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The International Comparative Legal Guide to:

Product Liability 2018

16th Edition

A practical cross-border insight into product liability work

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Contributing Editors
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Senior Editors
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Caroline Collingwood

CEO
Dror Levy

Group Consulting Editor
Alan Falach

Publisher
Rory Smith

Published by
Global Legal Group Ltd.
59 Tanner Street
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Tel: +44 20 7367 0720
Fax: +44 20 7407 5255
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General Chapters:

Country Question and Answer Chapters:

EDITORIAL

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

This guide provides corporate counsel and international practitioners with a comprehensive worldwide legal analysis of the laws and regulations of product liability.

It is divided into two main sections:

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

Country question and answer chapters. These provide a broad overview of common issues in product liability laws and regulations in 23 jurisdictions.

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

Special thanks are reserved for the contributing editors Adela Williams and Tom Fox of Arnold & Porter for their invaluable assistance.

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

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

Ian Dodds-Smith
Partner
Arnold & Porter
Ian.Dodds-Smith@arnoldporter.com

PREFACE

I'm delighted to have been asked to introduce the sixteenth edition of *The International Comparative Legal Guide to: Product Liability*.

The guide continues to be an ideal reference point with seven excellent general chapters covering significant developments in European, Asian and US law. This edition also has a special focus on product recalls, a practical guide around costs issues and considerations in the context of group actions in England & Wales and finally commentary on liability and insurance matters in the context of driverless cars.

As always, the bulk of the edition remains the enormously helpful country question and answer section, covering 23 jurisdictions, new to the guide this year being Albania and Kosovo.

I frequently have cause to make reference to the guide for matters concerning product liability all over the world and will continue to do so as the guide remains a thoroughly informative and comprehensive publication.

Tom Spencer
Senior Counsel
GlaxoSmithKline
Dispute Resolution & Prevention

Recent Developments in European Product Liability

Adela Williams

Tom Fox

Arnold & Porter

Introduction

The Product Liability Directive, 85/374/EEC ("the Directive") lays down common rules governing liability for defective products in the European Union ("EU"). It imposes strict (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

Periodically (every five years), under Article 21 of the Directive, the Commission has reported to the Council and Parliament on the status of the application of the Directive. These reports tend to review any significant case law developments and highlight any perceived issues but, aside from an extension to the scope of the Directive to include primary agricultural products in 1999, no changes have been made to date. The fifth report ("the Report"), covering the period 2011–2017 was published on 7 May 2018.[1]

The European Commission (DG-GROW) carried out a formal evaluation of the performance of the Directive, noting that no formal evaluation has taken place since the Directive was enacted in 1985.[2] The evaluation considers the operation of the Directive by reference to criteria of effectiveness, efficiency, coherence, relevance and EU added value and, importantly, focusses on how the Directive is applied to new technologies, such as advanced robots, autonomous systems, complex Internet of Things ("IoT") products and apps or other non-embedded software.[3]

Digital Market Strategy Context

The evaluation took place in the context of the EU's Digital Single Market strategy. That strategy recognises that new technologies present economic opportunity in the form of further innovation, new products, services, and business models, and seeks to maximise the positive impacts of the digital revolution. Potential benefits envisaged include re-industrialisation of Europe (as e.g. technologies such as 3D printing may allow products to be manufactured without outsourcing), and greater efficiencies in delivery of goods and services within the single market. In relation to product safety and liability, the Commission stated that it would "…consider the possible need to adapt the current legal framework to take account of new technological developments…especially from the angle of civil law liability" and said it would take into account the results of the ongoing evaluation of the Directive.[4]

Public Consultation

The Commission's formal evaluation procedure followed a public consultation on the Directive ending in April 2017,[5] asking stakeholders a range of questions tailored to the organisation type (e.g. producers, members of the public, public authorities and law firms). The consultation sought to assess whether the Directive continues to "meet its objectives of guaranteeing at EU level the strict liability of the producer for damage caused by a defective product, while also ensuring free movement of goods and offering a high level of protection to EU consumers".[6] Specific aspects of the Directive addressed included:

- The definition of "product" and whether this is adequate to cover e.g. apps, non-embedded software and products based in the IoT.
- The definition of "defect" and whether this is adequate to cover e.g. unintended autonomous behaviour of advanced robots.
- Whether the definition of "producer" is adequate to address allocation of liability in complex value chains in the IoT, where connected objects or sensors may not necessarily be under the control of a single producer.

Summary of Consultation

A brief factual summary of the results of the public consultation was published in May 2017 and a synopsis published along with the Report on 7 May 2018. Broadly, there was good awareness of the Directive's product liability regime and support for its continued operation. The questions asked in the consultation had two principal focuses: (1) establishing how well the Directive works in practice and whether it strikes a fair balance between consumers and industry; and (2) establishing to what extent the Directive is "future-proof".

Awareness of the Directive among respondents was high. Over 85% of respondents of all categories considered that the Directive was advantageous to both consumers and producers, providing the same rights throughout the EU, with 68% of respondents saying that it struck a fair balance between the interests of producers and those of consumers.[7] Most stakeholders support the continuation of the system of strict liability, but opinions differ as to whether a fair balance is struck between consumers and industry.[8]

Some specific aspects of the Directive were the subject of criticism by consumers and consumer organisations. Around 17% of respondents in this category (n = 8 responders) found the process of recovering damages "burdensome". Some consumer/consumer organisation respondents also found the following "burdensome": proving that the product was defective (12.5%); proving a link between damage and defect (14.58%); attributing liability to a specific defendant (14.58%); the lower limit for property damage claims of EUR 500 (2.08%); proving the product was intended and used for private purposes (4.17%); the three-year limitation period (10.42%); and the 10-year "long stop" period, following which claims are extinguished (14.58%). Such criticisms were however arguably prompted by the questionnaire, which asked for these aspects of the product liability regime to be rated "burdensome", "neutral" or "easy".

Respondents were more divided in their views regarding the application of the Directive to new technologies. Of those directly affected (e.g. producers and consumers) just over half (52%) said the Directive addressed their needs. Among other respondents (e.g. public authorities and academics), just under half (48%) thought the Directive addressed the needs of producers in relation new technologies and around a third (32%) considered that it addressed the needs of consumers in relation to such products.

A substantial proportion of all respondents (45% of producers, 58% of consumers, and 44% of others) thought that dealing with specific types of products (e.g. software and applications obtained from other sources after purchase, products performing automated tasks based on algorithms, data analytics, self-learning algorithms or products purchased as a bundle with related services) could be problematic or uncertain under the Directive.

Adaptation of the Directive to address new technologies was thought to be necessary by just 25% of producers, but 54% of consumers, and 40% of others, with smaller numbers in favour of alternative strategies, such as wholesale revision of the Directive or the issue of guidelines to aid interpretation. The overall picture, based on position papers submitted by respondents, was that around half felt that the present regulatory framework was adequate to address issues arising from the introduction of new technologies.[9]

Commission Product Liability Conference

In October 2017, the Commission held a Product Liability Conference, where a further study reviewing the operation of the Directive and its fitness for purpose was presented by Technopolis and Ernst & Young[10] ("the Technopolis Study") and the Directive was further evaluated in discussions with stakeholders.

Commission Report

The Commission's Report of 7 May 2018 was published together with a synopsis of the stakeholder consultation and a working document, which drew on the Technopolis Study and the discussions with stakeholders and analysed the Directive in line with the Commission's evaluation categories, as follows:

Effectiveness

The Technopolis Study identified 798 claims in Member States in the period 2000 to 2016. Relatively few cases were cross-border cases, which is thought to be due to language barriers and unfamiliarity with different legal systems.[11] The rate of success for injured parties in product liability claims was around 60%, which, Ernst & Young said, was also the average success rate for court cases in general. This was disputed by some participants in the Product Liability Conference, who said that claims were successful in over 80% of cases in England and Wales under a fault-based national system.[12] Industry is largely satisfied with the Directive,[13] while consumer organisations highlight the difficulty for injured parties in proving defect or the causal link between defect and damage,[14] it was, however, noted during the evaluation, that this difficulty has been mitigated by the CJEU via case law.[15] The Directive's regime appears readily applicable to tangible products in general. However, the evaluation recognised, in response to representations by consumer groups, that the concept of defect may be more problematic for some types of product including, in particular pharmaceuticals, where there are known risks as well as unexpected risks.[16] Theoretical application of the Directive to developments such as smartphones, 3D printers, cloud technologies, robots and self-driving cars were considered in the course of evaluation, leading to concerns that the requirement to prove defect and causation, and the joint liability of different parties could cause difficulties.[17] The overall conclusion following evaluation was that some clarification of concepts such as "product" and "defect" might be desirable, but overall further evidence is needed in order to form a clear opinion on the functioning of the Directive in relation to new technology.[18]

Efficiency

The Directive was found to strike a balance between the costs and benefits borne by producers and consumers. However, the balance was also impacted by factors external to the Directive which may create difficulties for consumers.[19] By way of example, the Commission recognised that legal procedures and costs vary between Member States, and these impact directly on consumers seeking redress.

Coherence

The evaluation suggested that the Directive is fully coherent with the EU legal framework, including rules on consumer protection in contractual liability, digital contracts proposals, rules on applicable law, arbitration and litigation, and product safety legislation. It will be kept under review to make sure it is still coherent with any changes that are made to other product legislation.[20] The consistency of the Directive with product safety legislation was queried by some participants in the Product Liability Conference,[21] who suggested that medicines, in particular, ought not to be covered by the Directive, apparently on the basis that the Directive was coherent with general product safety legislation, whereas medicines had their own regulatory regime and so should also be covered by separate liability legislation.[22]

Relevance

The Directive remains relevant, but it continues to be uncertain whether it will require amendment as a result of technological change, e.g. to clarify whether software, non-embedded software, objects interconnected with services, or advanced robots should be considered "products" for the purposes of the definition at Article 2.[23] In particular, new technology calls into question the existing distinctions between services and products, private and professional use, the definitions of product, producer and defect. The defences available to the producer, e.g. the development risks defence, may be problematic in the context of technologies such as artificial intelligence.[24]

EU added value

The Directive was said to have contributed to consumer protection and innovation. No stakeholders canvassed in the study suggested repeal of the Directive, viewing such a step as likely to reduce consumer protection and bring uncertainty and fragmentation to the internal market. A number of specific criticisms were made of the Directive at the Product Liability Conference, particularly by claimant lawyers and consumer interest groups concerned with injuries relating to medicines. Some of the points raised related to issues of funding and procedure in different civil litigation regimes at national level:

- Cost of expert opinions to prove causation.
- No right to information disclosure under the Directive which assists in proving a defect.
- Inequality of resources because of absence of legal aid.

Some commentators suggested that the German national scheme for liability in medicines cases was more favourable to claimants.[25] However this is consistent with the fact that the Directive does not seek to achieve full harmonisation; it exists as a regime in addition to, not instead of, national contractual, quasi-contractual and negligence-type liability regimes. Furthermore, matters of evidence, procedure and the funding of litigation are functions of national civil litigation regimes rather than being determined at EU level by the Directive.

Two criticisms of the Directive relating to medicines cases did not fall within this category:

- the concept of defect; and
- limitation.

Representatives of French claimant associations said that defect and causation were especially hard to prove in medicines cases,[26] either the adverse effect of the medicine is known about and warned about in product information, in which case judges find there is no defect, or the adverse effect is unknown, in which case causation is very hard to establish and the producer may in any event benefit from the development risks defence. However, while they argued that the full burden of scientific uncertainty is placed, unfairly, on the injured patient, the situation described may follow from the fact that the development and supply of medicines, including the testing conducted and the warnings provided, are subject to extensive regulatory controls.

The three-year initial limitation period and the 10-year "long stop" established under the Directive, were also said by some commentators to be too short and to disadvantage injured patients in medicines cases arguing that these provisions are unfair to child claimants or injured persons where the adverse effects may be evident only in the long term, or even in subsequent generations.[27]

The Directive represents, as is clear from its recitals,[28] and from review of the *travaux préparatoires*, a compromise position, agreed only after extensive debate in the European Parliament over a number of years. It acknowledges that there are risks associated with products, including with innovative products, and seeks to establish a regime by which the burden of such risks is apportioned fairly as between users and producers of such products. That "fair apportionment" was, however, called into question at the Conference on the basis of the results of consultation which, it was claimed, showed that the Directive is not balanced, because producers view it more favourably than do consumers.[29]

While, it is plainly reasonable to review and reassess from time to time whether the apportionment of risk between industry and consumers is still fair and to consider whether there are particular products for which that might not be the case, it is difficult to say, based on previous reviews of the application of the Directive and the preliminary reported results of the current evaluation, that there have been any changes so significant that these should prompt a fundamental reappraisal of the "fair apportionment of risk". The Commission's Report acknowledges these issues, but puts forward no firm conclusions in favour of changes to the existing regime. Clarification via guidance and/or amendment to adapt the Directive to technological change may, however, occur following the report of an expert group on liability and new technologies being set up by the Commission to consider such issues further.[30]

We consider further below some of the issues arising from the Report and the evaluation process, including the coherence of the Directive with other product safety related rules and the extent to which specific new technology issues may be dealt with under the existing product liability regime.

Coherence of the Directive with the EU Product Safety System

Some of the discussion at the EU's Product Liability Conference proceeded on the basis that the Directive forms a coherent part of a wider product regulatory ecosystem, comprising the General Product Safety Directive 2001/95/EC ("GPSD") and safety-related sectoral legislation.[31] However, there are material differences in the application of these regimes. By way of example, while both the Directive and the GPSD impose liabilities on the "producer" of a product, the definition of producer is are not identical. Under both the Directive and the GPSD, the producer may be the manufacturer or own-brander. For the purposes of the Directive, "producer" is also defined as including other persons in the supply chain, who may potentially be liable to the consumer if they fail to identify the person who supplied the product to them, whereas the GPSD focuses on the producer as a person whose activities may affect the safety properties of a product and includes, within its definition, the manufacturer's representative in the EU and anyone who reconditions a product. Clearly the purposes of the Directive are different from those of the GPSD and this explains the different definitions of producer under the two regimes; however, the use of the same term in these related but distinct contexts may, nevertheless, be confusing.

A great deal of sectoral product safety legislation is applicable in the EU, including that covering highly regulated and technically complex products, such as medicines, medical devices and motor vehicles. There is also specific legislation covering e.g. low voltage electrical products, radio equipment, machinery, and toys. Such legislation does not use the legal concept of a "producer", relying instead on more precise functional terms, such as manufacturer, distributor, importer (collectively, typically "economic operators") to identify parties in the supply chain and their duties with regard to product safety. Furthermore, the draft Consumer Product Safety Regulation, which is intended to replace the GPSD, no longer uses "producer". If that comes into force, then the term "producer" as defined in the Directive as the party bearing liability for a defective product, will be a legal concept found only in the Directive.

Interestingly, the new EU Medical Devices Regulation[32] ("Regulation"), provides that an authorised representative of a non-EU manufacturer can be liable for defective medical devices on a joint and several basis with the manufacturer and importer.[33] This is said to be "without prejudice" to the provisions of the Directive.[34] At present this appears to be an arrangement unique to medical devices. However, in view of proposals[35] to require all non-EU manufacturers selling products subject to harmonised EU legislation to have an authorised representative based in the EU, it is a point to watch.

A further area of overlap between the Directive and the GPSD is in relation to the concept of "safety". The Directive defines defect by reference to its safety. Under the GPSD, Article 2(b) a "safe" product is one which "under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account defined factors. These factors comprise, in particular: (i) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance; (ii) the effect on other products, where it is reasonably foreseeable that it will be used with other products; (iii) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product; (iv) the categories of consumers at risk when using the product, in particular children and the elderly. The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be "dangerous". The sectoral specific safety legislation also addresses such issues in the particular context of the products to which it applies. While compliance with regulatory requirements is not a complete defence to an allegation of defect under the Directive (unless the alleged defect is due to compliance with mandatory regulations issued by the regulatory authorities), it is clearly a material circumstance for the purposes of determining what level of safety "a person" is entitled to expect in accordance with Article 6 and the fact that a product does not meet the requirements of safety legislation or associated standards relevant to safety may result in an inference of defect under the Directive.

Overall therefore, the Directive constitutes a coherent part of the EU product safety system, promoting consumer safety in products along with recourse for loss and a degree of uniformity and certainty for industry.

Subject to further analysis by the Commission's expert group, the overall position of Directive (described in the course of the evaluation as a "safety net"[36]) does not seem particularly challenged by the results of the evaluation. Below we address some specific issues mentioned in the course of the evaluation which relate to the possible need to adapt the Directive to technological change in the context of the digital market economy.

Changes Needed to the Directive to Deal with Technological Change

Software

Software is a suite of computer programs assembled to perform an application. The main concern regarding software expressed during the evaluation of the Directive, is the extent to which it can be regarded as a "product" in this context. The Directive states that the term "product" includes all moveable property (as distinct from land),[37] but does not say whether such property must also be tangible. Electricity, which is specifically included within the scope of the Directive, is not a tangible good, so the fact that software is made up of intangible data does not appear to be a barrier in principle to it being treated as a product.

Software which is embedded in a physical product clearly falls within the scope of the Directive: the manufacturer of the final product in which the software is incorporated can be treated as the producer and found liable to the injured party, even if the problem is in fact caused by a defect in the software.[38] In this situation, the manufacturer of the finished product would, in turn, have to seek indemnity from the software provider. On the other hand, in cases where software may be regarded as a component of the final product, then the software manufacturer would be caught by the definition of "producer".

The distinction between products and services

The erosion of the boundary between services and products (as traditionally understood) presents even more of a challenge, particularly in new technological areas. Uploading and downloading software via the internet occurs by electromagnetic transmission; with the software being transmitted as intangible digital files. Software, being intangible and sold subject to a licence, is arguably a service rather than a product and this argument is stronger where the software is not incorporated into any physical product such that it might be described as a component. This situation was specifically noted by the Commission, who commented that it can be "…increasingly difficult to differentiate a product from a service". The Commission also noted that products and services can be treated in quite different ways in different Member States, and this may lead to different levels of consumer protection and producer liability across the internal market.[39]

Software and mobile apps, whether embedded or not, are classified as medical devices if they meet the definition provided by the medical device legislation,[40] and whether they are intangible or supplied as a part of a subscription to a service under licence makes no difference to that analysis. Recent CJEU case law has confirmed this position and helped to clarify the circumstances in which software may be classed as a medical device.[41] It would be surprising if a piece of software was classified as a medical device, but held not to be a "product" for product liability purposes, not least because the new EU Medical Devices Regulation contains reference to manufacturers having sufficient financial coverage to meet their potential liability under the Directive.[42]

IoT systems have a physical embodiment (and could thus be considered a product), their main added value is derived from them being embedded in a network and the service that is provided through this network".[43] However, in circumstances where the Directive does not apply to services, the Commission highlighted the need to consider the definition of "product" under the Directive (including when software is deemed to be a product) to ensure that it covers both tangible and intangible elements of the IoT.[44]

Some software, at least, may therefore need to be treated as a "product" for the purposes of the Directive and it would probably be helpful for this to be made explicit via guidance or amendment. However, caution will need to be exercised to avoid extending the definition to include a wider range of systems that are currently viewed as services.

Software updates

One issue raised in the discussion of whether software should be treated as a product, was the question of extinguishment of claims. At present, there is a 10-year "long stop", commencing on the date when a particular product is put into circulation,[45] after which time any claim under the Directive is extinguished. However, since software is periodically updated, this potentially means that the 10-year period re-starts with each upgrade,[46] depending on whether the software update is itself regarded as a product. If the software update is a product or a component of a product, then the 10-year period will run from the date that the software update is put into

circulation. However, if the software update is instead viewed as a service, then the Directive will not apply to the update and, assuming the original software is viewed as product for the purposes of Article 2, any claim under the Directive will be extinguished 10 years after this was put into circulation.

Software installation

Another issue raised in the context of software updates was that, while manufacturers make software updates available, it is ultimately for the user to install the update.[47] Can the producer (i.e. the manufacturer of the final product into which the software update should have been installed) be held responsible if the user does not do this? The answer is likely to depend on "all the circumstances"[48] and, in some situations, it may be necessary to recall a product so that a safety critical software update can be installed. However, in other cases, failure to install a software update may provide a defence to a claim that the product was defective. Users may not be entitled to expect a product to contain a software update, of which they were aware, but failed to install or, alternatively a user's damages may be reduced as a result of contributory negligence in accordance with Article 8(3) of the Directive.

In summary, while, the answers to such questions may be highly fact-dependent, they seem likely to be capable of being dealt with comfortably within the existing liability regime of the Directive.

Problems of Complexity

Some participants in the evaluation of the Directive pointed to the fact that increasing technological complexity in the context of the overall digital market strategy, may mean that it is difficult for a consumer to know who to sue: "Faulty sensors, vulnerable software or unstable connectivity may make it difficult to determine who is technically and legally responsible for any ensuing damage."[49] However, under the Directive an injured party is not required to identify the party who is in fact responsible for the defect in the relevant product; they simply need to identify the producer of the product they believe to be defective and if that person is not the correct defendant, must identify the person they believe to be the correct defendant within a reasonable time.[50]

Defects in Complex and Self-learning Systems

There may be difficulty in proving defect in complex systems, particularly in a self-learning system, where the manufacturer and other economic operators who come into contact with the system, may not be able to predict with any confidence what it will do. Similarly, it may not always be evident that a new, machine-learned, behaviour or action is an error as opposed to an innovative and desirable feature. However, it should be remembered that it is not defectiveness in a natural language or technical sense which must be shown, but rather the legal concept of defect under the Directive i.e. a lack of the safety which a person is entitled to expect in all the circumstances, as underlined by recent CJEU case law.[51] The results of other evaluations e.g. of the Machinery Directive,[52] and moves towards standardisation in the robotics and other industries will help to inform what may or may not be regarded as a "safe" robot or autonomous artificial intelligence ("AI") system, and it will no doubt be a challenge for lawmakers and industry to balance understandable precautionary instincts and the need to set appropriate safety parameters around new technologies with the fast-moving fluidity of a phase of ongoing innovation which, in line with its Digital Market Strategy, the EU seeks to harness rather than stifle.[53] However, for the purposes of product liability, "defect" is defined broadly enough to be capable of applying to all sorts of products, including existing, extremely complex products, such as medicines. It has not so far been made clear in the course of evaluation of the Directive, what features of advanced technological products would prevent them from being dealt with in the same way. Arguably "future-proofing" exists already due to the broad definitions of "defect" and "producer".

Development Risks Defence

It was been suggested in the course of evaluation that the development risks defence may be inappropriate in the context of new technologies such as AI and machine learning.[54] This defence is available to the producer where the state of scientific and technical knowledge at the time when the product was placed on the market was not such as to enable the existence of the defect to be discovered.[55] It is directed at protecting innovators in a limited way from some unknown risks resulting from their innovations. The defence was a highly contentious issue in the discussions leading to the original framing of the Directive, so the fact of its inclusion can be regarded as part of the "fair apportionment of risk" between industry and consumers which the Directive represents. It is also an aspect of the Directive which is optional for EU Member States to include in their implementation of the Directive.[56]

The Commission noted that the availability and application of the development risks defence is an issue that is particularly hotly contested. However, it took into account the defence's role in limiting litigation and providing certainty for industry and the fact that the study did not reveal significant differences between Member States which operate the defence and those that do not, or do so only partially. It found no evidence that the defence presented an obstacle to the effective operation of the internal market, nor to consumer protection.[57] Pending further analysis of this issue by the Commission's expert group, it has not yet been established that there are reasons why the defence should not apply to new technologies to the same extent that it does to existing ones.

New Collective Redress Proposal

The Commission has recently (11 April 2018) published a new proposal for a Directive[58] to replace Directive 2009/22/EC (the Injunctions Directive). As currently drafted, this would expand significantly the rules permitting representative organisations to bring collective redress actions on half of consumers for infringements of EU consumer protection legislation. The proposal allows collective redress actions to pursue not just injunctions, but also compensation, repair or price reduction, as available under national laws. The proposal significantly expands the list of EU legislation whose infringement may give rise to a collective redress action. According to the Annex to the proposal, it will include (among over 50 other listed items of legislation) the advertising and promotion provisions of Directive 2001/83/EC on medicinal products, the EU's General Data Protection Regulation, and Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. The list does not include medical device legislation, or general product safety legislation but does include the Product Liability Directive 85/374, although it is not clear that the Directive can actually be infringed in the same way as e.g. safety legislation. It will be interesting to see how the proposal develops and the extent to which it is taken into account in the further evaluation of the Directive.

Endnotes

1. Report from the Commission to the European Parliament, the Council, and the European Economic and Social Committee 7.5.2018 COM(2018) 246 final.
2. Evaluation of the Directive 85/374/EEC on the liability for defective products – Consultation Strategy. Ref. Ares(2016) 5572770 – 27/09/2016.
3. There is currently no EU legal definition of robot, but broadly what is understood by 'advanced robot' is a system that is at least partially physically embodied, which derives some degree of autonomous decision-making by adapting its behaviour to data obtained from sensors, exchanged, or traded (see e.g. the European Parliament's Draft Report with recommendations to the Commission on Civil law Rules on Robotics 205/2103(INL)). An autonomous system refers to a system, that operates without direct human agency, and may be cyber i.e. internet based. Such systems will vary in complexity, but at their most complex will entail some degree of machine-learning. The Internet of Things refers to the interconnection via the Internet of computing devices embedded in everyday objects, enabling them to send and receive data, which may be used in autonomous systems, robotic or otherwise.
4. Commission Communication on the Mid-Term Review on the implementation of the Digital Single Market Strategy A Connected Digital Single Market for All – 10.5.2017 COM(2017) 228 final, page 11. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52017DC0228.
5. Public consultation on the rules on liability of the producer for damage caused by a defective product http://ec.europa.eu/growth/content/public-consultation-rules-liability-producer-damage-caused-defective-product-0_en.
6. This quote is from the Consultation Strategy document. A subsequent Commission presentation on the evaluation of the Directive at the OECD on 27 October 2017 referred more precisely to guaranteeing "the liability without fault of the producer…" [emphasis added].
7. Brief factual summary on the results of the public consultation on the rules on producer liability for damage caused by a defective product 30.5.2017 GROW/B1/HI/sv(2017) 3054035 http://ec.europa.eu/docsroom/documents/23471.
8. Stakeholder Consultation – Synopsis Report 7.5.2018 SWD(2018) 158.
9. For example, the Law Society of England and Wales urged the Commission to exercise caution when considering any change in the Directive in the absence of clear public calls for amendment, but supported changes if there was evidence that these were necessary as a result of technological developments. (Response of the Law Society of England and Wales to Public Consultation on the rules on liability of the producer for damage caused by a defective product 26 April 2017).
10. Minutes of the Product Liability Conference 20 October 2017 at https://ec.europa.eu/docsroom/documents/26661/attachments/1/translations/en/renditions/native.
11. Commission Staff Working Document accompanying Commission Report on the application of Directive 85/374/EEC 7.5.2018 SWD(2018) 157 final, pg 23.
12. Minutes of the Product Liability Conference 20 October 2017, section 2.1 at page 4 comment by Hugh James, Solicitors.
13. Report from the Commission to the European Parliament, the Council, and the European Economic and Social Committee on the application of Directive 85/374/EEC 7.5.2018 COM(2018) 246 final, section 5.1.
14. Report from the Commission to the European Parliament, the Council, and the European Economic and Social Committee on the application of Directive 85/374/EEC 7.5.2018 COM(2018) 246 final, section 5.1.
15. Minutes of the Product Liability Conference 20 October 2017, EY presentation, slide 15, page 26. The cases referred to are C-503/13 and C-504/13 *Boston Scientific* and C-621/15 *N. W and Others v Sanofi Pasteur MSD SNC and Others*.
16. Commission Staff Working Document accompanying Commission Report on the application of Directive 85/374/EEC 7.5.2018 SWD(2018) 157 final, pg 25.
17. Minutes of the Product Liability Conference 20 October 2017, EY presentation, slide 17, pg 28.
18. Commission Staff Working Document accompanying Commission Report on the application of Directive 85/374/EEC 7.5.2018 SWD(2018) 157 final, pg 37.
19. Commission Staff Working Document accompanying Commission Report on the application of Directive 85/374/EEC 7.5.2018 SWD(2018) 157 final, pg 43.
20. Commission Staff Working Document accompanying Commission Report on the application of Directive 85/374/EEC 7.5.2018 SWD(2018) 157 final, pg 49.
21. Minutes of the Product Liability Conference 20 October 2017, EY presentation, slide 23, page 34.
22. Minutes of the Product Liability Conference 20 October 2017, pg 6.
23. Commission Staff Working Document accompanying Commission Report on the application of Directive 85/374/EEC 7.5.2018 SWD(2018) 157 final, pg 57.
24. Minutes of the Product Liability Conference 20 October 2017, EY presentation, slide 19, pg 30.
25. The German medicines compensation scheme was set up under national law in 1976. It was permitted to persist under Article 13 of the Directive. It includes a right to obtain information from the producer in a legal regime in which disclosure would otherwise not be routine. The pre-existing regime was amended slightly in 2002 and that amendment was challenged unsuccessfully in Case C-310/13, *Novo Nordisk Pharma GmbH v S.*
26. Minutes of the Product Liability Conference 20 October 2017, pg 3.
27. Commission Staff Working Document accompanying Commission Report on the application of Directive 85/374/EEC 7.5.2018 SWD(2018) 157 final, pg 27.
28. Recital 2 of the Directive: "Whereas liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production." Recital 7: "Whereas a fair apportionment of risk between the injured person and the producer implies that the producer should be able to free himself from liability if he furnishes proof as to the existence of certain exonerating circumstances."
29. Minutes of the Product Liability Conference 20 October 2017, comments by Hugh James at pg 7.
30. Report from the Commission to the European Parliament, the Council, and the European Economic and Social Committee on the application of Directive 85/374/EEC 7.5.2018 COM(2018) 246 final, section 6, pg 9.
31. Minutes of the Product Liability Conference 20 October 2017, page 6, Slides 24–25, pg 35–36.
32. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2017:117:FULL&from=EN.
33. Regulation (EU) 2017/745 at Article 11(5): "…where the manufacturer is not established in a Member State and has not complied with the obligations laid down in Article 10, the authorised representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer".

34. Regulation (EU) 2017/745 at recital 35.
35. COM (2017) 795: Proposal for a Regulation of the European Parliament and of the Council laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2017:0795:FIN. See also the Commission's Notice to Stakeholders concerning the withdrawal of the United Kingdom and EU rules in the field of industrial products 22.1.2018: https://ec.europa.eu/docsroom/documents/27241/attachments/1/translations/en/renditions/native.
36. Minutes of the Product Liability Conference 20 October 2017 at pg 2.
37. Directive, Article 2.
38. Directive Article 8(1) "Without prejudice to the provisions of national law concerning the right of contribution or recourse, the liability of the producer shall not be reduced when the damage is caused both by a defect in product and by the act or omission of a third party."
39. Commission Staff Working Document accompanying Commission Report on the application of Directive 85/374/EEC 7.5.2018 SWD(2018) 157 final, pg 51–52.
40. Article 1(2)(a) of the Medical Device Directive 93/42/EEC.
41. In Case C-329/16 *Snitem v Philips France*, the CJEU held that software can be classified as a medical device under EU law if it has at least one functionality that allows the use of patient-specific data to assist the physician in prescribing or calculating the dosage for treating the underlying condition. It does not matter whether the software acts directly or indirectly on the human body. The decisive factor is whether the software is specifically intended by the manufacturer to be used for one or more medical objectives specified in Article 1(2) of Directive 93/42/EEC (the Medical Devices Directive), including the diagnosis, prevention, monitoring, treatment or alleviation of disease.
42. Regulation (EU) 2017/745 at Article 10 (16): "Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law. Manufacturers shall, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC, without prejudice to more protective measures under national law."
43. Commission Workshop Agenda 13 July 2017.
44. Commission presentation on the evaluation of the Directive at Commission Workshop 13 July 2017.
45. Directive, Article 11.
46. Minutes of the Product Liability Conference 20 October 2017 at pg 5.
47. EUnited Robotics presentation on Cybersecurity in the industrial Internet of Things, EC Workshop in the area of autonomous systems/robots/IoT Brussels, 13 July 2017.
48. Directive, Article 6(1).
49. Commission Communication 10.5.2017 COM(2017) 228 final on the Mid-Term Review on the implementation of the Digital Single Market Strategy: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52017DC0228, section 3.2.
50. Directive, Article 3(3).
51. C-503/13 and C-504/13 *Boston Scientific*.
52. Evaluation of Directive 2006/42/EC on Machinery: final report http://ec.europa.eu/docsroom/documents/25661.
53. Commission Communication on the Mid-Term Review on the implementation of the Digital Single Market Strategy A Connected Digital Single Market for All – 10.5.2017 COM(2017) 228 final, page 11. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52017DC0228.
54. BEUC (European Consumer Organisation) presentation at Commission Workshop on liability in the area of autonomous systems and advanced robots and Internet of Things systems, 13 July 2017: https://ec.europa.eu/digital-single-market/en/news/workshop-liability-area-autonomous-systems-and-advanced-robots-and-internet-things-systems.
55. Directive Article 7(e).
56. It has not been implemented by, e.g. Finland and Luxembourg.
57. Commission Staff Working Document accompanying Commission Report on the application of Directive 85/374/EEC 7.5.2018 SWD(2018) 157 final, pg 26.
58. Proposal for a Directive on representative actions for the protection of the collective interests of consumers, and repealing Directive 2009/22/EC COM(2018) 184 final. https://ec.europa.eu/info/sites/info/files/proposal_for_a_directive_on_representative_actions_for_the_protection_of_the_collective_interests_of_consumers_0.pdf together with its Annex I listing the affected legislation: https://ec.europa.eu/info/sites/info/files/annex.pdf.

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, advising clients in relation to the regulation of medicinal products and medical devices in the UK and at the EU level. She also specialises in product liability litigation and advice. She has extensive experience in this area, handling both unitary claims and group actions, and co-ordinating litigation brought throughout the UK and EU. Her 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 has also acted in proceedings involving a range of products including pharmaceuticals, medical devices and food.

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 13 offices in the US, London, Frankfurt, Shanghai and Brussels. With 40 partners and counsel specialising in product liability matters, the firm is one of the most experienced firms internationally, providing clients with an integrated product liability service on a transatlantic basis.

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

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 (New York) for US enquiries.

Update on U.S. Product Liability Law

Daniel A. Spira

Michelle A. Ramirez

Sidley Austin LLP

Introduction

Product liability law has continued to evolve dramatically within the past year. Recent U.S. Supreme Court opinions have narrowed the jurisdictions in which product manufacturers can be haled into court, *see Bristol-Myers Squibb Co. v. Superior Court of Calif.*, 137 S. Ct. 1773, 1778 (2017); *BNSF Ry. Co. v. Tyrrell*, 137 S. Ct. 1549, 1554, 1559 (2017), while various courts' interpretations of law on federal pre-emption, the admissibility of expert causation testimony, and class certification requirements continue to impact the defences available to companies facing product liability litigation.

Although the use of multi-district litigation ("MDL") has decreased in recent years, it continues to be a major vehicle for product liability litigation, and one capable of subjecting defendants to significant litigation, particularly through industry-wide MDLs and multi-plaintiff trials.

As the design, manufacturing, and function of traditional products rapidly evolve through the advent of new technologies, courts, regulators, practitioners and companies alike will be forced to reexamine, develop, and adapt product liability law in the years to come.

This chapter provides updates on each of the following topics:

- Personal Jurisdiction;
- Federal Preemption;
- Class Actions;
- Multidistrict Litigation (MDL) Trends;
- Admissibility of Expert Causation Testimony; and
- Emerging Areas of Product Liability Law.

Personal Jurisdiction

The requirement of personal jurisdiction, which is grounded in the Due Process Clause of the Fourteenth Amendment to the U.S. Constitution, protects defendants from being sued in jurisdictions in which they do not have certain minimum contacts. Personal jurisdiction allows a court to exercise its authority over a company, such as by requiring the company to appear in court, produce documents and witnesses for deposition or trial, and enforce a judgment against the company.

Personal jurisdiction requires the defendant to have sufficient contacts with the judicial forum to make it reasonable for the defendant to defend the lawsuit in the forum state. *See Int'l Shoe Co. v. Wash.*, 326 U.S. 310, 316 (1945). The defendant must have also purposefully availed itself of the privileges of conducting activities within the forum, which ensures that the contact within the forum is the result of the defendant's own actions, as opposed to those of the plaintiff or a third party. *See Hanson v. Denckla*, 357 U.S. 235, 253 (1958); *Walden v. Fiore*, 571 S. Ct. 1115, 1122 (2014).

There are two different types of personal jurisdiction: general; and specific. A court must have one of these two forms of jurisdiction over a defendant; otherwise, the claims against it must be dismissed. "General jurisdiction" exists when a defendant has such a substantial connection to a forum that it justifies jurisdiction over the defendant based on *any* claim that may arise, regardless of whether the lawsuit relates to conduct that occurred in the jurisdiction. *See Helicopteros Nacionales de Colombia v. Hall*, 466 U.S. 408, 414 & n.9 (1984). By contrast, "specific jurisdiction" can be invoked even when the defendant has relatively few contacts with the forum, as long as the claim arises directly out of those contacts. *Id.* at 414 & n.8.

Case law in recent years has dramatically impacted the scope of both general and specific jurisdiction, narrowing the jurisdictions in which plaintiffs asserting product liability or other claims can sue defendants.

General Jurisdiction

A corporation is subject to general jurisdiction in the forum where the corporation's affiliations are so "continuous and systematic" as to render it "at home" in that forum. *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 924–25 (2011). Historically, the U.S. Supreme Court provided little guidance for what constituted "at home" for purposes of general jurisdiction over corporations. But in 2014, the Court addressed this question in *Daimler AG v. Bauman*, and narrowed the scope of general jurisdiction over a nonresident defendant, finding that the paradigm bases for general jurisdiction are the "place of incorporation and principal place of business". 134 S. Ct. 746, 760 (2014). The determination of whether a corporation is "at home" for purposes of general jurisdiction "does not focus solely on the magnitude of the defendant's in-state contacts . . . General jurisdiction instead calls for an appraisal of a corporation's activities in their entirety, nationwide and worldwide. A corporation that operates in many places can scarcely be deemed at home in all of them". *Id.* at 762 n.20. 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 n.19; *see also id.* at 761–62 (declining to find general jurisdictional over Daimler in California despite its subsidiary's sales of $4.6 billion in the state, because "the same global reach would presumably be available in every other State in which [the subsidiary's] sales are

sizable. Such exorbitant exercises of all-purpose jurisdiction would scarcely permit out-of-state defendants 'to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit'") (citing *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985)).

The ruling in *Daimler* has since had significant implications for the application of general jurisdiction on defendants in product liability litigation and other actions alike. Recent cases analysing jurisdiction under *Daimler*'s framework show that it is "incredibly difficult to establish general jurisdiction in a forum other than the place of incorporation or principal place of business". *Monkton Ins. Servs., Ltd. v. Ritter*, 768 F.3d 429, 432 (5th Cir. 2014).

Indeed, in *BNSF Ry. Co. v. Tyrrell*, the Supreme Court recently reaffirmed *Daimler* and further demonstrated the narrow circumstances under which general jurisdiction over a defendant may be found. Specifically, 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 BNSF had over 2,000 miles of railroad track and more than 2,000 employees in the state. 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. 137 S. Ct. 1549, 1554, 1559 (2017).

Other courts have recently reached similar conclusions. *See, e.g., Hood v. Ascent Med. Corp.*, 691 F. App'x 8, 10–11 (2d Cir. 2017) (general jurisdiction in New York inapplicable to a medical supplies company registered in Oman that was operating an office and conducting product sales in New York); *Martinez v. Aero Caribbean*, 764 F.3d 1062, 1064–65 (9th Cir. 2014) (general jurisdiction in California did not attach to a French airplane manufacturer that had no physical presence and was not licensed to do business in that forum, even though the manufacturer purchased parts from California suppliers, advertised there, and had multimillion-dollar contracts to sell planes to a California corporation).

However, subsequent to *Daimler*, courts have continued to differ with regard to whether registering to do business in a state is sufficient to establish general jurisdiction over a corporation. Notably, certain courts enforce state statutes providing that registering to do business in the forum state confers "consent" to general jurisdiction in that forum. *See, e.g.*, *Bors v. Johnson & Johnson*, 208 F. Supp. 3d 648, 653 (E.D. Pa. 2016); *see also Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, 78 F. Supp. 3d 572, 588 (D. Del. 2015), *aff'd*, 817 F.3d 755 (Fed. Cir. 2016), *cert. denied sub nom. Mylan Pharm. v. Acorda Therapeutics*, 137 S. Ct. 625 (2017) ("*Daimler* does not eliminate consent as a basis for a state to establish general jurisdiction over a corporation which has appointed an agent for service of process in that state, as is required as part of registering to do business in that state"). By contrast, an influential Delaware state court recently held that registering to do business and maintaining an agent for service of process in a state alone does not establish general jurisdiction. *See Genuine Parts Co. v. Cepec*, 137 A.3d 123, 148 (Del. 2016) (no general jurisdiction over Georgia corporation that registered to do business in compliance with a Delaware registration statute; compliance with the statute did not constitute "consent" to the general jurisdiction of the Delaware courts).

Specific Jurisdiction

Specific jurisdiction may attach over a dispute that arises out of the company's direct or indirect activities in the forum state. *See Int'l Shoe*, 326 U.S. at 316.

The U.S. Supreme Court's 2017 decision in *Bristol-Myers Squibb Co. v. Superior Court of Calif.* (*BMS*) changed the rules of specific jurisdiction in product liability and mass tort litigation by greatly limiting the available forums for plaintiffs to file lawsuits to those in which the specific plaintiff herself has contacts with the forum. BMS 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 in, 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. The Court found that the actions of plaintiffs and their connections to the forum – and not just the actions of the defendant in selling products in California – were relevant to the inquiry. *Id.* at 1781.

District courts have consistently applied *BMS*, putting the proverbial "nail in the coffin" to forum shopping by out-of-state plaintiffs. *See, e.g.*, *Jordan v. Bayer Corp.*, 4:17-cv-00865, 2018 WL 837700 (E.D. Mo. Feb. 13, 2018) ("[S]ince *Bristol-Myers Squibb* . . . judges in this district have held that the issue of personal jurisdiction is now the more straightforward inquiry."); *Dyson v. Bayer Corp.*, 4:17-cv-02584, 2018 WL 534375 (E.D. Mo. Jan. 24, 2018); *Covington v. Janssen Pharm., Inc.*, No. 4:17-CV-1588, 2017 WL 3433611, at *6 (E.D. Mo. Aug. 10, 2017); *Spratley v. FCA US LLC*, No. 3:17-CV-0062, 2017 WL 4023348, at *7 (N.D.N.Y. Sept. 12, 2017). These decisions have a significant impact for product liability defendants who manufacture and sell products nationwide, and who can no longer be dragged into unfavourable or inconvenient forums by plaintiffs whose claims have little or no connection to those forums.

Federal Preemption

Where state law conflicts with federal law, state law is preempted under the Supremacy Clause of the U.S. Constitution. U.S. Const. art. VI, cl. 2. In deciding whether a claim is preempted, courts determine whether Congress intended the federal law at issue to supplant state law. *See, e.g., Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992). Preemption may be expressed in an explicit provision of federal law or implied in the structure and scope of the federal regulatory scheme. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Preemption with respect to pharmaceutical products and medical devices approved by the U.S. Food and Drug Administration ("FDA") has continued to receive considerable attention from federal courts, and will continue to evolve in 2018.

Pharmaceutical Preemption

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

Plaintiffs asserted three bases on which the manufacturers could have independently modified the warnings: (1) by using FDA's changes-being-effected ("CBE") process; (2) by sending Dear

Doctor letters to physicians; or (3) by proposing stronger warnings to the FDA. *Id*. at 614–16. The Court rejected the first two bases, noting FDA's position that a generic drug maker – unlike a brand name manufacturer – could not unilaterally strengthen its labelling by using the CBE process or disseminating a Dear Doctor letter. *Id*. at 614–15. As to the third basis, the FDA, writing as *amicus curiae*, urged the Supreme Court to hold that there was no true "impossibility" of complying with federal and state law, because it was undisputed that the manufacturers could ask the FDA to strengthen the warnings but had never done so; absent such a request, plaintiffs and the FDA contended the manufacturers' preemption defence should fail. *Id*. at 620. The Court rejected this argument, because even if the generic manufacturer had proposed different labelling from the FDA, it was not clear that the agency, in exercise of its public health judgment, would have agreed and permitted the new warning. *Id.* at 619–20. "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id*. at 623–24.

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

Subsequent to *Mensing* and *Bartlett*, manufacturers of generic and brand name pharmaceuticals have continued to succeed in arguing that state law tort claims are likewise subject to "impossibility preemption". *See, e.g., Beswick v. Sun Pharm. Indus., Ltd.,* No. 10-CV-00357A, 2018 U.S. Dist. LEXIS 15012, at *18, 23 (W.D.N.Y. Jan. 30, 2018) (holding that plaintiffs' warranty claims were essentially "state law tort claims attacking a drug label warning as insufficient" and echoing *Mensing* that stopping sales would make impossibility preemption "all but meaningless" (citation omitted)); *Cerveny v. Aventis Inc.*, 855 F.3d 1091, 1099, 1105 (10th Cir. 2017) (holding plaintiffs' failure-to-warn claim preempted because it would have been impossible for Aventis to comply with both FDA regulations and state law); *Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 298-300 (6th Cir. 2015) (holding claims preempted because "once a drug, whether generic or brand-name, is approved [by the FDA], the manufacturer is prohibited [by federal law] from making any major changes to the qualitative or quantitative formulation of the drug product . . .", and the plaintiff's additional argument that the defendant could have utilised a different design "in the first instance" *before* obtaining FDA approval was "too attenuated"); *Houston v. U.S.*, 638 F. App'x 508, 513 (7th Cir. 2016) (rejecting failure to warn, design defect, negligence, and other product liability claims because "[f]ederal law imposes on [a generic drug manufacturer] an 'ongoing duty of sameness' to ensure that [a drug's] chemical design and labeling are the same as its brand-name counterpart", and "[t]he duty preempts a state-law claim against a generic manufacturer if, as here, that claim would require the manufacturer to redesign its drug, change its labeling, or exit the market in order to avoid liability"). *But see, e.g., In re Fosamax Prods. Liab. Litig.*, 852 F.3d 268, 293 (3d. Cir. 2017) (reversing the district court's ruling that the plaintiffs' claims were preempted due to FDA's denial of additional warnings to the drug's label regarding the risk of femur fractures, and holding that what FDA would have done had plaintiffs' requested warnings been presented to FDA was a question for the jury); *Guidry v. Janssen Pharms., Inc.*, 206 F. Supp. 3d 1187, 1206-08 (E.D. La. 2016) (holding that "[a]ny state requirement that a brand name drug manufacturer should have adopted an alternative design to a prescription drug *after* it was approved by the FDA is preempted", but rejecting "the Sixth Circuit's reasoning in *Yates* concerning preemption in the *pre*-FDA approval context", and holding that "[f]ederal law does not prevent a drug manufacturer from complying with this state-imposed duty [to consider feasible, alternative designs] before seeking FDA approval") (emphasis added).

In the past year, there have been several noteworthy opinions addressing whether design defect claims are preempted where a manufacturer can unilaterally change the design of its drug prior to FDA approval. In *Trejo v. Johnson & Johnson*, 13 Cal. App. 5th 110, 155–56 (2017), the court reversed the district court's opinion and held that a plaintiff's design defect claim was preempted where it sought changes that severely altered that drug's chemical composition and would have required preapproval by the FDA. There, the plaintiff had argued the manufacturer should have withdrawn its product (Motrin) from the market and changed its chemical compound, and the jury had found the defendant strictly liable for a defective design. The court of appeals reversed judgment, finding that based on *Yates*, a design defect claim is preempted where it seeks design changes that would significantly alter the chemical composition and require FDA preapproval.

But, the court in *In re Xarelto Prods. Liab. Litig.,* MDL No. 2592, 2017 WL 1395312, at *3–4 (E.D. La. April 13, 2017) came to a different conclusion. There, the court held that design defect claims were not preempted because state and federal law are "complimentary". The court found that Louisiana law "imposes a duty on all manufacturers to consider feasible, alternative designs and reasonably weigh the risks and utility of the final product before it leaves the manufacturer's control [and] [f]ederal law does not prevent a drug manufacturer from complying with this state-imposed duty before seeking FDA approval". The court also concluded that the defendant could have strengthened the label post-approval.

The FDA had previously proposed a rule that would permit generic drug manufacturers to unilaterally change their product labels through the CBE process, which, as discussed in *Mensing*, is currently only available to brand-name manufacturers. The rule, originally introduced in 2013, was supposed to be finalised in April 2017. *See* Federal Register, "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products", available at www.federalregister.gov/documents/2013/11/13/2013-26799/supplemental-applications-proposing-labeling-changes-for-approved-drugs-and-biological-products (last visited Jan. 25, 2017); Office of Information and Regulatory Affairs, "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products", available at www.reginfo.gov/public/do/eAgendaViewRule?pubId=201604&RIN=0910-AG94 (last visited Jan. 25, 2017). If implemented, the rule change would have significantly curtailed preemption of failure to warn claims brought against generic manufacturers, who could no longer argue the inability to independently supplement product warnings. The FDA, however, withdrew the rule on Sep. 29, 2017. *See* Federal Register, "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological

Products", 83 Fed. Reg. 1867 (Jan. 12, 2018) (withdrawn Sep. 29 2017). It is not certain whether this rule will be re-introduced, and companies should continue to monitor the legislation.

