in Korea. However, it has been partially introduced to criminal trials in the form of "Civic Participation in Criminal Trials".

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, but, in principle, such experts do not "sit" literally with judges. Yet, under the expert commissioner system (Article 355 of the Civil Procedure Act), 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?

So-called modern-type lawsuits (including lawsuit for public

nuisance, citizens suit, lawsuit by consumers or investors, environmental lawsuit, and mass tort lawsuit) are generally related to victims who sustain a small amount of damage. It is actually or legally inappropriate for all of the victims to directly participate in a lawsuit as a party and thus, in the case of class action, only a representative party is allowed to participate therein, after receiving permission from a court. According to the Personal Information Protection Act (Article 54 of the same Act) or the Securities-Related Class Action Act (Paragraph 1 of Article 2 of the same Act), a representative party who receives permission from a court may take the lead in carrying out a lawsuit for all of the relevant victims.

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

There is no such mechanism under the Product Liability Act.

4.5 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

In Korea, based on Article 23 of the Attorney-at-Law Act, the Korean Bar Association takes the lead in strongly regulating the advertising of lawyer's business. However, starting from emission manipulations by Volkswagen and Audi, class action has become a rising area in the legal market, and ways of advertising legal services have become varied.

In particular, a popular way of advertising is to receive class action applications from victims by posting how to participate in a class action on an online news article or law firm's website. Recently, law firms are advertising for participation in a class action for BMW fire risk and a class action for Toyota's false ad of RAV4.

It is expected that such a marketing through online media or social networking service will be further activated in the future.

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

It normally takes three to four months from the receipt of complaint to the first hearing date.

4.7 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 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).

4.8 What appeal options are available?

Korea adopts a three-tier system that allows appeals twice to ensure a party's remedy against misjudgment.

4.9 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 above for the explanation of expert opinion pursuant to a judge's appointment or a party's application.

4.10 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 is currently accepted only when justifiable reasons are provided to and approved by the courts. In general, factual or expert witnesses are required to testify during the court hearing. 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.

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

In Korea, 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 manufacturer, causation, the existence of a defect, and the feasibility of safer alternate designs.

However, Korea has enhanced the system called "Order to Submit Document", in order to achieve aims for comprehensive disclosure of evidentiary documents held by the other party (Article 343 of the Civil Procedure Act).

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.

4.12 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. However, a court may attempt an amicable resolution by recommending a settlement or sending the case to conciliation.

4.13 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 naturally arises if a person is willing to submit to a trial in the court of Korea including jurisdiction by agreement and jurisdiction by pleading among international jurisdictions. Otherwise, disputes are resolved by the Act on Private International Law. Article 2 of the same Act provides that if a party or a case in dispute is substantively related to Korea, a court shall have the international jurisdiction and that, in judging the relation, a court shall take into consideration the territorial jurisdiction provisions of domestic law and consider the ideology of the allocation of international jurisdiction (i.e., the ideology of appropriateness/fairness and immediacy of a lawsuit).

In particular, a judicial decision for the determination of jurisdiction of a product liability suit has held that: "In a product liability suit against a manufacturer who manufactures/sells goods, whether the manufacturer and the place of occurrence of damage have a connection substantial enough for the manufacturer to be able to reasonably anticipate that in case damage occurs, the manufacturer may be brought before the court of the place of damage, should be considered in deciding whether the court of the place where damage occurred has international jurisdiction." (Supreme Court Judgment 2006Da17553 dated July 12, 2013.)

To sum up, in product liability cases, the lawsuit could be filed in Korea even if the plaintiff is not domiciled in Korea, as long as the infringement was committed in Korea or the consequence of the infringement also took place in Korea. Therefore, even if the distributor or manufacturer is not domiciled in Korea, it can be sued as a defendant in a product liability case in the courts in Korea.

5 Time Limits

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

Yes, there are statutes of limitations 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 right of claim for damages under the Product Liability Act is extinguished by the completion of prescription if the injured person or his/her legal representative does not exercise his/her rights within three years from the date on which the injured person or his/her legal representative became aware of the damage and the person liable for the damage (Paragraph 1 of Article 7 of the Product Liability Act), or if the right of claim for damages is not exercised within 10 years of the date on which the manufacturer supplied the product which caused the relevant damages (Paragraph 2 of Article 7 of the Product Liability Act).

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 on which the plaintiff should have known that their rights were damaged, issues of concealment or fraud could change the calculation of the time limit. In practice, however, such cases are rare.

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. Only monetary compensation is available as a remedy under Article 8 of the Product Liability Act and Articles 394 and 750 of the Civil Act, respectively. Under the Product Liability Act, the manufacturer is liable for damage and injuries to the life, limbs or property of the medicine accident. The manufacturer shall not be liable when the damage only occurs 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.

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 above.

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 plaintiff can request for any defects to be removed, any dangers to be eliminated, or any other appropriate actions to be taken, but costs such as medical monitoring cannot be recovered. In addition, if the plaintiff is also the consumer, it may consider filing a claim against the operator to stop selling the product or providing the service, or even request a recall from the manufacturer with potential product malfunction, in accordance with the Consumer Protection Act.

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

According to Paragraph 2 of Article 3 of the Product Lability Act, "if a manufacturer causes serious damage to life or body of a person as a result of not taking necessary measures against a defect of a product despite the manufacturer's knowledge of such defect, the manufacturer shall be liable up to three times the damage sustained by the person". In such cases, the court shall consider the following factors when determining damages:

- degree of intentionality;
- severity of damage caused due to the defect of the relevant product;
- financial gains obtained by the manufacturer from supplying the relevant product;
- where any criminal punishment or administrative disposition is imposed on the manufacturer due to the defect of the relevant product, severity of such criminal punishment or administrative disposition;

- period during which the relevant product is supplied and supply volume;
- financial status of the manufacturer; and
- efforts made by the manufacturer to repair the damage.

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?

There are no special rules under the Product Liability Act with respect to this question.

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 equivalent or similar system in Korea.

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?

Lawsuit costs refer to the costs falling within the scope prescribed by laws out of the actual costs spent by the parties to a lawsuit, and include expenses for trial, expenses of the parties, and attorneys' fees. Such lawsuit costs are borne by the losing party under the principle of bearing costs of lawsuit by the losing party. However, the statutory ceiling is quite low.

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

Yes. The Civil Procedure Act prescribes a litigation aid (Article 128, *et seq.* of the same Act) under which a lawsuit may be instituted first without paying costs, to make sure that the economically weak actually have the "right to a trial" (i.e., easy and equal access to the civil justice) and to ensure judicial welfare.

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

One of the requisites for litigation aid is where "it is obvious that a 'person who falls short of the solvency' to pay the 'cost of lawsuit' will not lose the lawsuit".

"Lawsuit costs" refer to the legal expenses prescribed in the Civil Procedure Act and all other costs and expenses required for carrying out the lawsuit.

"A person who falls short of the solvency" refers to a case where there may be a threat to the economic life of his/her own or of his/her family living together if he/she pays all of the costs mentioned above.

"It is obvious that … will not lose the lawsuit" refers to a case where the claim at issue itself is groundless or where losing is obvious since it seems to be a vexatious suit, etc.

Therefore, if "falling short of the solvency" is explained, litigation aid may be granted unless there is a special circumstance (Supreme Court Decision 2001Ma1044 dated June 9, 2001).

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.

Meanwhile, the Supreme Court allows a contingency fee only for civil cases, and not for criminal cases.

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

"Third party funding" as that term is conventionally understood in international practice – i.e., the funding of claims in arbitration or litigation in return for a share of the proceeds recovered in those proceedings, by an entity that does not otherwise have an interest in those proceedings – is an unfamiliar concept in Korea. While there are no explicit prohibitions under Korean law analogous to common law doctrines of champerty and maintenance, there is also no established legal framework for third party funding, no specific legislation or court judgments in this area, and no known instances of its use in litigations or arbitrations based in Korea.

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 costs required for raising a suit in Korea include the amount of revenue stamps and delivery/service fee. In particular, the amount of revenue stamps is determined by the Act on the Stamps Attached for Civil Litigation, Etc. and varies depending on lawsuit value. Lawsuit value refers to the value of the object of a lawsuit, and is the economic interest of the object of a lawsuit (in other words, the object that a plaintiff wishes to achieve through the lawsuit), which is assessed in a currency unit. "The benefits as alleged by the lawsuit" mentioned in Paragraph 1 of Article 26 of the Civil Procedure Act can be considered the lawsuit value. Such lawsuit value is the basis of calculating the amount of revenue stamps, which must be paid at the time of submission of a complaint, etc. The amount of revenue stamps is a kind of adjudication fee to be paid by a person who uses the nation's lawsuit system.

8 Updates

8.1 Please provide a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

With the advent of a "software-centred society", obtaining the quality and security of software has become an important legal issue. In addition, the discussion on whether the Product Liability Act may extend to software has become important. Representative examples include self-driving cars and artificial intelligence robots.

Accordingly, with respect to software product liability, the methods of improving the Product Liability Act focusing on the following points have emerged in legal circles in Korea.

First, software must be included in the objects of the application of the Product Liability Act.

Second, an expert aid must be available to a victim so that he/she may prove a design defect.

Third, as the defence of development risk has an important significance in software product liability, it is necessary to establish the judgment criteria to encourage development desire and to promote consumer protection.

Tony Dongwook Kang
Bae, Kim & Lee LLC
133 Teheran-ro, Gangnam-gu
Seoul, 06133
Korea

Tel: +82 2 3404 0158
Email: tony.dw.kang@bkl.co.kr
URL: www.bkl.co.kr

Tony Dongwook Kang is the partner in charge of the cross-border litigations of Bae, Kim & Lee LLC.

Tony's practice is focused on litigation in the fields of civil, commercial (including post M&A disputes and hostile takeovers), control disputes, white-collar crimes, product liabilities, real estate and finance. He served as a judge for 12 years in the Korean judiciary before joining Bae, Kim & Lee LLC in 2006 in various posts starting from the Seoul Criminal District Court and the Seoul Civil District Court to the Seoul High Court of Appeals. He earned respect from his peers while serving as a judge through his diligence, devotion, and legal mind which is why, for instance, he was awarded in 2004 as the most valuable judge in the Daegu district. This experience as a judge and praise from his peers inevitably seasons Tony's ability in vigorously achieving satisfaction of and success for his clients in a wide spectrum of various cases.

Tony received his bachelor degree from the School of Law, Seoul National University (1991; *cum laude*), and his master degree (LL.M.) from Harvard Law School (2002). He is fluent in English and frequently serves as arbitrator for domestic and international arbitrations.

Yongman Bae
Bae, Kim & Lee LLC
133 Teheran-ro, Gangnam-gu
Seoul, 06133
Korea

Tel: +82 2 3404 6577
Email: yongman.bae@bkl.co.kr
URL: www.bkl.co.kr

Yongman Bae focuses his practice on management rights disputes, hostile takeover, general meeting of shareholders, and board of directors, share ownership disputes, equity investment disputes, as well as commercial and financial litigation. He has provided advisory and litigation services to a broad array of listed and unlisted companies. Mr. Bae joined Bae, Kim & Lee LLC in 2010 after receiving an LL.B. degree from Korea University and completing the Judicial Research and Training Institute course. He also earned an LL.M. degree from UC Berkeley School of Law and was seconded to the firm's Vietnam office in Ho Chi Minh City. He actively engages in *pro bono* work related to North Korea and North Korean defectors.

bkl BAE, KIM & LEE LLC

Founded in 1980, Seoul-based BKL is one of the premier law firms in Korea. We provide market-leading legal services in every practice area we cover, including Corporate/M&A, Capital Markets, Finance, Dispute Resolution, Antitrust, Tax, Intellectual Property, Employment, Real Estate, TMT, Maritime and Insurance.

With over 600 attorneys and other professionals located throughout our offices in Seoul, Beijing, Hong Kong, Shanghai, Hanoi, Ho Chi Minh City, Yangon and Dubai, BKL has a diverse mix of Korean attorneys, foreign attorneys, tax advisors, industry analysts, former government officials and other specialists in various practice areas who work together in teams to handle matters critical to our clients.

BKL advises a broad range of clients such as Korean conglomerates and government organisations, major international financial institutions and multinational corporations with headquarters in the U.S., Europe and throughout Asia.

We are widely recognised as one of a handful of law firms in Seoul that work with international clients on a daily basis. Many of our professionals speak more than one language and have worked at leading law firms in other countries, equipping them with experience and familiarity in cross-border transactions to assist international clients' business in Korea as well as Korean clients' business overseas.

BKL is also a member of the World Law Group with its global network of over 50 law firms and has strong relationships with financial, tax and accounting advisors in various jurisdictions throughout the world, which allows BKL to serve its clients with a global reach.

Client service is the foundation of our legal practice, and our committed professionals view themselves as strategic partners to provide full-service capabilities necessary to meet the needs of our clients.

Netherlands

Antoinette Collignon-Smit Sibinga

Carolien van Weering

Legaltree

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 Dutch Civil Code ("DCC"), a product liability claim can be based on several articles, depending on the relation between parties.

1. **Contractual liability (article 6:74 DCC)**: If there is a breach of contract, a party can be held liable according to article 6:74 DCC for a defective product. A contracting producer of a defective product cannot contractually exclude or limit its strict liability for a defective product (article 6:192 DCC).
2. **Fault-based liability (article 6:162 DCC)**: Liability can be based on the general article regarding tort. This is fault-based. The Dutch principle of tort not only encompasses acts or omissions as such, but also the violation of (statutory) rights and obligations. There are no exhaustive limitations with regards to possible claims, causes of actions or defences under this general system.
3. **Strict liability for defective products**: In the case of consumer goods, a producer can be held liable by the consumer for a defective product. Articles 6:185 through 6:193 DCC are the Dutch implementation of the EC Product Liability Directive (European Directive 85/374/ EEC) ("the **Directive**").

According to the Directive and aforementioned articles, producers are subject to a regime of strict liability with only limited defences available to them.

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

There is no State-operated 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?

For a claim based on the Directive, 'producers' are liable. Article 6:187 par 2 DCC defines 'producers' 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 further extends the scope of the meaning of 'producer'. 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 a 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 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

Yes, based on the general provisions of article 6:162 DCC, a regulatory authority can be held liable for unlawful actions by issuing regulations for products. A claim will only be successful if there is a causal link between the defectiveness of the product, the regulations imposed on the manufacturer and the damage.

1.5 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 strict liability regime of article 6:185-193 DCC, there is no obligation to recall defective products or pay damages for a failure to recall defective products. An obligation to recall products or a claim for damages can flow from the general system of tort. 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 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 ("FCA") of the existence or possibility of dangerous or hazardous products and foodstuffs. If the recall is not undertaken voluntarily or is done inadequately, the FCA has the authority to order or initiate the recall of such products. For information of the FCA, see https://english.nvwa.nl/. The FCA can also impose a fine. More information about these fines can be found

at https://www.nvwa.nl/over-de-nvwa/hoe-de-nvwa-werkt/toezicht-maatregelen-en-boetes/bestuurlijke-boete/de-hoogte-van-de-bestuurlijke-boete.

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

Yes, criminal sanctions do 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?

According to article 6:188 DCC, the injured party bears the burden of proof with regards to the damages, the defect of the product and the causal link 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). In case the product liability is based on article 6:74 DCC (contractual negligence) or article 6:162 DCC (tort), the burden of proof of fault, defect, damages and the causal link between these lies on the claimant (article 150 DCCPR).