Buckman Preemption

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

For instance, in 2013, the Ninth Circuit held that federal law did not impliedly preempt Arizona state law failure-to-warn claims predicated on a medical device manufacturer's alleged failure to "report to the FDA any complaints about the product's performance", about which the product's labelling did not otherwise warn. *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. *See also McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1040 (9th Cir. 2015) (negligent failure to warn and strict liability claims based on inadequate warnings were not preempted under *Buckman*, because the plaintiff's claims were not for "fraud-on-the-agency", but rather were "parallel" to federal law).

More recently, in *In re Incretin*, the Ninth Circuit analysed claims that defendants did not adequately warn plaintiffs about the risk of pancreatic cancer in connection with prescription diabetes drugs. *In re Incretin-Based Therapies Prod. Liab. Litig.* No. 15-56997, 2017 WL 6030735 (9th Cir. Dec. 6, 2017). The district court granted summary judgment in favour of the defendants, holding that plaintiffs were relying on "fraud-on-the-FDA" allegations that were preempted under *Buckman*. *In re Incretin*, 2017 WL 603075, at *2. The Ninth Circuit reversed and remanded, however, holding that plaintiffs were *not* seeking discovery under a "fraud on the FDA" theory, but instead were pursuing a traditional failure-to-warn claim like in *Stengel*. *Id.* (citing *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (*en banc*)).

The Ninth Circuit's decisions continue to depart from the holding of some other courts that allegations that a manufacturer "failed to provide the FDA with sufficient information and did not timely file adverse event reports, as required by federal regulations" are "foreclosed by [the FDCA] as construed in *Buckman*". *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205–06 (8th Cir. 2010). *See also, e.g., Cerveny v. Aventis Inc.*, 855 F.3d 1091, 1099, 1105 (10th Cir. 2017) (failure to warn claim was preempted because the FDA would not have approved an additional warning about the risks of taking the drug (Clomid) prior to pregnancy and FDA's conclusion "controls here"); *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1010 (S.D. Ohio 2016) (failure to warn, negligence, and product liability claims were impliedly preempted, because "[a]ny tort claim based on an alleged failure to submit adverse-event reports to the FDA would not be relying on traditional state tort law which had predated the FDCA") (internal quotation omitted); *Pearsall v. Medtronics, Inc.*, 147 F. Supp. 3d 188, 202 (E.D.N.Y. 2015) (declining to follow *Stengel*, because the "Plaintiff's failure to warn claim is predicated on Defendant's alleged failure to provide the required reports to the FDA", and "authority to enforce that claim rests with the FDA").

Express Preemption of Claims Against Manufacturers of Certain Medical Devices

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

Numerous federal courts of appeals and district 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 the plaintiff's design defect, breach of warranty, failure to warn, negligence, and negligent misrepresentation claims, because the plaintiff failed to offer a "parallel" federal requirement that had been violated); *Otis-Wisher v. Medtronic, Inc.*, 616 F. App'x 433, 434 (2d Cir. 2015) (affirming dismissal of design defect and failure to warn claims, because the plaintiff sought "to impose safety-related requirements on the device or its labeling beyond those imposed by the FDA"); *Burrell v. Bayer Corp*., 260 F. Supp. 3d 485, 491 (W.D.N.C. 2017) (appeal docketed June 12, 2017) (dismissing plaintiffs' design defect and failure to warn claims among others because Essure is a Class III medical device regulated by the FDA, and plaintiffs failed to fall within the "narrow gap" left open by *Buckman*); *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 – precisely the result that the MDA preemption provision seeks to prevent" (citation omitted)).

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

of the violation and demonstrate a causal connection to the alleged injuries, are all that is required to . . . avoid preemption under . . . *Riegel*") (emphasis in original).

Class Actions

"The class action is an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 348 (2011) (quotation omitted). Under Federal Rule of Civil Procedure 23, a plaintiff can proceed with claims on behalf of absent class members by demonstrating numerosity, commonality, typicality, and adequacy of representation, as set forth in Rule 23(a), and meeting at least one of the criteria in Rule 23(b). One common area of class litigation in recent years has been claims of consumer fraud, pursuant to which plaintiffs seek damages for economic losses based on a manufacturer's alleged misrepresentations about a product.

Claims of individual putative class members, particularly in the area of consumer fraud, often involve small potential recoveries. On their own, they may have a difficult time justifying the legal costs required to obtain recovery; however, if class certification is granted, the overall, classwide recovery and attorneys' fees available in these cases can be significant. *See, e.g., Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 617 (1997) ("The policy at the very core of the class action mechanism is to overcome the problem that small recoveries do not provide the incentive for any individual to bring a solo action prosecuting his or her rights. A class action solves this problem by aggregating the relatively paltry potential recoveries into something worth someone's (usually an attorney's) labor") (citation omitted). As such, denial of class certification or resolution of a case prior to class certification can be critical for corporate defendants.

In recent years, courts have continued to clarify the circumstances under which they will allow litigation to proceed on behalf of proposed classes.

Article III Standing for Injunctive Relief

The doctrine of standing serves to determine which matters brought before federal courts qualify as justiciable cases or controversies within the requirements of Article III of the U.S. Constitution. *See* U.S. Const. art. III. § 2. Among other Article III standing requirements, a plaintiff must show that it is likely that his or her injury will be "redressed" by a favourable decision by the court. The party invoking federal jurisdiction must demonstrate constitutional standing separately for each form of relief requested. *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 185 (2000). In the context of putative class actions, named plaintiffs must individually demonstrate that they have standing to seek the relief sought. *Warth v. Seldin*, 422 U.S. 490, 502 (1975) ("Petitioners must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent").

Recently, federal courts have grappled with the issue of standing as it applies to injunctive relief sought by class action plaintiffs asserting consumer fraud claims. The issue often arises where individual plaintiffs allege that they purchased a product based on a misrepresentation later learned to be deceptive or misleading, and seek injunctive relief in the form of a court order enjoining the product manufacturer from continuing the complained of practice, for example by ending a "misleading" advertising campaign. The standing issue arises in part because injunctive relief is a forward-looking remedy, seeking to stop behaviour that may cause individual consumers future harm. When such prospective relief is sought, a named plaintiff who now knows of the deceptive behavior and has no intention of buying the product in the future must nevertheless show that "he [i]s likely" to suffer that future harm, and that the injunctive relief sought would therefore "redress" his injury. *See City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983). In recent years, federal courts of appeals have differed in their approaches to Article III standing under these circumstances.

On one hand, several circuits embrace the argument that consumer plaintiffs lack standing because they are in actuality "former" customers who now know of the defendant's allegedly deceptive practice, and are not in any danger of being mislead in the future. In *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220 (2d. Cir. 2016), for instance, plaintiff brought a putative class action arising out of Amazon's sale of a weight loss pill, alleging that the product contained an undisclosed amount of a stimulant drug that had been removed from the market by the FDA due to an association with cardiovascular risks. *Id.* at 226–27. The district court granted Amazon's motion to dismiss, in part because the plaintiff lacked standing to seek injunctive relief. On appeal, the Second Circuit affirmed, because Plaintiff had not adequately shown that he would be subject to any future injury. *Id.* at 239. The Court explained that by the time of the lawsuit, Amazon had taken the particular product off the market, and Plaintiff did not allege that he would purchase *any* Amazon products in the future, let alone the complained-of diet pill. *Id.*; *see also, e.g., Kommer v. Bayer Consumer Health*, – F. App'x –, 2018 WL 627498, at *1 (2d Cir. Jan. 31, 2018) (affirming dismissal of plaintiff's complaint and rejecting request for injunctive relief because "[a]s [plaintiff] concedes, now that he knows of Defendants' alleged deception and false advertising, . . . he is no longer likely to purchase another [of Defendants' products] ever again. . . . Accordingly, he has no standing under Article III to enjoin the defendants' sales practices") (internal quotations omitted); *McNair v. Synapse Group Inc.*, 672 F.3d 213, 224–25 (3d Cir. 2012) (injunctive relief inappropriate where plaintiffs "h[ad] effectively acknowledged that they, unlike the class members they [sought] to represent, [were] not Synapse customers and are thus not [] subject to Synapse's allegedly deceptive techniques for obtaining subscription renewals. . . . Perhaps they may accept a Synapse offer in the future, but, speaking generally, the law accords people the dignity of assuming that they act rationally, in light of the information they possess"); *Ulrich v. Probalance, Inc*., No. 16 C 10488, 2017 WL 3581183, at *7 (N.D. Ill. Aug. 18, 2017) ("Most courts to have considered the issue agree . . . that consumer plaintiffs cannot pursue injunctive relief if they are already aware of the alleged deceptive practice").

The Ninth Circuit Court of Appeals, however, recently broke from this trend and held that "a previously deceived consumer may have standing to seek an injunction against false advertising or labeling, even though the consumer now knows or suspects that the . . . advertisement or label was false in the past". *Davidson v. Kimberly-Clark Corp.*, 873 F.3d 1103, 1115 (9th Cir. 2017). In *Davidson*, plaintiff alleged that she had paid a premium for sanitary wipes that defendant had advertised as "flushable" but that she alleged could cause damage to home plumbing. She sought to represent a class of consumers of the wipes, seeking, *inter alia,* an injunction barring defendant from advertising its wipes as "flushable". The District Court dismissed plaintiffs' claims for injunctive relief, finding that that she "ha[d] no intention of purchasing the same Kimberly-Clark product in the future". *Id.* at 1112. However, the Ninth Circuit rejected the view that injunctive relief is never available to a consumer who learns that a label is false: "In some cases, the threat of future harm may be the consumer's plausible allegations that she

will be unable to rely on the product's advertising or labeling in the future, and so will not purchase the product although she would like to." *Id.* at 1115. The court also seemed to weigh the policy implications of denying standing under these circumstances. *Id.* at 1115–16 (explaining that "our holding alleviates the anomalies the opposite conclusion would create", and suggesting that finding no standing could effectively "gut" California's consumer protection laws). Kimberly-Clark petitioned the Ninth Circuit for a rehearing of the issue *en banc*.

The Ascertainability Requirement

In addition to the requirements of Federal Rule 23, certain courts have recognised an implicit "ascertainability" requirement for class certification. A plaintiff must demonstrate that class members are identifiable through objective criteria without resort to extensive and individualised inquiries. In part, ascertainability eliminates "serious administrative burdens that are incongruous with the efficiencies expected in a class action", protects absent class members by facilitating the "best notice practicable" in a Rule 23(b)(3) action, and protects defendants by ensuring that those who will be bound by the final judgment are identifiable. *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 593 (3d Cir. 2012) (citations omitted).

Conflicting decisions among the Courts of Appeals continue to muddy the waters regarding what standard should determine whether a class is "ascertainable". At one end of the spectrum, the Third Circuit has imposed a heightened ascertainability requirement that requires plaintiffs to demonstrate an "administratively feasible mechanism" for identifying putative class members. *See Byrd v. Aaron's Inc.*, 784 F.3d 154, 169–70 (3d Cir. 2015) (a class must be defined by (1) objective criteria, and (2) via an administratively feasible method).

However, a number of other appellate courts have rejected this "heightened" ascertainability standard. Specifically, the Sixth, Seventh, Eighth, and Ninth Circuits have ruled that plaintiffs do not have to meet the "administrative feasibility" standard, and instead a class merely must be defined by objective criteria. *Rikos v. Procter & Gamble Co.*, 799 F.3d 497, 525-26 (6th Cir. 2015); *Mullins v. Direct Digital, LLC*, 795 F.3d 654, 659-60 (7th Cir. 2015); *Sandusky Wellness Ctr., LLC v. Medtox Sci., Inc.*, 821 F.3d 992, 995–96 (8th Cir. 2016); *Briseno v. ConAgra Foods, Inc.*, 844 F.3d 1121, 1125-26 (9th Cir. 2017).

Two recent decisions from the Second Circuit highlight the varying applications of the ascertainability requirement. Prior to 2017, the Second Circuit appeared to have joined the Third Circuit in embracing the "administrative feasibility" requirement. *See Brecher v. Republic of Argentina*, 806 F.3d 22, 24 (2d Cir. 2015) ("A class is ascertainable when defined by objective criteria that are administratively feasible"). This same standard was applied by the Second Circuit in February 2017 in affirming a lower court's decision to deny class certification in *Leyse v. Lifetime Entm't Servs., LLC*, 679 F. A'ppx 44, 47 (2d Cir. 2017) (citing *Brecher*). The plaintiff in *Leyse* proposed identifying class members by soliciting individual affidavits; however, the court affirmed the trial court's finding that such a method was not administratively feasible. *Id.* at 47. Despite what appeared to be growing Second Circuit precedent, the court reversed course in its July 2017 decision in *In re Petrobras Sec. Litig.*, 862 F.3d 250 (2d Cir. 2017). In *Petrobras*, the court explicitly noted that "*Brecher* did not create an administrative feasibility requirement". *Id.* at 269. Instead, the court relied on precedent from other circuits rejecting the "administrative feasibility" standard, and affirmed the lower court's finding that the class was ascertainable as long as the class was defined by objective criteria. *Id.*

In *Briseno*, the Ninth Circuit similarly upheld the district court's ruling that plaintiffs need only define a class by an objective criterion. *Briseno*, 844 F.3d at 1132–33. Central to the court's ruling was the plain meaning of Rule 23, which does not explicitly include an "administrative feasibility" requirement: "Because the drafters specifically enumerated '[p]requesites', we may conclude that Rule 23(a) constitutes an exhaustive list." *Id.* at 1125. The court also rejected arguments that the heightened ascertainability standard was necessary to "mitigate the administrative burdens of trying a Rule 23(b)(3) class action", to protect absent class members from fraudulent claims, or to protect defendants' rights. *Id.* at 1127–29. The U.S. Supreme Court declined to grant *certiorari* in *Briseno* on October 10, 2017, leaving district and appellate courts to continue to grapple with this issue.

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Given the massive implications that class certification has on the potential value of consumer fraud lawsuits pertaining to the purchases of inexpensive products, courts' efforts to clarify the criteria for certification, including with regard to Article III standing and ascertainability, will continue to have significant implications for product manufacturers.

Multidistrict Litigation (MDL) Trends

The nature of product liability litigation can lead to plaintiffs filing a large 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 an unwieldy and expensive process for plaintiffs and defendants alike. As a result, at times, 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, by 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 is "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.

To form an MDL, one of the parties petitions the Judicial Panel on Multidistrict Litigation or "JPML", which is comprised of seven sitting federal judges tasked with making determinations on MDL centralisation. The JPML also decides the venue for the MDL and the judge who will preside over it. If the JPML grants the petition, all related federal cases are transferred to the JPML's chosen venue and judge for pretrial proceedings. *See* 28 U.S.C. § 1407. Once the MDL is created, the JPML makes no procedural or substantive decisions in the case; instead the JPML defers to the transferee court.

As of December 31, 2017, there were 221 active MDLs. *See* U.S. JPML, Calendar Year Statistics, Jan. through Dec. 2017, available at http://www.jpml.uscourts.gov/sites/jpml/files/JPML_Calendar_Year_Statistics-2017.pdf (last visited Feb. 13, 2018). Although this number is significant, there has been a trend over the last several years against centralisation. For example, in 2009, the JPML granted more than 80 per cent of MDL petitions. In 2017, however, the panel granted fewer than 50 per cent of the petitions before it (19 of 40). *Id.* In fact, the 19 MDLs created in 2017 constituted the lowest number in more than 25 years. *Id.* Despite the overall trend against centralisation, the JPML continues to create more MDLs in product liability litigation than in any other type of case. Of the 221 currently pending MDLs, 70 of them (31.7 per cent) are classified by the JPML as "Products Liability" litigation. *Id.*

Factors in JPML Decisions Whether to Create an MDL

Pursuant to 28 U.S.C. § 1407(a), the Panel is authorised to create an MDL "upon its determination that transfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions. . . ". In applying this flexible standard, the Panel often considers the following factors:

Number of actions. The JPML considers the number of actions filed (or potentially to be filed) when deciding whether to certify an MDL. In cases where there are a small number of filed actions, the petitioner "bears a heavier burden to demonstrate that centralization is appropriate". *In re Xytex Corp. Sperm Donor Prod. Liab. Litig.*, 223 F. Supp. 3d 1351, 1352 (JPML 2016) (MDL certification denied); *In re California Wine Inorganic Arsenic Levels Prods. Liab. Litig.*, 109 F. Supp. 3d 1362, 1363 (JPML 2015). Even where there are common factual issues, a small number of cases and the potential for informal coordination between the parties are often weighed against centralisation. *See id.* At times, the JPML will consider the number of unfiled cases, but that is not always sufficient to sway the Panel. *See In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.* ("*In re Mirena IUS No. 1*"), 38 F. Supp. 3d 1380, 1381 (JPML 2014) ("[a]lthough plaintiffs assert that the number of actions is likely to expand substantially, the mere possibility of additional actions does not convince us that centralisation is warranted"); *but see In re AndroGel Prods. Liab. Litig.*, 24 F. Supp. 3d 1378, 1379 (JPML 2014) (MDL certification granted where "related cases will number in the thousands").

Number of counsel and informal coordination. In cases where many of the plaintiffs are represented by the same counsel and there are a limited number of defense counsel, the JPML has promoted voluntary coordination as a preferable alternative to centralisation through an MDL. *In re Sorin 3T Heater-Cooler System Prods. Liab. Litig.*, 273 F. Supp. 3d 1357 (JPML 2017); *In re Mirena IUS No. 1*, 38 F. Supp. 3d at 1381.

Pending 28 U.S.C. § 1404 requests for transfer. Under 28 U.S.C. § 1404, the parties can move to transfer a lawsuit to another district court. The JPML strongly prefers the transfer of cases to the same district court rather than centralising the cases in an MDL. *In re 3M Company Lava Ultimate Prods. Liab. Litig.*, 222 F. Supp. 3d 1347, 1348 (JPML 2016) ("transfer under Section 1404 is preferable to centralization").

Procedural posture of existing cases. The JPML has not been consistent on whether the maturity of a litigation weighs in favour of or against centralisation. *Compare, e.g., In re Yellow Brass Plumbing Component Prods. Liab. Litig.*, 844 F. Supp. 2d 1377, 1379 (JPML 2012) (MDL certification denied; "relatively advanced progress" of one action would inconvenience parties), *with In re Mirena IUS No. 1*, 38 F. Supp. 3d at 1381 (MDL certification denied; cases that "are in their infancy" are less likely to be centralised and "are well-positioned for informal coordination"); *see also In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. ("In re Mirena IUS No. 2")*, 249 F. Supp. 3d 1357, 1360-61 (JPML 2017) (creating an MDL and deferring to the transferee judge to formulate pretrial procedures that take into account differences in the procedural postures of the cases in the MDL). The JPML recently decided not to certify an MDL of cases involving the drug Cymbalta, where the procedural posture of the 41 personal injury actions varied significantly. Some of the actions had already gone to trial with millions of pages in discovery produced, whereas others did not even have scheduling orders. *In re Cymbalta (Duloxetine) Prods. Liab. Litig. (No. II)*, 138 F. Supp. 3d 1375, 1376 (JPML 2015). But in cases related to talcum powder products, the advanced nature of related state court proceedings weighed in favour of creating an MDL, because, the JPML held, the MDL judge could use the prior state court discovery as a guide to resolve similar discovery issues in the federal actions. *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Prods. Liab. Litig.*, 220 F. Supp. 3d 1356, 1358 (JPML 2016).

Need for individual fact determinations. If a party demonstrates that individualised factual issues will predominate in the litigation, the JPML is more likely to deny MDL centralisation. In *In re Proton Pump Inhibitor Prod. Liab. Litig. No. 1*, the JPML denied centralisation of cases against manufacturers of proton pump inhibitors, in part because a significant amount of discovery would be defendant-specific, arising from each drug's "unique development, testing, and marketing history". 273 F. Supp. 3d 1360 (JPML 2017). The case came back to the JPML a few months later, and this time the JPML ordered centralisation because the defendants no longer opposed centralisation, the number of cases had grown, the actions all shared certain factual issues and involved the same kinds of injuries, and several plaintiffs took more than one drug at issue. *In re Proton Pump Inhibitor Prods. Liab. Litig. No. 2*, 261 F. Supp. 3d 1351, 1354 (JPML 2017). The factual similarities, therefore, generated enough overlap for the JPML to order centralisation.

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In short, the rule governing whether the JPML will create an MDL is extremely flexible, often allowing the Panel to weigh the same factors for or against centralisation depending on the outcome that the Panel believes will best serve the parties and courts in a given scenario.

The JPML's decision whether or not to establish an MDL can have significant implications, as the creation of an MDL can encourage the filing of additional lawsuits, place pressure on defendants faced with hundreds or thousands of cases to consider settlement, and raise the stakes of transferee court decisions that may impact the outcome of many or all cases pending in an MDL.

Factors in JPML Decisions Regarding Where to Send an MDL

Once the JPML decides to create an MDL, it also has broad discretion in determining the court and judge before which the cases will be centralised. Indeed, there is no rule governing that aspect of the JPML's decision. Factors often considered include the court in which the largest number of cases are pending, the courts in which cases have already progressed the furthest, where cost and inconvenience will be minimised, and the experience, skill, and caseloads of available judges. Manual for Complex Litigation (Fourth) § 20.131 (2010). Again, the JPML has significant leeway to utilise those and other factors in different ways to fit the desired outcome in a given case. *Compare, e.g., In re 100% Grated Parmesan Cheese Mktg. & Sales Practices Litig.*, 201 F. Supp. 3d 1375, 1379 (JPML 2016) ("centralization in this district allows us to assign the litigation to Judge Gary Feinerman, an able and experienced jurist who has not had the opportunity to preside over an MDL"), *with In re: Fluoroquinolone Prods. Liab. Litig.,* 122 F. Supp. 3d 1378, 1381 (JPML 2015) (assigning MDL to a judge in part because his "experience in overseeing [another MDL] will benefit the parties and facilitate the just and efficient conduct of this litigation").

Industry/Class-Wide MDL Certification

Plaintiffs have increasingly brought class-wide or industry-wide product liability lawsuits alleging that a class of products sold by several different pharmaceutical manufacturers has caused similar injuries in hundreds or thousands of people. At first glance, these class-wide lawsuits appear to be prime candidates for an MDL. They

typically involve a large number of plaintiffs and have a common set of factual issues because the plaintiffs allege that the drugs treat the same conditions in the same or similar patient populations and act in a similar way in the body.

However, these cases have their own unique set of challenges for the JPML when deciding whether to create a class/industry-wide MDL, create an MDL for each product/manufacturer, or defer to some other method of coordination. One of the concerns with class/industry-wide litigation is the need to protect trade secrets and confidential information from disclosure among direct competitor manufacturers. For this reason, the JPML is "typically hesitant to centralize litigation against multiple, competing defendants which marketed, manufactured and sold similar products". *In re Yellow Brass*, 844 F. Supp. 2d at 1378; *In re Spray Polyurethane Foam Insulation Prods. Liab. Litig.*, 949 F. Supp. 2d 1364 (JPML 2013); *In re AndroGel*, 24 F. Supp. 3d at 1378. Another consideration is how cases that involve a plaintiff who has taken more than one of the implicated drugs will impact the decision to centralise. In recent years, the JPML has both granted and denied centralisation of class/industry-wide MDLs that raise these concerns:

- In *In re Fluoroquinolone Prods. Liab. Litig.*, plaintiffs requested centralisation of cases against the manufacturers and distributors of fluoroquinolone antibiotics, alleging peripheral neuropathy injuries. All defendants opposed centralisation. The JPML acknowledged, but dismissed, its hesitancy to centralise litigation on an industry-wide basis. Instead, the court relied on the virtually identical class warnings required by the FDA and the resulting shared factual questions regarding general causation, science, and regulatory issues in deciding to create the MDL. 122 F. Supp. 3d 1378, 1379 (JPML 2015).
- In *In re Invokana (Canagliflozin) Prods. Liab. Litig.*, plaintiffs alleged that SGLT-2 inhibitors (a class of anti-diabetes medication) caused injuries such as diabetic ketoacidosis and kidney damage. The SGLT-2 inhibitors were manufactured by several competing drug companies, but the majority of the lawsuits were filed against Janssen for Invokana/Invokamet. Plaintiffs proposed either an Invokana/Invokamet-only MDL or a class-wide MDL, and defendants opposed one or both proposals. The JPML created an Invokana/Invokamet-only MDL, and declined to include combination-use cases involving Invokana and another SGLT-2 inhibitor, citing concerns about protecting market competitors' trade secrets and confidential information, and prolonging pretrial proceedings with the need for separate discovery tracks. The court also mentioned the "relatively small number" of cases involving the other non-Janssen drugs as grounds for excluding the other manufacturers from the MDL. 223 F. Supp. 3d 1345, 1348 (JPML 2016).
- In *In re Proton Pump Inhibitor Prods. Liab. Litig. No. I*, plaintiffs alleged that various proton pump inhibitors manufactured by different defendants caused kidney injuries, including acute interstitial nephritis, chronic kidney disease, end-stage renal disease, and kidney failure. The JPML initially declined to centralise the actions into an MDL relying in part on the justification that the defendants were competitors in the market; "[c]entralizing competing defendants in the same MDL likely would complicate case management due to the need to protect trade secrets and confidential information". 273 F. Supp. 3d at 1360. In re-considering the case, however, the JPML established an MDL, this time brushing over the concerns of competition and trade secrets, seemingly because, at that point, the defendants all supported centralisation. *In re Proton Pump Inhibitor Prods. Liab. Litig. No. 2*, 261 F. Supp. 3d at 1354.

Multi-Plaintiff Trials after MDL Certification

Although the parties have the right to have their cases remanded to their originating courts for trial, with the consent of the parties, an MDL judge often selects a few cases to be tried. These "bellwether" trials are intended to be representative of the range of cases in the MDL. *See Manual for Complex Litigation, Fourth*, § 22.315. The goal is for the bellwether cases to promote judicial efficiency by allowing the court and parties to determine the nature and strength of the claims, and provide ranges of values for possible settlement. *Id*.

Typically, MDL courts try individual cases as bellwethers, but a recent trend has developed of consolidating or "batching" cases for trial. FRCP 42(a) grants courts the broad discretion to consolidate cases for trial "[i]f actions before the court involve a common question of law or fact", and certain MDL judges have taken full advantage of this rule.

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

Many of these consolidated trials have resulted in sizeable plaintiffs' verdicts, which defendants have appealed, arguing that grouping trials encourages unfair outcomes. Boston Scientific appealed a $27 million verdict won by four plaintiffs in a pelvic floor repair kit suit, but the Eleventh Circuit rejected the argument that plaintiffs' cases were too distinct to be consolidated in a single bellwether trial and that the jury became confused as a result. Accordingly, the Court held that the trial court did not abuse its discretion to consolidate the cases. *Eghnayem v. Boston Sci. Corp.*, 873 F.3d 1304, 1314 (11th Cir. 2017). Johnson & Johnson is appealing a $150 million verdict (reduced from a $502 million jury verdict) awarded to five plaintiffs in the *DePuy* hip implant multi-plaintiff bellwether trial, a $543 million verdict (reduced from a $1 billion jury verdict) awarded to six plaintiffs in another multi-plaintiff trial, and a $247 million verdict awarded to six more plaintiffs. Shayna Posses, "J&J Can't Speed Up Appeal in Hip MDL, Patients Tell 5th Circ.", Law360, July 26, 2016; Tina Bellon, "Johnson & Johnson Hit With $247 Million Verdict in Hip Implant Trial", Thomson Reuters, Nov. 16, 2017.

The potential confusion and prejudice that arises when mixing different plaintiffs' facts presents obvious concerns for defendants, particularly in light of these sizable plaintiffs' verdicts in consolidated bellwether trials. It remains to be seen whether additional appellate courts will reject or affirm the use of consolidated bellwether trials.

What to Watch in 2018: The Opioid Crisis MDL

In December 2017, the JPML centralised cases in which plaintiffs alleged improper marketing and distribution of prescription opiate medications across the United States. *In re National Prescription Opiate Litig.*, MDL No. 2804, 2017 WL 6031547 (JPML Dec. 5, 2017). The MDL, pending in the Northern District of Ohio, involves

numerous cities, counties, and states, including political divisions, that allegedly have been damaged by widespread addiction to narcotic painkillers. Most of the actions have been filed against three defendants who distribute over 80% of the drugs at issue in the case, although several additional defendants have been sued in certain of the centralised cases. In establishing the MDL, the JPML cast aside concerns about the diversity of plaintiffs and injuries, and found that common questions of fact predominate. The JPML, perhaps cognizant of the MDL's far-reaching impact, warned that "this litigation might evolve to include additional categories of plaintiffs and defendants, as well as different types of claims", thus foreshadowing a potentially massive MDL that will likely take years to resolve. *Id.* at *3.

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Although the overall number of MDLs being established has diminished in recent years, they continue to play a significant role in products liability litigation. Through industry-wide MDLs, multi-plaintiff bellwether trials, or simply the pooling of hundreds or thousands of cases together for settlement considerations, MDLs can have an immense impact on product manufacturers and other defendants faced with these centralised cases.

Admissibility of Expert Causation Testimony

Product liability cases "involving pharmaceuticals, toxins or medical devices involve complex questions of medical causation beyond the understanding of a lay person, and thus expert testimony is required". *In re Mirena IUD Prod. Liab. Litig.,* 202 F. Supp. 3d 304, 311 (S.D.N.Y. 2016) (internal citations omitted) *aff'd*, No. 16-2890-CV(L), 2017 WL 4785947 (2d Cir. Oct. 24, 2017). In most jurisdictions, expert testimony is required in a product liability action for the plaintiff to satisfy his or her burden of proof on the issue of whether the product caused the alleged injury. Moreover, in pharmaceutical and toxic tort cases, a plaintiff generally is required to show by expert testimony both that exposure to a substance can cause a particular injury (general causation), and that such exposure was a cause of his or her individual injury (specific causation).

To ensure that any and all expert testimony is based on a reliable methodology and helpful to the trier of fact, the rules of evidence impose a "gatekeeping" responsibility on trial courts. Courts exercise their gatekeeping function by excluding unsubstantiated and unreliable expert testimony and ensuring that the jury only hears reliable scientific principles, methods and results. Although all federal courts and most state courts apply the rigorous standard for admissibility of expert testimony set forth in *Daubert v. Merrell Dow Pharms, Inc.*, 509 U.S. 579, 589, 592–93 (1993), some state courts apply their own varying standards. No matter the standard applied, the exclusion of expert testimony can have profound effects on litigation at any phase. The following notable cases of 2017 highlight the significant and dispositive impact *Daubert* rulings can have in complex medical and scientific cases.

In re Mirena IUD Products Liability Litigation. In the *Mirena* litigation, plaintiff-appellants claiming secondary uterine perforation following insertion of an intrauterine device (IUD) asserted product liability claims against the device manufacturer. The key issue in dispute was general causation – *i.e.* whether Mirena *can* cause the injury alleged. *In re Mirena IUD Prod. Liab. Litig.,* No. 16-2890-CV(L), 2017 WL 4785947, at *1 (2d Cir. Oct. 24, 2017). Plaintiffs proffered three general causation experts, but the District Court excluded all three purported experts for failing to meet the *Daubert* standard because "their testimony was not reliable and thus not helpful to the trier of fact". *Id*. Following its *Daubert* ruling, the District Court granted an MDL-wide summary judgment motion because plaintiffs could not prove that secondary perforation could occur from Mirena. *In re Mirena IUD Prods. Liab. Litig.*, 202 F. Supp. 3d at 327–28.

Plaintiffs-appellants appealed both decisions to the United States Court of Appeals for the Second Circuit. The Second Circuit affirmed both District Court decisions and, in so doing, highlighted three "particularly noteworthy" problems with the opinions offered by plaintiffs' general causation experts. *In re Mirena IUD Prod. Liab. Litig.,* 2017 WL 4785947, at *2. First, the experts' theories were not accepted in the wider obstetrics and gynecological scientific community. *Id.*, at *3. "Not only do the experts fail to identify any authorities that directly support the existence of secondary perforation, but what scientific authority there is casts doubt on the phenomenon's existence." *Id.* Second, the experts "developed their theories for the purposes of this litigation". *Id.* And third, "finding no direct support in the literature for secondary perforation and having conducted no prior research on the subject, the experts all assumed the existence of the very phenomenon in dispute and then hypothesized how it could occur". *Id.* Because the parties disputed whether secondary perforation had ever occurred, "[t]he experts thus begged the very question they were trying to answer". *Id.* Having concluded that the District Court properly excluded plaintiffs' general causation experts, the panel further agreed with the District Court's order granting the defendant's motion for summary judgment, finding that "no reasonable juror could find general causation more likely than not based on the Plaintiffs' admissible evidence". *Id.* at *4.

In re Accutane Litigation. Plaintiffs in 2,076 multicounty litigation cases in New Jersey state court brought products liability claims against the manufacturer of the prescription acne medication Accutane alleging that it caused them to develop Crohn's disease. Defendants, Hoffman–La Roche Inc. and Roche Laboratories Inc., filed a motion to bar the general causation testimony of plaintiffs' experts – a statistician and gastroenterologist. After conducting a hearing to determine the admissibility of plaintiffs' experts' opinions, the trial court granted the motion, concluding that under New Jersey's standard for admissibility of expert testimony (*Kemp*), Plaintiffs had the burden to demonstrate that the methodology used by their experts was "consistent with valid scientific principles accepted in the scientific and medical communities", and they had failed to do so. *In re Accutane Litigation*, No. 271, 2015 WL 753674 at *6 (N.J. Super. Ct. Law Div. Feb. 20, 2015). Although the trial court found that "both Plaintiffs' experts are eminently qualified", it determined that their reasoning and methodology is slanted away from objective science and in the direction of advocacy, making it unreliable. *Id.* at *17 ("the opinions expressed by Plaintiffs' experts are motivated by preconceived conclusions, and . . . they have failed to demonstrate that the data or information used were soundly and reliably generated and are of a type reasonably relied upon by comparable experts") (internal citations and quotation marks omitted). Accordingly, the court granted defendant's motion to exclude testimony of plaintiffs' experts and subsequently issued an order dismissing the 2,076 claims with prejudice. *Id.* at *22.

Plaintiffs appealed and, in July 2017, the Appellate Division reversed the trial court's exclusion of plaintiffs' experts and reinstated the more than 2,000 cases to which it applied. *In re Accutane Litig.,* 165 A.3d 832 (N.J. Super. Ct. App. Div. 2017). The Appellate Court explained that although "[i]n most cases, the proponent of scientific evidence must demonstrate that the opinions are 'generally accepted, within the relevant scientific community'" (the *Frye* standard) (*id.* at 855 (citing cases)), the New Jersey Supreme Court relaxed the standard for admissibility of expert testimony "in tort cases involving injuries caused by toxic substances or medications, involving new or

developing theories of causation". *Id.* Under the relaxed standard, "[a] court's assessment of scientific expert evidence should include an evaluation of the studies upon which the experts rely, but the court must not substitute 'its own assessment of the studies for that of an acknowledged expert'". *Id.* at 857 (quoting *Rubanick v. Witco Chem. Corp.,* 593 A.2d 733, 749 (N.J. 1991). Thus, the Appellate Division concluded that the "trial court took too narrow a view in determining whether the experts were using accepted scientific methodologies to analyse the evidence, and improperly determined the weight and credibility of the experts' testimony. Among other things, the judge inappropriately condemned the experts for relying on relevant scientific evidence other than epidemiological studies, despite their plausible explanations for doing [s]o". *Id*. at 837; *id.* at 867 ("regardless of a trial judge's view of the weight a party's evidence deserves, the judge should trust the jury to evaluate witness credibility and decide what weight to give each side's evidence. It is the jury's core function to weigh the credibility of expert witnesses, and the trial court should not use a *Kemp* hearing as a vehicle to dismiss a case the court perceives as weak") (internal citations and quotation marks omitted).

In August 2017, defendants filed a petition for certification to the New Jersey Supreme Court urging it to clarify the New Jersey standard for evaluating expert testimony and suggesting that the court adopt the more stringent admissibility test applied by federal courts and the majority of state courts. On December 8, 2017, the Supreme Court granted the manufacturer's petition and agreed to review the New Jersey Appellate Division's decision reinstating 2,000+ cases. *In re Accutane Litig.,* No. 079958, 2017 WL 6728709 (N.J. Dec. 8, 2017).

California State Court Talcum Powder Litigation. After a four-week trial of the first case in the California state court coordinated proceeding involving claims that plaintiffs developed ovarian cancer as a result of using talcum powder products, a Los Angeles County jury returned a $417 million verdict against Johnson & Johnson and its subsidiary and co-defendant Johnson & Johnson Consumer. After the jury returned the verdict, defendants moved for a new trial and for judgment notwithstanding the verdict ("JNOV"), arguing that plaintiff failed to present sufficient evidence that talcum powder was the probable cause of her ovarian cancer. Specifically, defendants argued that plaintiff's one specific causation expert (1) failed to present epidemiology showing that talc was the more probable than not cause of her cancer, and (2) used an improper methodology to reach her desired conclusion. *In re Johnson & Johnson Talcum Powder Cases*, No. BC628228, 2017 WL 4780572, at *11 (Cal. Sup. Ct. Oct. 20, 2017). The expert's methodology, as she explained it, was "differential etiology", which she testified "involved identifying risks for a disease; ruling out risk factors that you don't believe apply; and ruling in what you believe is the cause of the cancer". *Id.* at 12 (internal citations and quotation marks omitted).

Under California law, if, after trial, "the Court is convinced that there is no substantial conflict in the evidence and that the tendered expert opinions do not show specific causation (which, under *Jones v. Ortho. Pharm. Corp.* (1996) 163 Cal. App. 3d 396, must be shown by expert testimony in a case alleging cancer) a JNOV is properly granted". *In re Johnson & Johnson Talcum Powder Cases*, 2017 WL 4780572, at *13 (citing *Osborn v. Irwin Mem'l Blood Bank*, 5 Cal. App. 4th 234, 275 (1992)). Upon reviewing the testimony and evidence introduced at trial, the California court granted defendants' motions to set aside the verdict, finding that plaintiff's specific causation expert both failed to rule in talc as a probable cause of plaintiff's ovarian cancer and failed to rule out other causes and was therefore insufficient as a matter of law to support the verdict. *Id.* at *15. ("The Court is of the firm view that [the expert's] 'ruling out' of age and ovulatory cycles, amounted to no more than speculation. Her testimony that it was 'probable' the cause of the cancer was unknown, but then putting a 'less than 50% chance' on same (with no reasoning) likewise amounted to mere speculation. Those facts show that the expert did not properly employ the methodology she espoused and independent of the fact that there was no evidence of substance to rule talc 'in', persuade the Court that JNOV must be granted to JCCI and Johnson & Johnson on the basis that no specific causation was shown.")

Emerging Areas of Product Liability Law

New products and changing technologies are likely to be susceptible to a variety of product liability and tort claims in years to come. The following are three examples of the challenges and potential liabilities growing industries may face.

Three-Dimensional Printing

Three-dimensional ("3D") printing, also known as "additive manufacturing," refers to the creation of a 3D object by building successive layers of raw material, whereby each new layer is attached to the previous one until the object is complete. Objects are produced from a digital 3D file, such as a computer-aided design drawing or a Magnetic Resonance Image. While its applications are many, 3D printing has already begun to impact traditional health care treatments, including implantable and non-implantable medical devices and prescription drugs. 3D printing also has the potential to open the door for novel health care treatments. For example, physicians are using custom 3D-printed medical models to prepare for complex surgeries, and to create devices that are formatted for the particular patient.

But if these health-related 3D objects do not function as intended, medical device companies using 3D printing technology may face product liability litigation as well as other tort claims. The FDA has been laying the foundation for a comprehensive regulatory framework for 3D-printed medical devices through broad-based research and discussion, and provided recent guidance on 3D printing to medical device manufacturers, which culminated in the Dec. 4, 2017 Technical Considerations for Additive Manufactured Devices.[1] This guidance advises device manufacturers on the technical aspects of 3D printing, clarifies the FDA's recommendations on the pathway 3D-printed device manufacturers must follow to receive FDA approval, and provides manufacturers with transparency on the FDA's requirements for device design, function, durability, and quality as approval applications move forward. The FDA characterised the technical guidance as a "leap-frog" guidance that is intended to provide manufacturers with FDA's initial thoughts on a rapidly evolving technology, noting that the FDA intends to establish a comprehensive regulatory framework through the application of existing laws and regulations that govern device manufacturing to non-traditional manufacturers, such as hospitals or academic institutions that create patient-matched devices. Although FDA has issued guidance, many questions remain, and extensive developments and challenges are expected in the years to come.

Internet of Things

Internet-connected household products, also known as internet of things ("IoT") devices, have prompted consumer privacy concerns as well as product liability claims arising out of alleged manufacturing and design defects. While such alleged manufacturing defects have caused privacy advocacy groups to petition the U.S. Consumer Product Safety Commission for a recall of certain IoT devices, it

remains unclear how consumers will challenge such devices under the traditional product liability framework, and how IoT device manufacturers may shield themselves against such liability.

In *In re VTech Data Breach Litigation*, Plaintiffs sued the manufacturer of children's learning toys that were linked to certain web-based services for breach of contract, breach of warranty of merchantability, and violations of state consumer protection laws, 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, "[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. Defendants moved to dismiss the complaint, alleging that plaintiff suffered no actual injury and therefore lacked standing, because the complaint did not plead that the data travelled beyond the hacker, journalist, and a security analyst. The Court granted the motion to dismiss without prejudice, finding that the plaintiffs were unable to establish that they suffered actual harm as a result of the breach and that their alleged injuries were too "speculative" for the lawsuit to move forward. *In re VTech Data Breach Litig.*, No. 15 CV 10889, 2017 WL 2880102, at *4 (N.D. Ill. July 5, 2017). "With respect to this data breach, plaintiffs 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." *Id.* at *4, n.5. Thereafter, Plaintiffs filed an amended complaint, and VTech filed another motion to dismiss, which currently remains pending.

Medical devices that use integrated autonomous software have also been the subject of recent product liability litigation. In *Graves v. CAS Med. Sys., Inc.*, 735 S.E.2d 650 (S.C. 2012), plaintiffs brought a strict liability design defect claim against the manufacturer of a monitor that tracked the heart rate of a premature baby. The child died, and her parents subsequently filed a products liability lawsuit contending the monitor was defectively designed and failed to alert them when the baby's heart rate slowed. Although the plaintiffs offered the testimony of three experts, the court noted that "none of the experts did much actual testing of the software". *Id.* at 653. Further, none of the experts conclusively determined that the software in the monitor malfunctioned, causing the child's death. *Id*. The court affirmed summary judgment for the defendant, noting that this is "one such case [that requires reliable expert testimony] because it involves complex issues of computer science. Although we use computers in some form or fashion almost every day of our lives, the design and structure of the software they run is beyond the ordinary understanding and experience of laymen". *Id.* at 659.

Given the number of IoT devices currently on the market and the expected expansion of these devices in the future, the number of consumer claims likely will continue to grow, causing the reexamination of security, privacy, and traditional notions of product liability law.

Autonomous Vehicles

Autonomous vehicles, also known as driverless cars, are the future of transportation. They have the potential to reduce traffic, increase safety on the road, lower harmful greenhouse gas emissions, and generate more free time for individuals who otherwise would be occupied by driving. While the technology advancements and automated features may improve the safety of our roads, they also may lead to new liability risks. While theories of liability may be similar to those asserted in standard product liability cases involving vehicles (*e.g.*, negligence, strict liability, design defect, failure to warn, etc.), autonomous cars raise many additional difficult questions about liability, adequate warnings, and data security. With respect to liability, autonomous cars are designed to supplant the driver. Consequently, whether an accident was caused by a defect rather than driver error is likely to be a contentious battle ground. Indeed, within the past year, lawsuits and media attention related to driverless car accidents have emerged. *See, 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 self-driving Uber vehicle that struck and killed a pedestrian). In addition, future regulations and litigation will likely address questions concerning the sufficiency of warnings, and whether consumer training will be required. Most states are considering legislation regarding autonomous cars and a few, including California, Florida and Michigan, have already passed legislation. An entire regulatory body will undoubtedly grow to govern autonomous vehicle technology, but for now, these regulations are in their infancy.

Endnote

1. See Statement by FDA Commissioner Scott Gottlieb, M.D., on FDA ushering in new era of 3D printing of medical products; provides guidance to manufacturers of medical devices, available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm587547.htm (last accessed Jan. 17, 2018).

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

Daniel Spira is an associate in Sidley Austin LLP's Chicago office and 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. He has extensive experience writing and arguing successful motions at various stages of litigation, taking and defending depositions, managing complex discovery, and assisting clients reach favourable judgments and settlements ranging from single plaintiffs to nationwide classes.

Michelle A. Ramirez
Sidley Austin LLP
One South Dearborn
Chicago, IL 60603
USA

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

Michelle Ramirez is a litigator in Sidley Austin LLP's Chicago office. She has a diverse range of experience representing and advising medical device, pharmaceutical, manufacturing and consumer goods clients in complex product liability and commercial litigation matters in state and federal courts, including multi-district litigation. In this regard, she counsels clients at every stage of the litigation process, from case management and discovery strategy, dispositive motions and depositions through fact and expert witness preparation, mediation, trial and appeal. In addition, she advises clients on a number of e-discovery risks and obligations and guides clients through all phases of discovery.

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An Overview of Product Liability and Product Recall Insurance in the UK

Tony Dempster

Howard Watson

Herbert Smith Freehills LLP

Introduction

As many businesses have discovered to their cost in recent years, the consequences of placing an unsafe or defective product on the market can be devastating. In addition to the potential criminal penalties and civil claims (including group actions), the business will face the often significant costs of recalling the products and inevitable damage to its reputation and brand.

Product liability and product recall insurance can provide some protection against the financial consequences of placing an unsafe or defective product on the market.

In this article we set out the legal framework of product liability in the UK, and then explain the scope and nature of product liability and recall insurance.

Regulatory / Criminal Position

The main statutory rules on product safety in the UK are set out in the General Product Safety Regulations 2005 ("**GPSR**") and in the Consumer Protection Act 1987 ("**CPA**"). Both are derived from European Union law, but the legal framework they establish is unlikely to be affected by the UK's departure from the European Union. The GPSR implement the EC General Product Safety Directive (2001/95/EC) and apply to all products to the extent they are not covered by a sector specific regime. The CPA has been superseded in part by the GPSR, but remains relevant in particular as an umbrella under which various sector specific regimes have been enacted (e.g. for electrical products, toys and cosmetics). Some products (notably food and drink) are covered by sector specific safety regimes outside the CPA. Where any relevant matter is not addressed by a sector specific regime, the GPSR apply to "fill the gap".

The GPSR cover a wide range of products. "*Product*" is defined broadly and covers items which are sold or provided freely to consumers, as well as items not intended for consumers but which are likely to be used by them. New, used and reconditioned items are all included.

The GPSR impose the following principal obligations on producers and distributers of products:

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

These obligations are backed up by criminal penalties.

The "*general safety requirement*" is the conceptual bedrock of the GPSR. This prohibits producers and distributors from placing on the market or supplying (or offering or agreeing to offer) an unsafe product. A producer or distributor can place a product on the market in a number of ways, including by:

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

The GPSR identify a number of factors that will be relevant in determining whether or not a product is safe. These include: (i) its characteristics (including its composition, packaging, instructions for assembly); (ii) maintenance; (iii) its effect on other products; (iv) presentation of the product (such as labelling, instructions for use or warnings); and (v) any consumers who are particularly at risk when using it (e.g. children and the elderly). The European Commission has published guidance which sets out a detailed methodology for the assessment of risks associated with a product.

Producers and distributors who contravene the general safety requirement by placing an unsafe product on the market can be served with a notice by an enforcement authority. This notice can require them to suspend or halt the offending action, to withdraw or recall the product in question, label the product or otherwise warn consumers who are at risk of the dangers posed by it.

It is a criminal offence for a producer or distributor to: (i) fail to notify the relevant authority on discovery that an unsafe product has been placed on the market; (ii) fail to comply with a notice issued under the GPSR; (iii) fail to keep documentation necessary to trace products; and (iv) fail to cooperate with the enforcement authority to avoid the risk posed by an unsafe product. Persons found guilty of these offences will face a custodial sentence and/or a fine.

In February 2013 the European Commission adopted a package of reform (known as the Product Safety and Market Surveillance Package). This is intended to simplify and make more uniform the safety rules applying to non-food products, to streamline market surveillance procedures, and to better co-ordinate and monitor the carrying out of market surveillance activities in the EU.

The Package includes a proposed new Regulation on Consumer Product Safety (which will repeal and replace the EC General Product Safety Directive and apply automatically in qualifying member states), and a proposed new single Regulation on Market Surveillance of Products (intended to simplify the EU market surveillance framework in the field of non-food products).

Five years on, the proposed new Regulations have still not been enacted. The intention remains, however, that they will be enacted and come into force. Given the UK's departure from the EU, it remains unclear what effect the new scheme might have on UK consumers and manufacturers.

Civil Position

A product manufacturer or retailer may also be exposed to civil claims by businesses and consumers who have purchased defective or dangerous products. The various forms of civil liability under English law include in particular: (i) liability for breach of contract (including breach of statutory implied terms); (ii) liability in tort; and (iii) strict liability pursuant to the Consumer Protection Act (the "**CPA**").

Contractual liability

Contractual liability may arise in a number of ways. A contract for sale or supply may include express terms as to the nature or character of the product (i.e. in the form of a warranty or a guarantee). Failure of the product to comply with those express terms will generally give rise to a claim for breach of contract.

Statutory terms will also be implied into contracts for the sale or supply of products. Following the coming into force of the Consumer Rights Act 2015, there are two parallel regimes, with business to consumer sales covered by the Consumer Rights Act and business to business sales continuing to be covered by the Sale of Goods Act 1979 and the Supply of Goods and Services Act 1982. In practice, however, the statutory terms implied under the two regimes are much the same, and include in particular requirements that products should be of satisfactory quality and fit for purpose, and that they should match any description.

The implication of the implied terms can change whether the product supplied is a standard or bespoke product. In *Trebor Bassett Holdings Ltd v ADT Fire & Security Plc* [2012] EWCA Civ 1158 the Court of Appeal held that the design and installation of a bespoke fire suppression system could not be equated with a supply of goods that attracted the statutory implied terms of satisfactory quality and fitness for purpose.

The statutory implied terms give rise to strict liability. It is not necessary for the buyer to demonstrate fault on the part of the seller. The buyer need only show that the product did not accord with its description, was of unsatisfactory quality or was otherwise unfit for its purpose.

Contractual liability may also attach to pre-contractual statements which refer to the qualities of the product. Such statements can be incorporated into contracts as terms or, alternatively, form the basis of a separate contract between the buyer and seller or the buyer and a third party. Under the Consumer Rights Act, certain pre-contractual statements will now automatically become terms of the contract (on which the consumer can rely).

For breach of contract claims the buyer will be able to claim damages. In some cases a buyer will be able to reject the goods and terminate the contract.

Liability in tort

The tortious liability upon a manufacturer under English law was established in the landmark decision of *Donoghue v Stevenson* [1932] AC 562. That case imposed a duty of care on manufacturers of defective products, to a class of persons to whom damage (personal injury or property damage) is foreseeable if that product is defective. The standard is tested objectively and the manufacturer will not be at fault if a particular danger could not have been anticipated. Damage to the defective product itself (or the cost of a replacement product) will not be recoverable in a claim in tort for negligence.

Statutory liability

The UK (in common with other EU Member States) also imposes a strict liability regime on certain parties involved in the manufacture and supply chain, in respect of consumers who have suffered damage as a result of a defective product. The CPA (which transposes the Product Liability Directive (85/374/EEC and 1999/34/EC) into UK law) imposes strict liability on producers (including persons holding themselves out as producers by selling products under their brand and importers into the EU) for harm caused by defective products. The CPA allows consumers who suffer injury or damage as a result of defective products to sue for compensation without having to prove that the producer was negligent, provided that it can be demonstrated that the product was defective and the defect in the product caused the damage. A product is defective for the purposes of the CPA if the safety of the product falls below the standard the public are entitled to expect. The High Court has recently held that the ease and extent to which a risk can be eliminated or mitigated may be a circumstance that can be taken into account for the purposes of this assessment (*Wilkes v DePuy International Limited* [2016] EWHC 3096 (QB)). A person can sue for death, personal injury or damage to property. There are a number of available defences, including where the state of scientific and technical knowledge at the relevant time was such that the producer could not have been expected to discover the defect.

Product Liability Insurance

Policy Forms

There is no standard form of product liability insurance policy wording in the UK, unlike in the US, which has the Combined General Liability Policy wording. Despite this, the form of many product liability policy wordings is similar and regularly combined with public liability insurance.

Proposal Form / Insured's Duty of Disclosure

When a product manufacturer or distributor decides to take out a product liability insurance policy, they will be required to complete a proposal form. This form provides key information to the insurer about the insured's business, the type of products it sells/distributes and the countries where the products are sold/distributed.

The business seeking insurance cover will also be required to disclose to the prospective insurer any other material facts which it knows or ought to know, and which are relevant to the products being insured. This obligation forms part of the general duty of good faith imposed by law in respect of contracts of insurance (which are based on the principle of utmost good faith). If the insured fails to disclose a material fact, and if the insurer can show that such non-disclosure induced it to enter into the policy, it can avoid the contract in its entirety.

The Insurance Act 2015 (which came into force on 12 August 2016) changes a number of aspects of the existing law, including in particular the consequences of breach by the insured of its duty of disclosure. The Act provides remedies for breach which are more flexible and proportionate than those currently in force:

- The insurer can still treat the policy as void from the outset if: (i) the insured's breach of its disclosure duty was deliberate

or reckless (with no return of premium); or (ii) if the insurer would not have entered into the policy at all if proper disclosure had been given (but must return the premium).

- However, if the insurer would still have entered into the policy but on different terms, the policy may be treated as if it included those terms from the outset; and if the insurer would have entered into the policy but at a higher premium, the amount paid on claims may be reduced proportionately.

The changes are not retrospective, and so the old regime will continue to apply to policies entered into before 12 August 2016.

The Scope of Cover

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

The "*product(s)*" covered by the policy will not normally be defined as a specific item (or items). The definition will instead normally include any goods or products after they have ceased to be in the insured's possession or control, including packaging materials and containers. Disputes have arisen from the question of whether or not an item that has given rise to a loss is a "*product*" for the purposes of the policy.

In *Aspen Insurance UK Ltd v Adana Construction Ltd* [2013] EWHC1568 Judge Mackie QC considered whether a concrete base of a tower crane, constructed by the insured defendant which collapsed causing serious injury and property damage, constituted a "*product*" within the meaning of the product liability insuring clause of a building services combined contractors' liability insurance policy. The judge held that the base of the crane was not a "*product*" for the purposes of the policy: it was created on site (concrete poured *in situ*), not at the factory; coming into existence as a lump of concrete, it was not one of the insured's range of products (it could not be bought). The Court of Appeal ([2015] EWCA Civ 176) subsequently confirmed this analysis although it did find that dowels (iron rods connecting the crane base to the supporting piles) supplied and installed by the insured were themselves "*products*", notwithstanding the fact that they were incorporated into the overall crane support structure. This did not affect the outcome of the case since the dowels did not fail. The Court of Appeal commented that whilst the term product "*may elude precise definition*" it was "*a hallmark of a product … that it was something which, at least originally, was a tangible and moveable item which can be transferred from one person to another; and not something which only came into existence to form part of the land on which it was created*".

The use of the words "for or in respect of [bodily injury, property damage etc.]" in the insuring clause is of significance and has a limiting effect on the extent of the insurance cover, carrying with it the requirement that the liability relate to the loss or damage. It is not sufficient that the liability should simply have had some connection with the loss or damage (*Rodan v Commercial Union* [1999] Lloyds Rep IR 495). These words are generally taken as excluding pure economic losses from the scope of the indemnity (see further below).

Trigger and Notification

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

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

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

External Damage

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

In English law, "*damage*" usually refers to a changed physical state to external property in circumstances where the relevant alteration is harmful in the commercial context. A defect or deterioration in the commodity or product itself is not "*damage*". Some product liability policies may, however, contain express provision that damage caused by a defective part to another part or other parts of a larger item which is not defective or inadequate will be covered (again, this akin to the position in tort for negligence).

The application of the requirement for physical damage can give rise to difficulties, where the product supplied by the insured is to be installed in a larger item for use or onward sale by a third party. There will be a distinction between cases where the product causes damage to the larger item (covered), and where the defect in the product itself becomes manifest but without causing any damage beyond itself (not covered).

The test is whether there has been any physical change to the larger item as a result of the incorporation or inclusion of the defective product. If the defective product causes harm to the larger product, such that its value is diminished, physical damage will have occurred. In *Tioxide Europe Ltd v CGU International Insurance Plc* [2004] EWHC 2116 (Comm), a defective whitening pigment used in the manufacture of PVC doors which had caused the PVC to turn pink was found to have caused physical damage to the PVC, for the purposes of the insurance cover. In *Omega Proteins v Aspen Insurance UK Ltd* [2010] EWHC 2280 (Comm), although the question of whether there had been damage to property within the meaning of the product liability policy was not in issue, the judge proceeded on the basis that the mixing of contaminated material (fit only for disposal) with other materials caused damage to those other materials (by rendering them unusable).

The principle will not, however, apply where a product is installed or fitted alongside the property of a third party where no physical harm is caused and the harmful effects are confined to the product itself. In *Pilkington United Kingdom Ltd v CGU Insurance Plc* [2004] EWCA Civ 23, glass panels supplied by Pilkington were installed in the roof and vertical panelling of the Eurostar Terminal at Waterloo in London. A small number of the panels were defective and fractured on installation, although no physical damage was caused to the building. The insurance policy excluded cover for products which were defective at the time when installed and, as the Court held that the only damage was to the glass panels themselves (and not to third-party property), the claim failed.

Extensions are sometimes available which extend the scope of cover under a standard product liability insurance policy, to sums for which the insured becomes legally liable in respect of claims for the diminution in value of a product. This arises from any defect in any ingredient or substance supplied by the insured which is mixed or blended with other ingredients or substances for the purposes of creating an end product, and which results in that end product being defective or harmful. These are often referred to as mixing or blending losses extensions. Such extensions can be extremely valuable for manufacturers or retailers of ingredients and other substances which are mixed or blended in a finished product.

Pure Economic Loss

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

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

Some policies contain financial loss extensions, which cover liability for third party financial losses in the absence of injury or damage. Such coverage tends to be limited but can be particularly valuable; liability for pure economic loss can freely arise in contract, and in some jurisdictions, in tort as well. These extensions can also be combined with product guarantee insurance, which provides protection against an insured's legal liability for claims arising out of the failure of its product to fulfil its intended purpose or function (discussed further below).

Exclusions

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

- The costs of recalling, replacing or repairing the product itself. Plainly, these costs fall outside of the general ambit of a product liability policy which is principally concerned with liability for damage caused to persons and other property. Insureds can protect themselves against the costs of a product recall by obtaining product recall insurance (discussed below).
- Liability assumed by contract or agreement. This exclusion reflects the fact that product liability coverage is designed to cover the insured's liability for injury to persons or damage to physical property. It is not ordinarily intended to cover those types of losses which might be recoverable in a claim for breach of contract, unless such liability would have arisen in tort in any event. Such exclusions do not always make it clear, however, whether the test is: (i) liability in tort as if no contract between the claimant and the insured had existed; or (ii) liability in tort assuming the existence of a contract. In *Omega Proteins v Aspen Insurance UK Ltd* the judge considered that an exclusion for *"any liability arising ... under any contract or agreement unless such liability would have attached in the absence of such contract or agreement"* invited consideration as to what liability would have attached in the absence of a contract (but the facts were otherwise as they were), not whether there was a liability in tort, as well as contract.
- It is possible to obtain contractual liability extensions but care must be taken with the way these are drafted to ensure that they do not simply cover contractual liability which is concurrent with that in tort (which is normally covered in any event). Issues can arise where a policy extension provides cover for liability assumed under contract, but the extension remains subject to the insuring clause under which cover is restricted to liability "*for or in respect of [bodily injury, property damage etc.]*". In such cases pure economic losses (i.e. financial losses which do not arise directly from bodily injury or property damage) would not be covered by the policy even though they may be recoverable from the insured under contract.
- Liabilities which arise from the failure of an insured product to perform its function (so-called "*product efficacy*" exclusions). Product functionality is only relevant where the failure of product function may give rise to liability. The functionality failure of certain products (such as clothing, electrical goods or toys) will not necessarily cause liability for loss or damage. However, failure of other products to perform effectively (such as medicines or fire extinguishers) will almost certainly give rise to loss and/or damage.
- The insured's deliberate acts or omissions which can reasonably be expected to cause harm, loss or damage which is the subject of the claim. Where an insured fails to carry out adequate due diligence in respect of a product or reacts poorly in the wake of a product liability issue, insurers may seek to deny cover on this basis.

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

Damages for Late Payment

The Enterprise Act 2006 amends the Insurance Act 2015 and introduces an implied term into every insurance contract that "*the insurer must pay any sums due in respect of the claim within a reasonable time*", which includes a reasonable time to investigate

and assess the claim. What is reasonable will depend on all the relevant circumstances, but examples of things which may need to be taken into account include the type of insurance, the size and complexity of the claim, compliance with relevant statutory or regulatory rules or guidance and factors outside the insurer's control. Such a term is only implied into insurance contracts made after 4 May 2017. The insurer will have a defence where it can prove there were reasonable grounds for disputing the claim.

Product Recall Insurance

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

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

This form of insurance used to be something of a speciality but has become increasingly popular in recent years. A wider array of coverage options has become available although the number of insurers active in the field remains relatively small.

Scope of the Cover

Product recall policies are often arranged as part of or as an extension to products' liability insurance, but can be purchased on a stand-alone basis. Such policies generally cover the following types of risk:

- The insured's legal liability for:
  - the costs of removing, recovering, repairing or replacing a product which is defective or dysfunctional; and/or
  - financial losses incurred by customers or third parties which arise as a result of product impairment (i.e. a product failing to perform the function for which it was manufactured, designed or sold).
- The costs and expenses incurred by the insured which are associated with the cost of recalling its own products which may include:
  - business interruption losses;
  - the costs of the additional communications and media outputs required for the recall;
  - additional staffing to cover the recall operation;
  - brand restoration costs (such as consultants and advisors to assist in loss mitigation);
  - legal costs and expenses incurred in mitigation of a loss or potential loss; and
  - rehabilitation costs involved in re-establishing the product affected to the projected level of sales or anticipated market share prior to the recall.

Product recall policies may also provide cover for the costs and expenses of a product recall which are caused by malicious contamination of a product (although some policies will expressly exclude cover for such losses).

Event triggering the recall cover

The nature of the event that is necessary to trigger the insurance cover will normally depend upon the form of indemnity. Indemnities for legal liability tend to be written on a claims made basis requiring notification of a claim (or circumstances which may or are likely to give rise to a claim) during the policy period. Indemnities for the costs and expenses of a recall, by contrast, are normally triggered by the insured's decision to recall the product being taken (and notified to insurers) during the period of insurance.

Where the cover is for the costs and expenses incurred by the insured in respect of a product recall, the policy will often stipulate that the recall must be necessary in order to prevent or mitigate the prospects of legal liability arising from the use or consumption of the product. Some product recall insurance policies will contain more stringent limitations, which specify that there must be an actual or imminent threat of danger, injury or harm associated with the product's use. The regulatory regime in the UK encourages pro-active steps (including recall) when an unsafe product may have been placed on the market. Insureds may, therefore, find that they are potentially exposed to uninsured losses, where a precautionary recall was carried out in the absence of actual or imminent danger of injury or harm (if such was required by their policy). Similarly, product recall cover may not be available where a business decides to carry out a recall voluntarily for commercial reasons (e.g. due to a quality defect only in order to protect the brand).

Exclusions

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

- Where a product recall is necessitated by a product defect which has arisen solely due to:
  - exposure to weather or the deterioration or decomposition of a product (e.g. fresh food items); or
  - the fact that a product does not accomplish its intended purpose or comply with other implied statutory warranties, or has passed its shelf life; or
  - contamination or other defect arising out of bioengineering or GM treatment; or
  - the failure of any third party to store or consume the product in the prescribed manner.
- Prototypical or experimental products which, by their very nature, are expected to experience problems in the nascent stages of development are also generally excluded.
- Product recalls which are forced upon the insured by the government or a public authority, in circumstances where the insured would not have conducted the recall but for the said intervention.

Practical Considerations

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

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

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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.

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 and the Scania group action.

The Practicalities of Managing a Global Recall

Richard Matthews

Fabian Volz

Eversheds Sutherland (International) LLP

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 harmless. Equally, commercial concerns, and in particular the need to protect the reputation of a business for quality, can be a powerful factor.

Increasingly onerous regulatory requirements and more detailed monitoring by authorities further 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 advice on and co-ordinate action on product safety. The OPSS has issued a code of practice on consumer product safety-related recalls and further developments are anticipated over the coming months.

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 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. At the same time, the impact of a change in political regime in the US on trade and product regulation creates further uncertainty.

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

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

Investigation and Risk Assessment

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

- Assemble a team to investigate the facts – including details of any reported incidents or complaints – as thoroughly, yet rapidly, as possible. The team will need to be small so that it can act quickly and decisively and should typically include representatives from the technical, purchasing, sales, marketing, finance and legal functions within the company. The team should be led by a senior officer who has authority on behalf of the company, ideally has had crisis management training and will take responsibility for making difficult business decisions often based on incomplete and uncertain information.
- Commission a detailed technical analysis into the possible safety or quality issues using internal resources or an independent expert. The choice may depend upon the nature of the potential defect, the complexity of the investigation, the extent of relevant internal expertise and the time available. The importance of ensuring that the facts are properly evaluated and the truth determined mean that there is often a strong case for bringing in independent investigators, where circumstances allow.
- Seek to understand the scope of the problem, for example, whether it is limited to particular models or batches of products, the output of specific manufacturing sites and the affected date range, to establish how many units are affected, how many have already been sold and what proportion remains in the company's control or in the distribution network. The investigation will need to ascertain the key dates and key documents and determine how the issue has developed so that an effective risk assessment can be undertaken and appropriate actions agreed.
- Once the nature of the issue is identified, there is a need to undertake an assessment of the risk that the product may present a danger to users and the likely consequences if it does. There are a number of different risk assessment methodologies – but essentially most involve identifying the hazard and its cause, estimating how many products are affected, which users of the product are at risk and whether this includes particularly vulnerable sections of the population such as children or the elderly. The overall risk can then be estimated based upon the severity and likelihood of injury. Consideration should also be given as to how obvious the potential hazard is and whether there is any warning on the product or in user instructions to alert users of the hazard. The European Commission has prepared detailed guidelines for undertaking a risk assessment and determining whether notification of regulators is required in EU Member States where the product is sold (see http://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 some negative publicity in November 2009 when it failed to offer a free safety kit to European owners of a baby stroller in the same way as it had in the United States.

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

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

Dealing with Multiple Regulators

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

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

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

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

Changes in EU law over recent years have further broadened the range of products for which a notification to the relevant regulator

is required. As well as requiring immediate action to bring non-compliant product into conformity, the Low Voltage Directive (2014/35/EU) and Electromagnetic Compatibility Directive (2014/30/EU) require manufacturers to notify the authorities where a product presents a risk. In contrast to the position under the General Product Safety Directive, these obligations are not limited to consumer products. The decision to broaden the trigger for notification from "dangerous" to "non compliant" products is also novel, although three years on, it remains to be seen what impact this will have in practice 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 theories. The lead law firm should co-ordinate the global notification of regulators.

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

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

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

should attend. It is more common for lawyers (whether external or in-house) to attend in continental Europe than in the UK. A person with a technical background should attend to be able to explain the cause of the problem and the proposed solution.

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

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

A regulator in any European Union Member State is obliged to share information concerning "serious risks requiring intervention" with the European Commission using the Community Rapid Alert System for non-food consumer products ('RAPEX'). Where appropriate, and particularly where serious risks arise in relation to products in multiple jurisdictions, the Commission shares that information with other Member States and with regulators outside the European Union, in particular, the US and China (in respect of consumer products made in China). Each Friday, the Commission publishes a summary of the information notified to it by Member States on the DG SANCO website. The Commission does not disclose the whole notification to the public, especially not detailed risk descriptions, test reports or details of distribution channels which may be confidential. Whilst the overall number of notifications rose from 139 in 2003 to 2,044 in 2016, 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 2016, but five countries (Hungary, Germany, Spain, France and Bulgaria) accounted for nearly half of all notifications. Although it is principally a matter for the Member State in question as to whether it makes a notification, the Commission's notification guidelines provide the option for a company to notify in one Member State and for that country's regulator to make a RAPEX notification to the other Member States, e.g. upon a company's request, even if there is no serious risk. Companies may be permitted to have sight of the proposed RAPEX notification form.

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

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

Communications

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

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

On occasions, a company may need to broaden the scope of a recall or take additional corrective measures. This might be where new information comes to light which indicates that additional product models or batches also present a safety risk or, for example, where new information (e.g. a serious injury) leads to a re-assessment of the potential risk. This is an inevitable consequence of the need to take decisive action without being able to wait for all the relevant information to become available. This can be extremely damaging from a PR perspective as a further announcement tends to create a further wave of publicity and the company risks losing public credibility. In this regard, lessons have been learned from the recent 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 available and co-operative with the media, ensuring that journalists are made aware of the contact points and the proposed timing of any press statements.

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

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

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

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

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

Implementing a Recall

The appropriate response will depend upon:

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

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

The proposed corrective measures should reflect the nature of the product, where it is installed and how consumers use the product. The costs and practicalities need to be properly thought through. The proposed solution will want to ensure that only owners of affected products can take advantage of the recall and that the dangerous products are returned or destroyed (e.g. in exchange for a replacement or refund). In broad terms, it is easier to return smaller

consumer goods for refund or replacement, than it is large items or products which are in constant use, where measures to repair the product *in situ* may present the best solution. Real difficulties can arise when there is a risk that a product may not be safe to use, but consumers may not regard any significant period whilst it cannot be used as acceptable (e.g. a car or refrigerator).

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

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

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

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

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

Document Management

The management of documents is a crucial aspect of risk management in a product crisis. A company will want to be able to produce contemporaneous records to show that it acted responsibly, having regard to the relevant legislation and the best interests of consumers

and was justified in taking the decisions which it took. A record should be maintained throughout a crisis, documenting the information which was available at particular times, the investigation which was undertaken and the rationale underlying the decisions which were taken by the crisis committee based on such information and investigation. It is important to adopt and adhere to a document retention policy whereby documentation is available to assist in the defence of product liability claims in the future. Documents relating to product safety should not be destroyed.

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

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

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

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

Conclusion

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

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 European 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 Munich
Germany

Tel: +49 895 456 5391
Fax: +49 895 456 5158
Email: fabianvolz@eversheds-sutherland.de
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 nominated as a leading lawyer for product liability in Germany by the Legal Media Group's "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.

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Claims Brought by Funded Litigants – A Practical Guide

Louisa Caswell

Mark Chesher

Addleshaw Goddard LLP

Despite sharing a common law tradition, the jurisdiction of England & Wales is a very different proposition for litigants compared with the US. This is as true for litigants in product liability claims as for any other types of claim. The risks in bringing a claim are much greater for litigants in England & Wales. This is one of the main reasons why this jurisdiction sees proportionally fewer product liability claims brought, despite the same products having been marketed in both the US and UK.

The way that cases are funded differs greatly. In the US, a well-funded plaintiff bar tends to take on cases on a contingency basis, providing representation in return for a share in the proceeds of a successful claim. That approach has historically not been permitted in the UK. Instead claimants have either had to self-fund their claims or rely on legal aid provided by the state. In the last 30 years, the legal aid budget has shrunk significantly, and the eligibility criteria have restricted entitlement to only those with very limited means.

The Legal Aid, Sentencing and Punishment of Offenders Act 2012 (LASPO) substantially reduced the categories of cases for which legal aid is available, while the legal aid budget itself was slashed. LASPO also led to the Legal Services Commission (LSC) and its replacement by the Legal Aid Agency, an executive agency of the Ministry of Justice, on 1 April 2013. On the same day, the majority of the Jackson/civil litigation reforms came into force. As a result of these changes, damages-based agreements, a form of contingency fee agreement, are now permitted for civil litigation

In the courts of England & Wales, the general principle is that the "loser pays". The award of costs is entirely at the discretion of the judge but normally a successful party is entitled to recover its "reasonable costs" from a defeated opponent.

Not only does the withdrawal of legal aid remove funding for a claimant's own costs of bringing claims, it also removes another significant benefit to claimants provided by a public funding certificate. A public funding certificate removed a claimant's liability for their opponent's costs in respect of the aspects of the case covered by that certificate. Accordingly, the end of legal aid for product liability claims means that not only do potential claimants need to consider an alternative method of funding their claims, they also need to consider how they mitigate the risk of being liable for their opponents' costs should they lose.

The Post-Legal Aid Era

In this new era, claimants need either to self-fund, fund using a "before the event" insurance policy which includes legal expenses or look to one of the new methods of financing their claims. In this section we will take a look at these alternative methods in some more detail, and explain some of the terms.

Claimants who are able to avail themselves of the right combination of arrangements (for example, third party funding, lawyers on a no-win no-fee CFA, and ATE cover) may be able to pursue litigation with little or no financial risk to themselves (in exchange for giving away their right to a proportion of their damages in the event their claim succeeds).

It is important for lawyers involved in defending product liability claims to understand how these funding mechanisms operate, and consider what that may mean for case strategy. How is the claimant funding their claim? What are the prospects of recovering a successful defendant's costs? How do the funding arrangements impact on the approach to litigation and any potential settlement negotiations?

Third party funding

At its simplest, third party funding is the process by which a commercial investor, a "funder", pays the claimant's costs of bringing a claim in return for a share of the damages in the event of success. Funders will cover legal costs and expenses.

Once considered unlawful as a form of champerty, litigation funding and associated arrangements are now the mainstream and regarded as having a crucial role to play in allowing litigants to secure access to justice.

Historically, English law refused to recognise arrangements whereby litigation was funded or "maintained" by third parties. The principle extended to assignments of causes of action to third parties, and "champertous" agreements (under which a third party would maintain an action in return for a share of the spoils of litigation). The classic definition of the public policy behind the rules was expounded by Lord Denning MR in *Re Trepca Mines (No 2) [1963] Ch 199*:

> "*The reason why the common law condemns champerty is because of the abuses to which it may give rise. The common law fears that the champertous maintainer might be tempted, for his own personal gain, to inflame the damages, to suppress evidence, or even to suborn witnesses ...*"

Times have moved on, and important public policy considerations regarding impecunious claimants having access to justice led to the introduction of the Courts and Legal Services Act 1990 which began to pave the way for funding arrangements we see today. Meanwhile, concerns regarding the behaviours to which champerty may lead have been allayed, not least because a funder behaving in

the way warned of by Lord Denning would render the agreement champertous and expose the funder to unlimited liability for the opponent's costs should the claim fail. To date, no serious abuses have come to light and the funding industry has avoided being regulated.

Conditional Fee Agreements (CFAs)

Under a CFA, the solicitors' firm (and sometimes the independent barrister retained on the case) will agree to discount their fees in respect of its work on the claim. The discount offered can be up to 100% (often referred to as "no win, no fee"). If there are discounted fees to pay, these are paid throughout the life of the litigation. If success (as defined in the CFA) is not achieved, there is nothing more for the client to pay. If the claim succeeds, the client pays the balance of the fees (i.e. the difference between the discounted fees and the standard rates) plus a "success fee" of not more than 100% of the agreed discount. Funders will generally expect the law firm to work on a CFA.

After the event (ATE) insurance

At its simplest, ATE provides insurance to a litigant in respect of their liability to pay the legal costs of their opponent up to an agreed amount. A funder will generally require a claimant to take out an ATE policy on a claim it is funding.

In the early days of the market, ATE insurance provided cover only against adverse costs orders. While that remains its primary purpose, in recent years the ATE insurance market has matured and diversified such that it is now not difficult to obtain ATE cover for disbursements, such as experts' fees and Counsel's fees, and – in some cases – even for a proportion of the insured's own solicitors' fees.

ATE premiums are high, typically varying between 25% and 60% of the limit of indemnity (i.e. the total cover required). However, insurers have generally been willing to offer policies where liability to pay the premium is both contingent on success and deferred until the end of the case. Where liability for the premium is contingent on success, a claimant will not have to pay the premium in the event that it loses and has to make a claim under the policy. It will have to pay the premium only if it wins, but, rather like the CFA success fee, economically the insurance premium may in effect be paid out of the damages.

Insurers are increasingly reconfiguring their offerings, for example offering more staged premiums and other flexibility.

Since 1 April 2013, claimants with a personal injury element to their claim may be able to avail themselves of "qualified one way cost shifting" or QOCS. Subject to certain conditions, under QOCS, a claimant will not have to pay a defendant's costs in the event their claim is unsuccessful. The early use of without prejudice offers (pursuant to CPR Part 36) can neutralise the effect of QOCS.

Damages based agreements (DBAs)

A DBA is an agreement under which the law firm makes no charge for its services during the case and, if the claim succeeds, is paid a percentage of the damages actually recovered by the claimant. Even if the claimant wins but is unable to recover the damages awarded or agreed, e.g. because the defendant has no assets or has gone into administration, those legal costs do not have to be paid by the client (notwithstanding that the law firm may be liable for the fees of the barristers instructed).

During the course of the litigation, the claimant pays no solicitors' or barristers' fees. It does have to pay other expenses, such as the fees of expert witnesses. If the claim succeeds, and damages are recovered, the law firm is paid an agreed percentage (up to a ceiling of 50%) of those damages. The law firm must pay the barristers' fees out of those sums, before it is entitled to any payment for its own work. It therefore entails a significant level of risk for the law firm. Equally, the client potentially has to forfeit up to 50% of the damages recovered.

Some litigation funders are trying to find ways to mitigate the down side risk for the lawyers by, for example, offering to fund a proportion of the law firm's ongoing fees in return for a slice of the damages at the end of the case.

Funding arrangements in practice

CFAs and ATE insurance are in principle available to both claimants and defendants. Currently third party funding is limited to claimants, or defendants with counterclaims, but the market is developing fast. Funders are looking at the possibility of funding defences in return for one off payments. Assuming that the client is the claimant, economically the success fee under a CFA will in effect be paid out of the damages.

A CFA is therefore an attractive way for a claimant to share risk with their lawyers and mitigate costs down side. Another major advantage of CFAs is their flexibility. It is permissible to enter into a wide variety of CFAs which can be fine-tuned to fit the economics of the particular case and the financial requirements of the client. CFAs can be, and often are, combined with ATE insurance cover and/or third party funding.

Funders will generally require some form of ATE insurance to be in place and may also want the law firm to act on a CFA.

Funders, lawyers operating on CFAs and ATE insurers should all be paying close attention to the merits of the claim before signing up to their respective agreements with a claimant.

For a defendant, because the level of risk taken by the claimant is greatly reduced or even eliminated by a funding arrangement, it is not just the claimant and the court that a defendant needs to convince of the strength of its defence. If the defendant can cause the claimant's lawyers to reassess and downgrade their view of the merits of the claim it may help to bring an end to the matter or at least result in a more favourable settlement.

Generally, the decision of a funder as to whether to fund a case is driven by two primary considerations, what is the risk of the investment (i.e. the merits of the claim) and what is the potential return (i.e. the likely damages). In common with investors in other asset classes, they may accept a greater risk in return for a greater potential reward.

The third party funding market has developed considerably in recent years with a number of new entrants into the market. As a result, funders are now offering more commercially attractive terms. Typically, funders demanded a return of three times their investment in the case (i.e. the litigation costs paid by them) or one third of the damages, whichever was higher. However, as the market matures, many are willing to look at other ways of obtaining a return on their investment.

While third party funding is most likely to be relevant in substantial claims, some funders are keen to obtain exposure to smaller claims as well. However, risk/reward calculation will remain important, and a funder will carefully examine the ratio of the potential damages and the likely cost of pursing the claim.

Single claims which might individually be small, can become an attractive proposition for funders if there is a group of similar claimants whose claims collectively amount to a significant sum against a common defendant or group of defendants.

Increasingly funders are funding group claims. Follow-on damages actions in respect of breaches of competition law are proving particularly popular because such claims follow on from the competition authorities' finding of anti-competitive behaviour and the prospects of success are accordingly high if the claimants can demonstrate their losses. Worldwide, other group claims funded range from the Seroxat Litigation (of which more below) to claims brought by a group of Indonesian seaweed farmers against the operator of an oil rig which polluted the sea they farmed, destroying their livelihoods.

In the recent case of *Boston Scientific v AOK*[1], the Court of Justice of the European Union decided that where products belonging to the same group or production series have been subject to a voluntary recall due to a potential defect, it is possible to classify all products in the group or series as defective "*without there being any need to show that the product in question is defective*". While many defendant lawyers question that decision, if the law develops in this way, funders may be attracted to groups of claimants with damages claims in respect of a product that has been subject to such a voluntary recall in much the same way as competition follow on actions.

Considerations when facing a funded claim

While funders should not be involved in the day-to-day management of the case, they will closely scrutinise a case before funding and will expect to be appraised of all significant developments in the progress of the litigation. Inevitably this involves considering whether the circumstances and assumptions on which the original decision to fund the case was based still hold true.

Accordingly, defendants should be alive to ways of shaking the funders' faith in its own assessment of the case and the level of risk it has taken on. Equally, an inflated assessment by the claimant of the likely damages due should be challenged.

Defendants should also carefully consider (i) the adequacy of the ATE cover provided (if known), (ii) whether there is a risk the insurer may avoid liability, and (iii) the extent to which they are confident that the funder is able to meet its liabilities for any costs orders that the Defendant may obtain.

If concerns arise, and the ATE insurer is not willing to provide a deed of indemnity in favour of the defendant in a sum sufficient to meet those costs, a sensible course may be to seek security for costs from the claimant or, more likely their funder. This is the step recently taken by GlaxoSmithKline UK Limited.

Bailey & others v GlaxoSmithKline UK Limited (the Seroxat Group Litigation) [2017] EWHC 3195 (QB)

The Seroxat Litigation is a group claim pursuant to a group litigation order. Seroxat is the trade name in the UK of an antidepressant drug with the generic name paroxetine. Its trade name in the US and elsewhere is Paxil. The claimants allege that the drug is "defective" within section 3 of the Consumer Protection Act 1987 in that it has the capacity "*to cause adverse effects consequent upon or following discontinuance (withdrawal) [is] such as to prevent or make more difficult the ability of users to discontinue, withdraw from or remain free from taking [it], to an extent greater than with other* [drugs in its class]".

The Seroxat Litigation has straddled the "old" and "new" eras of litigation funding from a time of public funding via legal aid, to the present, fast developing arena of commercial funding.

When the Seroxat Litigation began (with potential claims first intimated from 2002) the Claimants benefitted from a public funding certificate in respect of "generic work" issued by the Legal Services Commission (LSC) in June 2004. In October 2010 the Seroxat Litigation was three months away from trial when the LSC decided not to fund the "generic" claims of the group (which numbered just over 500) to trial. Approximately 400 of the Claimants decided at that stage to discontinue their claims. The remainder were determined to fight on.

There was a hiatus of four years as the Claimants challenged the decision to withdraw funding. While that challenge was ultimately unsuccessful, the Claimants were able to secure funding from a commercial litigation funder in or around July 2015.

Last year, GlaxoSmithKline UK Limited (GSK) sought and obtained security for costs against the claimants' funder for a sum greater than the amount the funder had committed to fund the litigation. This was the first time that security was awarded in excess of the cap on adverse cost liabilities of professional third party funders applied in *Arkin v Borchard Lines (Nos 2 and 3)* [2005] 1 WLR 3055 (the Arkin cap).

The Court of Appeal's decision in Arkin came when litigation funding was in its relative infancy, and recognised the important role funders play in ensuring access to justice. The issue in that case was whether a commercial funder should be exposed to "a non-party" costs order if a claim which it funded was unsuccessful. Lord Phillips MR at paragraph 38 of the judgment stated:

> "*Somehow or other a just solution must be devised whereby on the one hand a successful opponent is not denied all his costs while on the other hand commercial funders who provide help to those seeking access to justice which they could not otherwise afford are not deterred by the fear of disproportionate costs consequences if the litigation they are supporting does not succeed.*"

The Court of Appeal's solution was as follows (at paragraphs 40 and 41):

> "*Our approach is designed to cater for the commercial funder who is financing part of the costs of the litigation in a manner which facilitates access to justice and which is not otherwise objectionable.*
>
> *We consider that a professional funder, who finances part of a claimant's costs of litigation, should be potentially liable for the costs of the opposing party to the extent of the funding provided.*"

Although in that case, the funder had only agreed to fund the provision of expert accountancy evidence, the Court of Appeal extended the approach described above to cases in which the funder had funded most or even all of the expenses in the case (at [43]):

> "*We can see no reason in principle, however, why the solution we suggest should not also be applicable where the funder has similarly contributed the greater part, or all, of the expenses of the action. We have not, however, had to explore the ramifications of an extension of the solution we propose beyond the facts of the present case, where the funder merely covered the costs incurred by the claimant in instructing expert witnesses.*"

The approach proposed in Arkin has been the subject of criticism since, including, notably from the judge appointed to conduct a review of civil litigation funding, Sir Rupert Jackson, who, in his final 2009 report, found that there was "*no evidence that full liability for adverse costs would stifle third party funding or access to justice*" and concluded that it is wrong in principle that a litigation

funder, which stands to recover a share of damages in the event of success, should be able to escape part of the liability for costs in the event of a defeat.

In GSK's application, the court was asked to consider, for the first time, the extent to which the Arkin cap should be applied to limit the sum a funder can be ordered to give by way of security for costs pursuant to CPR r.25.14.

The material facts were that GSK's estimated costs to trial in respect of generic issues were significantly in excess of the sum (£1.2m) that the Claimants' litigation funder, Managed Legal Solutions Limited (MLS), had committed to funding the litigation. The Claimants were said to have the benefit of ATE insurance to £750,000.

The key issues to be determined by the Court were:

- whether the Arkin cap applied in relation to GSK's application for Security for Costs; and
- to what extent the existence of ATE insurance should be taken into account when determining the amount of security to be ordered.

The Court considered the various criticisms that have been made of the Arkin cap and found:

- whether the Arkin cap should be applied was only a factor to be taken into consideration in the overall exercise of the Court's discretion to order security for costs under CPR r.25.14, and it is ultimately a matter for consideration after the trial; and
- it was accepted that it may be argued that in Arkin, the Court of Appeal was only addressing the situation where a third-party funder contributed to a part of the litigant's costs.

When considering the application of the Arkin cap at the conclusion of trial, the Court found:

- it was accepted that the wording in Arkin, that the cap applies where funding has been provided "*in a manner which ... is not otherwise objectionable*", leaves open the possibility that costs awards against third party funders may exceed the Arkin cap; and
- it would be wrong to ignore the possibility that the cap may not apply in this case, not least because there would be a risk that the security ordered would be insufficient.

Following a broad assessment of GSK's likely recovery of its estimated costs upon assessment, the Court reduced the resulting figure by 50% to reflect the foregoing considerations relevant to the exercise of its discretion and to do broad justice in the case. The Court did not limit the order for security to future costs. The award by the Court at this level was above the level of funding provided by MLS.

The Court accepted that the availability of ATE insurance was relevant to the exercise of its discretion. However, it did not consider it possible to discount the prospect of avoidance following the recent Court of Appeal case *Premier Motorauctions v PwC LLP & another* [2017] EWCA Civ 187. Adopting the approach taken by the Court of Appeal in that case, and reaching the view that in the absence of an anti-avoidance provision in the policy, the prospect of the ATE insurer avoiding the policy (e.g. for non-disclosure or misrepresentation) was "*not illusory*". The Court discounted two thirds of the total ATE cover from the sum ordered by way of security to reflect the Court's view that the policy is more than likely to be valid and available for payment of part of GSK's costs, whilst acknowledging the risk that it would not be. Even taking into account the discount for ATE cover, the security award against MLS remained above the funding committed by MLS.

Conclusions

As the litigation funding market continues to develop, and the means by which claimants can finance a claim, defendants and their lawyers will need to keep abreast of developments. This is essential to both understand the commercial drivers behind the claim and to put the defendant in the best possible position in respect of recovering its costs.

Finally, there is the potential for the defendant to seek alternative ways of financing its own cost and this market is developing, albeit at a slower pace than the market for claimants. It is possible to obtain defendant CFAs and many law firms offer alternative billing arrangements. Third party funding may also be available in certain circumstances. The market is likely to continue to develop products by which parties can share and it may pay a defendant to consider these if and when it is faced with a new claim.

Endnote

1. (Cases C-503/13 and C-504/13) *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt – Die Gesundheitskasse and Betriebskrankenkasse.*

Acknowledgment

The authors would like to acknowledge the third author of this chapter, Cécile Burgess. Cécile is a Managing Associate in the Litigation Group in London, having trained and qualified at Hogan Lovells.

Cécile has extensive experience of acting for global product manufacturers in relation to product liability claims and risk management. Cécile focuses on life sciences (pharmaceuticals, vaccines and medical devices), and is also experienced in the retail and consumer sector. She acts on a wide variety of disputes, including both contractual and tortious claims, as well as "pure" product liability disputes, with extensive experience in instructing both scientific/technical and legal experts. In 2017, Cécile was listed by *The Legal 500* as "a next generation lawyer" in product liability.

Cécile is currently working alongside Louisa and Mark on the Seroxat Group Litigation in the High Court for GSK, and has been involved extensively on the production of expert reports, the making of a number of interim applications and trial preparation. Tel: +44 20 7160 3299. Email: cecile.burgess@addleshawgoddard.com.

Louisa Caswell
Addleshaw Goddard LLP
Milton Gate, 60 Chiswell Street
London EC1Y 4AG
United Kingdom

Tel: +44 20 7788 5174
Email: louisa.caswell@addleshawgoddard.com
URL: www.addleshawgoddard.com

Louisa is a Partner with over 15 years' experience in commercial litigation, specialising in product safety and product liability.

She has advised manufacturers on claims and safety issues relating to food and drink, consumer goods, pharmaceuticals and medical devices, amongst others. Her clients include multinational companies, with a particular focus on the consumer, retail and pharmaceutical sectors. She regularly provides training on product recalls to manufacturing and retail clients.

She acts for GlaxoSmithKline in its defence of a product liability group action relating to its antidepressant Seroxat and has been involved in all stages of this high-profile and long-running litigation.

Louisa is a ranked lawyer in both *The Legal 500* and *Chambers* Directory.

"*Louisa Caswell is an experienced litigator with a considerable amount of expertise in product liability cases. Her practice encompasses litigation defence, risk management and product recall across a range of consumer and medical products. A source describes her as 'an extremely collected person under fire'.*"

Of the team: "*They are very good and skilful at handling group litigation – they mop issues up well, their acumen is very strong, and they are able to deal with difficult technical issues about what counts as a defect.*"

– Chambers UK 2017

"*Louisa Caswell 'expertly leads the highly experienced and well-regarded team', which includes legal director and 'class act' Mark Chesher.*"

– The Legal 500 2017

Mark Chesher
Addleshaw Goddard LLP
Milton Gate, 60 Chiswell Street
London EC1Y 4AG
United Kingdom

Tel: +44 20 7788 5146
Email: mark.chesher@addleshawgoddard.com
URL: www.addleshawgoddard.com

Mark is a Legal Director within the Litigation Group based in London and has over 14 years' experience acting for various clients including FTSE 100 companies, banks, hedge funds, private companies and high net-worth individuals.

He combines broad product liability experience combined with an in-depth knowledge of the pharmaceutical industry and acts for GlaxoSmithKline in its defence of the Seroxat Litigation having been involved in the case since 2003. Mark also spent seven months on secondment to GlaxoSmithKline's product litigation team. Mark also regularly gives advice on product safety issues to clients from a wide range of industry sectors from telecommunications to food and drink.

Mark worked as a lead associate on five of *The Lawyer*'s "top cases of the year" (2010 to 2015) and has been recommended in the Product Liability (mainly defendant) section of *The Legal 500* directory since 2016, where clients commented that he is "a class act" and "bright, hardworking and committed". Mark was listed by *The Legal 500* as "a next generation lawyer" for product liability. Mark was also recognised in *The Legal 500* as a "seasoned fraud litigator".

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

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

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

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

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

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

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

Efficacy of Legislation/Consumer Protection

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

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

compounded by the lack of sophistication of the legal systems (such as under-developed court systems and out-dated legislation) and the inadequate availability of resources to enforce any such laws.

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

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

Insurance

Another factor that affects the development of product liability is insurance claims. Insurers are generally the first point of contact when a product liability claim is made. The globalisation of the product supply has invariably contributed to the rise of global insurance claims. As such, the principles behind insurers' rights of subrogation are generally well understood. Insurers who indemnify an insured for a loss thereby become entitled to claim against the wrong-doer who has caused that loss, i.e. by paying a claim the insurer "steps into the shoes" of the insured and takes over any rights it has against the third parties who may be responsible for the loss. It is an equitable principle that prevents the insured from the retaining the benefit of a double recovery. Generally, in the automobile sector, a customer may be more inclined to make an insurance claim for any loss or damage resulting from any defect in the vehicle. Thereafter, it is up to the insurance company to proceed with a subrogation claim against the manufacturer or reporter. Again, in this regard, we see different trends in different parts of the Asia Pacific region. We have observed that in jurisdictions such as Japan, Korea and Taiwan, the insurance companies have been more proactive in seeking compensation against the manufacturer and/or importer of the products. However, as we move southward, the numbers of subrogation claims are significantly reduced. This is an interesting phenomenon, especially in countries with more developed legal systems such as Singapore or Malaysia where we might expect insurance companies to use subrogation to recoup the pay-outs if there is good cause to do so. If defective products are simply covered by insurance, there is less pressure on the 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 address product liability, be promulgated in consultation with each other such that the same basic principles of product liability and the protection of the consumer be consistent. In that regard, it may itself form a model that takes into account the cultural and political diversity in the region. This could very well cause other countries in the Asia Pacific region to look carefully at such legislation for use in their own jurisdictions. If this can be achieved, other non-ASEAN members in the region might be interested in either following the model or taking parts of it that would be useful in their country.

David Goh
Squire Patton Boggs
Suite 5904, 59th Floor, Central Plaza
18 Harbour Road
Wan Chai
Hong Kong

Tel: +852 2511 1040
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
Suite 5904, 59th Floor, Central Plaza
18 Harbour Road
Wan Chai
Hong Kong

Tel: +852 2511 1971
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.

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Chapter 7

The Liability and Insurance Ramifications of the Increased Usage of Autonomous Motor Vehicles

Francis P. Manchisi

Wilson Elser

Ernest V. Goodwin

The autonomous motor vehicle industry is growing exponentially. Various automobile manufacturers, including Audi, Ford, Volkswagen, GM, BMW, Toyota, Tesla, and Nissan, have announced that they plan to sell fully autonomous motor vehicles by 2021. Other manufacturers will surely follow suit. While these technological advancements will offer numerous benefits, including enhanced safety and mobility, 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. This article discusses how these technological advancements will affect the motor vehicle and insurance industries and the potential legal exposures they create.

Motor vehicles have become safer since their invention in the early 20th century. Many of these innovations led to increasing levels of motor vehicle usage. 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. The World Health Organization estimates that there were approximately 1.25 million worldwide traffic fatalities in 2013. *See Here's When Having a Self-Driving Car Will Be a Normal Thing*, Gene Munster, Fortune (September 13, 2017) (http://fortune.com/2017/09/13/gm-cruise-self-driving-driverless-autonomous-cars/). In 2016, motor vehicle accidents were responsible for the deaths of 37,461 people in the United States, an increase from 35,485 deaths in 2015. *See* NHTSA, Automated Vehicles for Safety – https://www.nhtsa.gov/technology-innovation/automated-vehicles-safety. Fatalities increased from 2015 to 2016 in almost all segments of the population – passenger vehicle occupants, occupants of large trucks, pedestrians, pedalcyclists, motorcyclists, alcohol-impaired driving, male/female, and daytime/nighttime. *See USDOT Releases 2016 Fatal Traffic Crash Date*, (October 6, 2017) (https://www.nhtsa.gov/press-releases/usdot-releases-2016-fatal-traffic-crash-data). There were increases in deaths in a variety of scenarios involving "human choices," e.g. occupants not wearing seat belts, speeding, and alcohol-impaired drivers. This is not surprising because the overwhelming majority of motor vehicle accidents are caused by human error, including drunken driving, poor judgment, poor driving skills, poor reflexes, inattentiveness, poor vision, and/or criminal negligence. *See Self-Driving Cars and Insurance*, Insurance Information Institute (July 2016) (http://www.iii.org/issue-update/self-driving-cars-and-insurance); *see also* NHTSA, Automated Vehicles for Safety – (https://www.nhtsa.gov/technology-innovation/automated-vehicles-safety).

A study by the Insurance Institute for Highway Safety ("IIHS") concluded that improvements in design and safety technology have led to a lower fatality rate in accidents involving late-model cars. *See Self-Driving Cars and Insurance, Insurance Information Institute*, July 2016 (http://www.iii.org/issue-update/self-driving-cars-and-insurance). The likelihood of a driver dying in a crash of a late-model vehicle decreased by more than a third over three years, and nine car models had zero fatalities per million registered vehicles.

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

Autonomous motor vehicles will surely be opposed by lobbying groups, such as those supporting the fossil fuel industry, truck drivers, taxi drivers, parking lot owners, car dealerships, and potentially the insurance industry if it does not adapt to technological advancements. However, it is hoped that vastly increased safety, increased mobility for those otherwise impaired, and the environmental benefits will lead to an increase in the use of autonomous motor vehicles. Indeed, forecasts predict that there will be 10 million automated vehicles on public roadways by 2020. *See 10 Million Self-Driving Cars Will be on the Road by 2020*, John Greenough, Business Insider (July 29, 2015) (http://www.businessinsider.com/report-10-million-self-driving-cars-will-be-on-the-road-by-2020-2015-5-6). Fortune estimates that autonomous motor vehicles will be on roads in a "noticeable way" by 2020 and that by 2040, 95% of new motor vehicles sold will be fully autonomous. *See Here's When Having a Self-Driving Car Will Be A Normal Thing*, Fortune (September 13, 2017) (http://fortune.com/2017/09/13/gm-cruise-self-driving-driverless-autonomous-cars/).

Accidents Involving Autonomous Motor Vehicles

While autonomous motor vehicles will lead to fewer accidents and fatalities, it is not surprising that some media outlets have sensationalised incidents involving autonomous motor vehicles. It is also not surprising that some media outlets have blamed incorrectly the autonomous motor vehicles. For example, this article (https://www.popularmechanics.com/technology/infrastructure/a28984/truck-hits-driverless-shuttle-on-first-day-at-work/) on the Popular Mechanics website (a company that will likely suffer as a result in an increase in the usage of autonomous motor vehicles), has a misleading headline of "Driverless Shuttle Has Accident on First

Day of Work" with a sub-headline of "A rough start for self-driver". *See Driverless Shuttle Has Accident on First Day of Work*, David Grossman, Popular Mechanics, (November 9, 2017) (https://www.popularmechanics.com/technology/infrastructure/a28984/truck-hits-driverless-shuttle-on-first-day-at-work/). Only at the end of the article is it noted that the human driver of the other vehicle in the accident was at fault for the accident.