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 *conditio sine qua non* test ('but-for' test). In exceptional cases, courts may apply proportional liability. For example, in cases where a claimant suffers damages, but a causal link cannot be established with certainty. Damage claims cannot be brought in the absence of damage. 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?

In cases where 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 if the claim is based on the strict liability system of articles 6:185 – 6:193 DCC (see article 6:189 DCC); or
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).

Under Dutch law, there is no market share liability. 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?

According 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 warn may therefore 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 a case which related to the side-effects of certain sleeping medication, the 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. (*Supreme Court judgment of 20 June 1989, NJ 1990, 652 Halcion.*) There is, therefore, no principle of 'learned intermediary' under Dutch law.

3 Defences and Estoppel

3.1 What defences, if any, are available?

For claims based on article 6:185-6:193 DCC, the following defences are available as set out in article 6:185 DCC. The producer is not liable for damage caused by a defect ('safety defect') in his product, if he proves that:

a. he did not put the product into circulation on the market;
b. having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation on the market by him or that this defect came into being afterwards;
c. the product was neither manufactured by him for sale or any form of distribution for economic purpose nor manufactured or distributed by him in the course of his professional practice or business;
d. the defect is due to compliance of the product with mandatory regulations issued by the public authorities;

e. the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered; or

f. 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.

These defences can also be used in cases based on articles 6:74 DCC and 6:162 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 question 3.1, article 6:185 par 1 e. DCC.

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 question 3.1, article 6:185 par 1 d. DCC.

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 Dutch law there is no specific provision that would prevent a claimant from re-litigating its claim in different proceedings against a different defendant. It is not possible to re-litigate the same claim against the same defendant (or its legal successors) after a final and conclusive judgment has been rendered by a Dutch court.

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

Yes; if a defendant wishes to take recourse against third parties, he is entitled to file a motion for indemnification proceedings (articles 210–216 DCCP). This motion has to be filed latest prior to the statement of defence in the main proceedings. A defendant can also bring subsequent proceedings. There is no time limit for subsequent proceedings, other than the limitation period.

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

In cases based on strict liability (articles 6:185-6:193 DCC), according to article 6:185 par 2 DCC, the liability of the producer may be reduced or disallowed when, having regard to all the circumstances, the damage is caused by both a defect in the product and the fault of the injured person or any person for whom the injured person is liable.

Furthermore, a defendant can rely on article 6:101 DCC. When the damage is also caused by circumstances which are attributable to the injured person himself, the obligation to compensate damages is reduced by imputing the total damage to the injured person and to the liable person in proportion to the degree in which the circumstances which have contributed to the damage can be attributed to them individually. However, the courts are free to take into consideration a fairness correction.

4 Procedure

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

All court proceedings in the Netherlands 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)?

According to article 194 DCCP, the court may appoint an expert, for instance a 'technical specialist'. The court may do this on its own motion or at the request of one or both parties. A court-appointed expert is independent, he and does not sit with the court. The court is not bound by, and may disregard, an expert opinion or statement (article 152 par 2 DCCP).

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

On 18 March 2019, a bill introducing a collective damages action on an opt-out basis for persons domiciled in the Netherlands was adopted by the Dutch Senate. It will likely enter into force later this year (2019) or on 1 January 2020. Under the current collective litigation regime, no monetary damages can be sought on a collective basis (articles 1013–1018 DCCP). The essence of the new law is that this restriction is removed, so that a group action for monetary damages is possible. In order to achieve a fair and balanced system, at the same time, the bar is raised for collective claims. Under the new regime, finality is also increased by making a court ruling awarding or denying the collective relief sought binding on the individual members of the group. Under the current regime there is no such binding effect.

The general principles of the new law are as follows (article 1018b-m DCCP):

1. The aim of the bill is to increase the likelihood of reaching a settlement by (i) improving the quality of collective action organisations, (ii) co-ordination of collective proceedings, and (iii) achieving more finality.
2. There will be one single statutory regime for collective actions, regardless of whether these are used to seek monetary damages or other relief. This new regime will apply to collective actions filed after the date on which the Bill will come into force and effect and must relate to an event or events which occurred on or after 15 November 2016.
3. The bill tightens the threshold requirements to be met by collective action organisations in order to have their collective claims admitted as far as governance, funding and representation are concerned.

4. In addition, there must be a sufficiently strong connection between the collective claim and the jurisdiction of the Netherlands in order to be admitted as a collective action. This is the case if (i) the majority of the persons in whose interest the action is brought reside in the Netherlands, (ii) the defendant is domiciled in the Netherlands and there are additional circumstances which are indicative of a sufficient link with the jurisdiction of this country, or (iii) the event or events to which the action relates took place in the Netherlands. This criterion is separate from the criteria applicable to the determination of the international jurisdiction of the Dutch court.
5. All collective claims must be entered into a central register for collective actions.
6. If there are more collective action organisations wishing to bring an action for the same event(s) on similar points of law and of fact, the court will select the most suitable organisation as the 'Exclusive Representative' for all injured parties domiciled in the Netherlands and for non-residents who have opted in.
7. The non-selected representatives remain parties in the proceedings.
8. After the appointment of the Exclusive Representative, individual members of the group for whose benefit the action has been brought can withdraw from this group by opting out. The action will then go forward on the merits. Those who opt out must pursue their claim individually and will not be able to benefit from the collective action. This should increase finality and should decrease the risk of free riding.
9. The court judgment is binding on all injured parties domiciled in the Netherlands who have not opted out and on all non-Dutch residents who opted in.

Class action cases are brought frequently in the Netherlands. Under the new regime, this will also be the case.

Another option under Dutch law is the WCAM. This procedure provides for an innovative collective resolution where certain persons are represented that are even unknown to the representative parties. It consists of an opt-out approach. As such an approach departs from the 'ordinary' civil procedural principles, several additional rules of procedural law had to be included in the Code of Civil Procedure to allow WCAM procedures that aim for legally binding settlement covering all similar claims. Consequently, no further claims will be litigated in the future, unless one has timely opted out.

Pursuant to Article 7:907(1) BW:

"An [settlement] agreement concerning the compensation for damages caused by an event or similar events entered into by a foundation or association with full legal capacity with one or more other parties, who undertake thereby to compensate these damages, may, upon the joint request of the parties that have concluded the agreement, be declared binding by the court upon [the class of] persons to whom the damages have been caused, provided the foundation or association, by virtue of its articles of association, represents the interests of these persons."

The following requirements must be met for the approval of the settlement agreement:

(a) the compensation amount may not be unreasonable;
(b) the defendant's performance must be sufficiently guaranteed;
(c) the representative organisation must adequately represent the class; and
(d) the number of class members must be sufficient to warrant 'certification'.

Nonetheless, no fixed number or threshold is set. In the *Shell* order, a threshold of 5% or more of the estimated class members was agreed upon in the settlement agreement which was approved by the court. On a case-by-case basis, the court decides whether such a threshold is fair and reasonable.

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.

4.5 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

Yes, representative bodies as well as lawyers may advertise for claims. Representative bodies frequently advertise for claims; lawyers do as well, but not as frequently. They usually have press contacts and spread their message via the media and social media. It is hard to say if advertising materially affects the number of claims brought in our jurisdiction.

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

It depends on the case. Parties have the option to request the court to hear witnesses (article 186 DCCP) or a preliminary expert's report (article 202 DCCP). Furthermore, there are possibilities to request documents before a trial commences (article 843a DCCP).

4.7 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. However, preliminary issues on interpretation of law 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 to the ECJ. Preliminary issues cannot relate to issues of fact. Such referrals may be made *ex officio*, or at the request of one of the parties.

In personal injury cases, there is a special ('preliminary') legal proceeding (article 1019w-1019cc DCCP) in which a court can determine one or more specific issues of the case, for instance only on liability, causation, provided it helps parties to reach an out-of-court settlement. In these proceedings, courts can relate to issues of fact.

4.8 What appeal options are available?

From a judgment in first instance, appeal may be lodged before the Court of Appeal. After a judgment of the Court of Appeal there is the option to go to the Supreme Court. In principle, a party may lodge an appeal to both a non-favourable and favourable judgment (for instance, a claimant may lodge appeal against a judgment in which the liability of the defendant was established, but the damages were not, or not fully, awarded).

4.9 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.

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

Expert witnesses are not required to present themselves for pre-trial deposition. Parties can however request the court to hear an expert (article 200 DCCP). Witness statements and expert reports are usually exchanged prior to trial. There is no procedural rule which requires parties to exchange statements and/or reports.

4.11 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 obligations to disclose documentary evidence other that via the pre-trial proceedings as mentioned in question 4.6. According to article 843a DCCP, a court may order a party to disclose or submit certain specific documents. There are strict conditions to prevent 'fishing expeditions'.

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

No, there is no obligation to mediate or start arbitration before proceedings commence, unless parties have agreed so.

4.13 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 a claimant or the defendants are domiciled in another country jurisdiction, the court is determined by the applicable Dutch Private International Law. According to Regulation nr. 1215/2012 (Brussels Recast), in cases concerning consumer contract, a Dutch court has jurisdiction if the claimant is domiciled in the Netherlands even if the defendants have their domicile in another country (article 18 par 1). A consumer can also issue court proceedings at the court where the defendant has his domicile.

If the company who sold a product issues court proceedings, the court where the consumer is domiciled has jurisdiction (article 18 par 2 Brussels Recast).

In other cases, the basic rules set out in Brussels Recast apply.

In cases where the Brussels Recast does not apply, the jurisdiction is determined either on the basis of other treaties, such as the Lugano Convention (30 October 2007, PbEU 2009 EVEX II) or Dutch Private International Law.

5 Time Limits

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

Yes. However, time limits differ. First of all, they depend on the nature of the claim. Second of all, there is a difference between the short time limit based upon the knowledge of the claimant and the long time limit. These time limits can be interrupted by starting legal procedures or by sending a letter to the defendant stating that the claimant reserves his rights.

Product liability (article 6:191 DCC):

- The time limit is three years after the injured party became or ought to have become aware of the damage, the defect and the identity of the producer. In case there are several producers of the product, the time limit of three years might differ for each and every producer.
- Based upon the compulsory article 10 of the European Directive, the DCC determines that the right to proceed expires 10 years after the damage-inflicting product has been brought onto the market. The only way to stop this expiration date is to start legal proceedings.

Fault-based liability (article 3:310 BW):

- Five years after the party that suffered damage became or ought to have become aware of the identity of the injuring party and the damage incurred.
- Twenty years after the damage-inflicting event has occurred.
- In the case the claimant suffered injuries or is a surviving relative of the victim, only the five-year time limit is applicable.
- In the case the claimant is a minor when he became or ought to have become aware of the identity of the injuring party and the damage incurred, the right to proceed is limited to five years after the day the minor becomes of age.

Contractual claims:

- The buyer of a product that does not meet the contractually agreed upon or reasonable requirements is obliged to inform the seller of the product of this within two months after the discovery (article 7:23 DCC in conjunction with article 6:89 DCC). The time limit is two years after the day the buyer notified the seller that the product did not meet the contractually agreed upon or reasonable requirements.
- Five years after the claimant became or ought to have become aware of the existence or extent of its claim for damages.

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

See question 5.1.

In addition, the Dutch court can in certain (rare) circumstances rule that the appeal of the defendant to the time limit is not reasonable.

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, but only in the case that the claimant or injured party is fraudulent with regards to the moment the damage was discovered.

6 Remedies

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

Monetary compensation:

- Compensation for damages.
- Contractual penalties.
- Recovery of the other party's breach of a judicially imposed penalty.

Other:

- Declaratory relief.
- Injunctive relief (e.g. product recall).
- Judicial termination.
- Annulment or nullification of an act or agreement.
- A buyer may demand delivery, repair or replacement of 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?

In case of product liability, article 6:190 DCC exhaustively lists the types of damage an injured party can claim:

- damage caused by death or personal injury; and
- damage to any item of property that is intended for and used by the claimant for his own private use or consumption. This is only possible when the damage exceeds the amount of EUR 500.

In the case of fault-based damages, it is possible to recover all the damage suffered, such as bodily injury, mental damage, loss of income, loss of ability to do chores in and around the house, housekeeping costs, damage to property, and 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?

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?

No, in the Netherlands this is not possible.

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. Under Dutch law, reasonable damage should be compensated for. In case this would lead to unacceptable consequences, the judge may mitigate this amount (article 6:109 DCC).

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, in several cases, court approval is required.

- For a collective settlement to have binding effect, the Amsterdam Court of Appeal will consider whether the settlement agreement meets certain formal requirements.
- The cantonal judge has to approve of settlements and of starting court procedures on behalf of minors or incapacitated 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?

In case of personal injury that is related to the fault or defectiveness of a product, the Government is able to claim the benefits and other costs paid on behalf of the victim from the producer.

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, this is possible.

(a) The court fees (articles 237–239 DCCP) are fixed and considerably less than the actual legal costs incurred by the successful party. Further, one can recover bailiff fees and incidental costs, such as the costs for experts.

(b) In case the procedure is based upon article 1019 w DCCP (*deelgeschilprocedure*), the reasonable costs of the proceedings can be fully recovered (article 6:96 DCC).

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

Yes, legal aid funded by the Dutch government is available when the claimant does not have enough income or savings to pay for the procedure. This is only possible 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?

See above at question 7.2.

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

The Rules of Professional Conduct (*Gedragsregels 1992*) forbid Dutch lawyers who are admitted to the Bar to make "no cure no pay" or contingency fee arrangements. An exception to this are personal injury cases provided that the Dean approves of the arrangement.

Fixed fees or capped fees are allowed.

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

Yes, third party funding of claims is permitted and no particular restrictions apply.

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, except when the court decides upon an expert report. In that case, the expert will have to inform the court about the expected costs. Both parties can object against these costs; however, the judge rules whether or not the expert can proceed.

8 Updates

8.1 Please provide a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

Gerechtshof Amsterdam (ECLI:NL:GHAMS:2018:4312):

Pharmaceutical producer Wyeth produces contraceptive pills. Part of the waste of this production was contaminated with the hormone MPA. Through – amongst others – a broker in waste, Cara, this contaminated water was delivered to Rined, a producer of pig feed. Rined was held liable by multiple pig farmers because of the fact that their pigs became infertile due to the hormone MPA in their food. Rined began procedures against Wyeth and Cara to recover the damages suffered.

The court rules that both defendants are liable because they did not exercise due caution. The court based this decision on the fact that defendants violated European Directive 259/93 with regard to the supervision and inspection of the transfer of waste within, to and from the European Community.

Interestingly, Wyeth remained liable as producer, even though the company had transferred the contaminated waste to the broker in waste, Cara.

Antoinette Collignon-Smit Sibinga

Legaltree
Olympisch Stadion 24-28
1076 DE Amsterdam
The Netherlands

Tel: *+31 88 0402120*
Email: *antoinette.collignon@legaltree.nl*
URL: *www.legaltree.nl*

Antoinette Collignon is a specialist in (cross-border) liability and bodily injury cases, product liability, employer liability and international private law. She advises insurers, international loss adjustment agencies, and businesses, as well as victims. In international cases, she works closely with law firms of good repute in Europe and the United States. She was one of the founders of the Pan-European Organisation of Personal Injury Lawyers European Association (PEOPIL) founded in 1997, of which she became the first Dutch member and also the first female president from 2009 up to September 2013.

Antoinette is a regular speaker at congresses and seminars. She is affiliated as lecturer, amongst others, at the SDU, Kerckebosch and Magna Charta. She also regularly publishes articles on her specialty.