Autonomous motor vehicle manufacturers will have to overcome the public relations issues related to incidents like these, even though they will likely occur with far less frequency than in vehicles driven by humans. Autonomous motor vehicles may have to convince humans that "the perfect should not be the enemy of the good" and that while there may be a learning curve with autonomous motor vehicles, they ultimately will be safer than motor vehicles driven by humans. Supporters of autonomous motor vehicles will have to convince the public, and thereby legislators, that autonomous motor vehicles are significantly safer, more cost efficient, and environmentally beneficial than motor vehicles driven by humans, and that these benefits outweigh what should be isolated incidents.

Legislative Issues

Federal and State Framework

A relatively sizable obstacle to the increased use of autonomous vehicles is the United States' unique legal and legislative framework. The U.S. system is comprised of 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 a revised set in 2017, which will hopefully bring more uniformity to the manufacture of autonomous vehicles.

Traditionally, the federal government's role in motor vehicle policy has been to dictate safety standards and deal with product recalls. States have provided drivers with licences and regulated behaviour, including enforcing speed limits. These roles may change in the future as autonomous motor vehicles become more prevalent. While the current administration is electing to take a passive role due to the complex technological and geographic issues, it is likely that the federal government's role will expand to provide a more comprehensive and uniform approach to autonomous motor vehicle policy.

Some state governments have enacted permissive regulations for autonomous motor vehicles to encourage technology and motor vehicle companies to create testing programs within their states. Since 2012, at least 41 states and Washington, D.C. have considered legislation related to autonomous motor vehicles. Twenty-two states – Alabama, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Illinois, Indiana, Louisiana, Michigan, Nevada, New York, North Carolina, North Dakota, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Vermont and Virginia – 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 26, 2018) (http://www.ncsl.org/research/transportation/autonomous-vehicles-self-driving-vehicles-enacted-legislation.aspx). Moreover, governors in Arizona, Delaware, Hawaii, Idaho, Maine, Massachusetts, 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. Autonomous motor vehicles in New York even require that autonomous motor vehicles follow an approved route with a police escort. An autonomous motor vehicle being tested in New York must also be accompanied by a pilot vehicle driving directly ahead of it.

NHTSA – Automated Driving Systems – A Vision for Safety 2.0 – September 2017

In September 2017, the National Highway Traffic Safety Administration ("NHTSA") released a new version of its guidance for autonomous motor vehicles in the United States. *See Automated Driving Systems – A Vision for Safety 2.0*, U.S. Department of Transporation and NHTSA (September 2017) (https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/13069a-ads2.0_090617_v9a_tag.pdf). It is not vastly different from the previous administration's guidelines, but it is noticeably shorter than the previous administration's version and emphasises repeatedly that it is only "voluntary guidance". Elaine Chao, the Secretary of the Department of Transportation ("DOT"), noted five times in her one page executive summary that this was only "voluntary guidance".

A Vision for Safety 2.0 calls 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).

The new Voluntary Guidance's key points are as follows:

- focuses on SAE International levels of automation 3–5 – automated driving systems – conditional, high, and full automation;
- clarifies the guidance process and that entities do not need to wait to test or deploy their automated driving systems;
- revises allegedly "unnecessary" design elements from the safety self-assessment;
- aligns federal guidance with the latest developments and industry terminology; and
- clarifies federal and state roles going forward.

A Vision for Safety 2.0 slightly altered the definitions for levels of autonomous driving. Those levels are as follows:

Level 0 – No Automation – Zero autonomy; the driver performs all driving tasks.

Level 1 – Driver Assistance – Vehicle is controlled by the driver, but some driving assist features may be included in the vehicle design.

Level 2 – Partial Automation – Vehicle has combined automated functions, like acceleration and steering, but the driver must remain engaged with the driving task and monitor the environment at all times.

Level 3 – Conditional Automation – Driver is a necessity, but is not required to monitor the environment. The driver must be ready to take control of the vehicle at all times with notice.

Level 4 – High Automation – The vehicle is capable of performing all driving functions under certain conditions. The driver has the option to control the vehicle.

Level 5 – Full Automation – The vehicle is capable of performing all driving functions under all conditions. The driver may have the option to control the vehicle.

A Vision for Safety 2.0 recommends that the Federal and State regulatory responsibilities are as follows:

NHTSA's Responsibilities

- setting Federal Motor Vehicle Safety Standards ("FMVSS") for new motor vehicles and motor vehicle equipment (with which manufacturers must certify compliance before they sell their vehicles);
- enforcing compliance with FMVSS;
- investigating and managing the recall and remedy of noncompliance and safety-related motor vehicle defects nationwide; and
- communicating with and educating the public about motor vehicle safety issues.

States' Responsibilities

- licensing human drivers and registering motor vehicles in their jurisdictions;
- enacting and enforcing traffic laws and regulations;
- conducting safety inspections, where states choose to do so; and
- regulating motor vehicle insurance and liability.

Congressional Legislation Regarding Autonomous Motor Vehicles

While the United States House of Representatives passed a bill regarding autonomous motor vehicles, the bill has stalled in the United States Senate after several Senators cited safety concerns. It is noteworthy that those safety concerns do not just relate explicitly to accidents, but also to cyber safety and consumer privacy issues associated with autonomous motor vehicles. There is an inherent conflict between the positions of some Senators and Derek Kan, the Undersecretary of Transportation for Policy, who has explicitly stated that the DOT is not going to select what technology will be used in autonomous motor vehicles.

However, no federal laws have been enacted. The DOT recently convened a "listening summit" on autonomous motor vehicles at which companies from the private sector, federal regulators, and state regulators discussed issues regarding autonomous motor vehicles and related policies. *See* U.S. DOT Public Listening Summit on Automated Vehicle Policy (March 1, 2018) (https://www.transportation.gov/AV/avsummit). The main takeaway from the listening summit was that regulators will not impose many rules, if any, and will let technology progress. The DOT noted that compliance with its guidance would be voluntary and that if anything was perceived as a mandate and/or a requirement, it would impede innovation. Elaine Chao, the Secretary of Transportation, stated that the Department is not in the business of "picking winners and losers".

Product Liability Considerations

High-profile incidents of autonomous motor vehicle accidents, and the public's natural resistance to change, will likely affect product liability considerations and legislative issues.

In a technologically advanced setting, apportioning liability will not be as straightforward as it used to be. There will certainly be novel and challenging legal issues. The exposure will likely evolve over time as autonomous motor vehicles are adopted by the public. Generally, it is likely that as control of vehicles shifts from manual operator-controlled to autonomous computer-controlled, liability will shift from the operator of the motor vehicle to the manufacturer of the motor vehicle and/or the manufacturer of the technological component that failed, thereby causing the accident. Several manufacturers, e.g. Volvo, Mercedes, and Google, have announced that that they will assume liability for autonomous motor vehicle accidents.

Motor vehicle manufacturers have long been subject to product liability lawsuits. However, the number and types of product liability lawsuits will likely increase because of autonomous vehicles. Autonomous vehicle manufacturers, and manufacturers in general, will likely face product liability claims based on various theories of liability, including *inter alia*, strict liability, negligence, and breach of warranty. Manufacturers of autonomous vehicles will not be the only entities to encounter increased exposure to product liability lawsuits. Manufacturers of the various component parts, e.g. software and hardware manufacturers, will also be exposed to greater product liability risk. Assessing liability with autonomous motor vehicles will be complicated by the possible combinations of driving modes, ranging from no autonomy to full autonomy. Potential factors include the comparative negligence of a human operator's actions, the functionality of software and sensors manufactured by potentially dozens of legally separate entities, the designs of the autonomous driving systems, and the training and/or warnings associated with operating an autonomous vehicle, including vehicle and system maintenance, among others.

Assigning liability will be more complicated when motor vehicles are operating in Levels 1 through 3, when the operator is more likely to be operating the vehicle. That calculation will likely resemble traditional motor vehicle liability calculations. When motor vehicles are operating in Levels 4 and 5, when a computer is likely operating the vehicle, the liability calculation will more closely resemble a traditional product liability analysis because it will involve the failure of an automated product. However, even at Levels 4 and 5, there will still be the possibility for human negligence if the owner/operator has not properly updated the motor vehicle, or if the owner/operator has modified the autonomous motor vehicle operating system.

These liability calculations and apportionments will involve determining which of the many component part manufacturers, if any, played a role in an incident. As software algorithms become more vital to the success and failure of autonomous vehicles, motor vehicle manufacturers will necessarily have to be more focused on the integration of software and hardware. In product liability practice, it is well-established that liability can be apportioned up and/or down the supply chain to the cause of a particular failure. These risks are often addressed between component parts suppliers and manufacturers under the terms of supply agreements where a contractual duty to defend and indemnify against damages caused by a malfunctioning device is delineated. However, that same automation and interconnectivity could also allow a clearer picture to develop via the vehicles' internal software, so it should theoretically be easier to discover what contributed to the accident than in an accident wherein there could potentially only be testimony from the two drivers.

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

upgrades and/or recall the defective products. Product recalls are relatively common for certain types of products and are usually handled by various regulatory agencies. Due to the increased connectivity, and access to information regarding product and consumer information, manufacturers and retailers will have fewer defences for not recalling almost all products.

The potential for hacking an autonomous motor vehicle's operating system to gain information and/or cause injury will present manufacturers with significant data security exposures. While those threats exist today, the growing interconnectivity with other vehicles and the internet will only amplify those risks. Users' personal data could be accessed and stolen. If these issues are prevalent with a certain product, manufacturers, including those of the component parts and/or security systems contained therein, would likely be subject to product liability lawsuits and/or class action litigation. The investigations attendant to litigation will also require the use of novel and educated experts in those fields. Since this will be a new area of litigation, identifying the relevant experts will be a significant undertaking.

It is likely that liability for accidents involving autonomous motor vehicles will be determined by courts on a case-by-case basis and will evolve over time, similar to traditional product liability jurisprudence.

Effect on Insurers

Almost all motor vehicle manufacturers have product liability insurance. Accordingly, insurers will have to consider all of the potential benefits and risks of automation when drafting policies and/or agreements with any potential insureds. Insurers will also need to hire claims representatives familiar with the technology incorporated in autonomous motor vehicles.

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

In the short-to-medium-term, the cost of replacing components on autonomous motor vehicles will be significantly more expensive than on regular motor vehicles. However, as market competition and efficiency increase, the cost of manufacturing autonomous motor vehicles, and the components therein, will decrease, leading eventually to significant declines in insurance premiums. In the long-term, an increase in the amount of autonomous motor vehicles paired with the increasing popularity of shared rides, could impact the types of insurance available and insurers' financials. KPMG estimates that in 2013, personal automobile insurance accounted for 87% of automobile loss insurance, while commercial auto insurance accounted for 13% of automobile loss insurance. KPMG estimates that by 2040, personal automobile insurance losses will fall to 58%, while commercial automobile insurance losses will rise to 28% (due to an increase in ride-sharing) and product liability automobile losses will comprise 14% of automobile insurance losses. *See* Marketplace of Change Automobile Insurance in the Era of Autonomous Vehicles, KPMG, (May 2, 2016) (https://home.kpmg.com/content/dam/kpmg/pdf/2016/05/marketplace-change.pdf). Moreover, KPMG estimates that in 2013, there were approximately $145 billion in total automobile insurance loss costs. It estimates that in 2040, the total will drop to approximately $100 billion in total automobile insurance loss costs, including a 60% decrease in personal automobile losses. KPMG notes that lower losses lead to lower premiums and the insurance industry will be impacted substantially by the increase in autonomous motor vehicles if it does not adapt.

Insurers may feel that they have ample time to prepare for these changes because the Insurance Institute for Highway Safety estimates that mass-market adoption (95% of registered vehicles) of vehicle safety features takes 30 years. *See Estimated Time of Arrival – New safety features take 3 decades to spread through entire fleet*, Insurance Institute for Highway Safety Highway Loss Data Institute, (January 24, 2012) (http://www.iihs.org/iihs/sr/statusreport/article/47/1/1). However, insurers do not typically wait until new safety features are adopted fully to adjust insurance premiums. Front airbags were invented in 1984 – and made mandatory on all new passenger vehicles since 1998 – but only achieved full adoption in 2016. Significant insurance premiums for airbags were incorporated long before then.

One potential way for insurers to adapt is to introduce hybrid automobile insurance policies that contemplate all levels of autonomous motor vehicles. Insurers should also increase their product liability capabilities as liability will shift from a traditional negligence calculation when humans are operating motor vehicles to a product liability calculation when motor vehicles are operating autonomously.

Insurers will also want to require that motor vehicle manufacturers insert hold harmless, defence, indemnification, and additional insured language in all contracts with downstream vendors and sub-contractors. They should also require motor vehicle manufacturers to have clearly defined maintenance procedures to be followed by the operators. Insurers will also want to align the interest of operators to ensure that operators have financial interests in avoiding losses.

Owners of autonomous motor vehicles will still want insurance policies for their vehicles for incidents other than accidents, e.g. theft, vandalism, storm damage, flooding, mechanical/electrical breakdown, etc.

Insurers will also have to contemplate cyber liability insurance implications. Manufacturers will need coverage for risks associated with cyber-attacks, hacking, and breaches of data privacy. If motor vehicle insurers do not have a cyber-liability capability, they will be avoided by manufacturers as motor vehicles only become more technologically advanced, thereby exposing manufacturers to further cyber liability risks.

The biggest risk to motor vehicle insurers is if motor vehicle manufacturers, through advances in their own technology and access to potentially proprietary loss data, become insurers themselves. Manufacturers will gather data on motor vehicle speed, distance between vehicles, brake pressure, weather conditions, distractions, and other information gathered by proprietary software in the autonomous motor vehicles. The manufacturers will then be able to aggregate that data from all of their autonomous motor vehicles to better understand and price the risk associated with their autonomous motor vehicles. Tesla has already started this, in conjunction with Liberty Mutual Insurance Company. *See* Insure My Tesla (https://www.tesla.com/support/insuremytesla%20). Tesla is not currently underwriting or retaining the risk, but it is gathering the data, learning the claims process, and likely preparing for the likelihood of maintaining a fully-captive insurance division. The insurance industry will have to adapt and provide added value to motor vehicle manufacturers to ensure that they are not severely impacted by advances in technology.

Conclusion

The use of autonomous motor vehicles continues to increase. While this increase provides new risks and product liability considerations, it will also lead to increases in safety. It is possible that federal and state legislatures will enact legislation protecting manufacturers from the attendant risks and legal exposure, but the federal government has explicitly stated 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. Accordingly, manufacturers and insurers will have to evolve to meet the demands of a new motor vehicle and driving framework.

Francis P. Manchisi
Wilson Elser
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 practiced at Wilson Elser throughout his career, helped build and now leads the firm's highly regarded Product Liability, Prevention & Government Compliance practice and is a member of the Executive Committee. 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 U.S. manufacturer of swimming pool products and to a Japanese manufacturer of lathes and machining centres. In connection with these and other engagements, Frank also frequently is retained by insurance carriers based in Finland, Sweden, Denmark and Norway to represent their insured manufacturers in U.S. lawsuits involving products made in Europe and sold in the United States.

Ernest V. Goodwin
Wilson Elser
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 defence 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, labor 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
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Wilson Elser, a full-service and leading defense 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.

Chapter 8

Albania


Genc Boga


Renata Leka

Boga & Associates

1 Liability Systems

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

Product liability is mainly governed by provisions of Law no. 9902/2008 "On Consumer Protection" and the Albanian Civil Code.

Subject to the above instruments the manufacturer *shall be liable* for the damages being caused by defective products, *except* for some specific cases (see question 3.1 below).

The Civil Code sets forth a fault-based kind of liability.

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

There are no provisions that provide for the operation by the State of compensation/indemnity schemes for particular products, unless the State acts as the producer of certain products (i.e. electricity) and in eventual cases of defective products would be obliged to compensate for the relevant 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 for the defective products is attached to the manufacturer. Subject to provisions of the Albanian Civil Code and Law no. 10480/2011 "On general safety of non-food products", the manufacturer is defined as:

a. The manufacturer of a finished product, of a raw material, or manufacturer of an integral part of a product, as well as any other person appearing as such (manufacturer), by putting its name, trademark or another distinguishing mark on the product.

b. The representative in Albania of the manufacturer, where the latter is not based in Albania.

c. The importer of the products in absence of the manufacturer or its representative in Albania.

d. Other persons included in the supply chain, insofar as its activity may affect the standard of the safety of the product.

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

The liability of regulatory authorities is regulated by Law no. 8510/1999 "On the non-contractual liability of public authorities".

Public authorities shall be held liable for the damages caused to individuals or legal entities, *inter alia*, in case of unlawful actions/omissions, in case non-functioning of technical equipment used by public authorities and in case they impose a continuous danger.

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 a general principle, under the Law on Product Safety, the manufacturer has to manufacture and market safe products.

The safety of the product is presumed if compliant with general safety requirements, imposed by applicable law.

The manufacturer and/or distributor within the framework of their activity, and in line with the features of the product supplied, should take appropriate measures to ensure that they:

i. have appropriate information on the risks posed by the products; and

ii. take appropriate measures to prevent these risks, including (where necessary) the notification of consumers through effective means, the suspension of trade of those products, the recall of the products from the market and the return of the products by consumers.

Measures subject to item (ii) above include, *inter alia*, (a) indicating information enabling the identification and traceability of the manufacturer (such as address, identity and other useful information in this respect) in the label or the packaging of the product, information in connection with the product itself or the group of products in case the products pertains to a group of products, and (b) conducting tests over samples of products placed in the course of trade, undertaking investigations with regard to the products, keeping a 'claims recording system', as well as the notification of distributors with regard to the tests being undertaken.

Measures herein above may be undertaken *voluntarily* by the manufacturer or upon instruction of the market supervision authority. Moreover, the manufacturer who considers or has reasonable grounds to believe that the products placed in the course of trade are not compliant with the general safety requirements must adopt corrective measures to remedy, to recall the product or to stop their trade. In addition, when a risk arises thereof, the manufacturer

should promptly notify the market supervision authority by also providing details on the incompliance and the corrective actions undertaken by the manufacturer.

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

Law no. 7895/1995 "Criminal Code in the Republic of Albania", provides that the manufacturing, importing, preservation and selling of dangerous foods, beverages and other materials as well as medicaments, and the incorporation in manufacturing of chemicals and other materials in the manufacturing and processing of foods and beverages, thus causing death or severe injury to the health of individuals, are subject to pecuniary fines or imprisonment of up to 10 years. When more than one individual is affected, the sentence cannot be less than five years.

2 Causation

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

Pursuant to Law no. 8116/1996 "The Code of Civil Procedure of the Republic of Albania", as amended ("Code of Civil Procedure"), the party that claims a right has an obligation to prove the facts on which the claim is founded.

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 the case-law in this regard, in order for liabilities under the non-contractual damage to arise, the following elements shall be taken into consideration:

- *existence of damage*;
- *existence of illegal acts/omissions*;
- *fault* – which in this case relies upon the defendant to prove its non-existence; and
- *causal relationship between the damage and acts/omissions*.

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 when more than one person is responsible for the same damage, their liability towards the injured person is joint and several and thus obliged to compensate such injured person. However, in cases when one of the responsible persons will compensate the injured party, it has the right to ask the others to recover the paid amount.

The market share liability is not available.

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 cases when the manufacturer suspects that the product put on the market may potentially impose risks, he must undertake tests, investigate, and if necessary, keep the complaint on register. Together with other obligations imposed by the applicable law, the manufacturer shall keep his distributor informed upon each development. The manufacturer makes sure that the product is accompanied with usage instructions and, depending on the case, safety instructions (in the Albanian language) which must be easily understood by the end consumer.

The principle of "learned intermediary" is not recognised by the Albanian law. However, it shall be noted that similar (if not identical) liabilities are imposed upon intermediaries (i.e. importers, resellers, etc.) that put the product at the disposal of the final consumer, in some particular cases.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Pursuant to article 628 of the Albanian Civil Code the manufacturer is liable for any damages deriving from product flaws, except when:

(i) the manufacturer has not placed the products on the market;

(ii) subject to certified events, the flaws did not exist at the moment the products were placed on the market;

(iii) the product has not been manufactured for commercial purposes or any other distribution purpose, for any profit aim of the manufacturer, neither is manufactured or distributed in the framework of any commercial undertaking;

(iv) the flaws are due to compliance with the requirements defined by the public authorities;

(v) technical and scientific knowledge available the moment the product was placed in the market did not allow the manufacturer to consider the product as defective; and

(vi) it is about the manufacturing of raw materials or spare parts, which in the entirety of the product represent flaws or such flaws derives from inaccurate instructions from the product manufacturer.

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 point (v) in our answer under question 3.1 above. The burden to prove that there is no liability, lies with the manufacturer.

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

Yes, see point (iv) in our answer to question 3.1 above. However, the defects shall relate to the fact that the product has been in compliance with the rules set out by the public bodies.

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 principle, different consumers all allegedly damaged by the same kind of product may initiate separate proceedings and raise claims on different legal grounds. Anyhow, the court would consider as a precedent (though not binding), cases where the court has decided on liability for the same product.

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

The liability of the manufacturer shall be reduced or lifted where, under certain circumstances, the damage is caused due to the defects of the product, as well as due to the guilt of the damaged person or of another person, where the impaired person is responsible. The liability of the manufacturer shall not be reduced as long as the damage is a joint consequence of the defects of the product and conduct of a third party.

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

See the answer to question 3.5 above.

4 Procedure

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

Jury trials are not applicable in Albania. All trials are judge trials and the court is composed of a single judge or a panel of judges (depending on the dispute).

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 case in question involves issues for which expert advice is required, it may resort to a court-appointed expert.

A court-appointed expert is considered to be an auxiliary of the court, whose main purpose is to offer the court their technical knowledge that the court may not have. The court is not bound by the opinion of a technical expert, and, in fact, it can ignore it if it has a justifiable reason to do so.

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?

Pursuant to Civil Procedure a joint action can be brought before the court by many plaintiffs or against many defendants when: (i) they have joint rights or obligations on the object of the lawsuit; or (ii) their rights or obligations have the same basis from the point of view of the fact or of the law. In a product liability claim, if many people are liable for the same damage caused by the defects of their products, each of them is liable for the whole damage (see, article 633 of the Civil Code).

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

The Consumer Protection Law provides for the right of consumers' association to initiate legal proceedings.

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

In virtue of the Civil Procedure Code, the trial proceedings start with the filing of the lawsuit.

Overall, the first instance proceedings may last from six months to one year. Timing may vary depending on several factors such as workflow, evidence gathering, third-party experts, etc.

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

Preliminary procedural matters include lack of jurisdiction, lack of competence, lack of legal capacity to sue, or any other incompleteness that might be identified by the judge related to the formal requirements of the lawsuit. These procedural matters also include verification on the lack of power of representation.

Such issues relate to matters of law. Issues of fact are evaluated during the trial.

4.7 What appeal options are available?

The final decision of a district court can be appealed by the parties to an appeal court, within 15 days of the judgment. Non-final and intermediate decisions of a district court can be appealed to an

appeal court, within five days of each decision, except when the law provides that they are appealed together with the final decision. Appeal court decisions can be appealed to the Supreme Court within 30 days of the judgment.

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

Yes, see the answer to question 4.2. Parties may present their own expert evidences, which do not imply that they will necessarily be under the court's consideration. In general, there is no restriction on the nature or the extent of this kind of evidence.

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

Factual or expert witnesses are not required to present themselves for pre-trial deposition. Neither are witness statements or expert reports exchanged prior to trial.

Witnesses are required to present themselves during trial and are sworn to speak the truth.

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

The plaintiff should attach to the lawsuit any documentary evidence that supports the arguments of the lawsuit. These documents should be attached in original form to the court and as a copy for each defendant or other party called to trial.

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

The situation regarding arbitration in Albania remains unclear, since the latest changes to the Civil Procedure Code were repealed in the chapter on arbitration and no arbitration law has been enacted so far. However, the New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards and European Convention on International Commercial Arbitration are applicable in Albania. Mediation is also applicable in resolving all civil, commercial and family law disputes, as well as cases in which it is requested and accepted by the parties, before or after the dispute has arisen.

Additionally, according to the Civil Procedures Code, the court shall try to seek an amicable resolution of the dispute and/or notify and instruct the parties for the option of resolving the dispute through mediation.

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

A person that is not domiciled in Albania can be brought within the jurisdiction of Albanian courts when there is a foreign element in his/her judicial-civil relationship. "Foreign Elements", for the purpose of implementing Law no. 10428/2011 "On private international law" ("Private International Law"), imply any legal circumstance that is related to the subject, content or object of a judicial-civil relationship and which is the cause of connection of such relationship to the Albanian legal system.

Also, article 63/a/b of Private International Law, provides that the responsibility for the damage resulting from the products is regulated by:

a) the law of the country in which the product was purchased, if the product was placed on the market in that country; or

b) the law of the State in which the damage was caused if the product was placed on the market of that State.

5 Time Limits

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

The limitation period for bringing products' liability claims is three years, running from the date when the was consumer allegedly damaged by the defective products, became aware of or should have become aware of the damage or the defect, or the date when he became aware of the identity of the manufacturer.

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

Please see the answer to question 5.1 above.

The right of the injured party against the manufacturer for damages, shall expire 10 years from the date when the producer put into circulation the product that caused the damage. The age or condition of the claimant does not affect the calculation of any time limits.

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

No specific provisions are set in this regard.

6 Remedies

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

In a product liability claim under the Civil Code, claimants can seek damages that have been caused and the loss of profit, as well as the expenses done reasonably to avoid or reduce the damage, or damages for death (i.e. living and nutrition expenses for minor children, consort and parents unable to work who used to be under the responsibility of the dead person, the necessary expenses of funeral); or personal injury, taking into consideration the loss or the reduction of working capabilities of the injured person, the expenses of his medical treatment and other expenses that are related to the damage caused.

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

In virtue of the Albanian legislation, the following can be recovered:

- economic damages, which consist of monetary damage due to pecuniary loss or loss of profits;

- biological damages, affecting the psychological and/or physical integrity of a person, directly related to his/her health;
- moral damages, essentially consisting of pain and suffering to the plaintiff; and
- existential damages, essentially consisting of any event that negatively affects someone's 'quality of life'.

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

The casual relationship between the damage and acts/omissions (see question 2.2 above) would be required to reach a conclusion on the case. Therefore, damages can be claimed, only when such damage has actually been caused.

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

This is not applicable in Albanian jurisdiction.

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

No limit is set forth.

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

When a settlement of the claim has been achieved prior to the court hearing, the minutes are kept for it, which are signed by the parties. The court than approves the settlement with a decision. In case of presentation of an agreement for the settlement of claim or an agreement for the resolution of the dispute through mediation, the court decides on its approval, if the agreement does not have conflict with the law. When the settlement is achieved during the court hearing, the terms of the agreement are reflected in the court minutes. The court decides on its approval, but in any case, the agreement shall not conflict with the law.

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

No specific rules are provided in this regard; however, in cases when an individual has received amounts as a result of fraudulent behaviour, in principle the state could initiate proceedings against such individual.

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. In principle, the losing party bears the legal costs of both parties, in full. However, in case the claim is partially accepted or when the court finds justified reasons, it may decide that the costs are to be paid by the losing party in proportion with the accepted claim, or that each party should pay its own costs.

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

Yes. The Albanian parliament recently adopted Law no. 111/2017 "On legal aid offered by the state" ("Law on Legal Aid").

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

Generally speaking, the legal aid is provided to all persons proving that their income is not sufficient in affording costs associated with counselling, representation and defence in criminal, administrative and civil law cases. However, there are also certain categories that, by default, are entitled to legal aid (i.e. victims of family violence, children, disabled persons, etc.).

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

Persons qualifying for legal funding under the Law on Legal Aid are entitled to be excluded from:

- payment of general and particular fees, under the law on judicial fees;
- payment of judicial expenses (i.e. experts, witnesses, translators) according to the procedural law; and
- the obligation to prepay the fee of enforcing a judgment by the public bailiffs.

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

The law is silent on the matter.

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

The court does not exercise control over the costs to be incurred by the parties. The damaged party quantifies its claims when starting the case. As for legal fees, the losing party is generally condemned to refund them to the winning counterparty.

8 Updates

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

Product liability legislation in Albania is under continuous development and improvement with the aim to be fully harmonised with the EU legislation. Though, a weak point of legislation remains its implementation. The supervising market authority, though legally established, is not yet operative and therefore the market is missing an efficient surveillance; hence, the consumers still remain unprotected in cases of defective products. Case law is also very weak and there are very few cases in this regard. Public awareness of consumer rights is weak and, in this regard, the authorities have still a lot to improve on.

Provisions on product liability should be incorporated in any new Law on Consumer Protection in future amendments of the Law. The present state of the legislation on product liability and consumer protection is not satisfactory enough and broader inclusiveness could be achieved through revisions of the Law.

Furthermore, it is important that the harmonised rules be implemented in practice through right incentives and enforcement mechanisms.

Genc Boga
Boga & Associates
40/3 "Ibrahim Rugova" Str
1019 Tirana
Albania

Tel: +355 4 2251 050
Email: gboga@bogalaw.com
URL: www.bogalaw.com

Genc Boga is the Founder and Managing Partner of Boga & Associates which operates in both jurisdictions of Albania and Kosovo. Mr. Boga's fields of expertise include business and company law, concession law, energy law, corporate law, banking and finance, taxation, litigation, competition law, real estate, environment protection law, etc.

Mr. Boga has solid expertise as advisor to banks, financial institutions and international investors operating in major projects in energy, infrastructure and real estate. Thanks to his experience, Boga & Associates is retained as legal advisor on regular basis by the most important financial institutions and foreign investors.

He regularly advises the EBRD, IFC and World Bank in various investment projects in Albania and Kosovo.

Mr. Boga is continuously ranked as leading lawyer in Albania by *Chambers and Partners* and *IFLR 1000*.

He is fluent in English, French and Italian.

Renata Leka
Boga & Associates
40/3 "Ibrahim Rugova" Str
1019 Tirana
Albania

Tel: +355 4 2251 050
Email: rleka@bogalaw.com
URL: www.bogalaw.com

Renata Leka is a Partner at Boga & Associates, which she joined in 1998. She is an authorised trademark agent and has ample experience in trademark filing strategy, portfolio management and trademark prosecution, and handles a range of international matters involving IPR issues. She manages anti-piracy and anti-counterfeit programmes regarding violation of copyright in Albania and assists international clients in all aspects of the IPR. She is also head of the IPR Committee of the American Chamber of Commerce in Albania and is active in all its activities *vis-à-vis* public authorities in matters of IPR in Albania.

For years, Renata has been recognised as a "Leading Individual" in "Intellectual Property" in *Chambers and Partners* and *Chambers Europe* – "Europe's Leading Lawyers for Business" (2010, 2011, 2012, 2013, 2016, 2017 and 2018). According to *Chambers Europe*, Renata continues to be highly active, and assists a number of international corporations with trademark protection. She is also contributing to *World Trademark Review* magazine for Albania.

Renata is fluent in English and Italian.

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Boga & Associates, established in 1994, has emerged as one of the premier law firms in Albania, earning a reputation for providing the highest quality of legal, tax and accounting services to its clients. The firm also operates in Kosovo (Pristina) offering full range of services. Until May 2007, the firm was a member firm of KPMG International and the Senior Partner/Managing Partner, Mr. Genc Boga was also Senior Partner/Managing Partner of KPMG Albania.

The firm's particularity is linked to the multidisciplinary services it provides to its clients, through an uncompromising commitment to excellence. Apart from the widely consolidated legal practice, the firm also offers the highest standards of expertise in tax and accounting services, with keen sensitivity to the rapid changes in the Albanian and Kosovo business environment.

The firm delivers services to leading clients in major industries, banks and financial institutions, as well as to companies engaged in insurance, construction, energy and utilities, entertainment and media, mining, oil and gas, professional services, real estate, technology, telecommunications, tourism, transport, infrastructure and consumer goods.

The firm is continuously ranked as a "top tier firm" by *The Legal 500*, by *Chambers and Partners* for Corporate/Commercial, Dispute Resolution, Projects, Intellectual Property, Real Estate, as well as by *IFLR 1000* in Financial and Corporate and Projects. The firm is praised by clients and peers as a "*law firm with high-calibre expertise*", "*the market-leading practice*", with "*a unique legal know-how*", a "*highly regarded team*" distinguished "*among the elite in Albania*" and described as "*accessible, responsive and wise*".

Chapter 9

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 to enable users to adjust their use of the product so as to avoid or minimise danger or to make an informed decision about whether or not to use the product.

A failure to warn may also found a claim that a product has a safety defect, is unfit for its purpose or is of unacceptable quality under the ACL. In deciding whether the product has a safety defect, is unfit for its purpose or is of unacceptable quality, the court may look at all relevant circumstances, including any warnings and the marketing strategy adopted by the manufacturer or supplier to determine whether they placed the user in a position to properly understand the risks associated with the product.

Australian courts have, to date, declined to apply the learned intermediary doctrine. However, for medical products which may only be accessed through a doctor, the doctrine is consistent with Australian law which acknowledges the importance of the relationship between doctor and patient in the provision of warnings about medical treatment.

Following the Tort Reform Process, in some jurisdictions, evidence from plaintiffs as to what they would have done had there been a warning about a risk of injury is now inadmissible in negligence cases except to the extent that it is evidence against the plaintiffs' interest.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Limitation periods apply to all causes of action pleaded in product liability litigation. Details of limitation defences are set out in question 5.2 below.

Negligence

The following defences may be available to a claim in negligence:

- *volenti non fit injuria* (voluntary assumption of risk);
- contributory negligence; and
- the learned intermediary defence.

Voluntary assumption of risk is a deliberate decision by the plaintiff to assume the risk of injury, loss or damage. To establish the defence of *volenti*, the defendant must show that the plaintiff not only perceived the existence of the danger, but also fully appreciated it and voluntarily accepted the risk. This defence is difficult to establish, but is a complete answer to any claim.

Contributory negligence may be relied on where the plaintiff's conduct fails to meet the standard of care required for his or her own protection and safety, and is a contributing cause in bringing about his or her injury. Damages are apportioned by the court in accordance with each party's degree of fault. In certain jurisdictions, contributory negligence can be a complete defence to an action if the court thinks it is just and equitable in the circumstances.

There is no express authority in Australia for a learned intermediary defence, although there is no reason why the defence cannot be accommodated within existing common law principles.

The Tort Reform Process has created new statutory defences to an action for negligence, although these differ from jurisdiction to jurisdiction.

For example, the following have been introduced as complete defences in New South Wales:

- where the harm was suffered as a result of the materialisation of an inherent risk, which is defined as the risk of something occurring that cannot be avoided by the exercise of reasonable care and skill;
- where the harm was suffered as a result of the materialisation of an obvious risk associated with a dangerous recreational activity. An obvious risk is a risk that, in the circumstances, would have been obvious to a reasonable person in the position of the plaintiff and includes risks that are patent or a matter of common knowledge;
- where a professional defendant acted in a manner that, at the time the relevant service was provided, was widely accepted in Australia by peer professional opinion as competent professional practice (unless the court considers such opinion to be irrational);
- where the defendant is a good Samaritan or volunteer and has exercised reasonable skill and care under the circumstances; and
- in certain cases where the defendant is a public or other authority.

Part 3-5 Australian Consumer Law

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

- the defect alleged did not exist when the goods were supplied by the manufacturer;
- the goods were defective only because there was compliance with a mandatory standard (see further, question 3.3);
- the state of scientific or technical knowledge at the time the goods were supplied was not such as to enable the defect to be discovered (the so-called 'development risk' or 'state of the art' defence) (see further, question 3.2); or
- in the case of the manufacturer of a component used in the product, the defect is attributable to the design of the finished product or to any markings, instructions or warnings given by the manufacturer of the finished product, rather than a defect in the component.

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

If a product is found to have a safety defect under the ACL, the manufacturer or supplier can argue what is commonly referred to as the "state of the art defence" or "development risk defence". The manufacturer or supplier must establish that the state of scientific or technical knowledge at the time when the product was supplied by its actual manufacturer was not such as to enable the defect to be discovered.

Under the statutory guarantee provisions of the ACL, the issue would be whether the product was fit for the purpose for which it was intended, giving consideration to any description applied to the goods by the corporation, the price received by the corporation for the goods, and all the other circumstances.

In negligence, the claimant must establish that the manufacturer failed to exercise reasonable care. The state of scientific and technical knowledge is often pertinent to this issue and forms the basis of the manufacturer's defence.

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

Under the defective goods action provisions of the ACL, it is a defence that the goods had the defect only because there was compliance with a mandatory standard. A mandatory standard is a standard for the goods or anything relating to the goods which, under law, must be complied with when goods are supplied, and which carries a penalty for non-compliance. A standard which simply requires a minimum standard to be achieved is not a mandatory standard.

In an action for negligence and under the statutory guarantee provisions of the ACL, compliance with regulations or standards is a relevant factor in determining whether goods are as fit for the purpose(s) for which goods of that kind are commonly bought as is reasonable to expect.

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

Claimants may re-litigate these issues. This is not possible in cases where the issue has already been determined in a representative proceeding (class action) in the Federal Court of Australia where the claimant is bound by a ruling made in that class action by virtue of their failure to "opt out" of the proceeding. There are also special rules in dust disease cases litigated in the New South Wales Dust Diseases Tribunal.

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

Yes. Defendants are permitted to rely on a statutory right to contribution from other concurrent tortfeasors (whether joint or several). Alternatively, defendants may seek to rely on a contractual right of indemnity. These remedies may be pursued either in the same or subsequent proceedings. If subsequent proceedings are required, time limits do apply. These differ between jurisdictions and depend on the cause of action.

Following the Tort Reform Process, all Australian state and territory jurisdictions enacted a statutory regime of proportionate liability for non-personal injury claims for damages. The liability of a defendant who is a concurrent wrongdoer is now limited to an amount reflecting the proportion of the damage the court considers just having regard to the extent of that defendant's responsibility.

Certain state jurisdictions allow parties to expressly contract out of the proportionate liability scheme.

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

Under the common law and certain legislation, if the defendant can demonstrate that the plaintiff contributed to the damage by failing to take reasonable care, damages will be apportioned by reference to the plaintiff's share in the responsibility for that damage. The regime expressly covers personal injury and loss of life.

4 Procedure

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

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

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

Courts in several jurisdictions may appoint a "court expert" to inquire and report on a question of fact arising in a matter before the court or an "expert assistant" to assist the court on any issue of fact or opinion identified by the court (other than an issue involving a question of law) in the proceeding, should the need arise.

An expert is generally accepted to be a person who has specialised knowledge about matters relevant to the question based on that person's training, study or experience.

The role of court experts or expert assistants is advisory in nature and does not extend to sitting with the judge and assessing evidence presented by the parties.

In most jurisdictions, the parties are joint and severally liable for the payment of the expert's fees.

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

There is a detailed class action procedure in the Federal Court of Australia and the Supreme Courts of Victoria and New South Wales. There are also representative action procedures in other State jurisdictions. An action can only be commenced in the Federal Court where it attracts federal jurisdiction, for example, if it involves a claim under the ACL under federal legislation.

Class actions have involved products including weight loss drugs, heart pacemakers, aircraft fuel, gas, water, tobacco and a variety of food stuffs ranging from oysters to peanut butter. Australia is now the most likely jurisdiction outside North America where a corporation will face a class action.

Federal and Victorian legislation provides for the commencement of a class action where seven or more persons have a claim against the same person and the claims are in respect of, or arise out of, the same, similar or related circumstances, and give rise to a substantial common issue of law or fact.

If these threshold requirements are met, any of those persons may commence an action on behalf of the group. There is no certification process as occurs in the United States. The representative plaintiff must describe the group, but need not identify, name, or specify the number of group members. With limited exceptions, a person's consent to be a group member is not required.

Once proceedings have been commenced, the court will fix a date by which a group member may opt out by written notice to the court, and will give directions regarding the procedure for notifying potential group members of the existence of the proceedings. Unless a person actively opts out of the proceedings, they will continue to be a part of the action and be bound by its outcome.

In order to protect absent group members, the action may not be settled or discontinued without the approval of the court. Similarly, the representative plaintiff may only withdraw from the proceedings or settle his or her individual claim with the leave of the court.

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

Yes. The ACL expressly provides for the institution of proceedings by the Australian Competition and Consumer Commission ("ACCC") on behalf of those who have suffered or are likely to suffer loss as a result of contraventions of the ACL, including certain provisions of Parts 3-5 (defective goods actions) and 5-4 (remedies relating to guarantees). Under these provisions, the ACCC requires the prior written consent of the persons on whose behalf the application is being made.

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

Time to trial depends on the particular jurisdiction and the nature of the claim. It may take anywhere from six months to several years for a matter to be heard and determined.

Proceedings in the Federal Court are usually heard faster than those in the state and territory supreme courts, due in part to the Federal Court's case management system, whereby each proceeding is

allocated to a particular judge who manages the case and usually hears and determines it, and the Supreme Courts' heavier case load.

There are provisions in all jurisdictions for expedited hearings in appropriate circumstances, including the ill health of a litigant.

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

In some jurisdictions, the court may try preliminary issues whether of fact or law or mixed fact and law.

Historically, courts have been of the view that trials of preliminary issues should only be granted on special grounds, such as whether the preliminary issue will substantially narrow the field of controversy, shorten the trial and/or result in a significant saving in time or money.

Preliminary issues are usually heard and determined by a judge.

4.7 What appeal options are available?

In virtually all jurisdictions, there is a right of appeal from the judgment of a trial judge. The procedure varies depending on the jurisdiction in which the original trial was conducted. Leave to appeal is usually necessary when the appeal is from an interlocutory judgment. Even though appeals generally turn on questions of law, it is not uncommon for parts of the evidence used at trial to be reviewed during the course of an appeal.

A party dissatisfied with the decision of a state or territory Court of Appeal or the Full Federal Court may seek leave to appeal to the High Court of Australia, the country's ultimate appellate court. Appeals to the High Court are essentially restricted to questions of law. The High Court will only grant leave to appeal if it is convinced that there is a significant question to be determined.

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

See question 4.2. Where the court has appointed an expert in relation to a question arising in the proceedings, the rules provide that the court may limit the number of other experts whose evidence may be adduced on that question, or that a party must obtain leave to adduce such evidence.

Court experts are rarely appointed. However, as a matter of course, parties adduce evidence from appropriate experts.

The nature and extent of expert evidence is subject to the discretion of the court. In a number of jurisdictions, practice notes provide guidance on the number of experts that might be called by any party in a particular area of expertise. In addition, the court may require the experts instructed by opposing parties to meet before giving evidence in court, to narrow the issues in dispute.

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

Depositions of the parties and witnesses are not taken before trial. However, the Australian legal system is more onerous in terms of the obligations imposed on parties to give discovery of documents (see question 4.10).

In some jurisdictions, most notably the Federal Court of Australia, pre-trial directions are made in the ordinary course that witness statements and expert reports be exchanged before hearing and that those statements and reports comprise the evidence in chief of those witnesses.

It is also common for directions to be made requiring the parties to exchange objections to their opponent's statements and reports before trial. Any objections that are not conceded or otherwise addressed are then argued, and ruled upon, before cross-examination of the witnesses at trial.

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

A party is obliged to discover – that is, to identify and allow the other parties to access – all documents in its possession, custody or power which are relevant to a matter in issue in the proceedings. Discovery occurs at the pre-trial stage so that all documents relevant to the case are disclosed by the parties before the hearing commences.

The obligation to give discovery extends to documents which are no longer in the party's possession, custody or power, but which were previously. This may occur where a relevant document has been lost, destroyed or provided to someone else. In such a case, a description of the document must be provided to the other parties.

Documents that are relevant to a case include those documents on which the party relies, documents that adversely affect the party's own case, documents that adversely affect another party's case, documents that support another party's case, and documents that the party is required by a relevant practice direction to disclose.

All discovered documents must be listed, and the parties' lists sworn and exchanged. Parties are entitled to inspect each other's documents and, if desired, copy them, save for those in relation to which a claim for privilege has been advanced.

Preliminary discovery before the substantive proceedings assists parties in identifying prospective defendants, to determine whether or not they have a claim or to gain information from third parties where any party to a proceeding reasonably believes that a particular party holds a document which relates to any question in the proceeding.

The obligation to discover all relevant documents continues throughout the proceedings. This means that any document created or found after providing initial discovery must also be discovered.

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

Alternative methods of dispute resolution ("ADR") such as mediation, arbitration and conciliation are available in Australia. There is now an emphasis on ADR, particularly mediation, enshrined in various court procedures.

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

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

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

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

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

5 Time Limits

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

Yes, time limits do exist under common law and statute.

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

There are considerable variations between the limitation periods applicable to common law proceedings in the various Australian states and territories, resulting from a profusion of specialist legislation and court decisions, although the Tort Reform Process has resulted in more uniformity in relation to the limitation period applicable to personal injury actions.

In general terms, limitation periods are routinely defined by reference to the nature of the cause of action, including whether the claimant alleges fault-based or strict liability. In most jurisdictions, the limitation period applicable to claims for personal injury is either:

- the earlier of three years from the date the cause of action is discoverable by the plaintiff ("the date of discoverability") or 12 years from the date of the alleged act or omission (the "long-stop period"); or
- three years from the date the cause of action accrued.

Limitation periods including those applicable to personal injury claims are usually suspended while a claimant is suffering from a legal incapacity, which encompasses the period prior to a claimant turning 18, or during which a claimant suffers from a mental or physical disability which impedes them from properly managing their affairs.

Australian Consumer Law

Defective goods actions brought under Part 3-5 of the ACL must generally be commenced within three years after the time the person becomes aware, or ought reasonably to have become aware, of particular circumstances giving rise to the action. There is also a 10-year period of repose, which requires actions to be commenced within 10 years of the supply by the manufacturer of the goods.

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

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

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

Most Australian jurisdictions provide for the postponement of commencement of the limitation period where the plaintiff's right of action or the identity of the person against whom a cause of action lies is fraudulently concealed. The limitation period is deemed to have commenced from the time the fraud was discovered or the time that a plaintiff exercising reasonable diligence would have discovered. Throughout all Australian jurisdictions, the courts have various discretionary bases for extending the time period where it is just and reasonable.

6 Remedies

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

Monetary compensation is available for both pecuniary and non-pecuniary loss. In addition, courts may grant injunctions, including interim injunctions, to restrain breaches or attempted breaches of the restrictive trade practices and consumer protection provisions. The potential breadth of remedies available is illustrated by sections 237 and 238 of the ACL where a court has power to make such orders as it thinks appropriate against a person who was involved in the contravention of the consumer protection provisions of the ACL.

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

The following damages are available for claims of bodily injury:

- general damages, including pain and suffering, loss of amenities and loss of expectation of life; and
- special damages, including loss of wages (both past and future), medical and hospital expenses and the like.

The Tort Reform Process has resulted in caps, thresholds and other limitations being placed on the amount of such damages that can be recovered.

Damages are assessed on a once and for all basis.

Damages are also recoverable for mental damage, provided it can be established that the claimant is suffering from a diagnosed psychiatric condition. In addition, common law damages are available for

damage to the product itself, or other consequential damage to property. One can recover damages for "pure economic loss" but the nature and extent of such damages is extremely complex.

Part VIB of the CCA

Under Part VIB of the CCA, damages are recoverable for losses suffered as a result of personal injuries, including medical expenses (subject to similar caps, thresholds and other limitations imposed on common law damages following the Tort Reform Process). A person other than an injured party may also claim compensation where that person suffers loss as a result of the other person's injury or death, for losses relating to personal, domestic or household goods other than the defective goods, and losses relating to private land, buildings and fixtures.

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

As a general rule, damages for the costs of medical monitoring in the absence of any established injury or loss are not recoverable.

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

Exemplary, punitive or aggravated damages can be awarded by the courts, although not in relation to claims brought under the ACL and, in some jurisdictions (as a result of the Tort Reform Process), not in negligence actions seeking damages for personal injury.

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

Generally, no. However, the Tort Reform Process has resulted in caps, thresholds and other limitations being placed on the amount of damages a personal injury claimant can recover.

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

Court approval is required for the settlement of representative proceedings in Australia and is also required for claims brought by infants or people suffering from a legal disability. A representative proceeding may not be settled or discontinued without the approval of the Court (e.g. section 33V of the Federal Court Act). If the Court gives such an approval, it may make such orders as are just with respect to the distribution of any money paid under a settlement.

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

Yes, government authorities can reclaim these amounts. A claimant is required to refund that part of the damages awarded or settlements paid, which have previously been awarded to the claimant as part of a social security benefit payment. This is to prevent "double dipping". The damages awarded or settlements paid are withheld from the claimant by the defendant until such time that repayment to the relevant government authority has been resolved.

7 Costs / Funding

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

The unsuccessful party usually pays the costs of the successful party. These costs include not only court filing fees, copying charges and other out-of-pocket expenses, but also the lawyer's professional fees. In this context, a reference to costs is not a reference to the total or actual costs incurred by the successful party. Recoverable costs are generally calculated by reference to a court scale, which invariably limits the amounts a successful party can claim for disbursements and services performed by their lawyers.

In some jurisdictions, the Tort Reform Process has resulted in further limitations being imposed on the legal costs recoverable in small personal injury claims (although there are exceptions including where the lawyer and client have entered into a costs agreement that provides otherwise).

The common law rule has been significantly modified in the case of representative or class actions. Statutory provisions restrict a costs order being made against class members other than those who actually commenced the proceedings. Where the representative action is successful, a costs order may be made in favour of the class members who commenced the representative proceedings in an amount determined by the court.

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

Yes, public funding (legal aid) is available.

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

Legal aid services rigorously apply means and merits tests to determine eligibility for aid. As a general rule, very limited, if any, funding is made available to assist claimants to bring civil actions, including product liability claims. Funding is available at the federal level for, *inter alia*, consumer protection matters arising under a federal statute such as the ACL.

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

Historical rules prohibiting lawyers from entering into contingency fee arrangements have been relaxed and a variety of arrangements are now sanctioned. These more recent arrangements allow lawyers and clients to enter into an agreement which provides for the normal fee, or a fee calculated by reference to some pre-determined criteria such as the amount of time expended by a lawyer, to be increased by a pre-agreed percentage. The relevant rules generally impose a cap on the percentage by which such fees can be increased. Some jurisdictions allow lawyers to enter into an agreement to be paid an "uplift fee" where an additional fee may be levied, calculable by reference to the initial fees. All jurisdictions continue to prohibit

contingency fee arrangements where the lawyer's fee is calculated by reference to a percentage of the client's verdict.

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

Third party funding of claims is permitted in Australia, subject to the rules set out in question 7.4 above.

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

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

8 Updates

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

Australia 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 guilt, 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 How long does it normally take to get to trial?

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

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

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

4.7 What appeal options are available?

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

There are the following types of 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).

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

Please refer to the answer to question 4.2.

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

There is no pre-trial in the Brazilian procedural system. The judge has the power to interrogate the parties and the witnesses. The judge may take the deposition of any party at any stage of the proceedings, but ordinarily parties and witnesses testify only under the final public hearing.

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

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

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

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

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

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

5 Time Limits

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

Yes, time limits do exist.

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

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

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

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

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

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

The limitation period starts running when consumers become aware

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

6 Remedies

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

The consumer can file court claims against suppliers for the redress of damages caused by defective products.

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

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

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

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

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

(iii) indemnity for defects in quality or quantity which render the products improper or inadequate for consumption or which reduce their value, as well as defects arising from inconsistency with information 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 is represents a material damage.

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

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

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

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

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

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

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

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

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

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

8 Updates

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

In the Brazilian procedural system, the decisions rendered in class actions, seeking protection of homogeneous individual interests or even collective interests, must be the subject matter of a subsequent award calculation proceeding, a procedure in which the consumer must, in his own name, apply for accreditation in the proceeding and adopt appropriate measures for the quantification of the indemnity attributable thereto.

However, in practice, even if a certain supplier is sentenced in a class action for violation against homogeneous individual or collective rights of consumers, there is a great procedural difficulty in the accreditation phase, in which the victims must prove the damage and causal relation on an individual basis, thus rendering the adverse decision in the class action moot. Recently, entities with standing to bring class action to purportedly protect homogeneous individual interests or even collective interests have treated them as diffuse rights (i.e. the practice deemed to be damaging violates the interest of the "consumer market", an indeterminate entity). With this strategy, the need for individual accreditation and award calculation is eliminated, resulting in a judgment for payment of a certain amount for diffuse injury, which may be channeled into the (state or federal) Diffuse Interests Fund, in case the class action is granted, to the detriment of consumers that in theory would have been individually injured.

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.

Languages: Portuguese; English; and Spanish.

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Canada

Blake, Cassels & Graydon LLP

Nicole Henderson

1 Liability Systems

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

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

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

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

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

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

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

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

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

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

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

1.4 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 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 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 at Canadian law. Exceptionally, some statutes provide for market-share liability for tobacco manufacturers.

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

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

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

3 Defences and Estoppel

3.1 What defences, if any, are available?

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

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

No specific state of the art/development risk defence has been recognised in Canadian law. However, the fact that a product was designed or manufactured in accordance with the state of the art at the relevant time can serve as evidence that the defendant met the applicable standard of care.

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

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

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

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

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

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

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

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

4 Procedure

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

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

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

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

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

Class actions are permitted in all provinces in Canada; all but one 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 How long does it normally take to get to trial?

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

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

Preliminary dispositive issues can be determined by judge alone. In most provinces, the court can determine a question of law, based solely on the pleadings, and can also be asked to grant summary judgment where there is no genuine issue for trial. However, summary judgment is not available in Quebec. 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.

4.7 What appeal options are available?

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

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

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

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

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

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

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).

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

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

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

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

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

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

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

However, parties are permitted 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.

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

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

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

b) the defendant carries on business in the province;

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

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

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

5 Time Limits

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

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

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

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

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

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

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

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

6 Remedies

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

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

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

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

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

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

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

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

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

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

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

There is no limit on the quantum of damages recoverable from one manufacturer, aside from the above-noted cap on general damages.

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

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

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

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

7 Costs / Funding

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

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

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

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

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

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

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

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

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

8 Updates

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

There has been a sharp increase in the number of privacy class actions in Canada over the last several years, and more recently, some plaintiffs' counsel have started bringing privacy class actions in connection with consumer products. In 2017, an Ontario court certified a class action against a computer manufacturer in connection with alleged security vulnerabilities in software that was pre-loaded onto certain laptops. The primary allegation was that the alleged security vulnerabilities could permit a hacker to obtain the end-user's private information. The certified common issues included questions related to breach of sale of goods legislation as well as intrusion upon seclusion and breach of provincial privacy legislation. Other similar class actions have recently been commenced 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 practices public law, including constitutional, freedom of information, administrative, and regulatory law. She is particularly skilled in large, document-intensive matters involving complex technical, scientific and medical evidence. Nicole has appeared as counsel at all levels of court in Ontario, representing clients across a range of industries, including leading manufacturers of medical devices, pharmaceuticals and heavy equipment.

Nicole was 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.

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Blake, Cassels & Graydon LLP (Blakes) is a leading Canadian business law firm. For more than 150 years, Blakes has proudly served many of Canada's and the world's leading businesses and organisations. The Firm has built a reputation as both a leader in the business community and in the legal profession – leadership that continues to be recognised to this day. Our integrated network of 11 offices worldwide provides clients with access to the Firm's international capabilities in virtually every area of business law. Whether an issue is local or multi-jurisdictional, practice-area specific or interdisciplinary, Blakes handles transactions of all sizes and levels of complexity. We work closely with clients to understand all of their legal needs and to keep them apprised of legal developments that may affect them. We also provide relevant legal services expertly, promptly and in a cost-effective manner to assist clients in achieving their business objectives.

China

Kelly Liu

Julien Wang

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 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 has to 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. As to whether it covers the damaged product itself, due to the inconsistency in the law (see question 6.2), different courts might have different opinions.

The law specifies that if personal injury is caused by the defect of a product, the party liable shall pay compensation for medical costs, nursing expenses during medical treatment and lost income due to absence from work; if the personal injury has resulted in disability, the liable party shall also be responsible for the expenses for self-supporting equipment, living allowances, compensation of the disabled person and the living expenses necessary for those under the support of the disabled person; if the defective product resulted in death, the liable party shall pay for the funeral expenses, compensation and the living expenses necessary for those who were supported by the deceased. If the defect of a product causes loss of property of the 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, although it is not mentioned in the Tort Law of the People's Republic of China ("Tort Law"), it is mentioned in the Consumer Protection Law of the People's Republic of China ("Consumer Protection Law") that punitive compensation is up to twice as much of the loss.

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

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

1.4 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, taking bribery and other crime.

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 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 140 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 amounts exceeds 50,000 RMB, such producer or seller shall bear criminal liability. Articles 141 to 149 further stipulate the criminal liability of the producer or seller of particular products i.e. medicines, cosmetics, food, etc.

2 Causation

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

Under the general principle of "the one who claims must prove", the 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 a consistent case law on burden of proof. We must also consider that judicial decisions are not legally binding upon other judges handling similar cases. This causes lack of consistency in court decisions in burden of proof.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

As long as the 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") 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 summary procedure is applied, there will only be one judge handing 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 plaintiffs 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 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.

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

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

4.7 What appeal options are available?

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

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

The court can carry out verification procedures when it is deemed necessary to verify a technical issue; a party can also file for such 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 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.

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

Pre-trial deposition is currently accepted only upon 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. 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.

4.10 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.

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

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

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

In product liability cases, the lawsuit could be filed in China even 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 in 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 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". In practice, different courts may hold different opinions regarding whether a product can be included in a product liability claim because of the inconsistency in the law. Other types of recoverable damage 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?

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 recall the products with potential malfunction, in accordance with 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 may recover the attorney's 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 the said application, it shall issue a ruling within 48 hours. Furthermore, the applicant is required to file the lawsuit or arbitration within 30 days after the people's court applies a preservation measure; the people's court shall revoke the preservation.

8 Updates

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

The 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 a tenfold damage, making the extorting activities even more lucrative comparing to the treble damage provided by the Consumer Protection Law. The professional extortioners usually target manufacturers and sellers with good reputations so as 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". However, 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 even car manufacturers, it is good to learn that the Supreme Court is now arming 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.

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

Ms. Liu is experienced in providing intellectual property counselling, especially in trademark and brand protection. She counsels in all aspects of trademark candidate selection, availability search, application, prosecution, opposition, dispute, litigation and anti-dilution. She also has experience in strategic planning for key markets for a multinational company. She conducts numerous brand protection activities, such as initiating and attending administrative action against counterfeit, providing training to customs officers in different ports in China, and leading and monitoring anti-counterfeiting action on different e-commerce websites. Ms. Liu also has experience in advising on copyright, trade secret/know-how issues, including drafting and reviewing non-disclosure agreement and research agreements.

She also provides legal advice in the field of product liability, especially for clients in the automobile industry. She has represented clients before arbitration commissions, as well as handled litigation.

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

Tel: +86 10 6589 3716
Email: julien.wang@squirepb.com
URL: www.squirepattonboggs.com

Mr. Wang focuses his practice on the defence of product liability and all types of commercial issues. He has experience defending product manufacturers and distributors in individual product liability actions involving injuries and wrongful death claims.

Mr. Wang also provides legal advice in the field of intellectual property and commercial issues.

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Chapter 13

England & Wales

Michael Spencer QC

Crown Office Chambers & Arnold & Porter

Adela Williams

1 Liability Systems

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

Product liability claims may be made under the Consumer Protection Act 1987 ("CPA"), in negligence or in respect of breach of contract. Although claims can be made in respect of the breach of some statutory obligations, such as certain duties imposed by product safety and health and safety legislation, consumer fraud legislation does not give rise to private law rights to claim compensation.

The CPA, which implements the Product Liability Directive, 85/374/EEC, in the UK, imposes liability on the producer of defective products for damage caused by the defect. A product is defective if it is not as "safe as persons generally are entitled to expect", taking account of all of the circumstances, including any instructions or warnings provided with the product and the manner in which it has been marketed. Recent authority suggests that this assessment depends on the facts of the case, but that a wide range of factors may be relevant circumstances, including compliance with regulatory requirements, whether the risks could be avoided, and the risks-benefit balance in the case of medicinal products where safety is always relative (*Wilkes v Depuy International Limited* [2016] EWHC 3096). This conflicts with an earlier decision that adopted a much narrower approach to the assessment of defect (*A and Others v The National Blood Authority and Others* [2001] 3 All ER 298 (the so-called "Hepatitis C" case). Liability is strict: it is not necessary to prove that the manufacturer was at fault in causing the defect. The Claimant need only prove a defect and a causal relationship between the defect and the injury.

Claims may only be brought under the CPA in respect of products put into circulation (i.e. entering the distribution chain) after 1 March 1988. Claims relating to products supplied before this date must be brought in negligence or for breach of contract. Even if the dispute is governed by English law, the CPA may not apply to non-EEA claims (*Allen v Depuy International Ltd* [2014] EWHC 753 (QB), where the court held that the CPA did not apply as the damage was caused outside the EEA, the Claimants had no connection with the EEA, and the defective product was supplied outside the EEA).

In order to establish negligence, it is necessary to prove that the Defendant owed a duty of care to the Claimant, that he breached that duty by failing to take reasonable care, and that the breach caused the damage complained of. Such claims are commonly brought against the manufacturer of a defective product, although they may also be brought against other parties in the supply chain, if fault can be established.

Claims for breach of contract may only be brought against the immediate supplier of the defective product to the person injured. Liability is strict where the contract has been breached and will depend upon the terms of the contract agreed between the parties or implied into the contract.

Consumer contracts are regulated by the Consumer Rights Act 2015, which provides consumers with certain statutory rights. All contracts to supply goods include a term that the goods are of satisfactory quality and comply with the description applied to them or a sample supplied. The goods must also be fit for any particular purpose made known by the consumer to the seller before the contract is concluded. However, the seller will not be liable for faults drawn to the buyer's attention prior to the contract, or which should have been revealed by the buyer's examination of the goods. There is a presumption that goods that malfunction during the first six months after delivery were in breach of contract at the time of supply. Public statements made by manufacturers, importers, distributors and retailers of the product, for example, in labelling and advertising, must also be factually correct and form part of the retailer's contract with the consumer. These statutory rights may not be excluded. Additional rights apply in respect of standard terms not individually negotiated with consumers.

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

Claims for breach of statutory duty can be brought where the courts are satisfied that a statute was intended to create a private law right, actionable by an individual harmed by the breach. It is well established that claims can be made in respect of damage caused by the breach of many product safety and health and safety regulations. However, no such rights have been found to arise from breach of consumer statutes such as the Trade Descriptions Act 1968, the Consumer Protection from Unfair Trading Regulations 2008 and the Business Protection from Misleading Marketing Regulations 2008, which regulate unfair commercial practices and the provision of trade descriptions and advertisements to consumers. To date, there has been no UK litigation similar to the consumer fraud litigation

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

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

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

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

At present, the position remains that, where it cannot be established which of several possible producers manufactured the defective product, the Claimant's evidential burden cannot be met and the claim will be dismissed. The English courts have not adopted so-called "market-share" liability. In *Fairchild* (see the answer to question 2.2 above), Lord Hoffman considered this issue and stated obiter that market share liability did not fall within the scope of the present law on causation as the existence of several manufacturers supplying the same defective product did not materially increase the risk of injury. However, he indicated that the issue should be left for further consideration. In *Barker v Corus* he drew a comparison between the *Fairchild* principle and market share liability, but again declined to decide the point. It remains to be seen whether the English courts will extend the *Fairchild* decision to impose market share liability where the manufacturer of the defective product cannot be identified. In this context, an important distinction needs to be made between liability based only on marketing a product ("market-share liability") and a fact-pattern closer to *Fairchild* in which the Claimant has been exposed to the same product, such as a medicine, made by different manufacturers and the actual dose or doses of the drug which caused or materially contributed to the cause of the injury cannot be identified.

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

A failure to warn may give rise to liability under both the CPA and in negligence.

The CPA specifically identifies the "get up" of the product and any instructions or warnings relating to its use as part of all the circumstances to be taken into account in assessing if the product is defective. In *Palmer v Palmer* [2006] All ER (D)86, the court found a device, designed to allow some slack on a seat belt to enhance comfort, to be defective on the basis that the instructions were incomplete and encouraged misuse, thereby compromising the effective operation of the seat belt itself.

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

This decision, combined with the decision in *Webster v Burton Hospitals NHS Foundation* [2017] EWCA CIV 62, can reasonably be viewed in the medical product field as increasing the spotlight upon the activities of the learned intermediary and, in practice, making it more likely that a claimant will focus a claim on the negligence of the clinician, rather than advance a speculative claim against the manufacturer that he is strictly liable for injury arising, despite the regulatory authorities having approved the product and patient information supplied with the product. In Webster, the court of Appeal determined that there was an overriding obligation for a health care professional to advise the patient directly on any material risks associated with a proposed treatment and reasonable alternative treatment, unless there was good evidence that this information would itself "damage the patient's welfare". In so doing, the court effectively set aside decades of jurisprudence that treated a doctor as not negligent in the counselling provided to a patient, if the doctor could show that a body of expert opinion would have behaved in the same way as the defendant behaved. This test almost certainly caused many claimants to advance a product liability claim for injury against a manufacturer based on strict liability (or even negligence) rather than seek to prove clinical negligence against a doctor.

In negligence, manufacturers and suppliers owe a duty to take reasonable care to provide adequate warnings and instructions with their products. There is no duty to warn of dangers that are obvious or a matter of common knowledge (see, for example, *B (A Child) v McDonalds Restaurants Ltd* [2002] All ER (D) 436, where the court found McDonalds were not negligent in supplying cups of hot tea and coffee without a warning as consumers generally knew that there was a risk of scalding if hot drinks were spilled). Manufacturers owe a duty to warn of dangers identified after the product was first supplied. Failure to warn of design defects identified after marketing may give rise to issues surrounding the application of the development risks defence (see question 3.2 below).

In some circumstances, warnings provided to learned or responsible intermediaries may be sufficient to discharge the manufacturer's duty of care in negligence. Whether such a warning is sufficient will depend on factors including the likelihood and gravity of the risk and the practicality of providing a personal warning to the ultimate consumer. The learned intermediary doctrine has become less important in cases involving medicinal products as manufacturers of medicines are now required to provide patient information leaflets with their medicines unless the warnings and information can be provided on the container or outer packaging of the product.

A failure to warn in breach of duty may sometimes be sufficient to establish liability even if it cannot be established that the inadequate warning caused the damage suffered by the Claimant. In *Chester v Afshar* [2005] 1 AC 134, the House of Lords found that a neurosurgeon was liable for his negligent failure to warn of a rare, but serious complication of spinal surgery even though the risk was unavoidable and the Claimant would probably have had the surgery in any event, even if later. The court considered that a remedy should be available where there was a failure to obtain informed consent. It is unclear whether the same principles would be extended beyond the facts peculiar to that particular case, or whether they would be adopted in a product liability context in relation to a company's obligation to warn in product information.

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

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under the CPA, the following defences are available:

- the defect is due to compliance with legal obligations imposed by UK or EU law;
- the defective product was not supplied by the Defendant;
- the product was not supplied for profit and in the course of business;
- the defect did not exist at the time the product was supplied;
- the so-called "development risks defence" applies: the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the allegedly defective product might be expected to have discovered the defect if it had existed in his products while they were under his control; and
- a producer of component products will not be liable if he can show that the defect was due to the design of the final product, or to defective specifications provided to the component producer by the producer of the final product.

The Defendant has the burden of proving each of these defences. Such defences have rarely been successful. However, in *Terence Piper v JRI (Manufacturing) Limited* [2006] 92 BMLR 141, the Court of Appeal found that the manufacturer of a defective hip prosthesis was not liable when the prosthesis fractured after implantation as the prosthesis was not defective at the time it was supplied to the hospital. The court was satisfied, based on evidence of the manufacturer's inspection and quality control systems, that a defect in the surface of the prosthesis would have been detected prior to delivery, even though there was no evidence of inspection of the specific prosthesis. It was not necessary for the manufacturer to prove the actual cause of the defect and when it arose.

Liability under the CPA and in negligence may also be limited by the principles of contributory negligence (see the answer to question 3.6 below).

In negligence, it is a defence if the Claimant freely and voluntarily agreed to run the risk of injury in full knowledge of the nature and

extent of the risk (*volenti*). Otherwise, the Defendant will defeat the claim if the Claimant cannot establish each of the elements of negligence. Thus, if the Defendant can show that no duty was owed, or his conduct was reasonable, or the negligent act or omission was not causally related to the damage, or that no damage was in fact sustained, he will escape liability. Proof that the fault in the product was not discoverable based on the state of scientific knowledge at the time of supply is often described as the 'state of the art' defence (see the answer to question 3.2 below).

In contract, no specific defences arise, but the claim will fail if the Claimant cannot establish the breach of contract and damage due to that breach.

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

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

Yes, there is a development risks defence. The UK Government opted to include it in the CPA: see the answer to question 3.1 above. Under the CPA it is for the producer to prove that the defect was not discoverable.

The defence was considered by the English courts in the Hepatitis C case, which found that its scope is limited. Based on current authority, the defence applies if the defect was not discoverable in the light of the scientific and technical knowledge at the time the product was supplied. The Defendant's conduct is irrelevant. The court found that the defence was not available if the existence of the defect in the product was, or should have been, known. It was irrelevant whether or not the defect could be avoided because measures to identify and rectify the defect were impractical or impossible; once the defect was known the defence became unavailable. (Such factors may, however, be relevant to the assessment of defect – see the *Wilkes v Depuy International* case cited above.) In negligence, whether the Defendant exercised reasonable care in relation to the design/development, manufacture, supply, marketing and, in appropriate cases, licensing of the product, will be assessed in the light of the state of scientific and technical knowledge at the time these activities were carried out. Manufacturers also owe a continuing duty to warn of any faults identified after the product has been supplied and, where a warning is not sufficient, to modify or withdraw the product. If the Defendant manufacturer is able to show that he acted in the way that a reasonable manufacturer would have done, this is often described as the "state of the art" defence. It is significantly wider than the development risks defence outlined above, because the court must assess the Defendant's conduct; not just whether the defect was discoverable. Factors such as whether the defect could be avoided and compliance with statutory obligations are relevant.

These issues are not relevant to claims for breach of contract.

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

It is a defence to proceedings under the CPA if the manufacturer can show that the defect is due to compliance with UK or EU laws. Otherwise, there is no general defence under the CPA, in negligence, or in contract, in circumstances where the manufacturer is able to demonstrate compliance with regulatory and statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product.

Such compliance is, however, of evidential value, and may help in the defence of negligence claims by demonstrating that the manufacturer exercised reasonable care. It is also a relevant circumstance for the purpose of determining what persons are generally entitled to expect in relation to the safety of a product for the purpose of proceedings under the CPA. In the *Wilkes* case, the court held that compliance with regulatory standards carried considerable weight because these "have been set at a level which the …[regulator] has determined is appropriate for safety purposes". Similarly, the court held that compliance with broader regulatory requirements was evidence of the level of safety of the product that persons are entitled to expect. Although the Defendant's conduct is generally irrelevant for the purpose of CPA claims, evidence that it had in place appropriate systems to detect any defects in the product and for post-marketing surveillance may also be relevant to the question of whether a defect was "discoverable" for the purpose of establishing whether the development risks defence is applicable. Such systems are commonly mandated by statute, for example, in the field of medicines and medical devices.

However, failure to comply with a regulatory standard, compliance with which is not required by law, may not be decisive in determining liability. In *Tesco v Pollard* [2006] EWCA Civ 393, Tesco was not liable for supplying a bottle of dishwasher powder with a screw top, where the child resistant cap fitted did not meet the British Standard, as there was no statutory requirement for such a cap to be fitted and all that the public could legitimately expect was that the bottle would be more difficult to open, which it was.

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

In general, a final judgment or order is conclusive as between the parties to the proceedings and their successors (save where the judgment can be set aside, for example, because of fraud, or because the decision was not based on the merits). An estoppel arises that prevents the parties from re-litigating in subsequent proceedings the decision or any issues that were an essential part of the legal basis of the judgment. In group litigation, a judgment or order is binding on the parties to all claims that are on the group register at the time the judgment or order is made, unless the court orders otherwise.

In principle, an estoppel cannot arise in proceedings involving non-parties. However, in certain circumstances, it may be possible to defeat a challenge to a prior decision by a party to that decision on grounds of abuse of process. Even if the doctrines of estoppel and abuse of process do not apply, the prior findings of another court based on similar facts are likely to be persuasive.

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

Yes. Claims for contribution or indemnity can be made against a third party where the third party is liable to the Claimant for the

same damage as the Defendant. Such claims can be brought either in the same proceedings (by means of a "Part 20" claim) or in subsequent proceedings. In the case of subsequent proceedings, the claim must be brought within two years from the date of judgment in or settlement of the Claimant's claim.

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

Yes. Liability under both the CPA and in negligence can be limited if the Defendant can prove that the Claimant's negligence caused or contributed to the damage.

4 Procedure

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

Trials are by a judge.

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

Yes, but this power has never been used in the product liability field. In practice, assessors are most commonly appointed where technical issues arise. In product liability claims, assessors have not been appointed to assist the court in deciding issues of liability; on the whole, in such cases, the court prefers to leave technical issues to the experts called by the parties themselves and to evaluate the experts' evidence having heard it tested in cross-examination.

The court can appoint one or more assessors to assist the judge to enable him to reach a properly informed decision on matters in which the assessor has skill and expertise. The assessor provides assistance as directed by the court. This can include sitting with the judge during all or part of the trial and preparing a report for the court on any matter at issue in the proceedings. The assessor does not have judicial status and does not play a part in deciding the case; his role is to educate and assist the judge.

Under the Civil Procedure Rules (CPR), which lay down procedural rules for the conduct of proceedings in England and Wales, the parties to any proceedings must be notified of the appointment of the proposed assessor and can raise objections.

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

Yes. Where claims give rise to common or related issues of fact or law the court has the power to make a group litigation order (GLO) enabling it to manage the claims covered by the Order in a co-ordinated way. Many group claims have been brought over the last 30 years in relation to defective products and medicines, cases of industrial disease and sudden accidents or disasters.

The procedure is 'opt-in'. Claims managed under a GLO remain individual actions in their own right. However, the court will usually order that one or more actions that are representative of the rest of the claims cohort are tried as lead actions. The outcome of the lead actions does not, in theory, determine liability in the remaining cohort of claims, but those actions will establish findings of law and fact that may, in practice, allow the parties to compromise or simplify resolution of the remainder of the litigation by focusing further proceedings on clarifying any remaining points of principle.

Proceedings can be brought by any party that has a claim, whether an individual, a company or another legal entity. There is currently no mechanism by which claims can be brought by a representative body on behalf of a number of claimants, 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 Annex to the proposal lists EU legislation, infringement of which could potentially give rise to a representative action, including the Product Liability Directive 85/374/EEC, the Community Code relating to Medicinal Products Directive 2001/83/EC and legislation relating to sale of goods and services, advertising, and data protection in various sectors. The General Product Safety Directive 2001/95/EC is not listed, nor is the sectoral product safety legislation covering e.g. toys, chemicals, machinery, and low voltage electrical equipment. It remains to be seen how this proposed legislation will develop and whether it will be implemented in the UK. However, representative actions may already be brought in England and Wales on behalf of consumers seeking damages for infringement of competition law.

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

This depends on the complexity of the case and the value of the claim. According to the Court Statistics Quarterly for October to December 2017, 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 58.3 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 took approximately six-and-a-half years from the issue of the first proceedings until judgment. In all cases, delay is largely a result of the conduct of the parties and is not inherent in the court system.

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

Yes. In accordance with general case management powers the judge can order the trial of preliminary issues of law and fact in separate proceedings prior to the main trial, and can decide the order in which issues are to be tried in the main trial. In a suitable case, the court also has power to give a summary judgment dismissing a claim which has no realistic prospect of success.

4.7 What appeal options are available?

An appeal may only be made with the permission of the court (either the appeal court or the lower court that made the decision subject to appeal) and such permission will only be granted if the appeal appears to have a real prospect of success or there are other compelling reasons why it should be heard.

The appeal will usually be limited to a review of the lower court's decision, but the court retains the power to order a re-hearing in the interests of justice. An appeal will be allowed where the decision of the lower court was wrong (because the court made an error of law, or of fact, or in the exercise of its discretion) or was unjust because of a serious procedural or other irregularity of the lower court. However, in practice, the courts will rarely disturb findings of fact made by the trial judge who had the benefit of hearing first hand the witness and expert evidence.

The appeal court may affirm, vary or set aside any order or judgment made by the lower court, order a new trial or hearing or make any other appropriate order.

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

Experts are generally appointed by the parties to litigation rather than by the courts. No expert may give evidence, whether written or oral, without the court's permission and the court may, in appropriate cases, dispense with expert evidence or require that evidence on a particular issue be given by a single joint expert. (The court will select a joint expert from a list prepared by the parties if they cannot agree who should be instructed.)

The extent of the expert evidence that is permitted will depend on the type and value of the claim, with more extensive evidence permitted in complex cases. In all personal injury cases, the Claimant must serve a medical report with his or her Statement of Case substantiating the injuries alleged in the claim.

Expert evidence should be independent and comprehensive. An expert owes an overriding duty to assist the court on matters falling within his expertise; this duty overrides any obligation to the party instructing the expert. Experts can only give evidence on matters of opinion falling within their expertise.

Evidence must be provided in the form of a report disclosed to the other parties. The Court Rules give the parties a right to put written questions to an expert about his or her report in order to clarify the report. Where several experts are instructed it is usual for experts in particular disciplines to meet on a "without prejudice" basis, after the exchange of reports and before giving oral evidence, in order to explore areas of agreement and narrow the matters in dispute.

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

The factual and expert evidence that the parties intend to rely upon at trial must be provided in the form of witness statements and expert reports that are disclosed by the parties prior to the trial. The court may make directions limiting the scope of factual and expert evidence by, for example, identifying those disciplines or issues to which such evidence may be directed. Evidence is usually mutually exchanged, but the court may, in appropriate circumstances, direct that it is served sequentially.

Factual and expert witnesses are required to give oral evidence at the trial unless the court orders otherwise. However, the witness can only amplify the evidence given in his/her written statement or report with the court's permission. Expert evidence is usually given sequentially, but the court may order that it is given concurrently (so-called 'hot-tubbing').

Witnesses are not generally required to present themselves for pre-trial deposition. However, the court may order evidence to be given by deposition if the witness is unable to attend the trial. The increased use of video conferencing facilities has reduced the use of depositions in proceedings in England and Wales. Evidence can be taken by video if the witness is abroad or too ill to attend court.

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

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

A document is in a party's control if he has, or had, physical possession of it, a right to possession of it, or a right to inspect and take copies of it. The obligation may therefore extend to documents in the hands of a party's professional advisers or an associated company provided control can be established.

'Document' means anything on which information of any description is recorded and includes paper records, drawings, microfilms, information held on tape, video, CD or DVD, and electronic documents such as emails and metadata (including electronic documents that have been 'deleted' which are held on servers and back up systems).

The parties are required to conduct a reasonable and proportionate search for disclosable documents. The obligation to give disclosure continues until the action is at an end and applies to documents created while the proceedings are underway. Additional obligations apply in the case of the disclosure of documents held in electronic form and the Court Rules require the parties to exchange information about the electronic documents that they hold and to seek to agree the scope of searches for electronic documents.

The duty to disclose the existence of documents is a strict one and is enforced by the court. A party may not rely upon any documents that it does not disclose. Moreover, if a party withholds documentation that should have been disclosed, the court may impose cost penalties or draw an adverse inference.

Disclosable documents are identified in a List of Documents served on the opposing party. All disclosed documents can be inspected save for those which are privileged from inspection. Two of the most important types of privilege are "legal advice privilege", which applies to confidential communications between a lawyer and his client made for the sole or dominant purpose of seeking or giving legal advice and assistance, and "litigation privilege", which applies to documents between the potential party, his lawyer and any third party, created after litigation is contemplated or pending, for the sole or dominant purpose of seeking or giving advice in relation to the claim, or collecting evidence for use in the litigation. Legal advice privilege only applies to lawyer-client communications with company employees who are regarded as the "client" (generally senior managers or the in-house lawyer), not all employees. Litigation privilege will only apply if there is a real likelihood of litigation, rather than a mere possibility.

Disclosure usually takes place after pleadings setting out the parties' cases have been served. In addition, a party may also seek an order for disclosure of specific documents or classes of documents. However, the court also has power to order pre-action disclosure in appropriate cases in order to fairly dispose of the proceedings. Such disclosure may only be ordered in respect of specific documents or classes of documents that would have to be disclosed in any event once the proceedings are underway. Any documents disclosed in accordance with these rules may only be used in connection with the proceedings in which they are disclosed until such time as they are referred to at a hearing held in public, or the parties agree, or the court otherwise gives permission.

A revised disclosure regime which seeks to limit disclosure is the subject of a proposed 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.

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

There are a variety of different methods of alternative dispute resolution (ADR) including mediation, arbitration and neutral evaluation, which can all be pursued as an alternative to litigation. Mediation is also commonly used during the course of litigation in an attempt to compromise the proceedings. The courts encourage the use of ADR to resolve disputes and the pre-action protocols to the court rules provide that the parties should consider whether some form of ADR is more suitable than litigation before commencing proceedings. While the courts cannot compel the parties to use ADR procedures (*Halsey v Milton Keynes General NHS Trust* [2004] EWCA Civ 576), failure to follow the protocols or to respond to an invitation to participate in ADR may amount to unreasonable conduct and result in a cost sanction (*PGF II SA v OMFS Company 1 Limited* [2013] EWCA Civ 1288). Courts have refused to award costs to a successful party where they unreasonably refused to mediate (*Dunnett v Railtrack plc* [2002] EWCA Civ 303), 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).

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

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

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

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

villagers against The Natural Environment Research Council, a British organisation which allegedly conducted a negligent survey, in respect of damage arising from contaminated ground water (*Sutradhar v Natural Environment Research Council* [2006] UKHL 33). 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 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).

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

Medical monitoring claims of the type pursued in the USA in recent years have not been litigated before the English courts. English law does not generally permit recovery of the cost of tests or investigations unless the product has actually malfunctioned and caused physical or psychiatric injury or damage. Such medical monitoring costs are recoverable only as medical expenses consequential upon the main injury or damage. In addition, the courts will not usually allow a Claimant to recover damages where he/she sustains a recognised, but unforeseeable, psychiatric illness as a result of becoming aware that he/she is at risk of sustaining a disease/illness, or to recover the costs of future medical monitoring to determine if that disease/injury has arisen (*Grieves v FT Everard & Sons Ltd* [2008] 1 AC 281).

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

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

Punitive or exemplary damages are rarely, if ever, awarded. They are not generally available in respect of claims for breach of contract. Although they are available in tort claims (see *Kuddus (AP) v Chief Constable of Leicester Constabulary* [2001] 2 WLR 1789), exemplary damages will only be awarded in certain limited circumstances, including where the Defendant's conduct was calculated to make a profit that exceeds the compensation recoverable by the Claimant or where there has been oppressive, arbitrary and unconstitutional conduct by Government servants (see *Rowlands v Chief Constable of Merseyside* [2006] All ER (D) 298 (Dec)). Exemplary damages may be awarded in claims regarding infringements of competition law, but only where the breach was intentional or reckless and the Defendant's conduct was so outrageous as to justify an award (*2 Travel Group Plc (in Liquidation) v Cardiff City Transport Services* [2012] CAT 19). Exemplary damages are not generally recoverable in circumstances where a Defendant has already been fined in respect of his conduct (see *Devenish Nutrition Limited v Sanofi-Aventis SA and Others* [2007] EWHC 2394 (Ch)).

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

There is no such limit.

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

In general, a Claimant may unilaterally discontinue all or part of his/her claim at any time. However, the court's permission is required for compromise or settlement of proceedings instituted against or on behalf of a minor (aged under 18) or an adult who is incapable of managing their own property and affairs. Court approval is also usually sought where there is a settlement or compromise of an unlitigated claim made by, or on behalf of, or against, such a person as a compromise is not enforceable without the approval of the court. There is no requirement to seek court approval in other circumstances, for example, on the settlement of the claims comprising a group action.

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

Yes. Under the Social Security (Recovery of Benefits) Act 1997, where compensation is paid in respect of an accident, injury or disease, the compensator is liable to repay to the Government state benefits paid to the Claimant in respect of that accident, injury or disease. The scheme is administered by the Compensation Recovery Unit (CRU), which issues certificates setting out the recoverable benefits (CRU payment). The compensator can offset the CRU payment against certain types of compensation paid to the Claimant (in respect of loss of earnings, costs of care and loss of mobility). No deductions can be made from the damages paid in respect of the injury/disease itself.

A similar scheme applies to the recoupment of National Health Service (NHS) charges in accordance with the Health and Social Care (Community Health and Standards) Act 2003. Where the Claimant has received NHS treatment or been provided with NHS ambulance services as a result of the injury which is being compensated, the costs of that treatment must be paid by the compensator in accordance with a statutory tariff.

7 Costs / Funding

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

The general rule is that the unsuccessful party pays the legal costs of the successful party, (including expert fees and other incidental expenses such as court fees). However, 'Qualified One-way Cost Shifting' ("QOCS") applies to claims for death or personal injuries (provided a funding arrangement was not entered into prior to 1 April 2013). This means that a Defendant may only enforce an order for costs against a Claimant, without the court's permission, to the extent of any damages and interest ordered in favour of the Claimant. In practice, this means that in most personal injury claims an unsuccessful Claimant will not be responsible for the Defendant's costs, although this principle will not apply if the claim is struck out, or if the court determines that the Claimant is fundamentally dishonest. If the Claimant is successful they may recover their costs

from the Defendant in the usual way, subject to a 'set-off' of any costs orders made in the Defendant's favour (provided such costs do not exceed the amount of damages awarded).

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

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

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

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

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

The Legal Aid, Sentencing and Punishment of Offenders Act 2012 largely 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).

8 Updates

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

See above. The key developments over the past year have been procedural. The changes to disclosure obligations, currently under consideration, could have substantial implications for the costs associated with litigation including in relation to product liability claims. 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.

Acknowledgment

The authors would like to acknowledge the assistance of their colleague Tom Fox in the preparation of this chapter.

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, labelling, and compliance with standards in relation to a range of consumer products including electrical and electronic goods, clothing, cosmetics and toys.

Michael Spencer QC
Crown Office Chambers
2 Crown Office Row, Temple
London, EC4Y 7HJ
United Kingdom

Tel: +44 20 7797 8100
Fax: +44 20 7797 8101
Email: spencer@crownofficechambers.com
URL: www.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 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. He is instructed by 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 is instructed 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, advising clients in relation to the regulation of medicinal products and medical devices in the UK and at the EU level. She also specialises in product liability litigation and advice. She has extensive experience in this area, handling both unitary claims and group actions, and co-ordinating litigation brought throughout the UK and EU. Her 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 has also acted in proceedings involving a range of products including pharmaceuticals, medical devices and food.

Arnold & Porter is an international law firm with over 1,000 attorneys in 13 offices in the US, London, Frankfurt, Shanghai and Brussels. With 40 partners and counsel specialising in product liability matters, the firm is one of the most experienced firms internationally, providing clients with an integrated product liability service on a transatlantic basis.

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

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 (New York) for US enquiries.

France

Carole Sportes

Squire Patton Boggs

Valérie Ravit

1 Liability Systems

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

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

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

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

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

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

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

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

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

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

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

The responsibility is borne by the producer who is strictly liable for a defective product. When they act as professionals, the manufacturer of a finished product, the producer of a raw material and the manufacturer of a component part are considered as producers for the purpose of the product liability regime (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 (Council of State, 9 November 2016, n°393926, Administrative Court of Appeal, Paris 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.

Specific regulations of recall are also provided in specific areas (medical products, food 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 *actus reus* of involuntary manslaughter is defined in the same way as that of involuntary bodily harm.
- In any event, the professional can be held liable for the **administration of harmful substances**. The offence requires the intent to conceal the noxious nature of the substance administered.
- The offence of **deliberate endangerment of human life** can also be retained if the producer has deliberately breached a special duty of safety or duty of care, imposed by law or regulation, which exposes the victim to an immediate risk of death or injury likely to result in mutilation or permanent disability.

The defendant can be held liable for **fraud** where there has been a deceit or an attempt to deceive a contracting party as to the substantive qualities of the goods or products.

2 Causation

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

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

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 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 product (ECJ, 5 March 2015, C-503/13 and C-504/13, *Boston Scientific*

Medizintechnik). This solution has already been applied in French case law, outside the Product Liability Law, granting compensation for anxiety to the patients and covering the monitoring/replacing medical costs.

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

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

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

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

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

Further, as to tortious liability, insufficient information on the product, even properly manufactured, may characterise a defective product and thus give rise to liability. It is now clearly established that the security which one can legitimately expect depends upon the information provided in the information leaflet. The French Supreme Court has held that the producer of propane bottles was liable towards a user who had not been given the necessary information, even though the producer was not bound by a contract to the victim.

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

3 Defences and Estoppel

3.1 What defences, if any, are available?

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

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

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

- he did 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 is the producer's responsibility 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 the 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.

- Environmental sector:

Pursuant to Article L 142-2 of the French Environmental Code, approved associations may bring a claim for infringement of the legislative provisions relating to the protection of nature and the environment, to the improvement of the living environment, to the protection of water, air, soils, sites and landscapes, to town planning, to sea fishing, or those whose purpose is the control of pollution and nuisances, nuclear safety and radioprotection, commercial practices and misleading advertising including environmental information and of the enactments for their application.

Under this claim, the court can grant two sorts of reliefs: injunction to cease the violation and compensatory damages for personal injury and material loss.

This action is only open to associations either approved by Decree or created for the protection of the environment (Article L141-1 of the French Environmental Code).

- Equal opportunity sector:

Law No. 2016-1547 of 18 November 2016 introduced class actions in the 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 by laws provide that the purpose of the association is the defence of that interest.

- Personal Data Protection:

Law No. 2016-1547 of 18 November 2016 also introduced class actions for data protection.

Under this claim, the court can only grant an injunction.

This action is open to associations which by laws provide that the purpose of the association is the protection of privacy and personal data. It is also open to consumer associations and trade unions.

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

In principle, the claimant has to prove a personal and direct interest to successfully bring a claim. In parallel, associations are entitled to bring a claim limited to the collective interest as defined by their articles.

In the exclusive context of the new class actions, some specific associations are able to bring claims on behalf of a number of claimants (see question 4.3).

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

A claim for civil liability usually lasts two years. It takes at least another year for an appeal, and 18 months more for the recourse before the *Cour de Cassation.*

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

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

As a matter of principle, claimants have to present their procedural claim *in limine litis,* i.e. before any claim is brought on the merits. These procedural issues can lead to an end of the trial without an examination of the merits of the case.

Requests for experts or for a stay of the proceedings could also suspend the examination of the merits of the case and affect the course of the proceedings.

Except from these elements, the French system does not allow preliminary issues to determine the need for a further trial.

4.7 What appeal options are available?

A decision rendered by a first instance court can be appealed before a Court of Appeal. Even though the appellant can raise new grounds and produce new evidence, it may not depart from its original claims except to: plead set-off; reply to the opponent's claims; or obtain a ruling on issues arising from the intervention of a third party.

The Court of Appeal's decision can in turn be subject to recourse before the *Cour de Cassation,* which only has jurisdiction to hear points of law excluding factual issues. This court then has discretion to refer a preliminary question on constitutionality to the French Constitutional Court, if there is a doubt as to the constitutionality of a legal provision applicable to the present case.

It must be highlighted that new rules are under discussion regarding the role of the *Cour de Cassation,* which may lead to a more restricted access before this court.

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

The court can appoint experts in case of technical difficulty of its own initiative. The expert's findings are not binding upon the court.

The parties may appoint their own expert and use their report as evidence to support their claim. The value of this evidence will be left to the unfettered discretion of the court.

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

Factual or expert witness statements are admitted before the courts as evidence. Such statements can be made in writing or (very rarely) orally.

The parties must exchange this evidence in the course of the proceedings to comply with the adversarial principle.

There are no pre-trial proceedings in France.

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

Under French law, there is no discovery. The French system requires each party to rely upon the evidence that they select to support their claim. A party can apply to the court for a disclosure order, which may be admitted or dismissed.

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

Conciliation, mediation and arbitration are available in France as ADR.

Since the Decree n°2015-282 of 11 March 2015, which entered into force on 1 April 2015, the parties must prove that they have taken steps to achieve an amicable resolution of the dispute, unless the urgency or nature of the matter does not allow it. However, a failure to comply with such an obligation is not sanctioned.

Further, since 1 January 2016, professionals are obliged to suggest a mediation procedure to their consumers to solve any dispute before going to court.

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

In many circumstances, a person not domiciled in France can be brought before French courts. French jurisdiction can be secured when provided by the Recast Brussels Regulation n°1215/2012 of 12 December 2012, which entered into force on 10 January 2015, by French international private law, by contractual provisions or in cases where the harmful event occurred in France.

5 Time Limits

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

Depending on the cause of action, various time limits apply.

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

Under the French general statute of limitation, a claimant can bring a claim on a contractual or tortious basis within five years from the date it knew or should have known the facts that enabled it to exercise its rights (Article 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.

However, these time limits vary depending on the age or condition of the claimant. As provided for in Article 2234 of the FCC, "*time does not run or is suspended where it is impossible to act following an obstacle resulting from the law, an agreement, or force majeure*". It is suspended for non-emancipated minors or adults with diminished capacity except for specific actions set out in Article 2235 of the FCC.

There are other specific rules which bar the time limit from running.

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

There is no relief for a claimant who is time-barred, except when interruption or suspension is provided by law.

However, the *Cour de Cassation* has already ruled that fraud which affected the proper process of the claim suspended the running of time.

6 Remedies

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

Monetary compensation and injunctive relief are available under French law but declaratory relief is not available for product liability claims.

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

All damages suffered have to be fully compensated under French law.

Any types of lawful damages are recoverable, as long as causation is proved.

However, the damage caused to the defective product itself is not recoverable.

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

Medical monitoring costs can be recovered when there is a serial defect, even though the product has not yet malfunctioned or caused an injury.

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

Punitive damages are not granted by French courts.

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

There is no maximum limit on the amount of the damages recoverable. Damages are compensated up to the amount to which they have been suffered.

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

Settlement of claims may be given judicial approval to be enforceable before the courts. However, when such settlements are contracted with minors or mentally impaired protected adults, the court must give approval.

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

National Health Insurance that bears the costs arising from the damages suffered by the victim can then bring an action against the liable third party or its insurer, and can recover up to the amount it has paid to the victim or incurred on behalf of the victim.

7 Costs / Funding

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

The losing party bears the court fees and other incidental expenses. A lump sum is also granted to the successful party for their legal costs, taking into account equity and the financial resources of the losing party.

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

Legal aid is available in France. It may cover the costs totally or partially incurred during the trial.

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

As a matter of principle, public funding is aimed at low-income litigants. Such financial thresholds are defined by decree and regularly revised. Legal aid can be granted to European citizens, foreigners legally residing in France, and asylum seekers.

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

Contingency fee arrangements are strictly forbidden under French law.

However, a written fee agreement with the client which is subject to uplift in the event of a particularly positive result and where the calculation is set out in advance is permitted.

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

Third party funding is not prohibited in France and is used mainly for international arbitral proceedings. Legal boundaries are not yet precisely defined in France.

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

The court does not exercise a control over the costs incurred by the parties.

8 Updates

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

- Class actions specific to certain sectors were enacted in 2016 in the fields of health law, anti-discrimination, data protection and environmental law.

  Decree n°2017-888 of 6 May 2017 implementing the Law of 18 November 2016 defines the procedure applicable to the class actions in the fields of health law, anti-discrimination, data protection and environmental law.
- A draft bill relating to the French tortious liability regime was issued on 13 March 2017.

  At this stage, one of the main changes relating to the defective product liability regime that is considered is to prevent the producer to free himself from liability, if he proves that the state of scientific and technical knowledge at the time he put the product into circulation was not such as to enable the existence of a defect to be discovered, where the damage has been caused by a medicinal product for human use.

This major proposed change is sure to be heavily challenged once the discussion in Parliament has started.

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

Tel: +33 1 5383 7400
Email: carole.sportes@squirepb.com
URL: www.squirepattonboggs.com

Carole Sportes is a partner in the dispute resolution department of Squire Patton Boggs' Paris office.

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

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 for 10 years to the development of a French boutique law firm, BOPS, 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 for her ability in dealing with technical and complex matters.

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

Tel: +33 1 5383 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 Chemicals, Marketing Services, Life Sciences, Aerospace & Defence, Energy, Automotive and Diversified Industrials.

Squire Patton Boggs' Paris Office is frequently recommended for Mergers & Acquisitions, Tax, Labour Law and Dispute Resolution.

Germany

Mirjam Schorr

Kennedys Law LLP

Benjamin Loechner

1 Liability Systems

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

There are two main product liability regimes available under German law: (1) the Product Liability Act (the "PLA"); and (2) tort law. These run in parallel with one another.

There are also more specific pieces of legislation, such as the Federal Drug Act which governs pharmaceuticals/medicines.

Contractual liability is relevant in the supply chain, including between the distributor/seller and the end user. However, there is no concept of implied warranties which could provide the end user with a direct contractual claim against the producer.

(1) The regime under the PLA

The PLA implements the EU Product Liability Directive (85/374/EEC) and imposes strict liability upon a producer/manufacturer of a defective product.

Under the PLA, the manufacturer of a defective product will be liable for personal injury or death or damage to property caused by the product. It rests upon 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.

There are a number of defences available to a manufacturer including on the basis of the technical and scientific knowledge at the time the product was put into circulation (see question 3.1).

The manufacturer is not liable for damage not exceeding €500, damage to the product itself or damage to a product used for business purposes.

(2) Tortious liability

Product liability claims may also be brought under the tort law provisions of the German Civil Code (the "BGB"), in particular, section 823 of the BGB. Liability is fault-based.

The burden is on the Claimant to establish that the defective product was put into circulation by the producer and that the defect caused damage. The burden then shifts to the producer to displace the rebuttable presumption that the producer acted negligently/failed to fulfil its duty of care.

Unlike under the PLA, damage caused where the product was primarily used for business purposes can be recovered. Also, the first €500 is recoverable under the tort regime.

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

The state does not operate any product specific compensation schemes. Germany does, however, in effect operate a compensation scheme for accidents at work or occupational diseases as part of the social security system. This will kick in where products have caused injuries at work.

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

Who may bear responsibility depends on the liability regime.

Under the PLA, the "producer" of a product is the party with whom the responsibility typically lies. This can be any of the following: the manufacturer, the producer of raw materials or component of the finished product; any person who puts their own name, trademark or branding on the product which represents themselves as a producer; the importer of a defective product into the EEC who imported the product in the course of their business; and each supplier of the product unless they inform the injured party, within one month being asked, the identity of the producer or its own supplier.

Under the tort law regime, the person who unlawfully and intentionally or negligently injured the life, body, health, or property of the claimant, may be found liable for the fault/defect. While this could in theory be anyone in the supply chain, the need to prove negligence means that mere onward suppliers and retailers will not normally be liable, unless, say, they knew of the defect.