Carolien van Weering

Legaltree
Rapenburg 83
2311 GK Leiden
The Netherlands

Tel: *+31 6 31953277*
Email: *c.vanweering@legaltree.nl*
URL: *www.legaltree.nl*

Besides practising as attorney-at- law, Carolien van Weering acts as a mediator. In practice, Carolien has conducted many legal proceedings and provided advice.

In the areas of liability and insurance law, Carolien deals with cases concerning bodily injury, (medical) professional liability, product liability, policy disputes, fraud and disability insurances.

In the area of health law, Caroline has had broad experience in the areas of medical disciplinary rules, privacy legislation and partnership disputes in health care.

Carolien has been a partner at Legaltree since 2011, with a break between 2017 and 2018 when training for the judiciary. Until her switch in 2011, Carolien practised at AKD Advocaten en Notarissen in Rotterdam. As lecturer, she is affiliated to Medilex, SDU and Nibesvv.

legaltree

In a changing world, it is time for the legal profession to take an innovative approach. This is exactly what we at Legaltree have chosen to do. We are a law firm consisting exclusively of partners who have had a minimum of 10 years' experience. They provide their services to clients directly. The contact clients have, therefore, is much more personal.

At Legaltree you will find one or more specialists per area of law. Because all the partners cooperate closely with each other and actively share their knowledge, clients can always be assured that the expertise is the most up-to-date.

Norway

Ole André Oftebro

Kyrre W. Kielland

Advokatfirmaet Ræder AS

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 called the Norwegian System of Patient Injury Compensation (No: *Norsk Pasientskadeerstatning*). 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*) also acts 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 several 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 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

For defective pharmaceuticals, the Norwegian System of Patient Injury Compensation (No: *Norsk Pasientskadeerstatning*) may have strict liability, see question 1.2 above.

Other than this, regulatory authorities may theoretically be held liable for defective products on the basis of negligence. One example can be that the defect is caused by the manufacturer designing the product in compliance with mandatory regulations issued by the public authorities. In these cases, the manufacturer will be relieved of strict liability, *cf.* the PLA section 2-2 c). If the regulatory body has acted negligently in relation to the regulations, however, the injured party may theoretically hold the regulatory authority liable on the basis of negligence.

1.5 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.

1.6 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 the 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 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

When a class action is approved by the court, other potential claimants shall be informed either by a notice or by an advertisement/announcement, in accordance with the Norwegian Dispute Act § 35-5. The court may decide in each case what type of notice/advertisement and whether the court or the group representative counsel shall be responsible for such notice/advertisement. Advertisement for claims in media is very rare in Norway, if it ever occurs at all. Thus, advertisement for specific claims does not significantly affect the number or types of claims brought in Norway.

4.6 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; however, it can take longer.

4.7 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.

4.8 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) it for other reasons is particularly important to have the case decided by the Supreme Court.

4.9 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.

4.10 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 an oral statement. The expert reports must be submitted to the court prior to the trial and made available to both parties.

4.11 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.

4.12 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.

4.13 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 based on strict liability 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 from sufficient knowledge 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 or alternatively 20 years from the date the negligent actions ceased. 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 a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

There have been no statutory amendments and only a 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.

Worth noting is a Court of Appeal decision from December 2018, concerning the distribution of liability between a non-EU producer, an EU importer and a Norwegian distributor following a house fire caused by inadequate recall measures for an electrical household product with a known fire risk. Represented by Advokatfirmaet Ræder, the liability insurer of the non-EU producer successfully sought (partial) recourse from the EU importer and Norwegian distributor and their insurers on the basis of negligence. In reaching its decision, the court found, *inter alia*, that the Norwegian distributor was jointly liable with the producer and importer towards the injured party as the lack of recall measures was considered a negligent breach of statutory duties.

With respect to new technologies and AI, we are not aware of any landmark cases yet. However, there has been some development in composing new laws related to the new challenges. For instance, recently a law on testing of self-driving vehicles (including provisions on liability) entered into force. With respect to liability for damage caused by robots and AI in general, the Norwegian authorities seems to be awaiting the outcome of ongoing discussions in the EU Parliament. Meanwhile the courts, if in receipt of damages claims related to new technology or AI, would have to apply existing concepts of law.

Ole André Oftebro

Advokatfirmaet Ræder AS
P.O. Box 2944 Solli
N-0230 Oslo
Norway

Tel: +47 23 27 27 00 / +47 97 56 74 32
Email: oao@raeder.no
URL: www.raeder.no/en

Ole André Oftebro specialises in product liability, employment law and civil litigation. He is co-author of the leading legal commentary on the Norwegian Product Liability Act (Gyldendal 2015), together with Kyrre W. Kielland.

Ole André holds broad experience with more than 100 product liability cases, and frequently represents leading producers and importers, especially within the electronics industry.

Kyrre W. Kjelland

Advokatfirmaet Ræder AS
P.O. Box 2944 Solli
N-0230 Oslo
Norway

Tel: +47 23 27 27 00 / +47 45 02 20 56
Email: kwk@raeder.no
URL: www.raeder.no/en

Kyrre W. Kielland holds broad experience of providing advice to and litigation for manufacturers, insurance companies and others within product safety and product liability law. In particular, he assists national and international clients within the industries of electronics, technology and shipping/offshore.

Kyrre works closely with the Norwegian Electronics Association and has been invited as keynote speaker on various conferences and legal courses within the electronics industry. Further, he is regularly appointed as an external examiner at the Faculty of Law, University of Oslo and Lillehammer University College.

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

Advokatfirmaet Ræder is a leading, Oslo-based law firm with more than 60 experienced lawyers within all fields of commercial law. The department for Insurance and Tort consists of 10 specialised lawyers. 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. Our clients appreciate personal and hands on partner attention alongside leading expertise and business insights.

Ræder has an international focus and has 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.

Poland

Paweł Wysocki

Marcin Rudnik

Wolf Theiss

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?

One must bear in mind that the Polish legal system does recognise a "hazardous product" as a potential source of damage as opposed to a faulty or defective product. A product is hazardous if it does not guarantee the safety that could be expected based on normal use of the product. For the sake of clarity, whenever the term "faulty" or "defective" product is used, we mean a hazardous product as defined in the Polish Civil Code.

Product liability in Poland is regulated by the Civil Code. The relevant provisions were introduced in 1994 as a result of the implementation of Directive 85/374/EWG. The claimant needs to prove the defectiveness of the product, damage and causal link.

Liability is strict and it does cover both damage to persons and to the property. The latter is limited, however, to EUR 500. Damage to property exceeding this amount may be subject to further claims under the general tort rules (fault-based liability).

Contractual liability may be relevant within the supply chain.

The product liability regime does not deny application of standard (fault-based) tort liability rules.

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

The state operates no schemes of compensation for particular products. It does, however, operate a social security system granting compensation for accidents at work which may be relevant for product liability matters depending on the circumstances.

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 regime, anyone who, within the scope of his business activity, manufactures a hazardous product is liable for damage caused to any person by the product. The manufacturer of materials, raw materials or a constituent part of a product bears the same liability as the manufacturer unless the sole cause of the damage was the defective construction of the product or the manufacturer's instructions were defective.

Anyone who, by placing his name, trademark or other distinguishing mark, purports to be the manufacturer bears the same liability as the manufacturer. The same liability is borne by anyone who introduces a product of foreign origin to domestic trade within the scope of its business activity.

Under the general tort rules, anyone who unlawfully and intentionally or negligently caused damage to the claimant may be held liable.

1.4 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

In theory, yes. An entity exercising public authority is liable for damage caused by an unlawful action or omission while exercising such authority. Failure to supervise the entity liable for the product may constitute grounds for such liability provided that the damage and causal link are established.

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

Liable entities are required to take all the necessary steps to mitigate the risk related to the product once the source of such risk is discovered. Upon such discovery, the product may be recalled from the market depending on the severity of the risks identified. The President of the Office for Customer and Competition Protection may issue the appropriate decision to enforce the recall.

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

Yes. The general provisions of the Criminal Code, as well as certain specific criminal regulations, may apply depending on the circumstances. Those include criminal penalties for exposure to loss of life or health, introduction of products that do not comply with the essential requirements, etc.

2 Causation

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

The claimant has the burden of proving the defectiveness of the product, damage and causal link.

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?

Only those damages that have a normal, adequate causal link with introducing the product to the market may give rise to liability. Establishing a causal link comprises two questions. The first one: would this consequence appear in the absence of the alleged cause? If the answer is positive, then the second question: is this consequence a normal, standard result of the alleged cause? If both answers are positive, a causal link is established.

The claimant needs to provide evidence that the particular product actually caused damage.

Currently, there are two main perspectives in Polish jurisprudence that deal with the level of likelihood of damage as standard in proving the causation. The first perspective provides that the causal link needs to be proven. The second perspective states that in certain situations only a certain level of probability is sufficient for the product liability claim. The latter standard is often seen in pharmaceutical product liability cases.

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 form of market-share liability is applicable in Polish law. Failure to establish a liable entity is not that uncommon and often jeopardises the lawsuit.

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 a general obligation for the manufacturers and distributors to inform the President of the Office for Customer and Competition Protection about faults and defects of products which have already been introduced to the market, immediately after obtaining such information.

If the final recipient of the product was properly informed about any potential risks associated with the usage of the product, his chances for success with a product liability claim become limited regardless of whether the information concerning the risk was served by a producer or an intermediary.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under the product liability regime, the defendant may claim, in particular:

- that he did not introduce the product to the market or that it was introduced outside of the scope of his commercial activities;
- that the product was not defective;
- that there is no causal link between the alleged defectiveness of the product and the damage;
- that there is no damage, or the claimant contributed to the damage;
- the properties of a product were revealed after the product was put into circulation;
- the hazardous properties of the product could not have been foreseen based on scientific and technological conditions at the time the product was put into circulation, or if the properties resulted from the application of legal regulations; or
- lapse of statutory limitation periods.

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 manufacturer is not liable if the properties of a defective product are revealed after the product is put into circulation unless they are due to an element inherent in the product. Neither is the manufacturer liable if the defective properties of the product could not have been foreseen based on scientific and technological conditions at the time the product was put into circulation, or if the properties resulted from the application of legal regulations. The claimant's obligation is merely to prove that the damage existed and was attributable to the product, not that fault or defect was discoverable or not.

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

It is not a defence by itself.

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 damage can be re-litigated by the same claimant if the circumstances have not changed. However, if new damages are discovered, they may be the subject of another claim. Other claimants need to instigate their own proceedings which are not directly affected by the judgments of the civil courts in other cases. However, indirect influence does exist as the claimants are allowed to present different judgments to the court trying their 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 defendants are jointly and severally liable thus may make claims against each other.

Statutory limitation periods apply.

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

Yes, it is one of the key arguments in many cases. If an aggrieved party has contributed to damage arising or increasing, the obligation to remedy the damage is appropriately reduced according to the circumstances.

4 Procedure

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

Trials are conducted by judges, there is no trial by jury in product liability cases in Poland.

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

Yes, the courts appoint experts to review the evidence and provide written and oral opinions.

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 Polish Act on pursuing claims in group proceedings in its Article 1 § 1 explicitly names the product liability cases as one of the cases which can be the subject of a group action.

Currently, group actions are based on an "opt-in" procedure.

Product liability cases in Poland are not commonly brought via a group action procedure.

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

A group is represented by one of its members or Consumer's Advocacy ("*Rzecznik Konsumenta*").

4.5 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

Codes of ethics of legal professions provide a general rule which prohibits advertising. Private entities financing litigation tend to draw media attention in order to attract potential claimants.

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

Civil claims generally take three to six months from the moment of filing the statement of claim to the trial.

4.7 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 general rule in Polish civil proceedings is that the courts adjudicate on the whole matter comprehensively in one judgment. However, the courts are allowed to issue preliminary rulings as well. In such judgment, the court, recognising the claim as justified in principle, can make a preliminary ruling only as to the principle of liability itself leaving the issue of damage for further investigation.

4.8 What appeal options are available?

Full appeal options are available. The courts of second instance try the case again in terms of merits. Cassation to the Supreme Court is also available in most cases. It may not address evidence examination and factual findings though.

4.9 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 courts usually appoint experts to assist it in considering technical issues. Opinions prepared by such experts serve as evidence. The parties are also allowed to present private expert opinions; however, these do not constitute evidence.

4.10 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 such requirement. Private experts' opinions are rarely exchanged before the trial.

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

There is no discovery procedure in Poland.

During the trial, the court may request certain evidence to be presented by the parties including documentation. Prior to the trial, the court may also secure specific evidence for the purpose of further examination.

4.12 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 not required by the law to be pursued prior to the litigation. Courts often encourage the parties to take part in the mediation process or negotiate a settlement between themselves.

4.13 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 claim may be brought before the Polish court if the defendant is resident in Poland.

Product liability claims may be brought against the foreign manufacturer of the product before the Polish courts if either the damage occurred in Poland or the circumstances leading to the damage occurred in Poland.

5 Time Limits

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

Yes. Statutory limitation periods 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 strict product liability regime, a claim for remedying damage caused by a product is barred by the statute of limitations three years after the day on which the aggrieved party learns or, having used due care, could have learned of the damage and of the person obliged to remedy the damage. In every case, however, the claim becomes barred by the statute of limitations 10 years after the product is put into circulation.

Under the general tort rules, a claim for remedying damage caused by tort is barred by the statute of limitations three years after the day on which the aggrieved party learns of the damage and of the person obliged to remedy it. However, this period cannot be longer than 10 years from the day on which the event causing the damage occurs. In the event of personal injury, the limitations period cannot end earlier than three years after the day on which the aggrieved party learns of the damage and of the person obliged to remedy it.

The court may find the defence based on the limitation period inadmissible. This happens if the debtor acted against the rules of social coexistence in order to delay the lawsuit prior to using this defence. In one of the rulings, the Supreme Court found the defence inadmissible because the hospital (defendant) deceived the claimant by making promises to provide treatment until the claim resulting from professional malpractice became time-barred.

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

If the damage results from a crime or an offence, the claim for remedying the damage is barred by the statute of limitations 20 years after the crime is committed regardless of when the aggrieved party learns of the damage and of the person obliged to remedy it.

6 Remedies

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

Full compensation of damages is the general rule in this regard. Both monetary compensation and declaratory relief are available.

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

The aggrieved party is entitled to full compensation of all damages including:

- damage to property;
- health disorders along with the medical costs;
- pain and suffering; and
- lost earnings (including those resulting from inability to work in the future).

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?

Punitive damages are not recoverable.

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

No 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?

As a general rule, there are two types of the settlements in the Polish legal system:

- out-of-court settlement, which does not need to be approved by the court;
- court settlement, which may be concluded in any civil proceedings, as long as the nature of the claims recognised so permits. Conclusion of the court settlement ends the court dispute between the parties – this needs to be accepted by the court.

In class actions, the conclusion of the settlement requires the approval of more than half of the group members.

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

There are no specific regulations or case law in this respect. Any such claim would need to be based on the general rules of the civil 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?

Yes, the losing party is obliged to return to the opponent, at his/her request, the costs necessary for the purposeful assertion of rights.

The reimbursement of the costs will ultimately be calculated by the court and provided in the judgment. The court is bound by the provisions of the Ministry of Justice regulations, which cap the awardable costs.

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

Legal aid is available in several forms:

- in civil proceedings, a party may request to be released by a court from costs in whole or in part (due to lack of ability to cover such costs);
- the party may also request a *pro bono* lawyer to be appointed;
- the Office of Intervention Legal Aid at the Chancellery of the President of the Republic of Poland offers free legal support in some cases; and
- state-funded Consumer's Advocacy.

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

Restrictions generally depend on the financial situation of the claimant. The prerequisite to be fulfilled is not being able to financially bear the costs of the legal aid that is required in the specific case.

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

Success fees are generally prohibited in the Polish legal system except for group actions.

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

Third party funding is not regulated in Poland.

There are several measures used currently by third party litigation funders:

- fiduciary transfer of receivables aimed at collecting those by a single entity in order to pursue the claims on its own behalf (very often this involves an obligation to reimburse the former owners of the claims after the lawsuit proves successful);
- civil law agreements conducted in accordance with the principle of freedom of contract; and
- funding within the class action proceedings.

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 costs being awarded at the end of the litigation are capped by the mandatory provisions of the law.

8 Updates

8.1 Please provide a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

The product liability legal framework and doctrine in Poland are quite well-developed. There is a significant number of publicly available decisions of the courts addressing the most relevant issues. Some aspects of liability remain controversial, in particular the standards of establishing causation. The relatively poor expert base is one of the most unpredictable factors of each litigation of this kind.

The most significant cases during the last decade involved the tobacco industry, as well as pharmaceuticals and medicinal products.

One can clearly notice a general increase in the amounts of compensation being awarded by the Polish courts for pain and suffering, as well as more generous approaches towards awarding damages related to medical treatments.

It appears that the introduction of group actions has not yet led to an increase in volume of product liability claims. The final results of these regulations remain to be seen.

Paweł Wysocki

Wolf Theiss
Mokotowska 49
00-542 Warsaw
Poland

Tel: +48 22 3788900
Email: pawel.wysocki@wolftheiss.com
URL: www.wolftheiss.com

Paweł Wysocki is a member the Dispute Resolution team and specialises in advising and representing clients in civil, administrative and arbitration proceedings regarding insurance, construction, product liability and employment, as well as white collar issues. Pawel's experience in the product liability area encompasses a variety of cases including tobacco, pharmaceutical and automotive related claims.

Prior to joining Wolf Theiss, Pawel worked at other prominent international law firms and at a Big Four accounting and consulting firm in Warsaw. He is admitted to the Polish Bar and speaks Polish and English.

Marcin Rudnik

Wolf Theiss
Mokotowska 49
00-542 Warsaw
Poland

Tel: +48 22 3788900
Email: marcin.rudnik@wolftheiss.com
URL: www.wolftheiss.com

Marcin Rudnik is a Senior Associate and a member of the Dispute Resolution, Competition and Antitrust and Real Estate and Public Procurement practice groups of Wolf Theiss in Poland. He focuses on advising and representing clients in civil, administrative, insolvency and arbitration proceedings regarding construction contracts, real estate, corporate and competition law. He has participated in numerous public procurement, PPP and project finance transactions, mostly on the side of lenders, and also advises clients on construction and development matters, including FIDIC contracts, as well on the leasing of commercial and industrial premises.

Marcin studied law at the Universities of Gdańsk and Toruń, the University of Regensburg, Germany, and was awarded an LL.M. degree. He also completed the English and European law school organised in cooperation with the University of Cambridge. He is admitted to the Polish Bar and speaks Polish, English and German fluently.

WOLF THEISS

Wolf Theiss is one of the leading law firms in Central, Eastern and South-Eastern Europe (CEE/SEE). We have built our reputation on a combination of unrivalled local knowledge and strong international capability. We opened our first office in Vienna 60 years ago. Our team now brings together over 340 lawyers from a diverse range of backgrounds, working in offices in 13 countries throughout the CEE/SEE region.

Over 80% of our work involves cross-border representation of international clients. Our full range of services covers: Banking & Finance; Business Crime; Capital Markets; Competition & Antitrust; Compliance; Corporate/Mergers & Acquisitions; Dispute Resolution; Employment Law; Energy & Renewables; Infrastructure; Intellectual Property & Information Technology; International Arbitration; Investment Funds; Life Science; Real Estate & Construction; Regulatory & Procurement; Retail; and Tax.

We have concentrated our energies on a unique part of the world: the complex, fast-developing markets of the CEE/SEE region. Through our international network of offices, we work closely with our clients to help them solve problems and create opportunities.

For more information, visit www.wolftheiss.com.

Chapter 24

Singapore

Dr. Stanley Lai, SC

Amanda Soon

Allen & Gledhill LLP

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 fail to 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, then 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 1.5.

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 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

No, as the regulatory authority is not the manufacturer, importer, distributor or "retail" supplier of the product, it is unlikely to be found directly or indirectly liable in respect of a defective/faulty product.

1.5 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 regulates 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.

1.6 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 must show that the product malfunctioned in a way that does not meet the standard that a reasonable person would expect 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 the claimants.
- All 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 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

It is permissible for a lawyer to publicise his practice or the practice of his firm within Singapore in accordance with the Legal Profession (Publicity) Rules. However, rule 7(1)(b) provides that no advocate and solicitor shall publicise his practice or the practice of his firm in a manner which may reasonably be regarded as being misleading, deceptive, inaccurate, false or unbefitting the dignity of the legal profession, and rule 7(2)(d) states that publicity shall be considered to be misleading, deceptive, inaccurate or false if it is likely to create an unjustified expectation about the results that can be achieved by the advocate and solicitor or his firm. Hence, advertisements in relation to specific claims may run the risk of being considered to be misleading as they are likely to create an unjustified expectation about the results that can be achieved, e.g. if the advertisement suggests that the law practice will be able to recover compensation in a certain claim for product liability. It is not common for lawyers to advertise for specific claims in Singapore.

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

Generally, a case in the High Court takes about 15 to 18 months from the issuance of the writ to the start of the trial.

4.7 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.

4.8 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.

4.9 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.

4.10 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.

4.11 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.

4.12 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 mediation, arbitration, neutral evaluation, expert determination and conciliation. 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). The Singapore International Mediation Institute (SIMI) and the Singapore International Mediation Centre (SIMC) were launched in 2014 to serve as international mediation service providers offering quality panels of international mediators and experts. 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.

4.13 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 means 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 Bureau is of the opinion that the applicant has a good reason to bring or defend his case under the law.

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.

In March 2017, the Civil Law Act was amended to allow third-party funding but only in the field of international (but not domestic) arbitration and related proceedings, and not in court-based litigation. Such related proceedings include:

(a) court proceedings arising from or out of 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 a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

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 of the time of writing, there have not been any reported court cases dealing with product liability issues in relation to new technologies and artificial intelligence. However, 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 fail to 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. The CPFTA provides the same protection to consumers whether their purchases are made online, or from physical stores.

In January 2019, *The Straits Times* reported that CASE had received complaints about an online fashion retailer that automatically enrolled consumers in a membership programme, without their knowledge, and charged them recurring membership fees (https://www.straitstimes.com/singapore/case-says-more-than-38-misled-by-e-shop-for-hiding-membership-fees-fashion-interactive). CASE took the matter up with the retailer, which agreed to fully refund consumers. CASE's position was that consumers must opt-in for the membership voluntarily and the recurring monthly charges should be clearly brought to their attention, instead of being written in fine print. Under the Second Schedule of the CPFTA, omitting to provide a material fact to a consumer, using small print to conceal a material fact from the consumer or misleading a consumer as to a material fact, is a specific unfair practice.

Dr. Stanley Lai, SC

Allen & Gledhill LLP
One Marina Boulevard, #28-00
Singapore 018989
Singapore

Tel: +65 6890 7883
Email: stanley.lai@allenandgledhill.com
URL: www.allenandgledhill.com

Dr. Stanley Lai, SC specialises in all forms of IP litigation and information technology disputes, and is also a commercial/chancery litigator. He maintains a strong advisory practice for IP/data management and cybersecurity, serving a broad spectrum of clients. He also represents clients in investigations that are undertaken by the Personal Data Protection Commission. In the biomedical and pharmaceutical sectors, Stanley has substantial experience in advising on healthcare and medical IP and regulatory issues concerning medicines, generics, patent linkage, bio-similars, medical devices, clinical trials, product recalls and product liability.

Stanley is currently the Chairman of the Intellectual Property Office of Singapore. Stanley is also a member of the Singapore International Arbitration Centre IP Panel and Singapore Copyright Tribunal. He has published extensively on IP and information technology law Stanley is currently an Adjunct Professor of the National University of Singapore. He serves as a Principal Mediator of the Singapore Mediation Centre.

Amanda Soon

Allen & Gledhill LLP
One Marina Boulevard, #28-00
Singapore 018989
Singapore

Tel: +65 6890 7531
Email: amanda.soon@allenandgledhill.com
URL: www.allenandgledhill.com

Amanda Soon is a Senior Associate in Intellectual Property and is a member of the IP Protection and Management Group.

Her areas of focus include both contentious and non-contentious aspects of intellectual property work. She has experience in the filing and prosecution of trade marks, advising clients on the management of their trade mark portfolios, as well as infringement of intellectual property rights. She also has experience in contentious trade mark opposition, revocation and invalidation matters and passing off.

Amanda has advised on and successfully negotiated commercial agreements related to various aspects of intellectual property, such as trade mark co-existence, assignment, licensing and non-disclosure of confidential information. Her area of work also includes advising on registered designs, copyright and domain names.

Amanda graduated from the National University of Singapore with an LL.B. (Hons) degree in 2008.

ALLEN & GLEDHILL

Allen & Gledhill is an award-winning full-service South-east Asian commercial law firm which provides legal services to a wide range of premier clients, including local and multinational corporations and financial institutions. Established in 1902, the Firm is consistently ranked as one of the market leaders in Singapore and South-east Asia, having been involved in a number of challenging, complex and significant deals, many of which are first of its kind. With a growing network of associate firms and offices, Allen & Gledhill is well-placed to advise clients on their business interests in Singapore and beyond, in particular on matters involving South-east Asia and the Asia region. With its offices in Singapore and Myanmar, its associate firm, Rahmat Lim & Partners in Malaysia, and its alliance firm, Soemadipradja & Taher in Indonesia, the Allen & Gledhill network has over 550 lawyers in the region, making it one of the largest law firms in South-east Asia.

Chapter 25

Spain

Faus & Moliner Abogados

Xavier Moliner

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?

Royal Legislative Decree 1/2007, of 16 November, approving the consolidated text of the General Law on the Protection of Consumers and Users and other complementary regulations ("RLD 1/2007") sets the main product liability rules in Spain (articles 128 to 146, both inclusive).

The regime for product liability established in RLD 1/2007 is of a strict nature. It imposes strict liability upon the "producer" of a defective product. The producer will be liable for personal injury or death, or damage to property caused by the defective product, provided that these might affect goods which are objectively intended for private use or consumption and have been utilised mainly as such by the injured party. It is on the claimant to prove that the product was defective, damage occurred and that there was a causal link between the defective product and the damage suffered.

This strict liability system does not preclude other liability systems providing an injured party with a greater protection, nor does it 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 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?

Under the product liability regime of RLD 1/2007, only the "producer" bears responsibility for the fault of the product.

It is considered as "producer", depending on the case, any or all of the followings: (i) the manufacturer or the importer in the European Union of a finished product, raw material or component of the product; and (ii) the apparent producer of the product (i.e. any person presenting itself as the producer of the product by providing its name, trademark or other identifying features along with the product, whether on the container, wrapping or other any protective or presentational component).

In the event that the "producer" cannot be identified, the supplier of the product (i.e. 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 before it is required to give such information. This same rule applies in the case of imported products in the European Union, in the event that the product does not indicate the name of the importer, even if it indicates the name of the manufacturer.

The supplier of a defective product shall be also liable towards the injured party as if he were the producer, in the event that he supplied the product knowing that the defect existed.

1.4 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

As mentioned above, under the regime on liability for defective products established in RLD 1/2007, the responsibility for the defective product is only borne by the "producer" (i.e.: (i) the manufacturer or the importer who introduces the product into the European Union; (ii) the apparent producer; and (iii) the supplier only under certain circumstance (see question 1.3)). Therefore, as the regulatory authority is not a producer, it will not be responsible under this regime.

However, it is possible to file a complaint against the regulatory authority that authorised the defective product. This is possible when the damage is derived from facts or circumstances that could be prevented or avoided, according to the knowledge of science or techniques at the time it authorised or reviewed the authorisation of the product. Therefore, the state of scientific and technical knowledge works as a defence that may be used by the regulatory authority.

As we will see in question 3.1, this regime differs from the responsibility regime applied to the producers in case of medicinal products, foods or foodstuffs. Under the latter regime, the person liable shall not be able to invoke the state of scientific and technical knowledge defence, as it is expressly excluded under RLD 1/2007.

However, the exoneration cause was introduced into the Law on Administrative Procedure in order to exonerate the public administration (regulatory authority) from responsibility, when the damage is derived from facts or circumstances that could not be prevented or avoided, according to the knowledge of science or techniques at the time it authorised or reviewed the authorisation of the product.

Therefore, when claiming damages against the regulatory authority, it is important to prove that based on the state of scientific knowledge, the authority did not act according to the scientific data and evidence available at that moment.

On 17 May 2017, the National High Court (AN) issued two resolutions resolving a case of liability for damages caused by the administration of two vaccines, which were addressed against the Ministry of Health, Social Services and Equality (MOH) and against the pharmaceutical companies that had marketed the products.

The AN rejected the complaints on the basis that the claimant did not prove that the competent authorities, based on the state of scientific knowledge, did not act according to the scientific data and evidence available at that moment. The claimants did not provide any firm and scientific evidence which would lead to the conclusion that such risk-benefit balance was unfavourable and that, therefore, the vaccines should not have been authorised.

1.5 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.

1.6 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 must be typifyed as an offence in the Spanish Criminal Code.

In case the damages caused by a company by means of its defective product were of a criminal nature, 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 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 the internal control tools to prevent the criminal conduct (the compliance system) were either non-existent or ineffective.

In any case, the criminal liability of a legal person is a relatively new matter in Spain, and so 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.

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, the claimant must provide solid and substantial evidence that supports such link and that damages were 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 presumption or circumstantial evidence.

In Spain, the principle of generic causation, i.e. that in order to prove the causal relationship it would be enough 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 can cause damage is not enough to establish the defective nature of such

product. In order to prove that a product is defective, the claimant must prove that the damages 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 joined cases C 503/13 and C 504/13, under which certain kinds 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.

On 21 June 2017, the Court of Justice of the European Union issued another case (C-621/15) referring to product liability of manufacturers, in the event that their products have a defect which poses a risk to the consumer. The Court, in these circumstances, decided that European law does not preclude a national court to consider, when medical research does not establish nor reject a relationship between the vaccine and the occurrence of a disease, that some facts alleged by the injured person constitute serious specific and consistent evidence, enabling the court to conclude that there is a defect in the vaccine and that there is a causal link between that defect and the decease.

On the other hand, the Court also ruled that judges should ensure that when applying this evidence regime, they do not reverse the burden of the proof. According to the Court, the directive precludes rules based on presumptions in which medical research neither establishes nor rules out existence of a link between the vaccine and the disease, the existence of a causal link between the defect attributed to the vaccine, and the damage suffered by the victim will always be considered to be established if certain predetermined factual evidence is presented.

In the Spanish cases issued by the AN mentioned in question 1.4 regarding liability for damage caused by the administration of two vaccines, the court confirmed that the burden of proving the defect, the damage and the causal relationship lies with the claimant and, in the absence of evidence from the claimant, it absolved the MOH and the pharmaceutical company of all the wrongdoings attributed to them.

The AN rejected the evidence proposed by the claimants consisting of opinions which, according to the Court, did not undermine the studies and clinical trials that endorsed the efficacy of the product.