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

Yes, it might in certain circumstances. TÜV Rheinland, a German provider of certification services which acted as the Notified Body for a French producer of breast implants, was sued directly by a number of patients in Germany and in France.

Most German courts had found no liability whereas French courts had. The German Federal Court of Justice referred various questions to the European Court of Justice ("ECJ"). The ECJ considered the scope of duties of a Notified Body under the EU Medical Device

Directive and whether a breach of any such duties constituted a tort that would entitle patients to hold the Notified Body liable.

In February 2017, the ECJ ruled (Case C-219/15) that the Notified Body is not under a general obligation to carry out unannounced inspections, to examine devices and/or to examine the manufacturer's business records. However, in the face of evidence indicating that a medical device may not comply with the requirements laid down in the EU Medical Device Directive, the Notified Body must take all the steps necessary to ensure that it fulfils its obligations to ensure the manufacturer's compliance with requirements.

In relation to the question of a potential tortious liability of the Notified Body, the court ruled that the purpose of the Notified Body's involvement is to protect the end users of medical devices, and that the conditions under which culpable failure by that body to fulfil its obligations under the Directive in connection with that procedure may give rise to liability on its part *vis-à-vis* those end users governed by national law, subject to the principles of equivalence and effectiveness.

In the particular case which was referred to the ECJ, the German Federal Court of Justice subsequently held that the claim against TÜV Rheinland must fail. The ECJ ruling is, however, likely to have an impact on the role of Notified Bodies not just in the medical device arena but also in the other areas of EU regulation, which require a producer or EU importer to have its products or quality management systems certified for compliance with applicable standards by Notified Bodies.

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?

A producer must take necessary steps to remove or mitigate any unacceptable risk which its product poses, upon the discovery of a defect. The most hazardous products may be the subject of a product recall. However, the action required will depend on the severity of the risks posed by the defective product, and pursuant to the principle of proportionality, this could require a warning or further instructions to be issued as opposed to a recall.

The producers' duties, including post-marketing surveillance, are found in public law, including the Product Safety Act (which implemented the EU General Product Safety Directive (2001/95/EC)), and tort law. Breach of these duties can result in liability.

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

Criminal sanctions can be imposed in certain circumstances, e.g. under the standard provisions of the Criminal Code in situations where the manufacturer identifies a defect but fails to implement the required field safety measures.

Another potential source of criminal liability is found in the Medicinal Products Act, pursuant to which the sale and distribution of unsafe pharmaceutical or medical products is a criminal offence. A breach of the Product Safety Act can also give rise to criminal liability.

2 Causation

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

The Claimant must prove fault/defect, damage and a causal connection between the damage and fault/defect. This is the case under both liability regimes.

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 pursuant to the normal standard of proof, namely, clear and convincing evidence of a causative link between the defect and injury or damages. A product is deemed to be defective if it does not provide the safety that a person is entitled to expect.

However, where the type of damage suffered is a common consequence of the specific product defect, there may be a presumption that the defect was causative. This presumption can be displaced by the producer demonstrating potential alternative causes.

If a risk of malfunction in a batch of products is deemed to be possible, it is not necessary to prove that the particular product malfunctioned and caused injury/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?

Market-share liability does not exist under German law. However, producers will be jointly and severally liable for damage where a number of products caused or contributed to the damage (see question 3.5).

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

Insufficient user instructions and deficient warnings can render a product defective.

There is no concept of "learned intermediary" under the PLA or tort law – a producer cannot, normally, rely on a third party to have issued the required warnings.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Although there is significant overlap, the specific defences available will depend on whether the claim against the producer is brought under the PLA or tort law.

Under the PLA, the producer may raise the following defences:

- It did not put the product into circulation.
- Based on the circumstances of the case, it may be assumed that the product was not defective when it was put into circulation.
- The product was not manufactured for sale or distribution for an economic purpose.
- The defect was due to its compliance with mandatory regulation at the time the product entered circulation.
- A state of the art/development risk defence (see question 3.2).

The producer of a component of the product will not be liable if it proves the defect can be attributed to the instructions given by the manufacturer or the design of the product.

Under tort law, the defences are very similar to those under the PLA, set out above. Other potential defences to a producer's alleged negligence also include: it selected, trained and supervised its employees with care; it had adequate quality control measures in place; it selected suppliers carefully and inspected their products; or it ensured that the product complied with relevant technical standards, laws and regulations.

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. However, this has been found by the German courts only to apply to design defects and not manufacturing defects, failure to warn or failure to monitor the market. The defence is also not available for pharmaceutical products.

The burden lies with the producer to prove the state of the art/development risk defence based on the normal standard of proof – clear and convincing evidence.

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 statutory requirements will be considered in the context of the legitimate safety expectation, i.e. when determining whether the product is defective. However, compliance is not a defence in itself. The producer must make out other defences (see question 3.1).

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

A judgment (notwithstanding that it may be possible to appeal (see question 4.7)) is binding on the parties and their successors. The parties cannot re-litigate the same issues based on the principle of *res judicata*.

No estoppel would apply to proceedings dealing with the same issues but between different parties, e.g. where the claim is brought by a different claimant.

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

Parties are jointly and severally liable if they have contributed to the damage and therefore may make claims for indemnity or contribution from one another.

A contribution must be claimed in subsequent proceedings. It is possible for a defendant to file a third-party notice against the other party in order to ensure that a detrimental judgment in the existing proceedings is binding against the parties in the subsequent contribution proceedings.

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

A contributory negligence defence is available under tort law and the PLA. The burden of proof rests with the producer.

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 the majority of cases, at the first instance, the judges sit alone. In some cases they will sit in a chamber of three.

In certain commercial matters a dispute in the regional court may be transferred to a special chamber which consists of one professional judge and two lay judges (the lay judges would, however, also determine legal 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)?

In German court proceedings, evidence is taken by the court. The court will determine what evidence, including expert evidence, it requires depending on the circumstances of each case.

The parties state the facts they wish to rely upon in their statements of case. They will attach the documentary evidence and witnesses they seek to rely on and proposals as to what expert evidence will be required. Once the written submissions have been filed by the court, the judge will determine whether or not an expert is required to deal with the issues in dispute.

If it is considered that an expert is required, that expert will then be appointed by the court. The court-appointed expert will generally provide a written report and can be requested to provide oral evidence at a hearing (see also 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?

German civil procedure does not permit class or group actions seen in other jurisdictions.

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

As German civil procedure does not permit class or group actions, consumer associations can only bring an individual claim on behalf of one of their members (as opposed to a number of members). These types of claims are not common.

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

Civil claims generally take five to eight months from the issue of proceedings to the final first instance hearing.

It may, however, take considerably longer than this depending on the evidence required and the complexity of the case. In particular, product liability actions will often take up to a year if not longer to get to trial, because it is usually necessary for the court to obtain expert evidence.

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

The courts can try preliminary issues. One such issue is that of jurisdiction. Both issues of fact and law may be determined; however, it is not commonplace.

4.7 What appeal options are available?

The appeal options available depend on the value, which consequently determines the first instance court, of the claim.

Local and Regional Courts are the courts of first instance. As a general rule, claims below €5,000 will be heard in the local court and those above this threshold in the regional courts.

The regional courts are the courts of second instance for the local courts, and the higher regional courts hear appeals from the regional courts.

Further appeals can be referred to the Federal Supreme Court.

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

Where circumstances require, and as is often the case in product liability cases, the court will appoint an expert. This expert will act as an independent advisor to the court. Where the parties agree that a specific expert should be appointed, the court will generally seek to instruct that expert. The court-appointed expert will generally produce a written report, which the parties may comment upon. The parties can also propose supplementary questions for the expert.

The parties may file their own expert's opinion together with their submissions but any reports provided by the parties' experts are treated as factual, not expert, evidence. The court-appointed expert will then have to consider the issues raised.

The expert may be called to give oral evidence (however, questioning will be conducted by the Judge and is not subject to examination by the parties).

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

No. There is no exchange of witness statements or expert reports prior to trial and there are no pre-trial depositions.

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

There is no pre-action or pre-trial discovery under German civil procedure law. Parties control the documentary evidence which they bring before the court and they need not disclose documents harmful to their case. Where a party seeks to rely on a piece of documentary evidence it must append it to its statements of case.

That said, there is a mechanism for requesting specific disclosure – however, the specific document(s) must be identified – and a further exception can be found in the Federal Drug Act, which allows the claimant to request disclosure from a manufacturer in relation to known and suspected adverse reactions and interactions.

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

There is no general obligation to pursue ADR prior to litigation. In 2016, a scheme promoting ADR for consumer disputes was enacted, but the scheme is not mandatory and does not apply in tort cases, so is limited in its effect.

The majority of product liability disputes are litigated in the courts, though mediation and arbitration are available. The courts will however themselves explore settlement options with the parties and may even propose terms to encourage negotiations.

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

The general rule is that the German courts have jurisdiction over a dispute when a defendant is resident in Germany. This is regardless of where a claimant resides.

There are a number of provisions through which claimants may sue foreign defendants in Germany. In a product liability context, claimants may bring their claim against a foreign producer/manufacturer in Germany where: (1) the events leading to the product defect occurred in Germany (whether the claim is grounded in the PLA or in tort); or (2) the damage has occurred in Germany.

German jurisdiction can also be agreed between the parties (e.g. a clause in a supply contract).

5 Time Limits

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

Yes. There are applicable limitation periods (see question 5.2).

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

The standard limitation period relevant to tort or contract claims under the BGB is three years, though this may be suspended, e.g. by agreement between the parties.

The limitation period starts to run at the end of the year in which the claimant knew or ought to have known of the damage, the defect and the identity of the potential defendant.

There are different long-stop dates depending on the type of claim. A claim for bodily injury has a long-stop date of 30 years, and a claim for property damage becomes time-barred either 10 years after the damaging event or 30 years after the product was put into circulation, whichever is earlier.

Claims under the PLA become time-barred three years after a claimant knew, or should have known, of the damage, the defect and the identity of the potential defendant. There is also a 10-year long-stop: claims expire 10 years after the product was put into circulation.

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

The 10-year long-stop under the PLA and 30-year long-stop under the BGB (see question 5.2) will be unaffected by issues of fraud or concealment. However, where these issues impact upon the claimant establishing knowledge regarding the defect and/or potential defendant this could delay the commencement of the standard three-year limitation period.

6 Remedies

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

Monetary compensation and declaratory relief are available. A person who suffered a loss is in principle entitled to be returned to the position they were in prior to the damaging event occurring.

It is common in product liability cases that the court will order declaratory relief in respect of future damage occasioned by a defective product.

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

A number of different types of damage are recoverable under German law, including damage to property. Non-material damages such as psychological harm and bodily injury are recoverable, subject to being evidenced.

Whether a product liability claim arises under the PLA or in tort, the damage to the defective product itself will be irrecoverable. This could only be recovered under contract.

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 are typically not recoverable.

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

Punitive damages are not available under German law.

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

Under the PLA, the producer's liability is capped at €85 million for damage resulting from personal injury or death and caused by a defective product or products (with the same defect). Aside from cases concerning personal injury or death, there is no maximum limit on damages under the PLA.

The Federal Drug Act has a one-off payment limit of €600,000 and a limit of €36,000 in respect of annual pension payments, per claimant. The cap in respect of damage caused by one pharmaceutical product is a one-off payment of €120 million and €7.2 million in respect of annual pension payments.

There is no maximum limit on damages recoverable in tort.

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

Court approval is not required for settlements reached between the parties. Cases can be settled in or out of court.

German civil procedure law does not permit class or group actions.

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

Where a social insurance carrier has paid for medical treatment or employment benefits to a person who suffered damages as a result of a defective product, the social insurance carrier takes a statutory assignment of the rights of that person and may bring a recovery action against the producer.

In the event of a settlement between claimant and producer which covers payments in fact made by the social insurance carrier, the social insurance carrier may seek reimbursement from the claimant (otherwise, the claimant would enjoy a double-recovery).

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 to (a) and (b). However, recovery of their own legal fees and expenses by the successful party is limited to the scaled statutory minimum fees and general expenses.

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

Legal aid is available in certain circumstances. Where it is granted it may not be contested by the other parties to the proceedings.

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

The Court must be satisfied that the potential claim or defence of the party applying for legal aid has merit and that the party meets the financial criteria for legal aid.

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

Success fees are only permissible if the client would otherwise not be in a position to fund the proceedings.

This remains the only exception to the rule that success, conditional or contingency fees are not permissible in Germany.

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

Third party litigation funding is permissible in Germany. Legal expenses insurance is common and a method by which consumers fund their legal costs in product liability 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?

There is no advanced costs-budgeting exercise undertaken by the courts, however recoverable costs are in any event limited to the scaled statutory minimum fees. There is no procedure for discovery/disclosure or extensive witness evidence, which limits the costs of bringing a case to trial.

8 Updates

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

German Product Liability Law is fairly settled. Apart from the ECJ and subsequent Federal Court of Justice decision in the TÜV Rheinland case (see question 1.4 above), there have been no particularly noteworthy decisions in the past year.

Following the ECJ's decision in Cases C-503/13 and C-504/13, there have been some German decisions applying that ruling. The ECJ, in cases concerning pacemakers and implantable cardioverter defibrillators which belonged to a group or production series that was *potentially* defective, held that "in the light of their function and the particularly vulnerable situation of patients using such devices, the safety requirements for those devices which such patients are entitled to expect are particularly high". It noted that such a product would have an "abnormal potential for damage" and concluded that such a product may be classified as defective without there being any need to establish that the particular product has such a defect. A German appeal court has since applied the reasoning to hip implants with a potential fracture risk and it remains to be seen where else it might be used.

Mirjam Schorr
Kennedys Law LLP
25 Fenchurch Avenue
London, EC3M 5AD
United Kingdom

Tel: *+44 20 7667 9484*
Email: *mirjam.schorr@kennedyslaw.com*
URL: *www.kennedyslaw.com*

Mirjam Schorr is dually qualified as a Rechtsanwältin in Germany and a solicitor in England and Wales.

Her areas of practice include insurance/reinsurance, product liability, employers' liability, environmental liability, and Health & Safety law.

She specialises in the conduct of complex cross-border disputes in the context of which she regularly advises on questions of jurisdiction and Private International Law.

In addition to her contentious caseload, Mirjam frequently advises insurers on policy coverage under both English and German law and has extensive experience of drafting German insurance policies including those relating to product liability, K&R, and environmental liability.

Mirjam has co-authored the chapter on Product Liability Claims in the third edition of Insurance Disputes edited by the Right Honourable Lord Mance, Iain Goldrein QC and Professor Robert Merkin.

Benjamin Loechner
Kennedys Law LLP
25 Fenchurch Avenue
London, EC3M 5AD
United Kingdom

Tel: *+44 20 7667 9282*
Email: *ben.loechner@kennedyslaw.com*
URL: *www.kennedyslaw.com*

Ben Loechner is a solicitor in Kennedys' London office.

He has considerable experience of product liability litigation, commercial litigation and insurance/ reinsurance disputes, many of which contain an international element and he has co-ordinated numerous cross-border disputes. Ben also advises insurers and reinsurers on policy coverage and has a broad range of experience in ADR, including mediation and arbitration.

Ben is a native German speaker and is currently cross-qualifying as a German Rechtsanwalt.

Kennedys

Kennedys is a global law firm with expertise in litigation and dispute resolution, particularly in the insurance/reinsurance and liability industries.

Kennedys has a market leading product liability, recall and mass tort litigation practice across the UK and Europe, Bermuda, Asia Pacific, the Americas and the Middle East.

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Greece

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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 (especially 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 the 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 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 How long does it normally take to get to trial?

Under the legal regime, up to 31 December 2015, and as an average, an action under ordinary proceedings was fixed for hearing approximately between 18 and 24 months following its filing, and the decision was issued six to eight (6–8) months after the hearing, provided that the initial hearing was not adjourned (one adjournment

being rather a practice). The above average times very much depend on the type of the court (see under question 4.1), as well as the place where it is located. To speed up proceedings, a new law was introduced in 2015 (Law 4335), in force as of 1 January 2016. Under the new regime the hearing is purported to take place around six to seven (6–7) months after the filing of a lawsuit (articles 215 & 237 of GCCP) but that time frame is in practice prolonged.

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

No, there are no separate proceedings especially for preliminary issues, such as on 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.

4.7 What appeal options are available?

Every definite judgment issued by a first instance court may be contested before the Appellate Court. An appeal can be filed not only by the defeated party, but also by the successful party whose allegations were partially accepted by the court. Further, a cassation before the Supreme Court may be filed against Appellate Court decisions.

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

As stated above under question 4.2, the court may appoint experts to assist it in considering technical issues. The expert(s) may take knowledge from the information in the case file and/or request clarifications from the parties or third parties. The parties are also entitled to appoint one technical advisor each, who reads the expert report, submits his opinion and raises relevant questions to the court expert. The opinion of the court-appointed expert is not binding on the court. Additionally, the parties may submit to the court an unlimited number of expert/technical reports supporting their allegations. In practice, the reports of party-appointed experts are of lesser evidentiary value than those of the court-appointed ones.

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

Factual or expert witnesses appointed by the parties may, instead of giving oral evidence before the court, give sworn depositions before a judge of a piece, a notary public or, if outside Greece, before a Greek consular authority. The opponent must be summoned to such depositions before two working days and he is entitled to obtain a copy prior to trial. Non-compliance to the procedural requirements renders the depositions inadmissible. There are restrictions to the number of sworn depositions (articles 421–424 of GCCP).

Court-appointed experts have to submit their reports at the time ordered by the court, adjourning the hearing for that purpose.

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

There are no pre-trial discovery proceedings. Each litigant has to disclose all documents supporting his case (except from a serious reason) by his submissions filed at the specified time, depending on the court and kind of proceedings. The general principles of good faith, *bonos mores* and honest conduct apply (especially articles 116 and 450 of GCCP). A litigant may request from the court to order disclosure of documents in the possession of his opponent or a third party under conditions (articles 450 *ff.* of GCCP and 901–903 of GCC).

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

Parties may choose (but are not obliged to opt for, 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.

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

As a rule, any person, either Greek or non-Greek, is subject to a Greek court's jurisdiction, thus he may sue or be sued, provided a Greek court is locally competent to try the case (article 3 of GCCP). Such competence is determined by a rather detailed categorisation; among the various legal bases and regarding a tortious act, the one regarding the place where the event that caused the damage either took place or is to occur establishes competence, thus jurisdiction, of a Greek court (articles 22 *ff.* and 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 Consumers' Law, a three- (3-)year limitation period applies to proceedings for the recovery of damages, while the right to initiate proceedings against the producer is extinguished upon the expiry of a ten- (10-)year period from the date the producer put the product into circulation. The age or condition of the claimant does not affect the time limits' calculation, while the court may not disapply time limits.

In case of a collective lawsuit, it must be brought within six (6) months from the last unlawful behaviour challenged, unless the mere recognition by the court that an unlawful act had taken place is sought, where the general five- (5-)year prescription period for torts applies (article 10 para. 18 of the Consumers' Law).

For a claim in tort, a general five- (5-)year prescription period applies, whereas the claim is in any case extinguished twenty (20) years from the date of the tortious act (article 937 of GCC).

Contractual liability claims under a contract of sale of goods are time barred after two (2) years for movables and five (5) years for immovable property, whereas further detailed regulation applies (articles 554–558 of GCC).

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

The Consumers' Law does not contain specific provisions. Article 6, para. 13 sets, as the starting point from which the time limitation runs, the day on which the plaintiff became aware or should have become aware of the damage, the defect and the identity of the producer. Regarding the knowledge of the damage, it is not required for the plaintiff to be informed of the individual damage, but the knowledge of the possibility of a forthcoming loss-making result is enough. The knowledge of the defect includes the circumstances from which it results that the use of the product does not meet the consumer's safety expectations. Furthermore, the consumer needs to be in a position to know that the damage is the result of the specific defect of the product.

Under the contract of sale of goods provisions, the seller's concealment or fraud deprive him from invoking prescription (article 557 of GCC).

6 Remedies

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

Monetary compensation under civil proceedings is available to the victim (see below under question 6.2). Criminal or administrative proceedings possibly pursued as well do not aim at compensating the victim. Especially under a collective claim, consumers' associations may ask: a) that a producer abstains from an unlawful behaviour even before it occurs; b) for the recall, seizure (as injunctive measures), or even destruction of the defective products; c) for moral damages; and d) that the court recognises consumers' right to restore the damage caused to them by the producer's unlawful behaviour (article 10, para. 16 of the Consumers' Law).

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

According to article 6, paras. 6 and 7 of Consumers' Law, the types of damage that are recoverable are: a) damages caused by death or by personal injury to anyone; and b) damage or destruction caused by the defective product to any consumer's asset other than the defective product itself, including the right to use environmental goods, provided that i) the damage exceeds €500, and ii) the product was ordinarily intended for and actually used by the injured person for his own private use or consumption. Compensation for moral harm or mental distress (to the family of the deceased) may also be claimed.

Under a claim in tort, full damages may be recoverable (article 914 *ff*. of GCC).

Lastly, under contractual liability (sale of goods), the buyer may request (especially articles 540–543 of GCC): a) repair or replacement of the defective product; b) a reduction of the consideration; c) rescission of the contract; and/or d) compensation, under conditions.

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

A causal link is always required between the defect and the damage in order for the producer to be held liable. So, in cases where the product has not yet malfunctioned and caused injury, there is an absence of this condition. If the product malfunctions in the future, medical monitoring costs may be recovered provided actual damage suffered by the consumer is proven.

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

No. In collective claims however, 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 (⅔) 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, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction.

a) The Consumers' Law has been amended several times. 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 & 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 & 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 is questioned and it is expected to be judicially challenged.

However, thus far, application of ADR remains limited.

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; and 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 (P/L, Competition, Business Transactions), Country Chair – Greece. IADC.

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

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

Squire Patton Boggs

Bindu Janardhanan

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?

No, there is no 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 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 probabilites", which means that the claimant's evidence must prove that it is more probable than not that the fault/defect occurred and damage suffered is due to the fault/defect.

However, it is open to the claimant to invoke the doctrine of *res ipsa loquitur*, 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 has to prove that "but for" the defect, he/she would not have sustained the injury or damage.

As for the causation in law, it has to 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 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 link was broken by a supervening act, and that act is the sole effective cause of the damage. The manufacturer can also rely on the state of the art defence (see below).

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

Yes, there is a state of the art/development risk defence. The manufacturer can rely on the defence to establish, on the balance

of probabilities, that it exercised all reasonable care and precautions in light of the state of scientific and technical knowledge at the time of distribution generally, it is for the claimant to prove that 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 How long does it normally take to get to trial?

The time to take a case from commencement of proceedings to judgment varies greatly depending on the nature, size and complexity of the proceedings. However, a relatively straightforward civil litigation action, involving witnesses of fact and expert witnesses, may take approximately one to two years from commencement of proceedings to judgment at first instance.

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

Yes, the court can try preliminary issues that relate to both facts and law.

4.7 What appeal options are available?

Generally, an appeal lies as of right from a decision on a final matter from a Court of First Instance judge to the Court of Appeal. However, no appeal against the following decisions in a civil case can be made: (1) a decision of a judge in the District Court; (2) a decision of a judge of the Court of First Instance in an interlocutory matter; and (3) an

appeal against the decision of a Court of First Instance judge solely on the question of costs, unless leave to appeal has been granted.

An application for leave to appeal should be made to the judge or master of the respective court who gave that decision. If the judge refuses to grant leave, the party may further apply to the Court of Appeal for leave to appeal within 14 days from the date of such refusal. The Court of Appeal may give leave on such terms as to costs, security, etc. as it deems fit. The decision of the Court of Appeal on whether to grant or refuse leave is final and not appealable.

If the party is not satisfied with the decision of the Court of Appeal, he or she may lodge an application for leave to appeal to 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 its decision.

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

Yes, the court can appoint experts to assist it in considering technical issues, but usually the court prefers parties coming forward with their own proposed expert appointments, and the parties can each appoint their experts. Each expert called by a party is subject to cross-examination by the other parties if the opinions of the experts diverge. Each expert should only address the specific issue of which they are asked to give their expert opinion. The court will not accept evidence provided by the expert of matters in which he/she is not an expert.

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

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 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.

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

The parties can seek discovery of all relevant documents and facts relating to the matters in questions in the action. It is possible to apply for discovery before commencement of proceedings, but usually discovery is not done after the pleadings have closed. Discovery may continue up to trial.

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

Since the Civil Justice Reform came into force on 2 April 2009, under Practice Direction 31, parties are required to go through mediation in the litigation proceedings right after filing the statement of claim. Parties may also agree to use mediation to resolve a dispute. Similarly, parties may arbitrate a dispute if they agree to do so.

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

A claimant can generally issue a claim in the Hong Kong courts unless the jurisdiction is challenged by the defendant. Where a defendant, whether a real person or a legal entity (such as 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 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, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction.

In Hong Kong, there is no explicit law 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, e.g., In *HKSAR v Chow Heung Wing Stephen* [2018] HKCFI 60, which involved a cytokine-induced killer ("CIK") blood product being administered to a patient, 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
Suite 5904, 59th Floor, Central Plaza
18 Harbour Road
Wan Chai
Hong Kong

Tel: *+852 2511 1040*
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
Suite 5904, 59th Floor, Central Plaza
18 Harbour Road
Wan Chai
Hong Kong

Tel: *+852 2511 1971*
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.

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Chapter 18

India


Karnika Seth


Amit Seth

Seth Associates

1 Liability Systems

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

In India, product liability law governs the liability of manufacturers, wholesalers, distributors, and vendors for injury to a person or property caused by dangerous or defective products.

Product liability in India is governed by:

a) The Consumer Protection Act, 1986.

b) The Sales of Goods Act, 1930.

c) The law of Torts.

d) Special statutes pertaining to specific goods.

Previously, the Monopolies and Restrictive Trade Practices Act, 1969 (hereinafter referred to as the "MRTP Act") dealt with provisions in respect of unfair trade practices. The Act now stands repealed and the pending cases of unfair trade practices have been transferred to the National Commission set up under the Consumer Protection Act, 1986.

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

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

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

Any person who trades in the goods (manufacturers, importers, distributors, wholesalers, etc.) may be made liable under Indian law.

As per the Consumer Protection Act, the definition of trader (Section 2(1) (q)) and manufacturer (Section 2(1) (j)) is exhaustive and includes: any person who sells or distributes any goods for sale; manufacturers; assemblers; dealers; or any person who causes his or her own mark to be put on any goods made or manufactured by any other manufacturer and claims such goods to be goods made or manufactured by himself or herself.

Bearing in mind the law on privity of a contract, if a consumer finds a defect in the goods, he or she usually sues the person from whom he or she has bought the goods. However, if the defect is a manufacturing defect, the consumer may sue the manufacturer along with the seller, particularly under the law of tort. This is an option for the consumer.

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

A regulatory authority can be held liable where it is negligent in inspecting, reporting or lack of exercise of monitoring control. For example, if it passes food products which do not meet the standards prescribed by law.

The Food Safety Officer under Food Safety and Standards Act, 2006 (FSSA) shall be liable to a penalty which may extend up to one lakh rupee if he/she is found to be guilty of an offence under section 39 of the Act.

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 14(1) (h) states that the District Forum under the Consumer Protection Act can require direct withdrawal of all hazardous goods from the market and direct compensation to be paid to affected parties.

As per Section 27 of the Consumer Protection Act, if a trader fails or omits to comply with any order of the District Forum, such person shall be punishable with a term of not less than one month, but which may be extended to three years or a fine of 2,000 rupees, but which may be extended to 10,000 rupees, or both. Also, Section 25 of the said Act empowers the District Forum or State Commission or National Commission, as the case may be, to attach property of the person who does not comply with its orders. If a person fails to pay an amount as per an order passed by a district court, then such person may move an application before the District Forum which shall issue a certificate to the collector of the district, and such collector shall proceed to recover the said amount from such person as arrears of the land revenue.

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

Under the Consumer Protection Act, as per Section 27, where a trader or a person against whom a complaint is made or the complainant fails or omits to comply with any order made by the District Forum,

the State Commission or the National Commission, as the case may be, such trader, person or complainant shall be punishable with: imprisonment for a term of not less than one month, but which may be extended to three years; a fine, which shall not be less than 2,000 rupees, but which may be extended to 10,000 rupees; or both. Criminal sanctions may also be imposed under other statutes specifically providing for such sanctions.

2 Causation

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

The burden of proof generally lies with the party who is alleging the fault/defect and damage or who initiates the civil action (plaintiff).

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

In order to recover damages under tort of negligence, a plaintiff must prove the following:

1. the manufacturer owed a duty to the plaintiff;
2. the manufacturer breached a duty to the plaintiff;
3. the breach of duty was the actual cause of the plaintiff's injury;
4. the breach of duty was also the proximate cause of the injury; or
5. the plaintiff suffered actual damages as a result of the negligent act.

The law requires that a manufacturer exercises a reasonable degree of standard of care akin to those who are manufacturing similar products. In case the plaintiff can prove that a manufacturer has failed to exercise the reasonable standard of care, the plaintiff still needs to prove two parameters of causation. The plaintiff must first show injury was caused to the plaintiff due to the manufacturer's negligence and further that the defendant could have foreseen the risks that led to such an injury.

On the other hand, in a contract, the plaintiff is required to prove that the breach of contract was the actual and effective cause of the loss which has been sustained.

The burden lies with the party alleging a fault has been made by the other party or the goods were defective. There needs to be a proximate cause and effect relationship and goods are considered defective where there is a high risk of malfunction.

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

Market-share liability does not generally apply. In many such cases, the claim stands dismissed.

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

When goods are transferred under a contract, the liability of parties is governed by the contract itself. In certain cases, there is an implied condition that goods will be reasonably fit for the purpose for which they are required by the buyer. If, while selling goods under a contract, the defendant expressly excludes his liability, he cannot be made liable for the loss caused to the plaintiff. Liability may arise.

Section 16 of the Sale of Goods Act prescribes implied conditions as to quality or fitness. Section 16(1) requires that the goods shall be reasonably fit for the purpose, made known to the seller by the buyer expressly or by implication. Section 16(2) requires only that the goods should be of merchantable quality. Secondly, Section 16(1) is excluded where the buyer does not rely on seller's skill or judgment. Section 16(2) is not so limited, although it does not apply when the buyer examines the goods with regards to defects and such examination ought to have revealed the defects. Where a defect is revealed to the buyer, not only is Section 16(2) excluded, but that fact will normally indicate that it is unreasonable for the buyer then to rely on the seller for the purposes of Section 16(1).

In addition, liability may be found under tort law. When a tin had a defective lid to the knowledge of the seller and he failed to warn the buyer about it, the defendant will be liable for injury caused to the buyer as a consequence thereof (*Clarke v Army and Navy Cooperative Society ltd* [1903] 1 K.B. 155).

Liability towards the ultimate transferee could be based on fraud where there is false representation that goods are safe. In the case of dangerous goods, such as loaded firearms, it is required to give added precaution and warning to the intermediary, as well as the ultimate transferee. In *Dixon v Bell* (1816) 4M&S 198, the defendant gave a servant a loaded gun which she fired on the plaintiff who was seriously injured. The defendant was held liable for the same.

In case of things which are not dangerous *per se*, but known to be so, the transferor owes a duty to warn about the known dangers not only to the immediate transferee, but to all persons likely to be endangered by such thing.

For the third category, things neither dangerous *per se*, nor known to be so by the transferor, but are in fact dangerous, the application of *Donoghue v Stevenson* principle requires the manufacturer to take reasonable care (when something is to reach the ultimate consumer without any possibility of intermediate examination) and is liable for not taking such care despite there being no privity of contract. This liability principle has extended to repairers, assemblers, builders and suppliers of products.

3 Defences and Estoppel

3.1 What defences, if any, are available?

A probable defence could be that the defect had occurred due to the negligence or contributory negligence of the buyer. An additional defence would be that the buyer had examined the goods prior to purchase. Also, the parties can rely on contractually agreed warranties or waivers or disclaimers and clauses on limitation of liability. The expiration of limitation periods for filing or initiating claims can also be a defence.

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

In general, in the Consumer Protection Act, onus is on the plaintiff to prove fault could have been discovered by the manufacturer.

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

Yes, if the product complies with statutory standards relating to manufacturing, licensing, marketing and supplying, the same can be argued as a defence.

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

Under the doctrine of *res judicata*, parties are estopped between themselves from re-litigating issues determined by the final judgment of any competent court or tribunal. Different claimants may be able to re-litigate issues in separate proceedings; however, a claimant could be prevented from re-litigating an issue decided in a previous proceeding on the grounds of abuse of process by re-litigation.

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

The liability of joint tortfeasors is joint and several. No tortfeasor is allowed to claim that the decree against him should be only to the extent of his fault. The court may apportion damages between tortfeasors for the purpose of respective liability *inter se* (*Amnthiben v SC, ONGC*). In *Amnthiben v SC, ONGC* [1976] ACJ (72) (Guj.), due to the negligence of the driver of a jeep and the driver of a bus, there was an accident and a passenger sitting in front of a jeep was thrown and killed. The ratio of the negligence of the driver of the bus compared to the driver of the jeep was 75:25. A decree against the defendants was passed making them liable jointly and severally to pay damages. Apportionment of damages was *inter se* made to work out the respective liability of the defendants. The limitation period to begin a case for recovery is generally three years from the cause of action.

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

Yes. For example, where a pedestrian tries to cross the road all of a sudden and he is hit by a car, he is guilty of contributory negligence.

4 Procedure

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

As the Indian legal regime is based on the common law system, the court system is adversarial and an impartial judge adjudicates a case. The jury system does not exist in India.

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

Yes, experts may be appointed by courts for any expert testimony if required under the Code of Civil Procedure, 1908.

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

Under the Consumer Protection Act, 1986, any voluntary consumer association registered under the Companies Act, 1956, or under any other law for the time being in force, can file a consumer complaint, and where there are numerous consumers having the same interest, they can file a consumer complaint with the leave of the court (forum).

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

Yes, a complaint for a class action can be filed by any trade association, consumer or registered consumer association or by the Central or State Government, where one or more consumers have a common interest. (Section 2(1) (b) Consumer Protection Act, 1986.) *In Consumer Protection Council, Rourkela v Indian Oil Corporation Ltd & OTHERS, ORIGINAL PETITION NO. 224 OF 2001*, dated 16 August, 2007, the National Consumer Disputes Redressal Commission (NCDRC) dealt with a case wherein the Consumer Protection Council, Rourkela, a voluntary organisation, had filed a complaint against the Indian Oil Corporation Indane LPG that the refill received by consumers was less than the represented weight. The NCDRC directed the Ministry of Petroleum, as well as the Ministry of Consumer Affairs, to ensure that all marketing companies issue necessary instructions and that the distributors will provide the delivery person with a proper weighing scale for the purpose of weighing the LPG Gas Cylinder in the presence

of customers. They are also required to give it due publicity by publishing the same in the vernacular language of each and every State, and in English and Hindi in newspapers, as well as providing a similar type of advertisement on TV for consumer information.

The NCDRC directed the Indian Oil Corporation to pay a sum of 50,000 rupees to the Complainant-Council to meet the expenses incurred by it in protecting the interest of consumers, and to continue to protect the interest of consumers, for a period of four weeks.

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

In practice, a civil suit may take two to three years to get to the trial stage and another three years for final disposal; while in a consumer forum, a typical case is disposed of within one to two years. Once the complaint is received by the District Forum, the District Forum may either admit or reject a complaint, generally within 21 days from the date from receipt thereof. Once the complaint is admitted, the District Forum shall refer a copy of the admitted complaint within 21 days from the date of its admission to the opposite party, directing it to give its version of the case within a period of 30 days or such extended period (not exceeding 15 days) as may be granted by the forum.

The Consumer Protection Act requires the District Forum to decide a complaint within a period of three months from the date of receipt of the notice by the opposite party where the complaint does not require analysis or testing of commodities, and within five months if it requires analysis or testing of commodities. Further, the Consumer Protection Act prescribes that an appeal filed before the State Commission or the National Commission shall be heard and finally disposed of within a period of 90 days from the date of its admission.

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

The court may decide matters on preliminary issues such as *res judicata*, limitation periods, or other legal grounds. Courts will not assess facts at preliminary stages before trial.

4.7 What appeal options are available?

Action under the Consumer Protection Act, 1986

Any person aggrieved by an order made by the District Forum may refer an appeal against such order to the State Commission within a period of 30 days from the date of the order. Provided the appeal is referred by a person who is required to pay any amount in terms of an order of the District Forum, the appeal shall be entertained by the State Commission only if the appellant has deposited in the prescribed manner 50 per cent of that amount or 25,000 rupees, whichever is less. (Section 15 of the Consumer Protection Act, 1986.)

Any person aggrieved by an order made by the State Commission may refer an appeal against such order to the National Commission within a period of 30 days from the date of the order. Provided the appeal is referred by a person who is required to pay any amount in terms of an order of the State Commission, the appeal shall be entertained by the State Commission only if the appellant has deposited in the prescribed manner 50 per cent of that amount or 35,000 rupees, whichever is less. (Section 19 of Consumer Protection Act, 1986.)

Any person aggrieved by an order made by the National Commission may refer an appeal against such order to the Supreme Court within a period of 30 days from the date of the order.

Provided the appeal is referred by a person who is required to pay any amount in terms of an order of the National Commission, the appeal shall be entertained by the Supreme Court only if the appellant has deposited in the prescribed manner 50 per cent of that amount or 50,000 rupees, whichever is less. (Section 23 of Consumer Protection Act, 1986.)

Action under civil courts

A suit is instituted in the lowest court competent to try such suit. An order or a decree passed by a district court is appealable before the high court. An order passed by the high court is appealable to the Supreme Court, which is the apex court.

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

Experts may be appointed by courts or consumer forums, depending upon the facts and circumstances of each case.

However, the case should be complicated enough to require the opinion of an expert. As per Section 45 of the Indian Evidence Act, expert testimony is possible, but generally cross-examination does follow. The expert testimony or opinions should be limited only to highly technical points.

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

Generally, in product liability cases, expert opinions are not taken, except if the court thinks it is necessary to determine important facts. Depositions, reports, and cross-examination all take place during the trial.

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

In Indian law, it is for the party claiming a relief to supply to court all documents upon which it relies. The court may also entertain applications seeking relief of discovery or production of records depending on the facts of every case. In *Ramrati Kuer v Dwarika Prasad Singh & Ors*., AIR 1967 SC 1134, this court held:

> "*It is true that Dwarika Prasad Singh said that his father used to keep accounts. But no attempt was made on behalf of the appellant to ask the court to order Dwarika Prasad Singh to produce the accounts. An adverse inference could only have been drawn against the plaintiffs-respondents if the appellant had asked the court to order them to produce accounts and they had failed to produce them after admitting that Basekhi Singh used to keep accounts. But no such prayer was made to the court, and in the circumstances no adverse inference could be drawn from the non-production of accounts.*"

(See also: *Ravi Yashwant Bhoir v District Collector, Raigad & Ors.*, AIR 2012 SC 1339.)

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

Parties to a contract may agree to adopt alternative means of dispute resolution (ADR) in their contract before resorting to litigation.

Such means could be negotiation, mediation or conciliation or other forms of ADR. Such contractual terms are binding on the contracting parties. In India, courts encourage settlement of disputes through ADR.

Alternative means of dispute resolution are not generally adopted in product liability cases wherein the consumer is aggrieved. Statutory forums, such as consumer forums, decide such cases.

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

The Consumer Protection Act can be applicable to a foreigner who avails service or purchases a product from India, as it does not limit its application to only Indian citizens. As a defendant, a plaintiff can file an action in Indian courts against a foreign service provider or manufacturer if he provides a service or sells goods in India. This judgment obtained by a plaintiff can be enforced in India if the defendant has any assets in India or enforced abroad if a reciprocal arrangement exists with the government/country in question. In case a judgment is passed by an Indian court, by virtue of Section 38 of the Code of Civil Procedure, a decree may be executed either by the court which passed it or by the court to which it is sent for execution. According to Section 51 of the Code of Civil Procedure, an execution order may entail delivery of any property specifically decreed or attachment and sale of any property, by arrest and detention in prison, by appointing a receiver, or other manner as the court may deem fit.

5 Time Limits

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

In an action under the Consumer Protection Act, the District Forum, the State Commission or the National Commission shall not admit consumer complaints unless they are filed within two years from the date on which the cause of action has arisen.

Whereas, in an action under the Indian Contract Act, Sale of Goods Act and other applicable statutes, a person will not be able to initiate a product liability claim after three years from the date of which the cause of action (product defect) which gives the right to initiate a product liability claim occurs.

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

The limitation of time does not vary depending on whether it is fault-based or strict liability.

The age of the claimant does not affect limitation. The court has discretion to extend time or condone delay if the plaintiff proves that there was sufficient cause for condoning the delay.

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

Where an action is based upon fraud or the right of action is concealed by fraud, the period of limitation only begins to run when the plaintiff has discovered the fraud, or could with reasonable diligence have discovered it.

6 Remedies

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

Generally, in tort cases under product liability, two remedies are common: one is damages such as to remove the defect from the goods or to seek replacement of the goods with new goods of similar description which shall be free from any defect; and, if damages is an inadequate remedy, the court may grant an injunction for discontinuance of unfair trade practice or restrictive trade practices, as the case may be and for withdrawal and to cease and desist orders in the manufacturing of hazardous goods from being offered for sale. A refund of the purchase price can also be availed by the aggrieved party in the form of monetary compensation.

(Section 14 of the Consumer Protection Act.)

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

In order to recover damages, damages must be foreseeable.

Foreseeable damages generally include pecuniary losses, such as those incurred by the plaintiff for damaged goods, medical expenses, and lost money. Recoverable non-economic damages include awards for pain and suffering and emotional agony. The court may award punitive or exemplary damages in certain severe cases of negligence.

Under the Indian Contract Act, 1872, the party who suffers loss on account of breach of a contract by the other party is entitled to receive, from the party who has breached the contract, compensation for any loss or damage caused to it, which directly arises from such breach, or which the parties knew, when they entered into the contract, to be likely to result from the breach of it. However, no compensation is to be given for any remote and indirect loss of damage sustained by reason of the breach. Thus, as per Indian law, indirect damages are generally not awarded.

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

Yes, compensatory damages can be recovered by the injured party if any damage stems or is likely to stem from the dangerous or defective product in future. For example, in the case of *Union Carbide Corporation etc v Union of India* (1991) 4 SCC 584, the Supreme Court, in addition to the compensation, directed Union Carbide Corporation to bear the expenses towards the setting up of specialised medical and research equipment for periodical medical checkups for victims of a toxic leak. Thus, in this case it has been witnessed that the court awarded damages towards the costs of medical surveillance.

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

As far as the award of punitive and exemplary damages is concerned, such damages can only be allowed at the discretion of the courts and in certain exceptional cases.

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

No, there is not.

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

Apart from the Consumer Protection Act where consumer associations can file a combined action to seek remedies as provided in Section 14 of the said Act, under Article 32 and Article 226 of the Constitution of India, any person may file a public interest litigation in larger public interest, wherein courts grant relief in case of infringement of fundamental rights of the public. The Supreme Court (under Article 32) and high courts (under Article 226), depending on facts of a case, can grant injunctions, damages, oversee the implementation of legislation or draft appropriate guidelines in the absence of a specific legislation.

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

Usually, the relevant government departments are party to the litigation itself.

7 Costs / Funding

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

The claimant usually seeks the reimbursement of litigation costs, interest, etc. It is at the court's discretion to order costs to be paid to the claimant if he wins a case.

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

Yes. Legal Aid clinics have been set up under the Legal Services Authority Act, 1987.

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

Legal aid clinics are governed by provisions of the Legal Services Authority Act, 1987, which receives funds and has policies for its utilisation.

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

Conditional or contingency fees are not generally adopted in India.

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

Third-party litigation funding is available only through legal aid and is subject to the terms as specified under the Legal Services Authority Act, 1987. The prevalent legislation, the Public Liability Insurance Act, 1991, aims to provide public liability insurance for the purpose of providing relief to the persons affected by an accident occurring while handling any hazardous substance for matters connected therewith. Every owner, i.e. a person who has control over handling any hazardous substance, has to take an insurance policy so that he is insured against liability in case of death or injury to a person, or damage to any property, arising as a result of an accident occurring while handling any hazardous substance. Further, the Motor Vehicles Act, 1988 makes the insurance of motor vehicles against third party risks compulsory.

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

No; the court does not exercise any control over costs to be incurred by parties so that it is proportionate to the value of the claim. However, it can direct the respondent to pay the costs of litigation if the consumer succeeds.

8 Updates

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

In India, consumer awareness is on the rise. A separate Department of Consumer Affairs was also created in the central and state governments to exclusively focus on ensuring the rights of consumers as enshrined under the CPA. CPA aims at providing speedy and cost-effective redressal to the consumers by award of compensation and other injunctive reliefs. Courts have generally awarded the claimant damages along with reimbursement of costs of litigation. Non-governmental organisations, such as the Consumer's Association of India, the Consumers' Forum and the Citizen Consumer and Civil Action Group, are actively working towards increasing awareness and informing consumers with regards to their rights and remedies under CPA.

The courts in India are providing effective redressal of consumer complaints.

In *M/s Avery India limited v M/s kaybee Sulphates limited*, MANU/CF/0002/2014, the respondent/complainant filed a consumer complaint against the petitioner alleging deficiency in service in not setting up the weigh-bridge at his Industrial Unit and supplying him a defective transfer lever. The National Consumer Rights Redressal Commission held that the respondent did not qualify as a consumer since it runs a sulphate industry and had purchased the weighbridge from the petitioner for the purpose of above industry only. Further, the commission observed that it was a commercial transaction between the petitioner and the respondent and the same is not a consumer dispute.

In another case, *Tata Motors v Rajesh Tyagi, and HIM Motors Showroom*, I (2014)CPJ132(NC), the Commission held that it was the duty of both the manufacturer and dealer to attend to the defect when a consumer complained of the defect in a vehicle and make it defect-free, and if they were not in position to do so, they should either refund the cost of vehicle or provide a new vehicle to the consumer.

In the matter of *Rediff.com India limited v M/s Urmil Munjal*, II(2013)CPJ522(NC), the Commission held that both the District Forum and State Commission did not hold the respondent, an online shopping platform, liable for any defects in the goods supplied, but for failure to inform the complainant about the manner in which defective goods were to be returned to their seller and the Commission upheld the decision of the forum.

In *Raj Bala v Managing Director, Skoda Auto India Pvt Ltd & Anr (Revision petition decided on 23.10.13 from the order dated 26.09.2012 in First Appeal Nos. 824/2009 of the Delhi State Consumer Disputes Redressal Commission)*, the National Consumer Dispute Redressal Forum considered a case where there was no inherent defect found in a vehicle, as per a report given by an expert, which may necessitate its replacement or refund of the value of the vehicle to the Complainant. The District Forum, *vide* their order, had already allowed a sum of 40,000 rupees to the complainant for inconvenience caused to the Complainant for taking the vehicle to a workshop frequently within a short period and also directed the Respondents to extend the warranty of the vehicle by at least one year. The said order was not challenged by the Respondents before any higher authority. The State Commission had also endorsed the order of the District Forum and the Commission upheld the same.

Courts in India have upheld the limitation of liability clauses, which parties have specifically agreed to in the contract, as recognised by the Supreme Court in *Bharathi Knitting Company v DHL Worldwide Express Courier* (1996) 4 SCC 704. Nonetheless, such clauses may be struck down if found to be unconscionable in nature.

In *Maruti Udyog v Susheel Kumar Gabgotra*, (2006) 4 SCC 644, the manufacturer of the vehicle had stipulated a warranty clause limiting its liability to merely repair the defects found, if any. In view of this clause, the Supreme Court reversed the findings of the National Commission to replace the defective goods and held that the liability of the manufacturer was confined to repairing the defect. Compensation was, however, awarded to the complainant for travel charges which were incurred due to the fault of the car manufacturer.

Karnika Seth
Seth Associates
721, Advant Navis Business Park
Tower B, Sector 142
Noida Expressway, NOIDA-201301
India

Tel: +91 120 458 5437
Email: karnika@sethassociates.com
URL: www.sethassociates.com

Professor Karnika Seth specialises in Cyber law, Business laws and Intellectual Property law, and is the Founding Partner of Seth Associates, an internationally networked full service Indian law firm. Ms. Seth is also the Chairperson and Founder of the Lex Cyberia at Seth Associates, an integrated cyberlaws research, forensics and legal consulting centre. She has significant and diverse transactional experience encompassing Internet and e-commerce laws, Business laws, International Commercial Arbitration, International Trade and Intellectual Property laws and is principal legal advisor to many multinational groups, corporate houses, public and private sector companies, corporations and government entities. In 2012, she authored a book titled '*Computers, Internet and New Technology Laws*' published by Lexis Nexis Butterworths that elucidates the key developments in the field of Cyberlaws across many important jurisdictions – India, United States and European nations. Ms. Seth was conferred the Law Day Award in 2012 from the Chief Justice of India for authoring this book. She received the Digital Empowerment Award for 2015 from the Government of India & BIF.

Amit Seth
Seth Associates
C-1/16 Daryaganj
New Delhi-110002
India

Tel: +91 11 4355 9488
Email: aseth@sethassociates.com
URL: www.sethassociates.com

Amit Seth is the Founding Partner of Seth Associates and heads the Commercial litigation division of the firm. Mr. Seth specialises in General Civil Litigation, Commercial disputes resolution, environment laws, real estate laws and employment disputes. He advises various corporate bodies and high net-worth clients of the firm on any business-related disputes and actively represents clients before all courts/forums in India.

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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 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 is currently at the initial parliamentary review stage.

Criminal liability is fault-based and must be proven beyond reasonable doubt.