With respect to the alleged lack of informed consent prior to its administration, the AN rejected the complaints because the claimants had not demonstrated that the pathologies they were diagnosed with were a frequent adverse reaction, and therefore the obligation to inform did not include such risk since it was not known.

Moreover, the AN considered that the causal relationship between the diagnosed diseases and the vaccines had not been demonstrated, since the medical history did not associate the ailments and symptoms from which the claimants suffered with the vaccine.

The liability of the pharmaceutical companies for defect of information in the Summary of Product Characteristics and the leaflet was also rejected because the claimants had not proved that his disease was caused by the vaccine.

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 producer who compensated the injured party shall have the right to claim recovery from the other producers, 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. Therefore, 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 producer 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 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 producer 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.

Finally, 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 producer 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 it was 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 producer 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.

Additionally, the doctrine points out that the apparent producer shall not be liable if he can prove that he was not the one who places the sign, brand, logo or stamp that identifies him as apparent producer in the defective product or its packaging.

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 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 producer 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 obligation on the manufacturer to produce the product in strict compliance and observance of these requirements. If this is the case, the manufacturer could invoke the exoneration cause pointed out in point d) of question 3.1 above. It is not possible to provide a precise answer to this question, and every case should be evaluated on a case-by-case basis.

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 producer 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 producer who paid compensation to the injured party shall be able to claim such compensation 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 producer 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 assessed on a case-by-case basis and must hold direct relation with the defect.

For example, in the case 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.

In exceptional cases, 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, the specific legislation of the 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.

As described in question 3.4, final judgments have the force of *res judicata* between the parties. However, when claims are lodged by associations, legal entities, or groups acting in defence of both supra-individual interests and individuals' uniform interests, the binding effect of the judgments may affect the non-claimant persons who were entitled to the rights protected by the collective claim.

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 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

In collective legal proceedings lodged by associations or entities constituted for the protection of the rights and interests of consumers and users or by groups affected, those who have been damaged due to being consumers of the product or users of the service which gave rise to the proceedings shall be called to appear in order to assert their individual rights or interest. This call shall be made by the Court, who shall announce the admission of the claim in the media with territorial coverage where the damage to these rights or interests has occurred.

When the proceedings involve determined or easily determined damaged parties, the claimant or claimants must have previously notified those concerned of their intention to lodge a claim. In this case, after the call, the consumer or user may act in the proceedings at any time but may only conduct the procedural acts which have not been precluded.

When the proceedings involve damage to an indeterminate number of persons or a number which is difficult to determine, the call shall suspend the course of the proceedings for a time limit which shall not exceed two months and which shall be determined by the Court in each case depending on the circumstances or complexity of the event and the difficulties concerning the determination and localisation of those damaged. The proceedings shall restart with the intervention of all the consumers who attended the call. As a rule, the individual appearance of consumers shall not be allowed subsequently, notwithstanding certain rights or interests that these may assert according to other provisions of the Code of Civil Procedure 1/2000.

4.6 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.

4.7 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.

4.8 What appeal options are available?

In legal proceedings on product liability, it is possible to file an appeal before the Provincial Court of Appeal against the judgment rendered in first instance by the Court of First Instance.

Against the judgment on appeal rendered by the Provincial Court of Appeal, 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 of Appeal 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.

4.9 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 regarding 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.

4.10 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. 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 appear in the trial in order to ratify, explain or clarify their reports, and in order to respond to any questions regarding their reports.

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

Under Spanish Civil Law, there is not any discovery obligation between the litigant parties, neither before Court proceedings are commenced nor as part of the pre-trial procedures. The Spanish civil system is based on the principle of own production of evidence, i.e. each litigant party shall obtain and present its own evidences to support its claims in a court proceeding.

Exceptionally, and only applicable in those cases in which the applicant is unable to obtain by himself certain data necessary to file a claim, he may request the Judge, prior to filing the law suit, access to certain sources of evidence specifically provided for, as preliminary proceedings, in the Code of Civil Procedure 1/2000. Among other preliminary proceedings provided in the law: (i) any interested party may request a copy of the medical records from the health centre or professional having the custody of said records; and (ii) the individual considering himself to be damaged by an event that could be covered by a civil liability insurance may request for the exhibition of the insurance contracted.

Additionally, on the pre-trial hearing, any litigant may request the Judge to order the other party or third parties unrelated to the proceeding to exhibit any document related to the subject of the dispute. In said request, the applicant must: (i) prove that the document is not available to him and justify the impossibility of

obtaining it; (ii) prove that the document refers to the purpose of the process (because it is a documentary evidence relevant to the case) or to the effectiveness of other means of proof (because it gives, or not, effectiveness to other evidence presented); and (iii) provide a photocopy or simple copy of the document or indicate its content in the most exact terms.

4.12 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, 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.

Additionally, according to the Code of Civil Procedure 1/2000, the litigants are empowered to dispose of the matter at issue in the proceedings and may waive, acquiesce, submit to arbitration or mediation and reach agreements on the matter at issue.

The submission of the parties to any of the referred methods is voluntary, and therefore alternative methods of dispute resolution are not required to be pursued before initiating any court proceedings.

4.13 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?

Provisions of Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012, on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, are applicable in Spain.

As a rule, Spanish courts have jurisdiction over a dispute when the defendant is domicile in Spain. This is regardless of where the claimant is domicile. Therefore, if the producer of the defective product is domicile in Spain a claim may be brought against him before Spanish courts.

In a product liability context, claimants not domiciled in Spain may sue before the Spanish courts: (i) if the events leading to the product defect occurred in Spain; or (ii) if the damage occurred in Spain.

5 Time Limits

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

The statute of limitations for proceedings claiming damages caused by a defective product under the regime of RLD 1/2007 is 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 a 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 limitation period for bringing proceedings 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 limitation 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 regarding 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 an economic compensation 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 for 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, therefore, it is not possible to establish a causal relationship between the defect and the damages. Furthermore, it is not possible to obtain a judicial award that imposes the obligation to pay compensation for the costs of medical monitoring. In such a 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 regard, the previously mentioned Judgment 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 the products 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 of his pleas rejected, unless the Court considers that the case posed serious *de facto* or *de jure* 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 total claimed in the proceedings for each of the litigants who have obtained such award. If the Court declares the recklessness of the litigant ordered to pay, 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, they shall be eligible for legal aid when they do 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 7,519.59 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 a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

We are not aware of new cases related to Product Liability Law referring to new technologies and artificial intelligence.

Among the product liability case-law arising in 2018–2019, we would like to highlight the Judgment of the Spanish Supreme Court of 14 September 2018. This Judgment concerns whether the elapse of time (from the moment the product is acquired/used until the damage occurred) might be sufficient evidence so that it can be presumed that a product is not defective.

In this case, the defective products were some copper elbows, installed in a heating circuit, that had internal fissures wich caused water leakage and damage to the claimant's house. The damage occurred six years after the elbows were acquired and installed and the defendant alleged this elapsed time was sufficient evidence to conclude that the product was not defective.

In this Judgment, the Spanish Supreme Court pointed out that the elapsed time (from the moment the product was acquired and installed until the damage occurred) itself does not prove that the product is not defective. In order to determine whether a product is defective or not, the Spanish Supreme Court concluded that, in addition to such elapsed time, there are other circumstances that must be considered, such as the type of product, the useful life of the product, its exhaustion, etc.

In the case, as no other circumstances in addition to the elapsed time concurred (the useful life of the product had not been exhausted), the Spanish Supreme Court concluded that the products analysed were defective. This was because according to its nature and features it considered that it was legitimate for the public to trust that the copper elbows analysed would work for more than six years without leaking water.

Xavier Moliner

Faus & Moliner Abogados
Rambla Catalunya 135
08008 Barcelona
Spain

Tel: *+34 93 292 2543*
Email: *xmoliner@faus-moliner.com*
URL: *www.faus-moliner.com*

Mr. Xavier Moliner holds a law degree from the University of Barcelona. In 1997 he founded Faus & Moliner together with his partner Jordi Faus.

Xavier Moliner regularly advises Spanish, European and US companies operating in the life sciences sector and has extensive experience in public procurement and product liability.

Xavier Moliner has written various articles on product liability, public procurement and data protection, and frequently speaks about these topics at conferences. In 2019 the *Chambers & Partners* Guide pointed out that clients praise Xavier Moliner for being "very clued up on the ins and outs of the law".

He speaks Spanish, Catalan and English, and he has wide international experience.

Faus & Moliner

Faus & Moliner is a Spanish boutique law firm which specialises in dealing with legal matters typical of the pharmaceutical industry and of other companies which operate in the life sciences sector.

Since its foundation in 1997, **Faus & Moliner** has been the market leader in the area of pharmaceutical law in Spain, recognised in several international publications.

Faus & Moliner has been designated as the best pharmaceuticals-focused law firm in Spain by the *Chambers & Partners* Guide 2019. Faus & Moliner has earned such recognition by *Chambers & Partners* for 10 years in a row.

The *Chambers & Partners* Guide highlighted that it is a "*prestigious Barcelona-based boutique with a stand-out reputation in regulatory issues relating to the life sciences market. Regularly retained by key players from the pharmaceutical, medical devices and biotech industries to advise on a range of matters, spanning draft regulations, product liability and compliance projects. Recommended for its prowess in issues relating to promotional material. Also well placed to advise on potential administrative and legislative disputes and transactional work and is regularly consulted by the Spanish Ministry of Health for pharmaceutical policy advice*".

The firm is widely regarded as "*the leader in regulatory matters*" and clients also enthuse "*it is a fantastic team that does some great litigation"*.

Switzerland

Dr. Claudia Götz Staehelin

Kellerhals Carrard

Nina Studer

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 based on (i) the Swiss Product Liability Act (PLA), (ii) contract law, (iii) tort law, or statutory provisions applicable to specific industries.

(i) The PLA is inspired by the European Union's Directive 85/374/EEC on product liability. According to the PLA, a manufacturer, importer or supplier is strictly liable for personal injuries and – to a certain extent – damage to property caused by a product which did not provide the safety which could reasonably be expected. However, under the PLA, the compensation of damage to property is limited: the injured person cannot claim compensation (a) for damage on commercially used property, (b) for damage on the faulty product itself, and (c) for property damage below CHF 900. Since the PLA is neither a complete nor an exclusive cause of action, an injured person may raise additional claims based on other legal grounds (Article 11(2) PLA).

(ii) If a contractual relation exists between the injured person and the supplier, a defective product can also give rise to a claim for breach of contract. The Swiss Code of Obligations (CO) contains general contractual liability provisions (Article 97 *et seq.* CO) and special contractual liability provisions, such as for sales contracts (Article 197 *et seq.* CO). While contractual liability is generally fault-based, in sales contracts the seller is strictly liable for direct losses caused to the buyer (Article 208(2) CO).

(iii) Finally, tort law provides for fault-based liability claims. Pursuant to Article 41 CO, a person is liable for unlawfully caused losses to another person. In practice, tort liability is often derived from the principal's liability (Article 55 CO). According to this specific provision, the principal – usually an employer – is liable for the loss unlawfully caused by its employees or ancillary staff in the performance of their work. An exemption from liability for the principal is only possible if he can prove that he took due care to avoid any loss. In practice, however, the Swiss Federal Supreme Court (FSC) has set the bar for such defences extremely high. As a result, the principal's liability amounts to that of strict liability.

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

There are no such schemes of compensation for specific products in Switzerland.

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

The PLA provides for a broad definition of the term "producer" and according to the statute, everyone who qualifies as a producer is strictly liable for losses caused by a faulty product. According to the PLA, producers are:

(i) the manufacturer of the final product, a part or a component of the product and the producer of any raw material (manufacturer; Article 2(1)(a) PLA);

(ii) every person who claims to be the producer by attaching his or her name, trade mark or other distinctive sign on the product (quasi-manufacturer; Article 2(1)(b) PLA); and

(iii) every person who imports a product for sale, rental, leasing, or any other form of commercial distribution into Switzerland (importer; Article 2(1)(c) PLA).

Each supplier is liable if the manufacturer or the importer are unknown and if the supplier does not reveal their identity after being requested to do so by the injured party (Article 2(2) and (3) PLA).

In tort law, the person who unlawfully caused the defect (Article 41 CO) or its employer/supervisor (Article 55 CO) is responsible for the defect.

In contract law, only the person who is in a contractual relation with the injured person can be responsible.

1.4 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

Liability cases against regulatory authorities are extremely rare in Switzerland. State liability is conceivable where products, for example certain medicines, are subject to market approval by a state authority. Such approval can only be granted if the product fulfils certain consumer safety requirements. If such market approval is granted even though these requirements were not met, the state may – in addition to the producer – be responsible for losses caused by the unsafe product (Article 3 Government Liability Act [GLA]).

Some products, for example some medical devices, do not have to undergo a state authorisation procedure but they are subject to mandatory assessment and certification by a private, state-accredited certification entity. The certification creates the (rebuttable) presumption that the product complies with the applicable laws and regulations with regards to consumer health and safety. Following certification, the producer may place the product on the market. Whether a private certification entity can be liable for the loss caused by a certified but faulty product has not yet been decided by Swiss Courts. In theory, such liability may be based on the concepts of state liability (Article 3 GLA), on tort (Article 41 CO) or on trust created by the certification.

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

Neither the PLA nor the CO state a general duty for the producer to recall a product. However, according to case law, a duty to recall can be derived from the general duty to manage and control risks which the producer created by placing a product on the market. In this case, the omission to recall a product which turned out to be unsafe could lead to liability based on the PLA, on contract law (Article 97 CO *et seq.*) or on tort law (Article 41 CO).

For consumer goods, the Swiss Product Safety Act (PSA) requires the producer to monitor such goods and to inform the supervising authority of potential risks related to health and safety. Upon such information, the supervising authority has to take the necessary actions, which may include ordering the producer to recall the product.

Finally, statutes applicable to specific industries may also apply. The Therapeutic Products Act (TPA) contains extensive monitoring and reporting obligations which can lead to an order to recall medicines and medical devices. An explicit duty to recall products can be found in the Swiss Foodstuffs Act (FSA) which is in principle also applicable to utility products such as cosmetics, clothing or furnishing articles.

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

The PLA does not provide for criminal sanctions. If the defective product leads to personal injury, criminal liability, however, can be triggered by general criminal law, for example involuntary manslaughter (Article 115 of the Swiss Criminal Code [SCC]) or negligent bodily injury (Article 125 SCC). Even though the Swiss Criminal Code is designed for individuals, pursuant to Article 102(1) SCC, companies can be liable if it is not possible to attribute the criminal act to a specific individual due to the inadequate organisation of the company.

In addition, criminal liability may arise from the breach of the PSA (*cf.* Articles 16 and 17 PSA). Finally, certain statutes governing specific products also include criminal provisions, for example Article 63 FSA or Article 86 TPA.

2 Causation

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

Depending on the type of claim either under the PLA, tort law or contract liability, the claimant or the defendant bears the burden of proof.

For claims based on the PLA, the claimant has to prove a loss and the product's fault, i.e. that the product does not offer the safety which could reasonably be expected under the circumstances of the case. Elements such as how the product is presented to the public, the type of usage which can reasonably be expected and the time when it was put on the market are all evaluated (Article 4 PLA).

According to general tort law, the claimant has to prove both a loss as well as that defendant acted negligently or with intent (Article 41 CO). To claim liability of the principal pursuant to Article 55 CO, the claimant has to prove a loss only, whilst defendant then may prove that he acted with due care.

To claim contractual liability, the claimant has the burden of proving a loss. The defendant's fault is presumed (Article 97 CO).

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?

For all liability claims, the claimant has to prove causation, i.e. that the loss would not have occurred if the product was not faulty/defective (natural causation) and that in light of general experience, the fault/defect at issue is generally of a nature to cause the loss at issue (adequate causation).

However, the FSC has lowered the claimant's burden of proof and held that the involvement of a faulty product in an accident is already a significant indicator of the causal link. Moreover, where the causation can only be proven indirectly and by circumstantial evidence, the applicable standard of proof is not 'full conviction' but the lower standard of 'preponderant probability' (BGE 133 III 81).

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 PLA, the manufacturer, the quasi-manufacturer and the importer are all jointly and severally liable to the injured party for losses caused by the faulty product (Article 7 PLA). If the manufacturer cannot be established, the claimant can therefore seek full redress from the quasi-manufacturer or the importer. Moreover, the claimant also has the possibility to pursue the product supplier *in lieu* of the manufacturer if the supplier refuses to reveal the manufacturer's identity (Article 2(2) PLA).

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

A product is faulty if it does not present the safety an average user of the product is entitled to expect (Article (4)(1) PLA). Safety expectations depend on how the product is presented to the public. Therefore, the manufacturer has to indicate the potential dangers of proper use and also conceivable misuse of the product. A failure to warn about these dangers may lead to increased safety expectations.

A manufacturer that produces a product for professional use can assume that the users are aware of risks typically associated with the use of the product, but must warn about untypical risks.

With respect to products which can only be obtained through a learned intermediary, the FSC had to decide a famous case where a patient who took a prescription contraceptive pill suffered a pulmonary embolism leading to irreversible brain damage. The patient sued the manufacturer of the contraceptive pill arguing that the pill did not provide for the safety which could reasonably be expected because the manufacturer's warning about increased pulmonary embolism risk was only included in the specialist information intended for the physician but not in the package insert intended for the patient. The Court reasoned that for prescription medication like the contraceptive pill, the notice in the specialist information intended for the physician was sufficient warning because a physician has the duty to assess and personally discuss the risks associated with the medication with the patient (FSC decision 4A_371/2014 of 5 January 2015).

3 Defences and Estoppel

3.1 What defences, if any, are available?

According to Article 5(1) PLA, the producer is not liable if he can prove that:

- he did not put the product on the market;
- it can be assumed from the circumstances that the fault causing the loss was not present at the time the product was put on the market;
- he has neither manufactured the product for sale or any other form of economically motivated purpose nor manufactured or distributed it in the course of commercial activity;
- the fault is due to the fact that the product complies with binding statutory requirements; or
- the fault could not be detected according to the state of the art in science and technology prevalent at the time when the product was put on the market.

Moreover, the producer of raw material or a partial product is also not liable if he proves that the fault was caused either by the design of the product into which the raw material or partial product was incorporated or by the instruction of the manufacturer of that product (Article 5(2) PLA).

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

Swiss law provides a state of the art defence which must be proven by the producer (Article 5 (1)(e) PLA, *cf.* question 3.1 above).

The state of scientific and technical knowledge must be established according to an objective standard and not according to the knowledge of a specific producer. The state of knowledge that existed when the specific product was released is relevant. It is for the producer to prove that the fault was not discoverable.

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

The manufacturer is not liable if the fault is due to the fact that the product complies with binding statutory requirements (see Article 5(1)(d) PLA; *cf.* question 3.1 above).

Moreover, compliance with regulatory and/or statutory requirements is an indicator that the product is not faulty. However, this does not automatically exclude the producer's 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?

A concept similar to estoppel only applies with regard to the same claimant and defendant. Therefore, a different claimant is entitled to re-litigate the above-mentioned issues. However, practically speaking, prior judgments on the same matter may have a substantial influence on later 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?

Article 7 PLA provides for joint liability of the manufacturer, quasi-manufacturer and importer for losses resulting from a faulty product, irrespective of the legal basis.

A defendant may seek recourse against other parties who are also liable to the claimant, be it based on the PLA or on another legal basis (Articles 50 and 51 CO). The defendant has the possibility to notify the third party of the claim (Article 78 of the Swiss Code of

Civil Procedure [CCP]) or may assert his potential right of recourse in the main proceeding (Article 81 CCP). In practice, the defendant usually seeks recourse against a third party in a separate legal proceeding.

There is no procedural time limit for commencing subsequent proceedings but the statute of limitations of the underlying recourse claims remains applicable.

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

Yes. If a serious self-inflicted fault on the part of the injured party is an adequate cause for the injured party's loss, this may lead to an interruption of the causation and thus to an exclusion of the liability of the defendant. Slight or medium self-inflicted fault does not constitute a reason for interruption, but may be a reason for a reduction of the compensation (Article 44(1) CO).

4 Procedure

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

All cases are tried by either one or multiple judges, depending on the applicable procedural rules in the competent Canton. There are no jury trials in Switzerland.

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

The court does not have expert assessors to sit with the judge. However, special courts, e.g. the commercial courts, include lay judges with experience in the industry of the case at hand. Moreover, the court can appoint experts to assist it in considering technical issues (*cf.* question 4.9 below).

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

To date, a procedure equal to the US "class action" system does not exist in Switzerland. A group action right is available to certain associations and other organisations who are authorised by their articles of association to protect the interest of a certain group of individuals. However, this group action right is limited to non-monetary claims such as cease and desist orders and declaration of unlawful conduct (Article 89 CCP). Because monetary group action claims are not allowed to date, group actions are practically irrelevant to liability claims. There are, however, alternative instruments for collective reparatory redress, such as simple rejoinder pursuant to Article 71 (CCP). According to this provision, two or more claimants whose rights or duties result from similar circumstances or legal grounds may jointly appear as plaintiffs or be sued as joint defendants provided that the same type of procedure is applicable.

However, in 2018, also against the background of developments in the European Union, the Swiss lawmakers suggested the introduction of collective redress as follows: first, associations and other organisations that protect the interest of a certain group of individuals shall receive a reparatory group action right. Upon authorisation of the group members (opt-in), the organisation shall be entitled to initiate court proceedings for damages and surrender of profit claims in its own name for the benefit of the group members. Second, the above-mentioned associations and other organisations shall have the opportunity to reach a collective settlement for their interest group with the infringer. In this case, a court would have to approve the collective settlement agreement. This settlement agreement would be binding for all persons affected by the infringement unless they opt out within three months from the approval of the settlement. As of today, it is not known, when the parliament will address the suggested amendments which are part of a larger proposal for the revision of the Swiss Code of Civil Procedure.

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

To date, the above-mentioned group action right for non-monetary claims (*cf.* question 4.3 above) is the only claim which can be brought by a representative body. In practice, individuals sometimes assign their damages claims to a representative body which then claims damages in its own name. This was the case for a lawsuit brought by the Swiss Foundation of Consumer Protection against Volkswagen/AMAG in the aftermath of the Volkswagen diesel scandal.

4.5 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

Lawyers advertising for claims to an undefined or big circle of addressees may be problematic from a professional ethics and practice rules perspective. Against that background, and because of the absence of class actions in Switzerland, advertising for claims is extremely rare in Switzerland.

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

Generally, the CCP requires a claimant to initiate conciliation proceedings, which usually take up to six months, before filing a claim with the court of first instance. If no amicable settlement is reached, the conciliation authority grants a temporary authorisation to proceed with the claim, and the claimant then has to file the claim with the competent court within three months.

The average length of proceedings before courts in Switzerland is between one and two years in commercial cases, but can be significantly longer if the case is complex. In smaller and less complicated cases, the duration of the proceedings is approximately around one year. The CCP provides for a simplified procedure which is less formal compared to the ordinary proceedings if the amount in dispute is below CHF 30,000.

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

According to Article 125(a) CCP, the court can limit the proceedings to individual issues or claims. The proceedings can be limited to issues of fact as well as issues of law.

4.8 What appeal options are available?

A final decision of first instance can be appealed to the Appellate Court if the amount in dispute is higher than CHF 10,000. The appeal can be filed on the grounds of incorrect application of the law and incorrect establishment of the facts (Article 308 *et seq.* CCP).

If the amount in dispute is lower than CHF 10,000, only an objection can be filed with the Appellate Court. An objection is admissible on the grounds of incorrect application of the law and obviously incorrect establishment of the facts (Article 319 *et seq.* CCP)

The Appellate Court's decision is subject to objection to the FSC if (a) the amount in dispute is higher than CHF 30,000 and/or if there is a legal question of fundamental importance, and (b) the objector claims a violation of federal or international law.

4.9 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?

Pursuant to Article 183 CCP, the court has the possibility to appoint an expert to help provide the court with the expertise it needs to collect and/or assess evidence. The parties can also present expert evidence to the court. However, the court will most likely give greater weight to the appointed expert who is presumed to be impartial. According to case law, the expert evidence presented by the parties has the same evidential value as a simple party assertion. Expert evidence is restricted in the sense that it is only admitted to relevant facts of the case and it is only admitted for the establishment of the facts but not for their legal assessment.

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

Pre-trial depositions are unknown to Swiss procedural law. Witness statements are generally not admissible as evidence. Witnesses have to present themselves at trial. Parties are free to submit expert reports prepared by their own experts.

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

There is no pre-trial discovery procedure in Switzerland, and generally, there are no obligations to disclose documentary evidence before the court proceeding. Rather, obligations to disclose documentary evidence only arise during the court proceeding.

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

In principle, a mandatory conciliation proceeding must be pursued before a claim can be filed with the court (Article 197 CCP). If the amount in dispute is higher than CHF 100,000, the parties can mutually agree to omit conciliation (Article 199(1) CCP). Moreover, the claimant can unilaterally forego conciliation if defendant's registered office or domicile is abroad or if the defendant's residence is unknown (Article 199(2) CCP). No conciliation proceeding takes place if the case must be filed with a special commercial court (Article 6 CCP).

Pursuant to Article 213 CCP, the parties can also jointly decide to replace the conciliation proceeding by mediation. In practice, the parties rarely make use of this possibility.

4.13 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?

Generally, a claim can be brought before Swiss courts if the defendant resides in Switzerland, regardless where the claimant resides.

There are a number of different provisions based on which a foreign defendant may be sued in Switzerland. If a product liability case is based on torts or the PLA, the claim can be brought in Switzerland if the defective or faulty product was manufactured there or if the damage occurred in Switzerland. If the claim is based on contract law, the foreign defendant can be sued in Switzerland if the product causing the loss was delivered to Switzerland, if the defendant is a consumer and resides in Switzerland or if the parties contractually agreed on Swiss jurisdiction.

5 Time Limits

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

Yes, *cf.* 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?

A claim based on the PLA must be brought within three years from the date the injured party became aware or reasonably should have become aware of the loss, the fault of the product and the identity of the producer (Article 9 PLA). In every case, the claim must be brought within 10 years after the producer put the product which caused the loss on the market (Article 10 PLA).

Tort claims are subject to a relative statute of limitation of one year counting from the day the injured party became aware of the loss and the identity of the person liable for it and to an absolute statute of limitations of 10 years after the tortious act.

Contract-based claims are generally subject to a statute of limitation of 10 years (Article 127 CO). However, this rule is subject to many exceptions. For example, there is a five-year statute of limitations for claims in connection with the delivery of foodstuffs and the purchase of retail goods (Article 128(2) and (3) CO). An action for breach of warranty of quality and fitness becomes time-barred two years after delivery of the object to the buyer, even if he does not discover the defects until later, unless the seller has assumed liability under warranty for a longer period (Article 210 CO).

The age and condition of the defendant does not affect the time limit. Statutes of limitations are regulated by law, and courts generally do not have discretion in applying or respectively disapplying 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 three-year time limit for PLA-based claims and the one-year time limit for tort-based claims only start to run once the claimant is aware of the fault, the loss and the producer. Hence, issues of concealment or fraud affect the running of the time limits. However, such acts do not affect the absolute time limit of 10 years (Article 10 PLA). If, however, the action for damages is derived from an offence for which criminal law envisages a longer limitation period, that longer period also applies to the civil law claim (Article 60(2) CO).

For sales contracts, the two-year statute of limitation does not apply if the seller wilfully misled the buyer (Article 210(6) CO). In this case, the 10-year statute of limitation of Article 127 CO is applicable.

6 Remedies

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

Generally, the PLA, tort and contract law provide for monetary compensation of losses caused by faulty/defective products.

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

The PLA provides for compensation of losses caused by death or personal injury, as well as damage to property if the object is, by its nature, normally intended for private use and was mainly used for private purposes by the injured party (Article 1(1) PLA). The PLA does not provide for compensation of the damage on the product itself (Article 1(2) PLA). Furthermore, damage to property is subject to a deductible of CHF 900 (Article 6 PLA).

Since the PLA is only a supplemental cause of action, claims for damages which are not covered by the PLA may be based on other grounds, in particular contract or tort law. In addition, in cases of homicide or personal injury, the court may, depending on the degree of the injury and the degree of fault of the tortfeasor, award the victim of personal injury or the dependents of the deceased an appropriate sum by way of compensation for pain and suffering (Article 47 CO).

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

Under Swiss law, the cost of medical monitoring is not considered a recoverable damage if the product has not yet malfunctioned and caused any injury.

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

Punitive damages are not available under Swiss law. Swiss courts refuse to award punitive damages even if the applicable foreign law provides for such damages (Article 135(2) Swiss Private International Law).

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

There is no maximum limit on the recoverable damages.

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

To date, no special rules apply to the settlement of claims, i.e. the parties are free to settle any claims without the intervention of the court. If legal proceedings are already pending, the settlement agreement must be filed with the court which examines if the agreement settles all controversies between the parties and if the court can conclude the proceeding.

However, the Federal Council's proposal to introduce group actions into the Swiss civil procedure (*cf.* question 4.3 above) stipulates that group action settlements must be approved by the court.

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

Private and state-owned social security insurance carriers, such as mandatory health insurance, accident insurance, invalidity insurance, survivors insurance, etc., subrogate in the claims of the insured person and his survivors at the time of the event up to the amount of their statutory benefits (Article 72 Federal Act on General Aspects of Social Security Law). Therefore, to the extent the injured party's losses are covered by one of the above-mentioned insurances, only these insurances and not the injured party are entitled to claim these damages.

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 general, Swiss law follows the "loser pays" rule, i.e. the prevailing party may recover its legal costs (attorney fees and expenses), from the unsuccessful party. However, party costs are awarded on the basis of statutory tariffs that mainly depend on the amount in dispute. In most cases, the compensations awarded cover only part of the actual costs incurred. The unsuccessful party has to bear the court fees and other incidental expenses as well as its own legal costs.

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

Yes, legal aid is available in certain circumstances (*cf.* Article 117 *et seq.* CCP). In principle, a person is entitled to legal aid if he or she does not have sufficient financial resources, and his or her case does not seem devoid of any chances of success.

In addition, if it is necessary to protect the rights of the party concerned, the court may appoint an attorney at no costs upon request of such party.

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

Yes, *cf.* question 7.2.

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

Full-success fee arrangements are not permissible in Switzerland. However, an arrangement pursuant to which the client pays a reduced fee and, in turn, the attorney receives a share of the compensation awarded by the court as an additional (contingent) fee component is permissible according to the FSC. In any case, the reduced fee that is unrelated to the litigation outcome must at least cover the attorneys' costs and expenses and must allow for a reasonable profit. The success-related component must not exceed the amount of the unconditional fee component.

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

Third party funding is permitted in Switzerland. Over the last years the FSC issued a couple of decisions addressing the question of legality of litigation funding and providing guidance on a number of critical aspects of litigation funding. There is, however, currently, no specific regulation and supervision of third party litigation funding in Switzerland.