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

This has been known to happen in Ireland in circumstances where some organ of the State may have a liability. The National Treasury Management Agency (the "**NTMA**") manages personal injury and property damage claims against the State. When performing these

functions, the NTMA is known as the State Claims Agency (the "**SCA**"). Whilst this particular case was excluded from the SCA's remit, the most notable instance was the Hepatitis C Compensation Tribunal, which was set up in 1997 to compensate women who had become infected with Hepatitis C having been transfused with infected blood during pregnancy. More recently, the 'Surgical Symphysiotomy *Ex-gratia* Payment Scheme' was set up in 2014 to compensate women who underwent historical symphysiotomy procedures in the State. There is also a scheme to compensate haemophiliac plaintiffs of contaminated blood products. Such schemes are *ad hoc*, rather than statutorily required.

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.

On 11 June 2013, the European Commission published a Recommendation calling on all Member States to adopt collective redress systems for both injunctive and compensatory relief. Although Member States are encouraged to implement the principles set out in the Regulations, the Recommendation is not binding. The Recommendation deals with "mass harm situations" where by two or more persons (natural or legal) claim to have suffered harm from the same illegal activity carried out by another person (natural or legal) in breach of EU rights. The Recommendation, which may form the basis for future implementing legislation, addresses a number of issues in collective redress, including: standing to bring a representative action; funding; cross-border disputes; ADR; damages; and legal costs and lawyer fees.

As of yet, however, there have been no steps taken by the Irish legislature to implement the recommendations of either the Law Reform Commission or the European Commission in this regard.

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

No. Representative and consumer associations will generally lack the necessary *locus standi* to bring such actions.

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

Following the enactment of the Personal Injuries Assessment Board Act 2003, any party wishing to bring personal injury proceedings must first submit their claim to the 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. Following the commencement of the Court of Appeal Act 2014, decisions of the High Court may be appealed to the recently established Court of Appeal.

In limited circumstances, decisions of the Court of Appeal and High Court may be appealed to the Supreme Court. The Supreme Court will hear such appeals only if it raises a matter of general public importance or is necessary in the interests of justice.

Directions of the 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, effective from 1 January 2018, 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.

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.

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 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.

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

No. However, if at the conclusion of proceedings an order is made allowing one party to recover their legal costs from another, the party who has been ordered to pay can require that the costs be "taxed" (i.e., reviewed and independently adjudicated upon by a "Taxing Master").

In deciding whether or not to make a court order, particularly in the discovery process, a court may consider the proportionality of the costs of fulfilling that order.

8 Updates

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

The Competition and Consumer Protection Act 2014 created the newly formed CCPC. On 31 October 2014, the new agency took over the product safety role of the former National Consumer Agency under the 2004 Regulations, including the responsibility for taking prosecutions and ordering product recalls. The CCPC has a broad mandate for conducting market surveillance in relation to the safety of products under various EU Directives.

The *Boston Scientific* CJEU decision, as discussed at questions 2.2 and 6.3, is significant, although its implications are yet to be explored by the Irish courts.

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. Specifically, he advises on life science and pharmaceutical regulatory law, EU medicine law, product recall and general liability issues. Tom also advises a number of hospitals, healthcare organisations, 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.

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Daniele Vecchi

Gianni, Origoni, Grippo, Cappelli & Partners

Michela Turra

1 Liability Systems

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

In Italy, product liability is governed by Legislative Decree no. 206 of September 6, 2005, the so-called Consumer Code, which is the last of a series of legislative acts, the first of which dates back to 1988, whereby EU Directive no. 374 of 1985 was implemented.

The Consumer Code sets forth a strict, non-fault-based kind of liability. This liability can be claimed by the consumer for damages caused by a defective product, including personal damages, consisting of death or physical injuries, and damage caused to goods normally destined to private use.

This liability is alternative to contractual and tort liabilities, as already governed by the Civil Code.

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

In particular circumstances, in case of a large-scale violation of a constitutional protected right, the State may operate indemnity schemes. Indemnity cannot be regarded as a form of compensation, but rather as a kind of welfare measure. Thus, being entitled to an indemnity does not *per se* prevent the damaged consumer from raising claims seeking full compensation for the relevant damage.

By way of example, Law no. 210 of 1992 provides for a publicly financed monthly monetary indemnity for subjects suffering permanent injuries or illnesses as a result of transfusions of infected blood or blood derivatives, or as a result of the injection of defective vaccines.

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

Under the Consumer Code, the manufacturer is the first subject liable for damages caused by the defective product. The manufacturer is anyone:

- manufacturing the product in the EU;
- presenting itself as manufacturer by placing a name, a trademark or any other distinctive sign on the product, or reconditioning the product;
- representing the manufacturer whenever the former is not established in the EU, and importing the product whenever the manufacturer has no representative established in the EU; or
- included in the supply chain, insofar as its activity may affect the standards of safety of the product.

The distributor (i.e. any professional operator that is part of the supply chain of a product, provided that it does not impact the safety of the same product) may also be held liable, but only in a residual way, in the event that the manufacturer is not identified. Nonetheless, the distributor can escape such a liability by allowing the identification of the manufacturer.

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

Italian law provides for a series of duties for public bodies (e.g. Ministry of Economic Development, Ministry of Health, etc.) to ensure that products placed on the market are safe and to adopt all necessary measures to ensure public safety (including ordering product recalls or prohibiting their sale). In the case of failure to properly perform such monitoring activities, it could be argued that harmful events derived from unsafe products which the competent public bodies had a duty to control would entitle the damaged party to claim compensation from the State as well for not having complied with its "duty to protect". However, it is not possible to assimilate such a liability to the one generally known as "product liability", since reference should be made to other rules.

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 Consumer Code, the manufacturer has to manufacture and market safe products.

The manufacturer and/or distributor who is or should be aware, based on the information in their possession and in their capacity as professionals in the sector, that a product they placed on the market exposes consumers to risks that are incompatible with general safety requirements, must adopt corrective measures commensurate to the characteristics of, and to the risks posed by, the same product.

Corrective actions have to be evaluated, taking into account the risk that the product poses to consumers. The assessment of said risk is usually made on the basis of the following steps:

- identification of the defect, with details of its nature and cause, the total number of products affected and the number of persons who could be affected by the defect;
- an estimate of the level of risk, which depends on both the severity of the possible injury to those using the product and the probability of injury; and
- evaluation of the acceptability of the risk for consumers.

In case a serious level of risk emerges from the assessment of the above-mentioned elements, the corrective measure to adopt usually consists of the recall of the product. If necessary, lacking any initiative on the part of the manufacturer in this regard, the relevant authority may impose the recall itself.

Failure to undertake a recall or other corrective actions aimed at keeping a dangerous product off the market is punishable under Criminal Law. In addition, such a failure may represent evidence in favour of the consumer in case of litigation aimed at seeking compensation for damages caused by the dangerous product.

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

The manufacturer and/or distributor that fails to adopt measures aimed at remedying the risks deriving from a defective product placed on the market may incur criminal liability. Unless the conduct constitutes a more severe criminal offence (for instance, in the event the defect causes death), the manufacturer/distributor may be subject to arrest for a period of between six months and one year, or to pecuniary sanctions ranging from €1,500 to €50,000.

2 Causation

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

The consumer who claims to have been injured by the defective product has the burden of proving:

- the defect of the product;
- the damage allegedly suffered; and
- causation, in terms of existence of a causal relationship between the aforesaid defect and the damage claimed.

In line with a trend in the case-law of merits courts, it has emerged that the existence of the defect of a product could be inferred by the existence of damage and of the causal link between the use of the products and the damage itself; in other words, according to this trend, the mere fact that the use of the product would have led to the causation of damages would be enough to infer the existence of defects of that product. Thus, no specific evidence of the defect would be needed.

Nonetheless, such a trend appears to have been overturned following a decision of the Supreme Court, which can now be regarded as a benchmark in the matter. Specifically, in accordance with this decision, the existence of a defect of the product has to be proved. In other words, evidence has to be offered that the same product lacks the general safety conditions which are required and can be expected with regard to the common use for which the product has been manufactured and marketed (Court of Cassation, decision no. 6007 of March 15, 2007; more recently confirmed by the Court of Cassation, decision no. 3258 of February 19, 2016).

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

The proof that the damaged party has to provide largely depends on the nature of the alleged defect.

In case the product itself is safe and only a single item, which the damaged party was exposed to, malfunctioned or was defected, the same damaged party has to prove the existence of the relevant defect (however, some authors state that said burden of proof could be satisfied by demonstrating that such single item differs from all other products of the same set).

In the event the injury derives from a defect which is common to all similar products (i.e. the product itself is unsafe or it has been wrongfully designed, or there is a lack of information provided by the manufacturer), it will be sufficient for the damaged party to prove that the entire category of products is defected, not having to demonstrate the existence of the defect of the single product he or she entered into contact with.

In cases where said proof is not easily reachable, presumptions may be considered sufficient by judges.

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

Under the Consumer Code, in the event several subjects caused the damage together, each of them is jointly liable and obliged to provide compensation. Should only one of the subjects compensate the damage at issue, it would have the right to act against the others to recover the amount due by each of them. Said amount has to be determined taking into account the extension of risk, the seriousness of the wrongdoing and the relevant consequences attributable to each subject. Should this assessment not be possible, depending on the circumstances, all the subjects involved have to be considered equally liable.

If the damage is not caused by a common activity but by a single manufacturer to be identified, the relevant burden is on the plaintiff, and no form of market-share liability is applicable.

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

Under the Consumer Code, the manufacturer has to provide the consumer with useful information to assess and prevent risks deriving from the use of the product as foreseeable given its scope, unless such risks are immediately obvious without any specific indication.

The content and extent of the information to be provided has to be determined with regard to the qualities and characteristics of the product. The ways the product is submitted to the attention of the public, including, for instance, packaging, warnings, handbooks, instructions and intermediaries, also have to be taken into account to this end.

Should the manufacturer fail to provide adequate information as above, preventing the consumer from understanding and consequently avoiding the risks arising from the use of the product, it may incur liability for defectiveness of the same product.

In general terms, in addition to publicly available information, only information provided to the consumer by the manufacturer is relevant in making an evaluation of the defectiveness of the product.

A slightly different situation occurs when the consumer can obtain the product only through an intermediary, who then has a personal duty to evaluate the suitability of the product. In this case, the intermediary, as a result of its professional skills and knowledge, may incur personal liability should it make an inappropriate evaluation or in turn fail to provide the consumer with adequate information in its possession. Despite the intermediary's liability, if a product turns out to be defective, the manufacturer will also be liable.

No principle of "learned intermediary" is applicable.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under the Consumer Code, liability is excluded in case:

- the manufacturer did not place the product on the market. In general, a product is considered as marketed if it is delivered to the purchaser, to the user or to an assistant of one of them; which also includes samples or products to be viewed or tested only;
- the defect which caused the damage did not exist at the time the manufacturer placed the product on the market;
- the manufacturer did not manufacture the product for sale or distribution against payment of consideration, or did not manufacture or distribute it in the exercise of its business;
- the defect is due to the compliance of the product with a mandatory legal provision or with binding public measures; or
- the scientific and technical knowledge available when the manufacturer placed the product on the market did not allow the manufacturer to consider the product as defective.

In terms of exclusion of liability of the distributor, please refer to the answer to question 1.3 above.

Provided the above, liability is also excluded if the consumer caused the relevant damage. Specifically, compensation is excluded if the consumer, despite having been aware of the defect of the product and the related risks, voluntarily exposed himself or herself to them.

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

Please refer to the answer to question 3.1 above.

According to some authors, however, the actual application of this exemption of liability should be limited in light of the provisions of product safety regulations imposing post-selling obligations on the manufacturer.

In any case, the burden to prove that there is no liability lies with the manufacturer.

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

Please refer to the answer to question 3.1 above.

According to the majority of authors, liability can be escaped only when the mandatory legal provision or the binding measure imposes specific conditions or formalities on the manufacturer, and not when it sets forth minimum safety standards. As a matter of fact, compliance with such minimum safety standards would not amount to a valid defence.

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

Different consumers, all allegedly damaged by the same kind of product, can each initiate separate proceedings and raise claims based on different legal grounds. No form of issue estoppel can prevent a different consumer from re-litigating issues related to liability for a certain product.

Provided the above, however, previous rulings over cases regarding liability for the same product, albeit not binding, may be regarded by judges as precedents to be followed when evaluating the relevant claims.

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

The defendant allegedly liable for the damage claimed by the consumer can in turn raise a claim, in the same or in subsequent proceedings, against any third party that caused or contributed to the fault or defect of the product at issue.

Such a claim would be subject to its own statute of limitation period, in general:

- 10 years for contractual liability;
- five years for tort liability;
- three years for product liability (please refer to the answer to question 5.2 below); and
- one year for liability of the seller in case of the sale of a defective product to a professional. A professional is considered to be anyone purchasing goods within the exercise of its business.

Each of the above terms starts running from the day on which the relevant right can be exercised, i.e., in general terms, respectively when:

- the non-performed obligation became due or the breach of the relevant contractual obligation occurred;
- the harmful event occurred;
- the consumer became aware or should have become aware of the damage, the defect of the product and the identity of the liable subject (please refer to the answer to question 5.2 below); and
- the purchaser became aware or should have become aware of the defect of the sold goods.

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

Liability is excluded in cases where the damage has been caused by the consumer who claims to have been damaged by the defective product; specifically, compensation is excluded if the consumer, although having been aware of the defect of the product and the related risks, voluntarily exposed himself or herself to the same risks.

Furthermore, in cases where the consumer who has been damaged by the defective product contributed to the causation of the relevant damage, compensation is reduced proportionally with regard to the seriousness of the negligence attributable to the same consumer and the extent of the consequences arising therefrom.

4 Procedure

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

As a general rule, civil proceedings are held by a single judge or by a panel of judges in some specific cases.

Juries are not contemplated in civil proceedings.

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

Should the case require specific technical knowledge, the judge may appoint, also upon a party's request, one or more experts (*Consulente Tecnico di Ufficio* – "CTU") to act as the judge's assistants and provide technical expertise.

The CTU is selected from lists of experts filed in each court. Otherwise, the CTU's appointment has to be previously authorised by the President of the Court. The parties can oppose the appointment of the CTU on proper grounds, such as risk of impartiality or bias.

Each party can appoint its own retained expert to work together with the CTU (*Consulenti Tecnici di Parte* – "CTPs").

The CTU cannot make legal assessments, establish the existence and meaning of legal provisions or assess documentary evidence. His/her role is strictly limited to technical questions posed by the court.

The expertise proceeding is carried out in writing. The CTU shares a preliminary report with the CTPs; subsequently the CTU files a final report, including comments or remarks from the CTPs.

The content of the final report filed as above is not binding for the judge, who may disagree with its outcome and provide adequate grounds in support of his/her decision.

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

A modification of the Consumer Code dating back to 2008 has introduced class actions as a mechanism to seek damage compensation for certain kinds of multiple claims, including claims arising from the same defective product.

A class action can be brought in relation to wrongful events which occurred after 15 August 2009.

The relevant procedure consists of a preliminary admissibility stage (certification), which may be followed by the merit stage for the assessment of liability and damage. Homogeneity of the rights claimed by the members of the group is an essential condition for admissibility.

Class actions are based on an opt-in system.

The decision of the court, ruling in panels, can provide for a direct condemnation or set forth the criteria to calculate the amount due to the members of the group or the minimum amount due to each of them. Assessment of individual damage can, in this second case, be remitted to a subsequent settlement or litigation.

Since class actions have been introduced in Italy, approximately 70 cases have been initiated, but only a very limited number of them have been certified. In fact, this procedural instrument appears to have not been very commonly used so far: an average of only 10 class actions per year has been brought. This is a very small result, considering that approximately four million new civil cases are initiated in Italy every year.

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

Class actions can be brought by any single consumer as a class representative, providing there is evidence that the claims raised are worthy of being litigated as class actions due to the existence of homogenous rights to protection within the potential group.

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

In Italy, there is no formal distinction between the trial and pre-trial phases.

In case of class actions, the certification phase (pre-trial phase) may last some months; including the appeal on certification, this phase can last up to a year.

On average, the complete first instance proceedings may last from one to five years. Timing may vary depending on different factors, such as the workflow of each court or the way the specific case develops, for instance whether or not evidence-gathering activities have to be carried out.

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

The court can decide to evaluate preliminary issues first. They include preliminary procedural matters (e.g. lack of jurisdiction, lack of venue, lack of legal capacity to sue) or preliminary matters on the merits (e.g. time-barred claims).

In practice, however, judges tend to evaluate both preliminary and non-preliminary issues together at the end of the proceedings.

There is no jury in civil litigation.

4.7 What appeal options are available?

All parties have the right to appeal.

In general, in Italy there are three levels of courts:

- first-instance courts (justices of the peace and tribunals);
- second-instance courts (courts of appeal for judgments rendered by tribunals, and tribunals for judgments rendered by justices of the peace); and
- the Court of Cassation (Supreme Court).

Decisions issued in first instance proceedings can be appealed before courts of second instance, which can rule again on the merits of the case. Nonetheless, new claims and new challenges are not admissible; new evidentiary means or requests cannot be admitted unless they are deemed as essential for deciding the case or unless the party proves that they could have not been submitted during first instance proceedings for reasons not attributable to the same party.

All parties have the right to challenge the merit decision before the Supreme Court, which stands at the top of the court hierarchy. It is the court of last resort and its task is to ensure the consistent interpretation and application of the law. The Court's review is limited to issues regarding the interpretation and correct application of the law, without any further evaluation on the merits of the case.

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

Please refer to the answer to question 4.2 above.

The parties may appoint their own experts, even if the judge fails to appoint a CTU, in order to draft written reports which shall be filed as exhibits in the proceedings. In general, there is no restriction on the nature or the extent of this kind of evidence.

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

Pre-trial deposition or exchange of witness statements or expert reports is not allowed.

Pre-trial technical investigations can be initiated whenever there is the need to ascertain a factual situation which may be subject to modification or deterioration before evidence-gathering activities in subsequent proceedings are initiated. In general terms, these proceedings, which are court-ruled, are not widely used.

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

No discovery rule is applicable.

Pending the proceedings, during evidence-gathering activities, the judge may, upon a party's request, order the counterparty or any third party to exhibit documents. In case the counterparty or any third party as above refuses to do so and fails to provide a valid reason to support the refusal, the judge may infer from its conduct to rule over the case.

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

There are no pre-filing requirements to begin a formal, ordinary lawsuit for product liability. As a result of a recent reform of Italian procedural law, since 9 February 2015, for claims for payments of any amount between €1,100 and €50,000, before litigating in court parties to a dispute have to carry out negotiations in the presence of their attorneys at law to try to amicably settle their dispute (assisted negotiation). Assisted negotiation is not mandatory in the case of disputes that arise as per obligations set forth by agreements entered into by professionals and consumers.

In addition, Law no. 28 of 2010 provides for a "mediation procedure" for an out-of-court settlement, to be carried out before a mediation authority. Said mediation procedure is compulsory before trial in some specific matters (listed by Art. 5 of Law no. 28 of 2010), some of which (damages arising from medical and healthcare liability) may be relevant for product liability suits. In all other cases, the choice as to whether or not to initiate said mediation procedure is up to the parties.

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

Jurisdiction over product liability cases is governed by EU Regulation no. 1215 of 2012, as well as Italian Law no. 218 of 1995, setting forth conflict of law provisions.

In general, on the basis of the above, Italian courts have jurisdiction over claims for compensation of damages due to an event which occurred or which may occur in Italy, irrespective of the fact that the claimant or the defendant is domiciled in Italy.

Italian courts also have jurisdiction over claims raised by a claimant who is not domiciled in Italy against any defendant who is domiciled in Italy.

5 Time Limits

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

The limitation period for product liability claims is three years, running from the day on which the consumer was allegedly damaged by the defective product, the day on which the consumer becomes aware or should have become aware of the damage or defect, or the day on which the consumer becomes aware of the identity of the liable party (please refer to the answer to question 3.5 above).

In any case, the right to be compensated for the defect of a product expires after 10 years from the day on which the manufacturer or importer within the EU placed the relevant product on the market.

However, the claimant may bring an ordinary tort action instead of a product liability action and exploit the relevant five-year term.

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

Please refer to the answers to questions 3.5 and 5.1 above.

The limitation period does not vary based on the age or condition of the claimant. The court has no discretion in this regard.

The running of the limitation period can in any case be interrupted. In general, this occurs whenever proceedings are initiated to raise the relevant claim or such a claim is raised in pending proceedings. In case of interruption, the limitation period starts running again afresh as soon as a binding decision is issued as an outcome of aforesaid proceedings. In the field of product liability, as in several other fields under Italian law, the running of the limitation period can be interrupted also by way of a demand letter or letter of formal notice sent to the manufacturer by the allegedly damaged party denouncing the harmful event and asking for compensation.

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

No specific provision is set forth in relation to the effects of issues of concealment or fraud over limitation periods. Nonetheless, the aforesaid issues may impact the running of the same period. Indeed, as per the general rule set forth by the Consumer Code, the limitation period starts running from the day on which the consumer acknowledged or should have acknowledged, *inter alia*, the defect in question on the basis of ordinary diligence and overall circumstances; therefore, a concealment or fraud could postpone the beginning of the running of the limitation period (please also refer to the answers to questions 3.5 and 5.1 above).

Provided the above, in general, should such issues of concealment or fraud amount to criminal offences, the longer limitation period, generally of six years, provided by the criminal law to prosecute the offender, applies instead of the period indicated above.

6 Remedies

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

As a general remark, product liability claims can be raised to seek compensation for personal damage, causing death or physical injuries, as well as for damage to objects normally used for private purposes and destroyed or damaged by the defective product.

Having said that, both pecuniary and non-pecuniary damages suffered by the consumer (as above) are recoverable.

The Consumer Code does not provide for injunctive/declaratory relief for individual consumers, but only for consumer associations.

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

For some decades now, both case-law and authors have identified four categories of damages:

- material (pecuniary) damages, which consist of monetary damage due to pecuniary loss or loss of profits;
- non-material damages, i.e.:
  a) biological damages, affecting the psychological and/or physical integrity of a person, directly related to his or her health;
  b) moral damages, essentially consisting of pain and suffering, to be awarded only in cases provided for by law (mainly as a result of a criminal offence); and
  c) existential damages, as 'created' by case-law to allow for compensation of damages not included within the above category of moral damages and essentially consisting of any event that negatively affects someone's 'quality of life'.

By a stand-out ruling, the Joint Sections of the Court of Cassation maintained that non-pecuniary damages are compensable only in cases provided for by the law, i.e. whenever compensability is expressly acknowledged in a law provision and whenever, even lacking such a law provision, the damage entails the violation of a personal right which is constitutionally safeguarded (Court of Cassation, decision no. 26972 of 2008). In view of the above and on the basis of such ruling, existential damage is no longer compensable as an autonomous category of damage, but rather as a component of non-material damages. It is worth mentioning that decisions from Italian courts, even those issued by the Supreme Court, do not amount to binding precedents, even though they may have a persuasive effect. So far, the trend of lower level courts is to follow the above interpretation.

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

In general terms, compensation is allowed only as restoration of damages actually suffered as a consequence of the defective product. Otherwise, in principle, no compensation is possible.

Having said that, once the damage has occurred, compensation may also cover costs for future medical monitoring, including costs related to investigations, tests and treatments, whether or not they were foreseeable as a result of the ascertained injury.

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

In general terms, Italian law does not provide for punitive damages in the field of product liability and, more in general, in the field of tort liability.

However, it should be highlighted that, by an unprecedented judgment (no. 16601 of July 5, 2017), dealing with a case of product liability, the Joined Sessions of the Court of Cassation clarified that such damages are not *per se* incompatible with the Italian legal order and with the function of tort liability under Italian law. Therefore, according to the court, punitive damages should be granted in case Italian judges are called to enforce a foreign decision rendered by a judge belonging to a legal order in which punitive damages are allowed. No similar cases have followed.

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

No limit is set forth.

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

No specific rule applies in the case of settlement of claims or proceedings. As far as class actions are concerned, in general, conciliation or settlement between class representatives and the defendant do not affect class members who are not party to the out-of-court agreement.

Regardless of product liability rules, some kinds of settlements involving minors have to be authorised by the judge.

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

No specific regulation is set forth, nor is there any case-law to report in this regard.

7 Costs / Funding

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

In its final decision the judge also awards costs of the proceedings. In general, it is the responsibility of the losing party to refund the winning party's court expenses and legal fees incurred during the proceedings. Nonetheless, depending on the circumstances, the judge may rule that each party bears its own costs. As a matter of fact, judges frequently deem that it is not appropriate for a company to recover costs against losing individuals.

Provided the above, in case they are awarded, recoverable fees are very rarely those actually paid by the winning parties. Fees are calculated to this end on the basis of parameters included in tariffs set forth by the Ministry of Justice; quite frequently, these parameters do not reflect the economic conditions applied by law firms.

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

In general, an indigent party can access legal aid by filing an application to the local Bar Association.

Legal aid is granted on the condition that the claim to be raised is not clearly groundless. Legal aid can be revoked at any time, also pending proceedings, should the judge ascertain that the income of the relevant party actually exceeds the threshold set forth by the law, that the requirements provided by the law are not actually met or that the same party acted or defended itself with malice or gross negligence.

Legal aid includes both costs and fees related to the proceedings. When legal aid is granted, some of the costs are paid by the State and others are waived.

Legal aid is not widespread, given strict limits of admissibility. Moreover, litigation in Italy is not particularly expensive.

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

Please see the answer to question 7.2 above.

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

Contingency or conditional fees have become admissible only in the last few years. Accordingly, parties can agree for legal fees to be calculated keeping the awarded sum as a parameter. Such agreements are only valid if they are in writing and particular limitations are provided.

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

Third party litigation funding is not regulated in Italy. In general, it is admissible, but at least so far it is not common at all.

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

The court does not exercise control over the costs to be incurred by the parties and the claim filed to the court. The (allegedly) damaged party quantifies its claim, if possible, when starting the case. The costs of the proceedings may be influenced, sometimes significantly, depending on the development of the evidence-gathering phase, and in particular when it is necessary to obtain the opinion of a court-appointed expert. In order to prevent these costs from discouraging damaged parties to file their claims, Art. 120 of the Consumer Code allows the judge to initially place these costs on the defendant when the claim of the damaged party is plausible.

As for legal fees, the losing party is generally condemned to refund them to the winning counterparty (in application of the general "loser pays" principle). They are always quantified by the court with its final decision and are proportionate to the parameters set out by Law no. 247 of 2012 (said parameters depend on the value of the claim, the complexity of the case, the number of parties, etc.). This mechanism avoids the risk of the losing party being condemned to refund to the counterparty a disproportionate amount in relation to the value of the claim, even if, on the other side, the winning party may be only partially refunded (amounts set out by the parameters are often lower than the amounts effectively paid as legal fees).

8 Updates

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

In the last few years Italian case-law on product liability has developed in line with previous trends as per: (i) the burden of proof – the Court of Cassation (no. 15851/15) confirmed that the damaged party is exonerated only from proving negligence/wilful misconduct by the damaging party, not from proving the "defect" – and (ii) the notion of "defective product", i.e. a product lacking safety in comparison with consumers' expectations – the Supreme Court (no. 3258/16) rejected a claim for compensation for damages allegedly caused by the explosion of a toxic house detergent, stating that the product itself could not be considered "defective", since it was manufactured and distributed in line with the safety standards required for this kind of product.

On this second profile, a decision of the Court of Justice of the European Union (March 5, 2015, Case nos. 503 and 504 of 2013) regarding medical devices to be implanted in humans for therapeutic purposes assessed that all medical devices placed on the market had to be considered defective – irrespective of whether or not anomalies in their functioning had actually been reported in the treated patients – since they did not provide the standard level of safety that patients may legitimately expect. Also, according to said decision, the quantification of damages suffered should include the costs of surgery required to remove the defect in the medical devices.

It is also worth mentioning that, in 2017, the same CJEU rendered a judgment (no. 621 of June 21, 2017) concerning the burden of proof for (medical) product liability claims, clarifying that the law cannot be interpreted as necessarily requiring definite medical evidence as to causation between the defect and the insurgence of an illness, it being sufficient to demonstrate probable cause (the case dealt with damages allegedly caused by vaccines).

With regards to updates on punitive damages, please see question 6.4 above.

Daniele Vecchi
Gianni, Origoni, Grippo, Cappelli & Partners
Piazza Belgioioso 2
20121 Milan
Italy

Tel: +39 02 7637 41
Fax: +39 02 7600 9628
Email: dvecchi@gop.it
URL: www.gop.it

Daniele Vecchi, Partner of the Litigation Department, practises general commercial and civil litigation and is a specialist in product liability. He has extensive experience in defending companies in consumer and group actions involving tobacco products, food and pharmaceuticals.

Over the course of his career he has worked extensively with in-house counsels and lawyers in Italy and abroad, developing an international defence strategy with important expert witnesses.

Internationally recognised as a leading expert on Product Liability and Class Actions, he contributes to international publications and speaks at national and international conferences.

He has been referred as a recognised expert in product liability in *Who's Who in Product Liability* (since 2005, on a continuous basis), *Legal Media Group* "Guide to the World's Leading Product Liability Lawyers" (since 2007), www.LegalComprehensive.com and *Expert Guides* "Litigation and Product Liability".

Michela Turra
Gianni, Origoni, Grippo, Cappelli & Partners
Piazza Belgioioso 2
20121 Milan
Italy

Tel: +39 02 7637 41
Fax: +39 02 7600 9628
Email: mturra@gop.it
URL: www.gop.it

Michela Turra is a Senior Associate of the firm.

She has gained solid experience in litigation, with a specific focus on civil and international actions.

She specialises in Product Liability, and over the last 15 years, she has assisted and advised several companies, both domestic and foreign, providing full assistance in matters concerning consumers' claims and multi-claimant group actions.

She regularly contributes to international publications in her field of specialisation.

She was awarded "Product Liability Lawyer of the Year in Italy" by Corporate INTL Global Awards (from 2014 to 2018) and by Global Law Experts Practice Awards (2015 and 2014), and Lawyer of the Year in Consumer Law – Milan, Italy by Corporate LiveWire – Global Awards (2015).

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Japan

Shinya Tago

Landry Guesdon

Iwata Godo Law Offices

1 Liability Systems

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

A. Traditionally, product liability claims had been brought as tort claims under the Civil Code of Japan. However, since 1995, claims can also be brought under the Product Liability Act (Law No. 85 of 1994) (PLA), which gives a plaintiff more flexibility to seek compensation for damages caused by a defective product. Products covered by the PLA are movable property which is manufactured or processed (therefore excluding real estate, electricity or agricultural products). If a defective product causes any damage to the buyer's life, body or property (excluding the product itself), the buyer can bring a product liability suit against the "manufacturer" (see definition in question 1.3) (Article 3 of the PLA).

The plaintiff is not required to prove that the manufacturer owed a duty to the plaintiff and negligently or intentionally injured the plaintiff. The plaintiff only needs to demonstrate that the product was defective, and that the defect caused the injuries. A product can be deemed defective if it lacks the level of safety which it should normally possess, taking into account its nature and characteristics, its ordinarily foreseeable uses, state of the art (scientific or technical) knowledge at the time of delivery and other relevant circumstances relating to the product.

B. Alternatively, if a claim cannot be brought or is unsuccessful under the PLA, the injured party may bring a tort claim under the Civil Code. This type of claim, which is still relied upon in civil cases to obtain monetary damages, is viewed as a last resort for persons injured by a defective product. Article 709 provides that a person who has intentionally or negligently infringed any right or legally protected interest of another will be liable for any resulting damage. In contrast with the PLA, the plaintiff must prove the defendant's intent or negligence, and the burden of proof is subject to a high standard. Causes of action under Article 709 include fraud and misrepresentation.

C. The Consumer Contract Act (Law No. 61 of 2000) (CCA) protects consumers in their dealings with merchants (business operators). Article 8 of the CCA provides that the following clauses are void if they are included in a contract made between a consumer and a business operator:

- Clauses which totally exempt a business operator from liability to compensate a consumer for damages arising from the business operator's fault.
- Clauses which partially exempt a business operator from liability for damages arising from the business operator's fault (limited to default arising due to an intentional act or gross negligence on the part of the business operator, its representatives or employees).
- Clauses which totally exempt a business operator from liability for damages to a consumer arising from a tort under the Civil Code committed during the business operator's performance of a consumer contract.
- Clauses which partially exempt a business operator from liability for damages to a consumer arising from a tort under the Civil Code (limited to cases in which the tort arises due to an intentional act by, or the gross negligence of, the business operator, its representatives or employees) committed during the business operator's performance of a consumer contract.
- If a consumer contract is a contract for value, and there is a latent defect in the subject matter of the consumer contract (including where a consumer contract is a contract for services, and there is a defect in the subject matter of that contract), clauses which totally exclude a business operator from any liability to compensate a consumer for damages caused by such defect, except in the event that:
  - the consumer contract provides that the business operator is liable to deliver substitute products without the defect, or to repair the goods when a latent defect exists in the products which are the subject matter of the consumer contract; or
  - the consumer contract is concluded between a consumer and a business operator simultaneously with, or after another contract is concluded between, the consumer and another business operator entrusted by the business operator, or between the business operator and another business operator for the benefit of the consumer, and that other contract provides that the other business operator is responsible to provide compensation for all or part of the damage caused by a defect, deliver substitute products without defects or repair the defective products where a latent defect exists in the products covered by the consumer contract.

Although the CCA limits the extent to which the seller of a product may disclaim warranties relating to a product or restrict the remedies available to a buyer injured by a product sold by the seller, it does not offer any specific cause of action for damage caused by defective products.

D. A claim based on breach of contract must be made by a party to the contract. A plaintiff (generally a buyer) can bring a product liability claim against a seller who is his counterparty in a sale and purchase

contract, either for breach of contract or breach of implied statutory warranties under the Civil Code, provided that there is a direct contractual relationship between the injured party and the seller of the defective product. Nowadays, in most consumer transactions, the end-user/buyer does not typically have a direct contractual relationship with the manufacturer as several intermediaries can be involved in the supply chain (manufacturers, suppliers, importers, wholesalers, retailers and so on). As a result, there may often be no cause of action based on breach of contract by a consumer against a manufacturer. Depending on the circumstances, there may be other legal avenues allowing a buyer to seek remedies against a manufacturer under the Product Liability Act or based on tort as explained above.

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

The parties to a contract can be released entirely or partially from their liability under the PLA or tortious/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 entered into between a consumer and a business operator. Notwithstanding any special agreement excluding statutory warranties, a seller's liability would not be excluded in the event of fraud or concealment of known facts (Article 572 of the Civil Code).

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

The Government operates special compensation schemes for pharmaceuticals and products deemed to have specific risks. One scheme is operated under the Preventive Inoculation Law (Law No. 68 of 1948), which compensates victims of injuries caused by inoculations and is entirely funded by the Government. Another scheme, industry-funded and administered by the Pharmaceuticals and Medical Devices Agency (PMDA), Act on Pharmaceuticals and Medical Devices Agency, Independent Administrative Agency (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 (*Seihin Anzen Kyoukai*) under the Consumer Products Safety Law (Law No. 31 of 1973). The "SG-Mark" (safe goods mark) is a product certification system. The Association prescribes stringent safety standards covering products that could be dangerous and cause injuries or death and only products complying with the safety specifications and requirements of the Association can bear the SG-Mark. The consumer compensation scheme operates for the benefit of persons injured by these products. Compensation from the Association is capped at 100 million yen per person and depends on the seriousness of the injury and the cause of the accident.

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

Any natural or legal person classified as a manufacturer under the PLA can be held liable. The PLA defines a manufacturer as:

- Any person who manufactures, processes, or imports the product as a business.
- Any person holding himself out to be the manufacturer of a product by putting his name, trade name, trade mark or other indication on the product, or any person who puts his name on the product in a manner that misleads others into believing he is the manufacturer.
- Any person who puts his name on a product and who, in light of the manner in which the product has been manufactured, processed, imported or sold, or any other relevant circumstances, may be recognised as a "substantial manufacturer" (*de facto* manufacturer).

Unless they fall within any of the aforesaid categories, the PLA does not provide any cause of action against distributors or sellers of a product. Claims against these persons must be brought under the Civil Code on other grounds (breach of implied statutory warranty, breach of contract or tort).

1.4 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 the PLA 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 regulated by the CPSA. Consumer products are defined as products to be supplied mainly for use by general consumers for their routine everyday activities.

The PLA does not contain provisions that would force a manufacturer (including an importer, distributor and so on) to recall or repair a product found to be defective in a product liability lawsuit. However, the CPSA vests powers in the competent Minister (for the majority of consumer products, the minister with regulatory oversight is the Minister of Economy, Trade and Industry) to investigate complaints relating to particular products, compel manufacturers and importers to disclose information relating to allegedly unsafe products, and order product recalls or other remedial actions if the minister finds it necessary to prevent the occurrence or decrease the risk of a danger. Under the CPSA, a person engaging in the manufacture or import of consumer products is legally obligated to investigate the cause of product accidents, and

if he finds it necessary to prevent the occurrence and decrease the risk of a danger, he must endeavour to recall said consumer products or otherwise take preventive action (Article 38, Paragraph 1). In the event of a serious product accident, or where serious danger has occurred to the lives or bodies of general consumers or the danger is considered to be imminent, the competent Minister may order the person engaging in the manufacture or import of said consumer products to recall the consumer products or otherwise take measures to prevent occurrence (Article 39, Paragraph 1).

Separate statutory rules apply to road transport vehicles, pharmaceutical products and other products which are not treated as Consumer Products regulated by the CPSA, for example: Article 63-2 of the Road Transport Vehicle Act; and Article 68-9 of the Pharmaceutical and Medical Devices Act.

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.
- The occurrence of damage and the amount claimed as damages.
- A causal link between the product defect and the injury or damage.

B. In a claim under Article 709 of the Civil Code, the plaintiff must prove that:

- The injury was caused by a defect in the product.
- The manufacturer negligently or intentionally breached a duty owed to the plaintiff and this breach of duty caused the plaintiff's injuries or damage.

In practice, the plaintiff is at least required to prove:

- The existence of the plaintiff's right or legally protected interest.
- The existence of a breach of the plaintiff's right or interest.
- The defendant's intention or negligence in relation to the breach.
- The occurrence of damage and the amount claimed.
- The causal link between the breach and the damage.

C. For breach of contract claims, the plaintiff must prove that the manufacturer has breached the contract through the supply of a defective product in breach of an express or implied warranty and that such breach has caused some damage to the plaintiff.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

The PLA does not prescribe any specific test for proof of causation. Instead, the courts will apply the standard test for causation used under the Civil Code. Under Article 709 of the Civil Code, the plaintiff must prove causation between the defendant's negligence and the resulting damage. The requirement has been somewhat relaxed over time, especially as a result of mass-torts cases such as environmental pollution, where causation has been almost presumed in light of circumstances (namely serious disease and contamination and inexperienced victims at a loss to show causation), thereby shifting the burden of proof onto the defendant. The Supreme Court sought to define the degree of proof necessary for causation in *Miura et al. v. Japan et al.*, Supreme Court, 29-9 MINSHU 1417, 24 October 1975, a medical malpractice case, indicating that proving causation in litigation differed from proving causation in a scientific context and that it was sufficient to show a high probability of causation between facts and the occurrence of a specific result.

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

There is no market-share liability in Japan and one or more specific manufacturers must be sued. When several manufacturers are involved in a product liability suit, they are jointly and severally liable under the PLA or based on tort. A named defendant who has compensated the victim in excess of the share of damages he is otherwise required to bear is entitled to seek indemnification from the 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 (under Article 418 or Article 722 of the Civil Code) is comparative negligence, which may be a partial or complete defence. Comparative negligence can also be claimed in relation to product defect claims brought under the PLA where the manner in which the plaintiff has handled, used or stored the product can be deemed to constitute unforeseeable misuse.

Statute of limitations may also provide a valid defence under Article 5 of the PLA and Article 724 of the Civil Code if the claim is time-barred and brought beyond the applicable three- or 10/20-year statute of limitations (see question 5.2).

Article 4 of the PLA provides for two more defences:

Under Paragraph 1, a manufacturer will not be liable if he could not have discovered the product defect given the state of scientific or technical knowledge at the time of delivery of the product. The manufacturer must prove that the state of scientific or technical knowledge at the time of delivery was such that the existence of a defect could not have been known. Basing a manufacturer's defence on the then current state of the art is rather difficult as Japanese courts have generally interpreted the state of scientific or technical knowledge very narrowly as knowledge meeting the highest scientific or technical standards then in existence.

Under Paragraph 2, a manufacturer of products to be used as a component of, or raw material for, another product is not liable when the defect has occurred primarily because he has complied with the design specifications and instructions given by the final product manufacturer, and he is not negligent with respect to the occurrence of the defect. The component manufacturer (e.g., a subcontractor) must prove that he could not have foreseen or prevented the defect in the product which was integrated into the final products.

B. For breach of contract claims, customary defences are available. The seller may argue that a claim is time-barred under the applicable statute of limitations (see question 5.2).

The other defences available to the seller are:

- Lack of simultaneous performance of the buyer's payment obligations in a contract where the parties' duties are concurrent (in other words, the seller is not under an obligation to perform its duty if the buyer has failed to fulfil its own obligations under the contract).
- Buyer's knowledge of the defect (or negligence in failing to spot the defect; see comparative negligence below).
- A special agreement between the parties disclaiming warranties and liability.

In addition and without limitation, the seller may seek to rely on:

- Comparative negligence, which can be invoked in a situation where the plaintiff can be shown to have assumed a certain level of risks, and therefore the plaintiff's own negligence contributed to the injury. The Japanese courts have adopted a comparative negligence approach as opposed to strict contributory negligence, where each party's negligence for a given injury is considered by the judge when determining damages.
- An agreement between the parties limiting compensation (for instance, the provision of liquidated damages) and liability.
- The absence of fault attributable to the seller.

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

See question 3.1. The development risk defence is available but narrowly interpreted as the state of technical and scientific knowledge is determined by reference to the highest standards available at the time. As a result, manufacturers may not easily avail themselves of this defence.

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

Compliance with applicable laws and regulations is an important factor in determining whether a product is defective. However, compliance or the failure to comply with applicable laws and regulations is not decisive and does not *per se* rule out or trigger liability.

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

Claims may be brought by different claimants having suffered a damage caused by the same product. Unless there are new grounds to re-litigate issues of fault, defect or the capability of a product to cause a certain type of damage, the court might dismiss the case under the doctrine of *res judicata*.

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

The defendant can seek a contribution or indemnity from a third party for damages incurred by the defendant in subsequent (or concurrent) proceedings if the third party is liable for the delivery of a defective product by the defendant.

Filing a motion asking for the consolidation (*heigo*) of actions pending between two parties while actions are pending between a third party and either party is allowed as long as the following requirements are satisfied: (i) the existence of a nexus and commonality between claims sufficient to justify a common judgment (Article 38 of the CCP); and (ii) the handling of claims through similar proceedings or the satisfaction of other objective consolidation requirements (Article 136 of the CCP). Based on this procedural option, a defendant can initiate proceedings against such third party and then seek to combine the proceedings with the original product liability suit.

There are time limits for claims against a third party depending on the type of claim: under the PLA, based on tort or breach of contract (see question 5.2).

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

Comparative negligence is a defence available under the PLA and the Civil Code (under Article 722 of the Civil Code) (see question 3.1). To mitigate the damages a defendant may have to pay, the courts have adopted a proportionality rule under which a portion of damages may be borne by the plaintiff if the defendant is able to prove his comparative negligence claim. The proportionality rule can go beyond comparing the negligence of the tortfeasor and the victim to reflect the role of, e.g., family members partially at fault in the resulting injury.

4 Procedure

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

Judges preside over civil trials and there is no jury system.

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

The court may order the appointment of expert witnesses (see question 4.8) but, in principle, such experts do not "sit" literally with judges. Yet, under the expert commissioner ("*senmon iin*") system (Article 92-2 of the CCP), expert commissioners can be appointed to support judges and provide support in arranging the contested issues, taking charge of and assisting in reconciliation, conducting research and providing opinions on issues requiring specialised knowledge, participating in the examination of evidence, etc. in their own specialised field.

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

There are currently no US-style class actions in Japan. The Act on Special Provisions of Civil Procedure for Collective Recovery of Property Damage suffered by Consumers (Law No. 96 of 2013) introduced a special procedure known as the Japanese class action system. This system provides for a two-tier opt-in procedure. During the first stage, a qualified consumer organisation files a lawsuit requesting the court to confirm the liability of a business operator for a common obligation arising under a consumer contract on behalf of potential consumer claimants. If the action is confirmed, the quantum of damages will be determined based on individual claims filed by consumers having elected to opt-in. However, the scope of claims under this Act is limited and only covers claims arising from consumer contracts and to certain categories of property damage, including claims for performance based on contractual obligations, for unjust enrichment, breach of contract, warranty against defects, and claim for damages arising out of unlawful acts. However, damage to property other than the subject matter of the consumer contract, lost profits, personal injury, and pain and suffering are expressly excluded by the Act.

There is also the so-called "appointed party" mechanism under Article 30 of the CCP, which allows certain plaintiffs (or defendants) appointed by other claimants (or defendants) to act on their behalf in pursuing (or defending) civil actions. Appointments can be made when there are enough claimants/defendants sharing a "common interest" (i.e., the main allegations or defences are common amongst them). The appointed party can pursue the case on behalf of the appointing parties and the result will be binding upon the appointing parties, including a settlement.

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

See question 4.3. There is no such mechanism under the PLA.

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

In 1996, the former CCP was replaced by a new CCP. One of the key objectives of the reform was to speed up the course of trials. This goal was further emphasised through the enactment of the Law Concerning the Speeding up of Trials in 2003 which provides that legal proceedings must be closed within two years of their commencement. First instance proceedings can last eight months on average but complex cases can take a longer time to resolve. Generally, the courts schedule the initial hearing within one to one-and-a-half months after the plaintiff has submitted a statement of claims and require the defendant to submit an answer about a week before the hearing.

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

Significant authority and powers to conduct the proceedings are vested in the courts and the judges may decide to close the proceedings and

enter a judgment at any time. Unless the matter is straightforward, various procedures are available under the CCP which are designed to facilitate pre-trial arrangements relating to points at issue (preliminary proceedings, preparatory proceedings for oral argument and preparatory proceedings by document such as briefs).

4.7 What appeal options are available?

A "*kouso*" appeal can be filed with the appellate court against a final judgment rendered in trial by a court of first instance (a district court or summary court). In principle, it is possible to appeal judgments twice. The first appeal is for the *ex-post facto* review of judgments entered by the first instance courts, and whether claims made in the first instance courts are right or wrong is not directly reviewed. In a sense, the first level appeal is a continuation of the first instance trial. The parties may introduce new evidence or new arguments not previously raised. The appellate court (most often the High Court in a product liability context) may conduct its own fact-finding within the scope of the complaint based on lower court materials or those submitted to the appellate court. A "*joukoku*" appeal against the final judgment rendered by a lower court (against "*kouso*" judgments; i.e., rendered by a District Court or the High Court) lies to the Supreme Court (or the High Court) as a second appeal. A "*joukoku*" appeal is permitted only when filed for a limited number of reasons (matters of law, excluding questions of fact) such as a violation of the Constitution, serious misinterpretation of laws and regulations, lack of sufficient legal basis and inconsistency of reasoning. The period during which a "*kouso*" or "*joukoku*" appeal can be filed is 14 days from the date on which the judgment has been served.

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

The CCP contains a number of provisions governing the appointment and examination of court-appointed experts (Articles 212 to 218). These expert witnesses who have experience and technical expertise can assist the court in understanding any issue in dispute by providing explanations and in dealing with fact-finding. Expert opinions can be delivered in writing or verbally and expert witnesses can be called to testify (and be challenged) before the judges at the hearing. In Japanese litigation practice, the parties often appoint their own experts who can also be summoned as witnesses to testify before the court. These experts are more willing to testify in support of the party that has hired them as opposed to court-appointed experts.

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

In principle, there are no restrictions to admissibility in evidence. Any person or item, including hearsay evidence and expert opinions, can be called or submitted as evidence, and judges determine whether or not evidence is admissible at their own discretion. Evidence that violates confession agreements made between the parties or agreements restricting methods of evidence gathering is not admissible. Examination of witnesses is performed in open court after the parties have filed petitions with the court and after the court has designated the witnesses to be admitted and summoned them in order to be examined on the examination date (Articles 180 and 181 of the CCP). Although there is no law or ordinance regarding witness statements, written witness statements are often exchanged instead of direct oral examination at the hearing.

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

In Japan, there are no disclosure obligations or an extensive discovery process in contrast with common law jurisdictions. Documents submitted as evidence by the parties are typically collected by the parties through their own efforts. Accordingly, if a manufacturer is not cooperating, critical evidence may be concealed from the plaintiff, which is both relevant and admissible in a product liability case, including, but not limited to, notice to the manufacturer of the existence of a defect in one or more of its products, causation, the existence of a defect, and the feasibility of safer alternate designs. It is nonetheless possible to petition a court to issue an order to submit documents after an action has commenced by providing valid reasons to compel the counterparty or a third party keeping certain documents, listed in Article 220 of the CCP in his possession, to submit said documents (Article 221 of the CCP). The person who is filing a motion must indicate (insofar as possible) the document, the identity of the person keeping it, its significance, what needs to be proved with it and the reasons why it is necessary. The obligation to produce documents has been recognised in the following situations: (i) documents a party has referred to for the purpose of presentation of assertion of proof; (ii) documents that a party submitting evidence has the right to require delivery or inspection of while in the possession of another person; (iii) documents showing legal relations which support the rights or legal position of the person filing a motion or documents showing a legal relation between the person filing a motion and the holder of the documents; or (iv) documents that are not excluded. Excluded documents include documents exclusively prepared for use by their possessor and documents that contain confidential technical or professional information (there are a few other exceptions listed under the CCP). Before filing an action, if the (future) plaintiff has given advance notice of the filing to the (future) defendant, the plaintiff or the recipient of the notice may, within four months of the date of the notice, make inquiries to the other party on matters necessary to substantiate his allegations or collect evidence (Article 132-2 of the CCP). In addition, the court may order the submission of documents and the commissioning of examinations 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).