Typically, after assessment of the case, third party funders do not purchase the claim, but they offer to finance the claim by paying all costs reasonably required to litigate (court costs, claimant's own attorney costs, party-appointed expert costs and defendant's attorney costs in case of unsuccessful claims). If the claimant wins, the funders typically receive 30–35% of the net revenue.

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?

Before trial, the court does not exercise control over costs to be incurred by the parties.

8 Updates

8.1 Please provide a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

The most notable development is currently happening in the field of medical devices. Due to the European Union adopting a new regulation on medical devices in 2017 (EU-Regulation 2017/745 on medical devices [MDR]), the Swiss legislation also has to be altered in order to comply with the Mutual Recognition Agreement (MRA) applicable between Switzerland and the EU. If the proposed new legislation enters into force, the suppliers of medical devices would not only have to register their medical devices in a centralised database, but they would also have increased monitoring and risk management duties after the medical device entered the market. Moreover, the new law would require the supplier to have adequate financial resources to compensate for losses caused by faulty medical devices. Finally, manufacturers outside of the European Union and Switzerland would have to designate an authorised representative who verifies that the product complies with the regulatory requirements and who would – together with the manufacturer – be jointly and severally liable to the patient. The Swiss parliament is expected to discuss this project this year.

In relation to the topic of new technologies and artificial intelligence, no court decision has been published in this regard. Scholars generally argue that (self-learning) software can be a product in the sense of the PLA. Moreover, an application of the PLA would be fitting because no (human) fault is required to make the producer liable. In the specific case, however, the producer of the software may raise the arguments that (a) the fault did not exist when the product entered the market (because the fault was "learnt" after by means of artificial intelligence), or (b) the state of the art defence applies.

Dr. Claudia Götz Staehelin

Kellerhals Carrard
Hirschgaesslein 11
P.O. Box 257
4010 Basel
Switzerland

Tel: +41 58 200 30 65
Email: claudia.goetz@kellerhals-carrard.ch
URL: www.kellerhals-carrard.ch/en

Claudia Götz Staehelin is a partner at Kellerhals Carrard in Switzerland, specialising in complex, often cross-border, litigation, arbitration and investigations across various industries. She also advises her clients in international mutual legal assistance and data privacy (CIPP/E). Claudia also acts as arbitrator, in particular in the area of pharma/life sciences.

Claudia combines litigation expertise with significant business experience. Before joining the firm, she was Head Litigation at Novartis. In that role, she led large multi-jurisdictional disputes and investigations. Prior to that she was for many years a partner in a dispute resolution law firm in Zurich. Claudia has extensive experience in representing companies in proceedings related to liability claims (D&O liability, product liability and other tort law related claims).

Her mandates include advising and representing companies from various sectors (including pharmaceutical and life sciences, insurance, health care, energy, consumer goods, industrial engineering) in court, arbitration and other legal proceedings.

Visit https://www.kellerhals-carrard.ch/en/claudia-goetz.html.

Nina Studer

Kellerhals Carrard
Hirschgaesslein 11
P.O. Box 257
4010 Basel
Switzerland

Tel: +41 58 200 30 00
Email: nina.studer@kellerhals-carrard.ch
URL: www.kellerhals-carrard.ch/en

Nina is an associate at Kellerhals Carrard. After receiving her Bachelor's degree in International Relations from the University of Geneva, she completed a bilingual (French/German) Master of Law at the Universities of Geneva and Basel ("*summa cum laude*") and received the Geneva Law and Legislation Society Prize (best Master degrees). Furthermore, she obtained an LL.M. from the University of California, Berkeley with a focus on US and International Intellectual Property Law, International Antitrust Law, Commercial Law and Litigation.

Nina is admitted to all Swiss courts. She advises and represents her clients in all areas of contract law and is also an active litigator. Her practice focuses on intellectual property law and commercial contract law.

Visit https://www.kellerhals-carrard.ch/en/nina-studer.html.

Kellerhals Carrard

With more than 200 professionals and offices in Basel, Bern, Lausanne, Lugano, Sion, Zurich and Geneva, as well as representation offices in Shanghai and Tokyo, the law firm Kellerhals Carrard is one of the largest in Switzerland and boasts a rich tradition (going back to 1885). The firm supports international and domestic clients regarding all aspects of Swiss law and efficiently handles challenging and complex disputes and legal transactions across a wide variety of market sectors and on a national and international basis.

The large size of Kellerhals Carrard's dispute resolution department allows the firm to build teams of professionals for each case, and the team consists of attorneys with special industry knowledge particularly in the areas of Pharmaceuticals and Life Sciences, Health Care, Insurance and Banking, Sports, Real Estate and Construction, Consumer Goods, and Industrial Engineering. Due to the significant experience of the firm's lawyers in cross-border matters, they also support clients in their litigation in other countries and coordinate parallel contentious matters in various jurisdictions.

Chapter 27

Taiwan

Patrick Marros Chu

David Tien

Lee and Li, Attorneys-at-Law

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 proving 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 Articles 7 through 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 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

Generally speaking, neither regulatory authorities nor public servants are liable in respect of a defective/faulty product.

1.5 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 in the absence 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 (Articles 36 and 38 of the CPA).

If a business operator violates the recall order of the competent authorities under Articles 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 is 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 (Articles 58 and 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 provision mentioned in question 1.1 are met.

1.6 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 have not occurred (but for rule). In other words, the claimant has to show that the injury would not have arisen without the defendant's actions, 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 Article 360 or 227 of the Civil Code or the CPA). However, if the claimant claims for damages according to Article 191-1 of the Civil Code, then 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 joint-and-several liability debtors simultaneously, or successively tender total or partial performance. Before the complete performance of the obligation is fulfilled, all of the joint-and-several liability debtors are jointly bound to tender the performance. According to Paragraph 1, Article 281 of the Civil Code, if one of the joint-and-several liability debtors has caused the other joint-and-several liability debtors to be released from the obligation by virtue of his performance of the obligation, he is entitled to demand from the other joint-and-several liability debtors 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, then 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 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 joint-and-several liability 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 10 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 speaking, 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, then 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, then 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 into 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 joint-and-several liability debtors simultaneously or successively to tender total or partial performance. Before the complete performance of the obligation is fulfilled, all of the joint-and-several liability debtors are jointly bound to tender the performance. According to Paragraph 1, Article 281 of the Civil Code, if one of the joint-and-several liability debtors has caused the other joint-and-several liability debtors to be released from the obligation by virtue of his performance, he is entitled to demand from the other joint-and-several liability debtors the reimbursement of their respective shares in the joint-and-several liability, plus interest from the date of release.

Therefore, if a claimant claims for a total amount of the compensation towards one of the joint-and-several liability persons, then 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 joint-and-several liability 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 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?

A 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 articles 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 ("**PDPA**") 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 articles of incorporation, bring an injunction litigation against the person causing injury to multiple people."

4.5 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

Strictly speaking, there is no law or regulation prohibiting lawyers from advertising their services. However, the Attorney Regulation Act stipulates that a lawyer shall not instigate or solicit people to file lawsuits by using improper means, and the Attorneys' Code of Ethics prohibits lawyers from promoting their businesses by making an untrue or misleading representation or implication or by paying brokerage fees. Therefore, following the unspoken rules, lawyers in Taiwan rarely place broadcast advertisements to promote their businesses (let alone advertising for claims). On the other hand, Article 157 of the Criminal Code prohibits any person, with an intention to make unlawful profit, from instigating or soliciting people to file lawsuits, and thus representative bodies in Taiwan do not advertise for claims either. Given the above, it is difficult to conclude whether advertising affects the number or type of product liability claims brought in Taiwan as, essentially, advertisement for claims is discouraged or deterred.

4.6 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.

4.7 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.

4.8 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.

4.9 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 Articles 284 and 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.

4.10 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.

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

According to Articles 368 and 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.

4.12 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 Articles 43 and 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).

4.13 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 discretion not to allow time limits 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 in any of the following cases: (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?

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?

Bodily injury, 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 a 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 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 are injured due to 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.

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 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 a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

In the past, the Taiwan Food and Drug Administration ("TFDA") has often been criticised for leaving the regulation of cosmetic products undone. For instance, although there was an adverse event reporting system for cosmetic products, the TFDA neither makes any follow-up nor has the authority to impose any administrative penalty where a business operator fails to comply with the reporting requirement. However, the amendment to the Cosmetic Hygiene and Safety Act ("Amended CHSA") was passed by the Legislative Yuan on April 10, 2018. Under the authorisation of the amended CHSA, the TFDA has began drafting relevant regulations and plans to bring the amended CHSA and such regulations into force in mid-2019.

Pursuant to the draft Regulations on Reporting Serious Adverse Reactions for Cosmetic Products and Health Hazards, a business operator receiving any suspected adverse event report for cosmetic products shall report the same through the TFDA's online system within 15 days thereafter. The draft Regulations on Recalling Cosmetic Products further stipulate that a manufacturer or importer of cosmetic products has to recall a cosmetic product within one month after receipt of the competent authority's notification where such cosmetic product was blended with any prohibited substances or any ingredient of which is harmful to human health.

Under the amended CHSA, if the competent authority discovers that a business operator fails to comply with the reporting or recalling requirements as described above, the competent authority will first designate a time limit for the business operator to rectify the failure. If the business operator does not rectify the failure within the time limit, then the competent authority may impose an administrative fine of up to NT$1,000,000. A material violation may result in an order from the competent authority to suspend business for a period from one month to one year.

There has not yet been any meaningful court case approaching any issues arising in relation to new technologies and artificial intelligence.

Patrick Marros Chu

Lee and Li, Attorneys-at-Law
9F, 201 Tun Hua N. Road
Taipei City 10508
Taiwan

Tel: +886 2 2715 3300 ext. 2122
Email: marrosju@leeandli.com
URL: www.leeandli.com

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.

David Tien

Lee and Li, Attorneys-at-Law
9F, 201 Tun Hua N. Road
Taipei City 10508
Taiwan

Tel: +886 2 2715 3300 ext. 2287
Email: davidjtien@leeandli.com
URL: www.leeandli.com

David Tien is an associate partner at Lee and Li. His primary areas of practice include mergers and acquisitions, venture financing, product liability, food safety and healthcare, general corporate matters, and cross-border dispute resolutions. He has deep knowledge about the food and healthcare industry and is experienced in representing multinational companies on various regulatory issues with respect to food, cosmetics and alcohol products. He was seconded to Kraft Foods for six months. David is dual-qualified in Taiwan and New York. David obtained his LL.B. and first LL.M. 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. David regularly contributes to the publication of the *Doing Business Report (Legal Rights)* of the World Bank, and is the co-author of Lexis PSL's several Jurisdictional Guides.

理律法律事務所
LEE AND LI
ATTORNEYS-AT-LAW

Lee and Li is the largest full-service law firm in Taiwan, with expertise in all areas of legal practice. Over the decades, Lee and Li has built one of the largest intellectual property right practice groups 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 practices in the 1980s, and played a pivotal role in the formation of media/technology law 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 150 Taiwanese lawyers, patent attorneys, technology experts, and specialists in other fields.

Chapter 28

United Arab Emirates

Hamdan AlShamsi Lawyers & Legal Consultants

Hamdan AlShamsi

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 product liability regulation is found in the UAE Civil Law of 1985 as amended (the Civil Code) and other regulations, including any requirements within certain departments in the UAE. The rules state that liability can arise from fault in creating a product or otherwise, and are strict; in particular the regulations found with departments or concerning consumer protection. The articles of the law allow parties for certain aspects to agree between one another and to depart from the articles of the law, otherwise the law maintains the minimum rights for one party towards the other. Liability may also be found for breach of any statutory obligations.

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?

The clauses under the Civil Code are general and may apply to any counterpart to a transaction. The definition of a provider under the UAE Federal Consumer Protection Laws is very broad in that it not only includes the local agents and distributors but also the manufacturer whether based in the UAE or abroad; the producer or provider supplies goods and services to distributors, other than consumers. Article (1) of CABINET OF MINISTERS' RESOLUTION (12) OF 2007 In respect of Executive Regulation to the Federal Law no. 24 of 2006 In respect of PROTECTION OF CONSUMERS ("CMR") supports the consumer in going against all of the aforementioned in their complaint or case and not just the local agents or distributors. There is a common misconception that a provider of a product or service to the consumer is limited to the entity or individual who directly dealt with the consumer, which, in most cases, is the local agents or distributors based in the UAE. The definition of provider in the same law also includes any representative office of the manufacturer based in the UAE that is somehow involved in the sale and circulation of the products and services.

1.4 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

No, they may not.

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

The above CMR provides that a provider shall adopt the procedures stipulated for herein to recall goods from the local markets or consumers in the following events:

1. A defect is found by him in the goods.
2. Reports or studies prove the presence of a defect in the goods.
3. Complaints are received from consumers or the concerned bodies for the presence of a defect in the goods.
4. A memorandum is issued by the Ministry for the recall of the goods.
5. Recall procedures are initiated outside the State for the same goods.
6. It is established that the goods do not conform with the Approved Standard Specifications.

There is no obligation to recall; however, there is an obligation for the manufacturer, when discovering a fault in any product or service, to inform the authorities and the consumers and provide a solution so that the consumer may use the product or service without being harmed by the fault.

As to the way a claim for failure to recall may be brought, it is clearly stated in the CMR as follows:

"In case the provider fails to recall the defective goods in accordance with this Regulation, while aware of the existence of a defect therein, this shall constitute a case of commercial fraud … and the Department shall refer the matter to the Public Prosecution to institute criminal proceedings against the provider."

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

Yes, the UAE consumer law prescribes penalties for the supply of defective products. A fine of between AED 10,000 and AED

1,000,000 is the primary sanction. This covers a wide range of offences, including: displaying, offering, promoting or advertising any goods or services which may cause damage to the consumer during ordinary usage; labelling the product in a way that is not compliant with legal requirements; failing to provide appropriate warnings to consumers which outline the risks associated with the product; failing to comply with approved standard specifications; and purposefully manipulating market conditions which control market price and forces an increase in the price of products.

2 Causation

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

As a general rule, this responsibility is on the claimant, and he/she must prove that they were harmed by the defendant's breach, and indeed that the defendant did breach his duty of care, to begin with. In product liability matters, defendants are strictly liable. The defendant's intention is of no importance to the outcome of the case, we can understand the answer through the provisions of regulation, namely the CMR, which allows that the consumer submits his complaint describing the condition of the goods as stated in the CMR and then the competent authorities, established for this purpose, examine the complaint and defective goods.

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?

Essentially, there are three causes of product liability: defective design; defective manufacture; and failure to properly instruct consumers on the proper use of a product or warn consumers of latent dangers in a product. The aim of product liability laws are to minimise the damage caused by defective products and to compensate those who have been affected.

The Ministry of Economy ("MOE") has the power to recall a product. In practice, it is the local coordinating bodies, such as Abu Dhabi Quality and Conformity Council ("ADQCC") or Dubai Municipality with assistance from Emirates Authority for Standardisation and Metrology ("ESMA") which investigates compliance breaches and coordinates between suppliers and the MOE to organise a product recall.

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 law does not explicitly recognise the market-share liability concept; however, it can be understood by reading the competent regulations. Manufacturers and suppliers are potentially liable for defective products, therefore if there are several of them that have manufactured a product, it will be detailed in the court proceedings that liability will be attached to one of them. Under the UAE Consumer Protection Laws, providers can be held liable for defective products in a strict sense. Providers are defined in a broad sense as including local agents, distributors, manufacturers and anyone involved in the circulation of the product or service. Notwithstanding the above, each of the manufacturer or supplier can be found liable according to the different articles found in the regulation where: the supplier can be liable and must not display or offer goods that are defective; the supplier will be liable if a defective product is sold; a supplier will also be liable for not adhering to labelling requirements, and for matters relating to warranties and after-sales services; and producers (or manufacturers) will also be liable for providing defective products.

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

Yes, failure to warn gives rise to liability. Essentially, there are three causes of product liability: defective design; defective manufacture; and failure to properly instruct consumers on the proper use of a product or warn consumers of latent dangers in a product. The aim of product liability laws is to minimise the damage caused by defective products and to compensate those who have been affected.

As to the information source, the regulations in its interpretation of the principal provider did not distinguish between the chain of providers, including traders and distributors.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The defences available for a defendant to demonstrate that they are not liable for the defects and can be a range of defences including third party factors and acts of god. A useful defence of limitation can also be one of the defences.

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 general product liability law does not allow for the development risk defence and, as a general rule, a latent/hidden defect may be established after the product is sold and when the defect is discovered and, at such time, there may be a claim made. The Civil

Code does not have any requirements on the buyer and offers the protection to the manufacturer in that, if the defect was visible or appeared, the buyer may not rely on any defence in such an instance. However, case law has also established that there is a requirement when dealing with goods/products that any reasonable person would require an expert to inspect such goods and that the buyer would be required to inspect goods when it would be reasonable to do so; therefore, in certain circumstances, any seller of goods may rely on the fact that it was prudent for a reasonable person to have inspected the goods to a specific level before purchasing them, thus offering a defence against the buyer for not having inspected the goods as any reasonable man should.

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 may be relied upon but, notwithstanding the compliance to statutory requirements, the Civil Code can find the manufacturer liable under the general liability articles.

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 claimants are able to re-litigate against the seller of the same product. The seller would have a very strong defence of having already litigated in respect of the goods/products; however, it does not forbid the courts to make a ruling in favour of claimants who are not the initial claimants who filed suit.

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, they can do this during the litigation with the claimant by an additional lawsuit against the claimant and the third party; the standard laws of limitation will apply in this instance.

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

The defendant can allege that the claimant's actions cause and contributed towards the damages and, in such a case, the judge can order partial damages in line with the proportion that the claimant's actions caused the damage.

4 Procedure

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

The trial is by a judge and 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)?

Yes, when a case is filed, the court may appoint an expert at its own discretion, also, the consumer tends to request the appointment of a technical court expert to deal with the case in its claim.

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 consumer's case before the court can be brought on the basis of tortious liability or contractual liability and for breaching the UAE Federal Consumer Protection Laws. There is no class action for this kind of suit.

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

Yes, it can be brought by the local competent authority within the concerned Emirate to which any law authorises.

4.5 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

Representative bodies may advertise for claims, but this does not frequently occur.

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

In product liability disputes, an application can be brought before a judge and parties are properly served in approximately three months; thereafter the judge and parties will submit responses and evidence to the courts, or otherwise the courts appoint experts and make orders, until the courts eventually deliver the judgment.

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

The courts may by law try preliminary issues like jurisdiction; however, generally the courts will deliver one judgment at the end which will deals with all the matters or otherwise a preliminary matter.

4.8 What appeal options are available?

The parties have a right to appeal the Consumer Protection Department's decision before the Ministry of Economy. Any judgment of the courts can be appealed to the Appeal Courts of the UAE.

4.9 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 usually appoints one or more experts to provide their opinion regarding the disputed matters; parties are able to rely on the evidence from the expert opinion. To this effect, the normal practice is to appoint technical court experts who have the knowledge, experience, and expertise in respect of the case at hand.

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

The courts can request that an expert attend before the courts and be examined if requested by a party or if the courts find it necessary; however, the general practice is that courts will rely on expert reports and, in case of any further examination required, the courts will direct the expert to look into additional matters and provide an addendum report.

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

In the UAE there is no mandatory pre-trail disclosure, parties are not obligated to file documents before the matter is before the courts. After a case is heard in court, a party to the litigation may request the court to compel his opponent to submit documents in accordance with the evidence laws.

4.12 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 general requirement for alternative methods of dispute resolution to be followed before suit. Only in exceptional cases does the law require parties to follow an alternative dispute resolution before claiming before the courts.

4.13 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 law on jurisdiction in the UAE provides that the UAE can entertain a case against a person that is domiciled outside of the UAE if the action is concerned with an obligation concluded, executed, or its execution was conditioned, in the UAE, and if one of the defendants has a residence or domicile in the UAE.

5 Time Limits

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

Yes, there are several time bars in bringing or issuing proceedings: in respect of latent defects, within six months; and in respect of general tort law and in respect of harm done, within three years.

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 bars do vary according to the fault and whether or not the defect was latent and other circumstances surrounding the case. In some instances, the time bar is immediate, the Civil Code provides that if the seller disposes of the goods as owner after becoming aware of the old defect, his option to sue lapses.

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

The period of limitation shall begin to run once the plaintiff has discovered the fraud or concealment.

6 Remedies

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

The CMR provides that consumers shall have the right to select the manner of remedying any defective goods, either by way of replacement, repair, or refund; provided that the type and nature of defective goods together with the time to be taken in remedying the defect shall be taken into consideration. The consumer shall, according to the type and nature of the defective goods together with the time to be taken in remedying the defect, be entitled to obtain substitute goods to avail thereof free of charge, until the remedy procedures are completed.

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

Please refer to question 6.1 above. Furthermore, the customer may claim before the courts for harm done, but in certain circumstances, the CMR laws may restrict a customer's claim of damages by its operation.

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?

Our experience is that the UAE will not compensate a person for future damage, rather, once the damage is sustained, the courts will assess the damages and compensate accordingly.

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

No, they are not.

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 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?

There are no such rules, with the exception of infants; a settlement of any claims by infants may involve the public prosecutor who may be required to accept the settlement.

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

This is generally not the case and authorities will not sue another company on behalf of any person entitled to their services.

7 Costs / Funding

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

A successful party can recover most of the court fees and fees associated with the courts and incidental expenses. A successful party is very rarely awarded his own legal costs with the exception of a nominal amount towards legal fees.

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

No, it is not.

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

This is not applicable in the UAE.

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 outside the DIFC is seldom used.

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 a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

Answer not available at the time of print.

Hamdan AlShamsi

Hamdan AlShamsi Lawyers & Legal Consultants
Office 1611, 16th Floor, Al Manara Tower
Al Abraj Street, Business Bay
Dubai
United Arab Emirates

Tel: +971 4 346 9262
Email: hamdan@alshamsilegal.com
URL: www.alshamsilegal.com

With nearly a decade of successful litigation experience across the United Arab Emirates, Mr. AlShamsi has built one of Dubai's most reputable and respected law practices. He is widely regarded as a top litigator in the Dubai Courts, with extensive experience in corporate, banking and finance and insurance law. Mr. AlShamsi advises both local and international companies and governmental entities in cases involving complex litigation. He appears regularly before the Appeals Court and the Court of Cassation, as well as UAE's Federal Supreme Court. Mr. AlShamsi has been described as being "*…very thorough and highly efficient – Hamdan faced each challenge with strategy, professionalism and confidence which ultimately resulted in our successful outcome*". It is no surprise that he has been awarded as one of the most influential young leaders in the Middle East and the young achiever award, amongst many more.

HAMDAN ALSHAMSI
LAWYERS & LEGAL CONSULTANTS

Hamdan AlShamsi Lawyers & Legal Consultants was established in 2011. It has since become a name synonymous with success and is well-known in the legal circuit. The success of the law firm is due to its specialisation in advising on commercial issues, insurance, due diligence, family law, intellectual property law, banking, companies law and other matters locally, as well as its dedication towards offering unparalleled, high-quality and culturally sensitive legal services, while adhering to the highest standards of integrity and excellence.

USA

David B. Sudzus

Daniel B. Carroll

Drinker Biddle & Reath LLP

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 programmes 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 May a regulatory authority be found liable in respect of a defective/faulty product? If so, in what circumstances?

Regulatory authorities are not subject to liability for defective/faulty products. As noted in question 1.1, it is the manufacturers, wholesalers, distributors, and retailers of products who are subject to product liability claims.

1.5 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.

1.6 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 the 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, but is 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 May lawyers or representative bodies advertise for claims and, if so, does this occur frequently? Does advertising materially affect the number or type of claims brought in your jurisdiction?

In a 1977 decision, the United States Supreme Court removed bans on lawyer advertising. Since then, lawyer advertising, while permitted, has been regulated by state court and bar association rules. The American Bar Association established Model Rules which serve as both guides and the foundation for most states' legal advertising rules. However, certain state courts and bar associations have set rules which impose more direct oversight and which are more restrictive than rules regarding legal advertising in other states.

Lawyer advertisements range from simple billboard signs to sophisticated, targeted social media ads. Among the most common legal advertisements are those by plaintiffs' tort lawyers, whose focus are product liability cases. There are studies verifying a relationship between increased case filings and attorney advertising, particularly in situations involving targeted, ubiquitous, product-specific advertising by plaintiffs' law firms. Further, concerns have been raised in the pharmaceutical product liability context that lawyer advertising regarding medications have caused patients to stop treating with these prescribed medications.

4.6 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.

4.7 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.

4.8 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.

4.9 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 Supreme 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.

4.10 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.

4.11 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.

4.12 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.

4.13 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 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.

In 2017, the Supreme Court significantly limited the ability of plaintiffs to bring defendants into whatever jurisdiction or court these plaintiffs choose. In *Bristol-Myers-Squibb v. Superior Court*, the Court rejected *the aforementioned* California expansion of specific personal jurisdiction as violative of the Due Process Clause of the US Constitution. The court concluded that for specific personal jurisdiction to be exercised by a state, there must be a connection between the forum state and the specific claims being brought in the matter. Per this opinion, the Court clarified that a corporation that markets and sells products throughout the US is not subject to litigation in any jurisdiction purely for those reasons. The *Bristol-Myers-Squibb* decision is deterring the plaintiffs' bar's practice of filing lawsuits in plaintiff-friendly jurisdictions.

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 per cent.

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 funding is becoming increasingly common and is now 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 a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction including how the courts are approaching any issues arising in relation to new technologies and artificial intelligence.

A highly-anticipated Supreme Court decision which will have great impact on potential defences in products liability cases is anticipated later in 2019. In January 2019, the Court heard arguments in *Merck Sharp & Dohme Corp. v. Doris Albrecht, et al*. In that case, plaintiffs argued that the manufacturer Merck should have warned about a risk of atypical femoral fractures associated with use of its medication Fosamax. The trial court concluded the claim was preempted on the basis that there was clear evidence FDA would not have approved the warning proposed by plaintiffs, specifically because the FDA refused to approve that very warning. The Third Circuit reversed, reasoning that plaintiffs produced sufficient evidence for a jury to conclude that the FDA would have approved a warning concerning the product's risk and defendant had not shown, via "clear and convincing evidence", that the FDA would have rejected the specific proposed warning label. The primary issue before the Supreme Court is whether a state law failure-to-warn claim is preempted following FDA's specific rejection of the proposed warning or whether the case should go to trial so a jury can determine the reasoning as to why FDA rejected the proposed warning. Merck has argued in the Supreme Court, that the Third Circuit decision, based on speculation about what FDA might have done, necessarily assumed that FDA ignored its own legal responsibilities. Of greater import, the Court's anticipated decision will impact the viability of both preemption defences and also the "presumption of regularity" defence, which presumes government agencies have properly discharged their official duties unless clear evidence shows otherwise.

With respect to new technologies, it is anticipated that courts will apply traditional product liability legal principles in addressing cases brought by individuals claiming harm from products such as autonomous vehicles and those involving 3D printing, artificial intelligence and Internet of Things. For example, manufacturers of IoT products that do not address cybersecurity issues to prevent software hacking, malfunctions, or failure to update, will likely face traditional products claims for negligence, breach of warranty, strict product liability, defective design and failure to warn.

David B. Sudzus
Drinker Biddle & Reath LLP
191 N. Wacker Dr., Ste. 3700
Chicago, IL 60606-1698
USA

Tel: +1 312 569 1498
Fax: +1 312 569 3498
Email: David.Sudzus@dbr.com
URL: www.drinkerbiddle.com

David B. Sudzus is a partner in the Products Liability & Mass Tort department of Drinker Biddle & Reath LLP. He advises clients on products liability, mass tort, pharmaceutical, medical device and asbestos litigation, class actions and e-discovery matters. Dave represents clients in single and multidistrict cases throughout the country. In addition, he advises companies in preparing on-line content, product manuals and warning labels and in developing and implementing complaint handling procedures and product-recall programmes to help clients guard against future claims and position themselves strategically to defend their products if litigation arises. Dave has extensive trial experience, as well as in preparing and arguing substantive motions before the courts.

Dave is a regular speaker and panelist on topics such as regulatory and liability issues relating to efforts to introduce products to market, controlling the effect of social media on products liability litigation, liability and policy issues associated with the use of autonomous vehicles, and product recalls.

Daniel B. Carroll
Drinker Biddle & Reath LLP
600 Campus Dr.
Florham Park, NJ 07932-1047
USA

Tel: +1 973 549 7296
Fax: +1 973 360 9831
Email: Daniel.Carroll@dbr.com
URL: www.drinkerbiddle.com

Daniel B. Carroll is a partner in and Co-Chair of the Products Liability & Mass Tort department of Drinker Biddle & Reath LLP. He represents clients in a wide range of litigation with a primary focus on pharmaceutical products liability defence. His experience in products liability litigation encompasses mass torts involving latex gloves, cough and cold medications, antibiotics, food flavourings, hypertension medications and anti-coagulants. Dan's practice also includes breach of contract actions, commercial litigation, insurance coverage litigation and personal injury defence. Mr. Carroll received his J.D. from Seton Hall University School of Law while serving as one of the editors for *The Home News.*

DrinkerBiddle®

Drinker Biddle & Reath LLP is a national law firm with more than 635 lawyers. The firm provides client service in corporate and securities, litigation, government and regulatory affairs, health care, products liability, corporate restructuring, investment management, labour and employment, life insurance and annuities, intellectual property, employee benefits and executive compensation, environment and energy, white collar defence and corporate investigations, trust and estates, and real estate.

Current titles in the ICLG series include:

- Alternative Investment Funds
- Anti-Money Laundering
- Aviation Law
- Business Crime
- Cartels & Leniency
- Class & Group Actions
- Competition Litigation
- Construction & Engineering Law
- Copyright
- Corporate Governance
- Corporate Immigration
- Corporate Investigations
- Corporate Recovery & Insolvency
- Corporate Tax
- Cybersecurity
- Data Protection
- Employment & Labour Law
- Enforcement of Foreign Judgments
- Environment & Climate Change Law
- Family Law
- Financial Services Disputes
- Fintech
- Franchise
- Gambling
- Insurance & Reinsurance
- International Arbitration
- Investor-State Arbitration
- Lending & Secured Finance
- Litigation & Dispute Resolution
- Merger Control
- Mergers & Acquisitions
- Mining Law
- Oil & Gas Regulation
- Outsourcing
- Patents
- Pharmaceutical Advertising
- Private Client
- Private Equity
- Product Liability
- Project Finance
- Public Investment Funds
- Public Procurement
- Real Estate
- Securitisation
- Shipping Law
- Telecoms, Media & Internet
- Trade Marks
- Vertical Agreements and Dominant Firms

glg global legal group

59 Tanner Street, London SE1 3PL, United Kingdom
Tel: +44 20 7367 0720 / Fax: +44 20 7407 5255
Email: info@glgroup.co.uk

www.iclg.com