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

There is no obligation to pursue alternatives to litigation. Japanese people and corporates typically prefer amicable settlement of disputes through negotiation over court litigation. Even then, a negotiated settlement (*wakai*) can be made at any time before or during the court proceedings.

ADR is available on a voluntary basis in the form of civil mediation under the Law Concerning the Promotion of the Use of Alternative Dispute Resolution Procedures (the ADR Law). The ADR Law has introduced an accreditation system (not mandatory though) for private dispute resolution services. If the parties can reach an agreement, this agreement is put on record by the court and becomes enforceable in the same manner as a final judgment. Civil mediation procedures are simple and cost-effective (costs are fixed) and proceedings are confidential.

Civil litigants can also agree to refer their dispute to civil conciliation (*chotei*) under the Civil Conciliation Law (the CCL). Conciliation under the CCL is conducted by a conciliation committee composed of one judge and two or more civil conciliation commissioners appointed from a group of knowledgeable and experienced citizens. The committee assists the parties in finding an amicable settlement and usually submits a settlement plan to the parties. If the parties can reach an agreement, this agreement is put on record by the court and has the same effect as a court judgment and can be enforced accordingly. If the parties are unable to reach an agreement, the plaintiff must file a suit before the ordinary courts to pursue their claims.

Although commercial arbitration (*chusai*) has not been used actively as a means of resolving domestic disputes in Japan, it has gradually become an important option, especially in an international context.

A number of industry-associated (product-specific) trade associations have established permanent dispute resolution organisations in the wake of the enactment of the PLA: the Federation of Pharmaceutical Manufacturers Associations of Japan; Japan Chemical Industry Association; Japan Heating Appliances Inspection Association; Association for Electric Home Appliances; Japan Automobile Manufacturers Association, Inc.; Center for Housing Renovation and Dispute Settlement Support; Consumer Product Safety Association ((in charge of the "SG" mark) which has established the Consumer Product PL Center); Japan General Merchandise Promotion Center; Japan Cosmetic Industry Association; Fire Equipment and Safety Center of Japan; Japan Toy Association; Japan Paint Manufacturers Association; and Japan Construction Material & Housing Equipment Industries Federation.

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

The CCP lays down international jurisdiction rules applicable to litigation in the Japanese courts without expressly referring to product liability claims. According to the prevailing view, they are classified and treated as tortious claims.

Pursuant to the general forum rules of the CCP, a claimant may initiate legal proceedings based on tortious liability or product liability before the Japanese courts against any manufacturer whose principal place of business or whose business office is located in Japan. Under special forum rules, a claimant can generally file a lawsuit in Japan against the manufacturer if the tortious act has occurred in Japan even if the manufacturer has no office in this country. A tortious act is deemed to happen where the tortious act was committed (including the place where the product has been manufactured) or where the results have occurred (unless the occurrence in Japan of the results of a wrongful act committed abroad was unforeseeable).

5 Time Limits

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

Yes, there are time limits.

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

A. Limitation periods for bringing a claim under the PLA and based on tort.

Under the PLA, the right to seek damages based on product liability is extinguished by prescription if:

- The victim or his legal representatives do not exercise such right within three years from the time they became aware of the damage and identify the party liable for the damages (the responsible manufacturer).
- 10 years have elapsed since the delivery of the product by the manufacturer.

In the event that damage or injuries are caused by substances which become harmful to human health after accumulating in the body, or where the symptoms linked to damage or injuries only appear after the passage of time, claims become time-barred after 10 years from the time of occurrence of the damage.

Claims brought under Article 709 of the Civil Code follow a similar prescription pattern of three years and 20 years, respectively.

Under Article 724 of the Civil Code, the right to demand compensation for damages in tort is extinguished by prescription if it is not exercised by the victim or his legal representative within three years (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 expire if it is not exercised by the victim or his legal representative within five years from the time when he or she 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 or she 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 awarded are divided into monetary damages and non-monetary damages.

Under the PLA, the manufacturer is liable for damage and injuries to the life, limbs or property of the victim. 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. 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 sold (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 (Article 562 and Article 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, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction.

An extensive reform of the Civil Code is underway. Its main purpose is to revamp the 1896 Civil Code and make it more comprehensive and user-friendly by turning general principles of law derived from court precedents into statute. The amendments adopted in 2017 will enter into force on 1 April 2020 and some of them will affect product liability albeit not drastically.

The PLA has helped to establish a more level playing field for plaintiffs and victims of product liability accidents. Yet the number of court cases has not increased dramatically following the enactment of the PLA (according to the Consumer Affairs Agency's latest tally (2016), 382 judgments (counting two for the district court trial and its appeal) including 71 court settlements). The development of PL insurance might be one of the reasons underpinning this low number. Another reason might be the nature of the Japanese legal system itself which is largely based on the German and French civil law models. The system lacks the three main ingredients of a robust plaintiff-driven practice compared with what is available in the US: jury trials; punitive damages; and contingent fee agreements. The system's severe limitations on pre-trial discovery, high attorneys' fees, costly court filing fees and protracted trials have curbed the expansion of PL litigation in Japan. The Japanese class action system is still at its infancy and does not offer attractive options in this context. In addition, many manufacturers have been quick to settle complaints and claims with individual consumers rather than risk bad publicity and litigation. Product recalls have nonetheless increased in number and publicity (mass recalls in the automotive industry have included the Takata air bags). Another lasting consequence of the PLA has been the manufacturers' emphasis on warnings and instructions across all industries. Labelling and marking requirements have also become stricter over the years in many industries.

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Akira Karasawa is a Japanese attorney at law and an associate. He has handled a wide variety of litigation cases, including antitrust, environmental, general commercial and securities matters. His product lability litigation clients have included manufacturers of industrial products (medical devices and electric appliances). Akira Karasawa has received a J.D. in law from the University of Tokyo.

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.

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Kosovo

Genc Boga

Boga & Associates

Sokol Elmazaj

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?

Kosovo product liability is based on the fault-based liability system under Law No. 04/L-077 "On Obligation Relationships" (hereinafter "Law on Obligation").

Strict liability derives from Law No. 04/L-121 "On Consumer Protection" (hereinafter "Law on Consumer Protection") only for sellers of products with a warranty period, who, during such warranty period, cannot repair the damaged products. In this case, they are obliged to give consumers similar products or to refund the money with indemnity.

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

There are no state-operated 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 Law on Obligation provides for the liability of the producer for putting into circulation products that pose a danger to persons or belongings as well as for failing to undertake necessary measures to prevent damage through a warning in a packaging or with any other relevant measure.

Subject to the Law No. 04/L-078 "On General Product Safety" amended with Law No. 04/L-189" (hereinafter "Law on Product Safety") the producer is defined as:

i. a product producer established in the Republic of Kosovo and any other legal or natural person who affixes to the product his name, trade mark or other distinctive mark, or the one who processes the product;

ii. the representative of the producer when the producer is not established in the Republic of Kosovo or the importer of the product in case there is no representative; and

iii. any other person whose activity may affect the characteristics of the product's safety.

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

We do not find any regulation stipulating the liability of a regulatory authority for defective 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?

Pursuant to the Law On Product Safety, the producer shall undertake action to recall the products from consumers only as a last resort, when (i) other measures are not sufficient to prevent the risks, (ii) producers themselves consider it necessary, or (iii) producers are obliged to do so due to measures undertaken by the competent inspection body (article 5 thereof).

In addition, subject to Law No. 04/L-039 "On Technical Requirements for Products and Conformity Assessment", if the producer considers or has reason to believe that the product placed on the market does not conform with the provisions applicable to that product, the producer is obligated to immediately take the necessary corrective measures, or otherwise withdraw the product from the market and prevent its distribution. Where the product presents a risk, the producer is obligated to inform the competent inspection authorities by specifying details, in particular the non-conformity of the product as well as any corrective action taken (article 6 paragraph 10).

A claim for failure to recall against the producer may be initiated for violation of the abovementioned legal grounds, as well as by the Law on Obligation.

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

The supply of defective products is not foreseen as a criminal offence under the Criminal Code (Code No. 04/L-082 "Criminal Code of the Republic of Kosovo, as amended").

However, the Criminal Code lists the production and distribution of harmful medicinal and food products as criminal offences. These criminal offences are punishable by a by a fine and imprisonment of three (3) months to three (3) years.

In general, criminal charges may be brought for criminal offences of causing bodily injury or death by defective products.

Please note that Law No. 04/l030 "On liability of legal persons for criminal offences" provides for the liability of a legal person for the criminal offence of its responsible person. The liability of a legal person exists even when the actions of the legal person were in contradiction with the business policies or the orders of the legal person. The liability of the legal person is based on the culpability of the responsible person. Types of penalties that can be imposed for a criminal offence of a legal person are fines and the dissolution of a legal person.

2 Causation

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

Pursuant to the provisions of Law No. 03/L-006 "On Contested Procedure" amended with Law No. 04/L-118, the claimant has the burden of proving the facts on which it bases its claim. In this regard, the claimant should prove the fault/defect of the product and the damage resulting from such fault/defect.

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

Subject to the Law on Obligations there is a duty to compensate damages for anyone who causes damage to others, unless it is proven that the damage was caused without the fault of the defendant. In this regard, it is necessary to prove that the product to which the claimant was exposed has 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?

Market-share liability does not apply under Kosovo law. The Law on Obligations provides for joint liability for damage caused by several participants.

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?

Subject to article 5, paragraph 1.1 of the Law on Product Safety, the producers should provide consumers with adequate warnings so that consumers may assess the risks related to the product during normal use, when such risks are not clearly visible.

Non-compliance with the above legal provisions may result in civil action or the imposition of fines against manufacturers.

There is no principle of "learned intermediary" or any other principle that would discharge the duty owned by the manufacturer, under Kosovo Law.

3 Defences and Estoppel

3.1 What defences, if any, are available?

As mentioned above, the liability under the Law on Obligations exists for producers that have put products into circulation that pose a danger to persons or belongings as well as for failing to undertake necessary measures to prevent damage through a warning in the packaging or with any other relevant measure. In this regard, the producer can avoid liability if it proves that it did not put the product into circulation or that has undertaken all necessary measures to prevent the damage.

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

Under Kosovo law, there is no state of the art/development risk 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?

Kosovo legislation does not state that compliance with regulatory or statutory requirements constitutes a defence for the producer. However, under the Law on Obligation, there is no duty to compensate damages for the one who causes damage to others, if it is proven that the damage was caused through no fault of its own. In this regard, the producer could rely on such defence, i.e. that is complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product, in order to prove the lack of fault for defects in the products.

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

Under Kosovo law, a final judgment in a case on the same issues between the same parties is considered *res judicata*. There are no provisions that would prevent re-litigation in separate proceedings by a different claimant.

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

There are no provisions that would prevent the defendant from filing a claim against third parties either in the same proceedings or in subsequent proceedings. Subject to the Law on Obligations, the claim for the compensation of the damage is prescribed after three (3) years from the date the injured party became aware of the damage and the person who caused the damage.

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

There are no specific provisions that would prevent defendants from alleging that the claimant's actions 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?

Court proceedings are conducted before a judge or a panel of judges; there is no jury. Most cases before the Basic Court (first instance court) are adjudicated by a single judge, while cases before the Appeal and Supreme Court are adjudicated in panel of three (3) judges.

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

The Court appoints experts at its own discretion or at the request of the parties, who provide their relevant findings and opinions to the case. However, such an expert is not entitled to sit with the judge.

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

Kosovo law does not provide for class or group actions. However, subject to the provisions of the Law on Contested Procedure, the claim can be raised jointly by many plaintiffs or against several defendants (i) if their rights, respectively obligations derive from the same factual or legal basis, (ii) the subject matter of the contest are claims or obligations of the same kind that are based on same factual and legal grounds provided that the same court is competent to decide on each claim and for each defendant, or (iii) such possibility is foreseen by another law.

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

Although there are no specific legal provisions in this regard, in theory, there are no restrictions for interest groups to bring actions on behalf of several individuals in order to protect their common interests.

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

It takes several months from the date of filing of the lawsuit until to scheduling the first hearing. Depending on the complexity of the case, the trial will consist of preliminary hearing and several oral hearings. The trial before the first instance court may last from one to three years.

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

Kosovo courts can decide preliminary issues first. Subject to the provisions of the Law on Contested Procedure, if the court decision depends on the preliminary resolution of whether there is any subjective right or legal relationship as to why the court or any other competent body has not made a decision (preliminary issue), then the court is entitled to settle the issue itself. The court's decision on the preliminary matter has legal effect only in the proceedings in which such a decision has been made.

4.7 What appeal options are available?

In contested procedure, parties may submit a complaint against the decision of the first instance court, within fifteen (15) days from the day a copy of the verdict is delivered. The Court of Appeal makes a decision regarding such complaint.

Against the decision of the second-instance court, the parties may submit a revision within thirty (30) days of the date of delivery of the decision. The Supreme Court of Kosovo decides on the revision.

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

As mentioned above, the court, at its own discretion or at the request of the parties, may appoint independent experts who provide their findings and opinions on technical issues. There are no restrictions with regards to the nature or extent of such evidence.

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

There is no requirement for experts or witnesses to present themselves for pre-trial deposition. In order to support their claims, parties in court proceeding should submit their facts and evidences during the trial, including expert opinions and witnesses.

Please note that subject to Law No. 03/L-006 "On Contested Procedure" amended by Law No. 04/L-118 (hereinafter "Law on Contested Procedure"), the appointed expert has a duty to respond to court summons and to submit findings and opinion. Also, any person summoned as a witness has a duty to testify.

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

There are no pre-trial procedures; however, the Law on Contested Procedure lists several elements that each submitted lawsuit must contain, such as: a) the main request; b) the facts on which the plaintiff bases the claim; c) the evidence which establishes such facts; d) the value of the dispute; e) the legal basis; and f) other formal requirements.

Therefore, the plaintiff should submit such documents to prove decisive facts from the lawsuit.

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

There is no obligation to apply alternative methods of dispute resolution unless the parties have agreed the application of such methods in advance.

However, subject to the provisions of the Law on Contested Procedure, the court may propose that litigants resolve their dispute through mediation, if it deems it necessary, taking into account the nature of the dispute and other circumstances. Such a proposal may be submitted by the parties themselves until the main hearing is completed.

Disputes can be settled by arbitration if there is an agreement between parties to that effect.

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?

Kosovo courts have jurisdiction if the defendant has residence in Kosovo, regardless of where the claimant is domiciled.

In the adjudication of disputes related to protection of the rights that are based on a warranty issued by the producer, as well as the court with general territorial jurisdiction for the defendant, the court with general territorial jurisdiction for the seller who has provided the buyer with the warranty from the producer is also competent.

5 Time Limits

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

Yes, the Law on Obligations provides for such 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 claim for the compensation of damages becomes statute-barred three (3) years from the date the claimant became aware of the damage and of the person that inflicted it. In any case, the claim becomes time-barred five (5) years after the damage occurred. Time limits should be raised by the defendant since they are not examined *ex officio* by the court. Time limits are stipulated by law, and the court has no discretion to disapply them if the party invokes them. Age, conditions or any other factor of the claimant has no effect on the calculation of time limits.

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

Concealment or fraud can interfere with the ability of the applicant to identify the person who inflicted the damage and thus postpone the beginning of the three-year time limit.

In addition, the Law on Obligations stipulates that when the damage is caused by a criminal offence and a longer limitation period is stipulated for criminal prosecution, the claim for compensation of damage shall become time-barred upon the expiry of the period stipulated for the criminal prosecution.

6 Remedies

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

Subject to general rules on indemnification of material damage, the Law on Obligation provides for the restoration of the previous situation and monetary compensation. The responsible person has a duty to restore the situation which was in place before the damage was caused. If the restoration does not completely eliminate the damage, the responsible person has the duty to pay monetary compensation for the rest of the damage. When restoring the previous situation is not possible, or when the court considers that it is not necessary, the court will order the payment of an appropriate amount of money on behalf of indemnity. In addition, the court will order payment of monetary compensation, if the claimant seeks this kind of remedy.

Monetary compensation is most common for compensation of damage due to defects in products.

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

Depending on the legal grounds of the claim, both monetary and non-monetary damages suffered by the consumer due to defects in products may be recovered.

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 are no such damages provided by Kosovo law.

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

There are no punitive damages provided by Kosovo 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 statutory maximum limit on the damages recoverable under the Kosovo law. They are recovered to the extent of damage caused by the defective product.

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

There are no group/class actions under Kosovo law, therefore no special rules apply regarding the settlement of claims or proceedings. Law on Contested Procedure stipulates that the parties are free to make a court settlement during their dispute. Minors do not have procedural capacity and should be represented by their legal representatives.

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

There are no specific regulations in this regard.

7 Costs / Funding

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

The court decides regarding the costs of the procedure in its final decision. The party that loses the trial has the obligation to refund all costs of the opposing party. Such costs include the court fees, some expenses, as well as legal costs of bringing the proceedings. The court will only consider the expenses that were necessary to prosecute the case at court, by carefully considering all the circumstances. If the claimant succeeds only in part, the court may decide that each party is to bear its own costs.

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

Yes, based on Law No. 04/L-017 "On Free Legal Aid".

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

Free legal aid is provided to persons who fulfil the following criteria:

i. qualification criteria – are citizens or residents of the Republic of Kosovo or other persons defined by law, or rules of international law, that bound Republic of Kosovo; and persons to whom assistance on free legal aid is provided on the basis of reciprocity;

ii. financial criteria – benefit from social assistance, or are in a similar situation to persons who benefit from social assistance and persons whose gross family incomes are lower than the average family incomes; and

iii. legal criteria by assessing validity of the case such as the real value of the claim, argumentative power of the evidences presented by the applicant; and probability for the success of the claim.

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

The Kosovo Law is silent regarding conditional or contingency fees.

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.

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 any control over the costs to be incurred by the parties. Each party carries in advance its own costs that are caused by its procedural actions.

8 Updates

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

We do not find any recent decision published by Kosovo courts related to product liability. Kosovo has not yet adopted a specific legal regulation on product liability, and consumers can only rely on limited provisions of the Law on Consumer Protection and the Law on Obligations.

Genc Boga
Boga & Associates
40/3 "Ibrahim Rugova" Str
1019 Tirana
Albania

Tel: +355 4 2251 050
Email: gboga@bogalaw.com
URL: www.bogalaw.com

Genc Boga is the Founder and Managing Partner of Boga & Associates which operates in both jurisdictions of Albania and Kosovo. Mr. Boga's fields of expertise include business and company law, concession law, energy law, corporate law, banking and finance, taxation, litigation, competition law, real estate, environment protection law, etc.

Mr. Boga has solid expertise as advisor to banks, financial institutions and international investors operating in major projects in energy, infrastructure and real estate. Thanks to his experience, Boga & Associates is retained as legal advisor on regular basis by the most important financial institutions and foreign investors.

He regularly advises the EBRD, IFC and World Bank in various investment projects in Albania and Kosovo.

Mr. Boga is continuously ranked as leading lawyer in Albania by *Chambers and Partners* and *IFLR 1000*.

He is fluent in English, French and Italian.

Sokol Elmazaj
Boga & Associates
27/5 Nene Tereza Str.
10000 Pristina
Kosovo

Tel: +381 38 223152
Email: selmazi@bogalaw.com
URL: www.bogalaw.com

Sokol Elmazaj joined Boga & Associates in 1996.

He is a Partner of the firm and Country Manager for Kosovo.

He has extensive expertise in corporate, mergers and acquisitions, project financing, privatisation, real estate projects, energy, telecommunication, and dispute resolution. He is continuously involved in providing legal advice to numerous project-financing transactions, mainly on concessions and privatisations, with a focus on energy and infrastructure, both in Albania and Kosovo.

Sokol also conducted a broad range of legal due diligences for international clients considering to invest in Albania or Kosovo in the fields of industry, telecommunications, banking, real estate, etc.

He is an authorised trademark attorney and has an expertise in trademark filing strategy andtrademark prosecution, including IP and litigation issues.

Sokol is continuously ranked as a Leading Lawyer in the well-known guides *Chambers Global*, *Chambers & Partners* and *IFLR 1000*.

Sokol graduated in Law at the University of Tirana in 1996 and is admitted to practice in Albania and Kosovo. He is also an arbiter listed in the roster of the American Chamber of Commerce of Kosovo.

He is fluent in English and Italian.

BOGA & ASSOCIATES

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Boga & Associates, established in 1994, has emerged as one of the premier law firms in Albania, earning a reputation for providing the highest quality of legal, tax and accounting services to its clients. The firm also operates in Kosovo (Pristina) offering full range of services. Until May 2007, the firm was a member firm of KPMG International and the Senior Partner/Managing Partner, Mr. Genc Boga was also Senior Partner/Managing Partner of KPMG Albania.

The firm's particularity is linked to the multidisciplinary services it provides to its clients, through an uncompromising commitment to excellence. Apart from the widely consolidated legal practice, the firm also offers the highest standards of expertise in tax and accounting services, with keen sensitivity to the rapid changes in the Albanian and Kosovo business environment.

The firm delivers services to leading clients in major industries, banks and financial institutions, as well as to companies engaged in insurance, construction, energy and utilities, entertainment and media, mining, oil and gas, professional services, real estate, technology, telecommunications, tourism, transport, infrastructure and consumer goods.

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Netherlands

Frans de Voldere

Jan de Groot

Blenheim

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 a number of different sections of the Dutch Civil Code ("**DCC**") that provide for liability for defective products. A distinction can be made between the following 'systems' of product liability:

1. **Strict liability for defective products**: articles 6:185 through 6:193 DCC contain specific provisions on product liability. These articles are the Dutch implementation of the EC Product Liability Directive (European Directive 85/374/EEC) ("**the Directive**"). Under this system, producers are subject to a regime of strict liability with only limited defences available to them. Claimants can only rely on the strict liability in connection with a restricted category of claims and actions.
2. **Fault-based liability**: the Directive has not affected the general system of fault-based liability arising from *onrechtmatige daad* (tort) under article 6:162 DCC. The Dutch principle of tort not only encompasses acts or omissions as such, but also the violation of (statutory) rights and obligations. Under this general system, there are no exhaustive limitations with regard to possible claims, causes of actions or defences.
3. **Contractual liability**: a party can also be held contractually liable for a defective product, subject to the particular provisions of the agreement or on the general principle of breach of contract (article 6:74 DCC). A contracting producer cannot contractually exclude or limit its strict liability for a defective product.

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

The Dutch State does not operate any such scheme.

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

Under the product liability system of article 6:185 DCC, 'producers' are liable for their defective products. Article 6:187 paragraph 2 DCC defines the producer as:

a) the manufacturer of a finished product;

b) the producer of any raw material; or

c) the manufacturer of a component part; and

d) any person who, by putting his name, trade mark or other distinguishing features on the product, presents himself as its producer.

Article 6:187(3)–(4) DCC extends the scope of the meaning of 'producer' by providing that strict liability for defective products also applies to:

e) any person who imports into the European Economic Area a product for sale, hire, leasing or any form of distribution in the course of his business; and

f) any supplier or importer of the product, in the event the producer cannot be identified, unless the supplier informs the injured party, in reasonable time, of the identity of the producer or of the person who supplied him with or who has imported the product into the European Economic Area.

1.4 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. This situation may occur if it is causally provable that the defectiveness of the product and the effective damage is in causal relation with the regulations imposed on the manufacturer.

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 obligation to recall defective products or pay damages for a failure to recall defective products under the product liability system of articles 6:185–193 DCC. Rather, such obligations or damages claims can flow from the general system of tort, as giving rise to a dangerous situation and allowing the continuation of that situation (by leaving defective or hazardous products in circulation) may be considered as tortious conduct.

An obligation to recall can also be imposed under administrative law. Pursuant to the so called Commodities Act (*Warenwet*) and the General Product Safety (Commodities Act) Decree (*Warenwetbesluit algemene productveiligheid*), the producer and supplier must inform the Dutch Food and Consumer Product Safety Authority ("**FCA**") of

the existence or possibility of dangerous or hazardous products and foodstuffs. The FCA has the authority to order or initiate the recall of such products, should the recall not be undertaken voluntarily or be done inadequately. An English version of the FCA website is accessible at https://english.nvwa.nl/.

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

Yes, criminal sanctions can apply to the supply of defective products.

Putting defective products into circulation, either wilfully or by means or culpable negligence, may be punishable by, *inter alia*, a fine (up to EUR 82,000), community service or imprisonment.

2 Causation

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

The product liability system explicitly addresses the burden of proof (article 6:188 DCC), stating that the injured party must prove the damage, the defect and the causal relationship between defect and (actual) damage. As a result of the strict liability, the injured party bears no burden of proof with regard to the *fault* of the producer, which is in principle already established (unless the producer successfully invokes the defences of article 6:185 DCC).

Please note that under Dutch law, evidence-broadening regulations may apply. These measures are sometimes applied with a certain restraint. The reversal rule (regarding causality), the *res ipsa loquitur* rule and reasonableness and fairness can affect the basis rule of article 150 Civil Procedures Code (*Affirmanti incumbit* probation).

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

The test applied to establish a causal link between the defective product on the one hand, and the actual damage arising on the other hand, is the 'but-for' test (*conditio sine qua non*), embodied in article 6:98 DCC. Courts may, only exceptionally, apply proportional liability in cases where damage has been suffered, but a causal link cannot be established with certainty. Damage claims cannot be brought in the absence of damage (*i.e.* a mere risk of malfunction will not suffice).

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

If it cannot be established which of several possible producers manufactured the defective product, the injured party:

1) may hold each of the producers jointly and severally liable for the same damage caused by the defective product on the basis of the product liability system (article 6:189 DCC);
2) may hold all of the involved parties jointly and severally liable if the damage resulted from two or more events, for each of which a different party is liable, provided that it has been established that the damage arose from at least one of these events (article 6:99 DCC).

In its decision in the *Des* case (Supreme Court judgment of 9 October 1992, *NJ* 1994, 535), the Dutch Supreme Court held that there is no principle of market share-based liability under Dutch law.

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

Pursuant to the general tort provisions of article 6:162 DCC, there is a duty to warn and inform about defective products. Under administrative law, the producer has a specific duty to inform the FCA of dangerous and hazardous products and foodstuffs. Failure to do so may, *inter alia*, result in civil liability and administrative measures (such as a fine).

Information provided to the consumers, as well as to intermediaries, is taken into account. In the *Halcion* case (Supreme Court judgment of 20 June 1989, *NJ* 1990, 652), which related to the side effects of certain sleeping medication, the Dutch Supreme Court held that although a product can only be obtained through an intermediary with a special duty of care (such as a medical practitioner), the producer itself is still under an obligation to inform the consumers of possible risks and side-effects. There is, accordingly, no principle of 'learned intermediary' under Dutch law.

3 Defences and Estoppel

3.1 What defences, if any, are available?

If a claimant relies on the product liability system, the possible defences open to the producer are exhaustively set out under article 6:185 DCC.

A producer will not be held liable for defective products that cause damage if it proves that:

1) it did not put the product into circulation;
2) having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when it put the product into circulation or that this defect came into being afterwards;
3) the product was neither manufactured by him for sale or any form of distribution for commercial purposes nor manufactured or distributed by it in the course of his business;
4) the defect is due to compliance of the product with mandatory regulations issued by the public authorities;

5) the state of scientific and technical knowledge at the time when it put the product into circulation was not such as to allow the existence of the defect to be discovered; or

6) in the case of a manufacturer of a component, the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product.

If a claimant relies on another cause of action (i.e. tort or breach of contract), the defendant may be able to rely on other defences.

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

Yes, see defence listed under 5) of question 3.1.

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

Yes, see defence listed under 4) of question 3.1.

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

No specific provision would prevent a claimant from re-litigating its claim in *different* proceedings against a *different* defendant. Issue estoppel under Dutch law can be found in the force of a final and conclusive judgment, preventing the claimant (or its legal successors) from re-litigating the *same* claim against the *same* defendant after a final and conclusive judgment has been rendered.

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

The Dutch Code of Civil Procedure ("**DCCP**") allows for (both derivative and subsequent) third-party proceedings. In these proceedings, a defendant may seek contribution or indemnity. A motion to implead a third party in derivative third-party proceedings must be filed prior to the statement of defence in the main proceedings.

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

Yes, on the basis of article 6:101 DCC. If successfully alleged, it can result in the (complete) mitigation of the liable party's obligation to recover the damages of the claimant.

4 Procedure

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

Civil court proceedings are governed by the DCCP. In 2016, new legislation was adopted, providing for the gradual digitalisation of civil proceedings from 2018 onwards. The questions in this chapter have been answered in accordance with the DCCP as currently in force.

All proceedings before a Dutch court, regardless of whether civil, administrative or penal, are trials by judge only.

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

While there is no special provision within the DCCP with regard to the appointment of 'technical specialists', on the basis of article 194 DCCP, the court may, either on its own motion or at the request of one of the parties, appoint 'experts' to provide an opinion or statement on certain issues.

The appointed expert is independent and does not 'sit' with the court or one of the parties. The court is not bound by and may disregard an expert opinion or statement.

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

Although the Dutch civil legal system does not provide for class actions in the 'common law' sense of the word, article 7:907 DCC enables an interest group to have a collective settlement on mass damages declared binding by the Amsterdam Court of Appeal.

Article 7:907 DCC was implemented by the Collective Settlement of Mass Damages Act (*Wet Collectieve afwikkeling massaschade*) ("**WCAM**").

The settlement must be reached between one or more interest groups and one or more liable parties. The settlement will be binding with regard to the persons whose interests might be represented by the interest group, unless such person opts out within a timeframe set by the judge of at least three months. Most recently, the Supreme Court held that due to the broad scope of the WCAM, settlements with regard to claims other than the claim for damages (for instance the partial waiver of a debt) may also be declared binding (Supreme Court judgment of 9 December 2016, *NJ* 2017, 13).

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

Article 3:305a DCC allows interest groups (in the form of special purpose foundations or associations) to initiate proceedings for the purpose of protecting the similar interests (as set out in their articles of association) of a defined class of persons. The interest group can bring any claim or action, except claims for pecuniary damages.

Prior to initiating proceedings, the interest group must have attempted to reach a settlement with the defendant. The proceedings can be opted out of and are without prejudice to individual class members' right to initiate proceedings on their own (regardless of whether or not they opt out). These proceedings are relatively common and considered to be quite effective.

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

Dutch civil procedural law does not provide for 'trials', in the sense of a full oral hearing where all of the evidence is presented and/or witnesses and experts are heard or examined by the parties. Consequently, several distinctions must be made between the various types of oral hearings:

- Oral hearings in preliminary relief proceedings: these are accelerated proceedings in which a claimant may apply to the court for provisional relief. A declaratory judgment or a definitive award for damages cannot be obtained by the claimant. Preliminary relief proceedings have only one oral hearing in which both parties present their oral arguments. Depending on the urgency of the claimant's case, it usually takes up to 2–6 weeks to get to the oral hearing. The provisional judgment is usually rendered within to 2–3 weeks.
- Oral hearings in proceedings on the merits: these hearings can be divided into:
  a) post defence hearing: a hearing in which the court aims to obtain information from the parties, to inquire whether a settlement can (already) be reached and to instruct on the further course of the case, usually held within 3–6 months after the case has been brought before the court;
  b) hearing of witnesses: only if deemed necessary by the court, this hearing is usually held within 3–6 months after the post defence hearing; and
  c) oral arguments: at the request of the parties, oral arguments may take place, usually as a conclusive hearing before a final judgment is rendered by the court.

The amount of time taken to obtain a final judgment in proceedings on the merits at first instance depends on the number of hearings.

Each hearing delays the course of the proceedings. As an estimation, claimants should expect one year in regular proceedings, and 2–3 years in more complex proceedings to obtain a final judgment.

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

Preliminary issues may, and in some cases must, be referred by a judge in preliminary relief proceedings, a court of first instance or a Court of Appeal to the Supreme Court of the Netherlands or the ECJ to provide an answer or interpretation on issues of law. Preliminary issues cannot relate to issues of fact. Such referrals may be made *ex officio*, or at the request of one of the parties.

4.7 What appeal options are available?

An appeal to a judgment in first instance may be lodged before the Court of Appeal, and before the Supreme Court to a judgment of the Court of Appeal. In principle, a party may lodge an appeal to both a non-favourable and favourable judgment (*i.e.* a claimant may appeal to a judgment in which the liability of the defendant was established, but the height of the awarded damages was less than claimed).

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

See question 4.1 on the appointment of experts.

Regardless of whether an expert has been *appointed* by the court, either party may present expert evidence (expert reports and opinions) or witness evidence as part of their statement of claim, statement of defence or as ordered by an interlocutory order. There is no restriction to the extent or nature of that evidence.

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

There is no requirement that factual or expert witnesses present themselves for pre-trial deposition. On the basis of article 1018a DCCP, which is only applicable to the collective settlement of mass claims as mentioned in question 4.4, a court may summon the parties involved to a pre-trial hearing, although no witnesses or experts will be heard.

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

There is no obligation to disclose documentary evidence before court proceedings. Once proceedings have been initiated, each party has the obligation to disclose the entire truth and to submit and produce all the documentary evidence on which they rely (articles 21 and 85 DCCP). If a party fails to submit or produce such documentary evidence, the court may draw adverse inferences. At the request of a party and subject to strict conditions (to prevent 'fishing expeditions'), a court may order the other party to disclose or submit certain specified documents (article 843a DCCP).

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

No alternative methods of dispute resolution are required to be pursued first.

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

There is no requirement that a claimant be domiciled within the Netherlands to bring a claim before a Dutch civil court.

Whether the Dutch courts are able to exercise jurisdiction over a matter is determined under the rules of private international law. Overall in product liability cases, a claimant can bring proceedings against a defendant domiciled outside the Netherlands before a Dutch court if:

a) the place of event giving rise to the damage (*Handlungsort*) is in the Netherlands; and/or

b) the place where the harmful event occurred (*Erfolgsort*) is in the Netherlands.

If the claim is based on the product liability system and the defendant is domiciled outside the Netherlands but within the EU, the *Handlungsort* will be considered as the place where the product

was manufactured and the *Erfolgsort* as the place where the initial damage occurred as a result of the normal use of the product for the purpose for which it was intended.

5 Time Limits

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

See question 5.2.

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

Time limits are statutory limitation periods that could result in unsuccessfully upholding a claim, as the court may deem the claim to be expired. Time limits can be interrupted by initiating legal proceedings or, more commonly, by sending a letter in which the claimant or injured party unequivocally reserves its right or title to performance, damages or any other remedy. Most time limits are not examined *ex officio* by a court, and must be raised by the defendant. The age or condition of the claimant has no effect on time limits.

Time limits depend on the legal basis of the claim:

- Non-contractual claims based on:
  - I. The product liability system:
    - three years after the injured party became or ought to have become aware of the damage, the defect and the identity of the producer (article 6:191(1) DCC); and
    - 10 years after the damage-inflicting product has been brought onto the market (article 6:191(2) DCC). The lapse of these 10 years may be raised *ex officio* by the court.
  - II. Fault based liability for wrongful acts:
    - five years after the injured party became or ought to have become aware of the identity of the injuring party and the (existence and extent of the) damage incurred; and
    - 20 years after the damage-inflicting event has occurred, regardless whether the injured party was aware thereof.
- Contractual claims:
  - promptly after discovery of *the buyer* that the product did not meet the contractually agreed upon or reasonable requirements (article 7:23 DCC in conjunction with article 6:89 DCC); and in any case
  - two years after the buyer has notified the seller that the product did not meet the contractually agreed upon or reasonable requirements (article 7:23 DCC); and
  - five years after *the claimant* became or ought to have become aware of the existence or extent of its claim for damages.

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

Concealment or fraud may affect the running of a time limit. The time limits aligned with the knowledge of the claimant or injured party, as mentioned in question 5.2, will likely be affected by concealment or fraud and could result in a time limit never having effectively commenced.

6 Remedies

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

Dutch civil law allows for a wide variety of remedies. The nature and applicability of the remedy depends on the legal basis of the remedy.

A distinction can be made between the following categories of remedies:

- pecuniary remedies: compensation for damages; contractual penalties; and recovery of the other party's breach of a judicially imposed penalty;
- general non-pecuniary remedies: declaratory relief; injunctive relief (including product recall); judicial termination; and annulment or nullification of an act or agreement;
- general performance-based remedies: specific performance or other injunctions; and
- performance-based remedies: notably applicable in B2C relationships, allowing a consumer, party to a sales agreement, to demand delivery, repair or replacement of the defective.

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

These types of damages are all recoverable if the liability is based on the system of tortious fault-based liability. If the liability is based on product liability system, article 6:190 DCC exhaustively lists the type of damage an injured party can claim:

a) damage caused by death or personal injury (also including psychological harm, as long as the psychological harm is caused by the physical personal injury); and

b) damage to any item of property other than the defective product itself, with a lower threshold of EUR 500, provided that the item of property:

(i) is of a type ordinarily intended for private use or consumption; and

(ii) was used by the injured party mainly for his own private use or consumption.

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

As a general rule, damages can only be claimed by an injured party if the product has actually resulted in damages or injury. It is possible to recover reasonable costs incurred to prevent the incurrence of damages as well as costs connected to the assessment of the basis and extent of liability and damages (article 6:96 (2) DCC). Should the product not malfunction and only theoretically malfunction in the future, it seems unlikely that a court would award costs made for such 'medical monitoring'.

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

Dutch civil law does not allow for the recovery of punitive damages.

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

There is no statutory maximum limit on the amount or height of damages. A court can *ex officio* or at the request of a party limit the quantum of damages (article 6:109 DCC). Pecuniary claims of EUR 25,000 or less must be brought before a subdistrict court, where parties may choose to self-represent.

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

The *conclusion* of a settlement is not subject to court approval. For a collective settlement to have binding effect, the Amsterdam Court of Appeal will consider whether the settlement agreement meets certain formal requirements. The Court of Appeal may rule that these requirements are not met, and consequently reject the request to have the settlement declared generally binding.

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

No, a government authority will not be able to recover such damages from a claimant.

7 Costs / Funding

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

As a general remark, a court may always order a party to pay its own legal costs even if it is the successful party. However, the court will usually issue a costs order against the unsuccessful party (article 237–239 DCCP) covering:

a) the successful party's court fees;

b) bailiff fees, such as costs for service;

c) the successful party's legal costs. These costs are calculated on the basis of a fixed and capped "court-approved scale of costs" and depend on the principal sum in dispute and the number and type of procedural steps in the proceedings. The amounts of the court-approved scale are often considerably less than the actual legal costs incurred by the successful party; and

d) incidental costs, such as costs for experts.

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

Yes, legal aid funded by the Dutch government is available; however, only in certain cases and under the conditions as set out in the Legal Aid Act (*Wet op de Rechtsbijstand*).

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

Pursuant to the Legal Aid Act, litigants are eligible for legal aid depending on:

a) their household's annual income (no more than EUR 26,900 for a single-person household or EUR 38,000 for a joint household); and/or

b) the applicant's net worth (for savings, the maximum amount is EUR 24,437).

The nationality of the litigants is irrelevant, therefore enabling non-Dutch litigants to apply for legal aid. However, the litigant can only apply for legal aid with regard to a case that is related to the so-called 'jurisdiction of the Netherlands', excluding cases that are not connected to Dutch law or fall outside the competence of the Dutch courts (for instance in relation to damage, if neither the *Handlungsort* or *Erfolgsort* is in the Netherlands).

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

As a result of the Dutch Rules of Professional Conduct for Dutch lawyers (*Gedragsregels 1992*), contingency fees or "no win, no fee" arrangements are prohibited with the exception of personal injury cases (although there is a cap on the percentage of the damages awarded that may be charged as a fee).

Fee arrangements, such as fixed fees or capped fees, are allowed and used fairly often.

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

The third party *funding* of claims is in principle permitted and no particular restrictions apply. However, a court may declare that an interest group (as mentioned in question 4.4) has no case to bring forward a collective claim, if the claim is solely brought for the purpose of commercially benefitting that interest group.

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

No, as due to the court-approved scale of costs (question 7.1), there is a maximum of legal and court fees the losing party risks paying to the successful party.

8 Updates

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

The question of when a product was brought into circulation has been decided in European case law, mainly in Veedfald/Arhus Amtskommune case (C-203/99) and in two decisions in the O'Byrne/Sanofi Pasteur case (C-127/04 and C-358/08).

The criterion for "bringing into circulation" is (in short): a product has been brought into circulation, when the product has left the

production process and has been made part of a sales process in a form in which it is offered to the public in order to use or consume, regardless of the question whether the product is sold to an end user or to an intermediary in a distribution process.

On January 13, 2017, The Supreme Court ruled in the DAF/Achmea case (NJ 2017/48) that legal action based on tort resulting from a defective product, when assessing whether a party has brought a product into circulation, one needs to apply the same definition as formulated for claims based on product liability.

Frans de Voldere
Blenheim
Westerdoksdijk 40
Amsterdam
The Netherlands

Tel: *+31 20 521 01 00*
Email: *fransdevoldere@blenheim.nl*
URL: *www.blenheim.nl*

Frans de Voldere advises and litigates in matters of intellectual and industrial property. Frans manages sizeable trademark portfolios, and advises on trademark strategy and management.

In this respect Frans advises on the selection and availability of trademarks, opposition proceedings and the protection against unauthorised use.

Apart from trade mark matters, Frans is also active in the fields of:

- Dutch and international protection of copyrights against unauthorised use;
- acquisition, licensing and other transactions relating to copyrights;
- intellectual property audits and setting up strategies and tactics to reduce the risk of infringements;
- unfair competition, media and unlawful publications; and
- product liability and general contract law.

Frans is a litigator in the best sense of the word, and also a proven specialist in conservatory arrests (prejudgement seizures).

Frans also authored articles on legal aspects of domain names on the internet, with an emphasis on trade mark related issues.

Jan de Groot
Blenheim
Westerdoksdijk 40
Amsterdam
The Netherlands

Tel: *+31 20 521 01 00*
Email: *janwillemdegroot@blenheim.nl*
URL: *www.blenheim.nl*

At the beginning of his career, Jan Willem de Groot studied as a fellow at King's College, University of London.

Jan Willem's main practice areas include:

- commercial litigation and arbitration in The Netherlands;
- IP and IT law; and
- – in general – Dutch business law.

Jan Willem de Groot's professional experience in these areas and his wealth of contacts puts him in a good position to offer comprehensive and practical legal advice in relation to a range of legal issues.

BLENHEIM

Blenheim is a full-service corporate law firm based in Amsterdam consisting of five partners and 21 associates. The core practice areas of Blenheim include corporate law, commercial law, employment law, litigation, administrative law, intellectual property, financial law, real estate and property law. Blenheim is an active member of the professional, international network "Lawyers Associated Worldwide", in which 130 law firms in 106 countries all over the world participate. The quality of Blenheim as Dutch corporate and business law firm rests mainly upon the quality of the attorneys, their accessibility and efficiency. Blenheim's attorneys share outstanding Dutch and international academic backgrounds, as well as a sincere commitment to legal excellence.

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 severable basis with the main manufacturer.

In addition, the retailer might in certain instances be held liable, e.g. if it fails to refer the injured party to a responsible manufacturer, importer or distributor within a reasonable time.

1.4 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 non-existence of a defect are closely linked to the ability of the defendant to prove alternative causes of damage, e.g. external influence on the product, lack of maintenance, etc.

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

By way of allowed derogation from the Product Liability Directive, the Norwegian PLA does not contain an express state-of-the-art/development risk defence. In principle, state-of-the-art products or products containing unforeseen or undiscoverable risks might therefore be deemed defective and the manufacturer/importer/distributor held liable. However, state-of-the-art products are less likely to be deemed defective than existing products posing greater risks of causing damages.

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

Yes, but only where the defect itself is caused by compliance of the product with mandatory regulations. Compliance with more general regulations relating to development, manufacture, licensing, marketing and supply would therefore rarely suffice as a stand-alone defence, although such compliance makes a good argument where the exact cause of damage is unknown.

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

Yes. A Norwegian court decision would only be legally binding on the parties to the case. Consequently, claimants may re-litigate issues of fault/defect/capability of damage which has previously been lost by other claimants. However, court cases in favour of the defendants might be submitted as evidence in later proceedings on the same issue.

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

Yes, the defendant may seek indemnity from third parties such as a sub-supplier. Recourse claims may be heard in the same proceedings or in subsequent proceedings upon the choice of the defendant.

In general, the time limit for initiating subsequent proceedings against the third party is one calendar year after the payment of damages to the injured party. However, in many instances, the third party is entitled to a notice of proceedings within a reasonable time in order to avoid statutory limitation.

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

Yes. A claimant's actions contributing to the damage would be relevant both in terms of whether or not the product was defective and whether or not there was a causal relationship between the defect and the damage (see question 3.1 on defences above).

Even if the defendant is held liable, contributory negligence on part of the claimant may lead to a reduction or annulment of the damages amount pursuant to the Norwegian Damages Act section 5-1.

4 Procedure

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

Juries are not used in court cases related to product liability. As a general rule, only one judge hears product liability cases at the District Court. More rarely, the case can be tried with one judge and two lay judges upon request of one of the parties or the court. In the Court of Appeal, there are three judges (plus five lay judges upon request). Lay judges are not used in the Norwegian Supreme Court.

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

The court may appoint two technical specialists to sit with the judge. The parties may also request this.

Also, the court may appoint an expert to give affidavit evidence on the facts in the case (see question 4.8 below).

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

According to the Norwegian Dispute Act, class actions can be brought to trial only if (i) several claimants/defendants have claims/

obligations based on the same or substantially the same factual and legal basis, (ii) the claims can be heard by the same court and essentially follow the same procedural rules, (iii) class action is the most appropriate form of proceedings, and (iv) the court is able to designate a class representative.

The procedure is normally "opt-in" (except in case of very small claims amounts), and can be initiated by (i) any natural or legal person with a claim covered by the class action, (ii) associations and foundations, as well as (iii) public bodies with the purpose of ensuring specific interests such as for instance consumer protection.

The class action vehicle is a relatively new possibility in Norwegian law, and although it has been available for some 10 years now, class actions are rarely brought in Norway.

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

Yes, see question 4.3 above.

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

The time it takes to get to trial depends on which District Court handles the proceedings, and the characteristics of the case. On average it takes less than six months from the date the subpoena is sent to the main proceedings, but it may take longer.

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

In a preliminary stage, the court tries whether the case is admissible (procedural issues). Some grounds for dismissal must be invoked by the parties and some should be taken into account by the court *ex officio*. A preliminary decision will be based on the facts provided by the parties.

Material issues, whether related to matters of law or matters of fact, will not be decided upon in a preliminary hearing.

4.7 What appeal options are available?

A party in a civil case may appeal a judgment or decision rendered by the District Court to the Court of Appeal. A judgment by the District Court may be appealed on the basis of errors (i) in the assessment of facts, (ii) application of the law, or (iii) the proceedings underlying the decision.

The Court of Appeal's ruling may be appealed to the Supreme Court with the consent of the Appeals Committee of the Supreme Court. Consent may only be granted if (i) the appeal concerns issues that have an impact beyond the present case, or (ii) if it for other reasons is particularly important to have the case decided by the Supreme Court.

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

According to the Norwegian Dispute Act, there are two types of expert evidence. There are experts appointed by the court to provide affidavit evidence, and there are expert statements or witnesses offered as evidence by one of the parties.

The court can appoint an expert if requested by a party, subject to such appointment being a necessary and proportionate means to get a thorough factual basis for the ruling. Furthermore, if it does not lead to disproportionate costs or delays, the court may appoint more than one expert if the character of the technical questions, the significance of the case or other circumstances make it desirable.

Because of the principle of "free evaluation of evidence", expert evidence does not put constraints on the court. However, expert evidence will often have great importance for the court's decision.

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

There are no pre-trial depositions in Norway, except for cases before the Supreme Court.

Expert witnesses presented by one of the parties have to meet in court and give an oral statement. Experts appointed by the court, on the other hand, submit written reports, which constitute an exception to the general principles stating oral examinations and presentation of evidence in court. It is up to the court to decide whether the experts should meet in court for oral statement. The expert reports must be submitted to the court prior to the trial, and made available to both parties.

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

As a part of the pre-trial procedure, the parties are obliged to disclose all evidence which is in their possession and which is of relevance to the case. Furthermore, a party must inform the other party of important evidence which is not in the first party's own possession and which it cannot expect the other party to have knowledge of, notwithstanding to whose advantage that evidence might be.

Evidence should be disclosed at least two weeks before the main proceedings.

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

There are alternative methods of dispute resolution available in civil cases, such as mediation.

When a subpoena is sent from the claimant to the defendant, both parties will receive information and offers on mediation. Judicial mediation presupposes as a rule that both parties agree to participate. Judicial mediation makes it possible for the parties to find a settlement to the conflict of matter by using a mediator, and the purpose is to agree on a reasonable solution that meets the interests of both parties.

The Conciliation Board is another option, which gives the parties an opportunity to resolve the dispute. The board consists of only laymen, and both conciliation and judgment have legal force. In certain cases, launching proceedings with the Conciliation Board is a condition for access to court.

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

According to the Dispute Act, a case can only be brought before Norwegian courts if the facts of the case are "sufficiently connected" with Norway. The application of this might differ depending on whether the case involves only EU jurisdictions or not.

Norway is a party to the Lugano Conventions, and the 2007 Lugano Convention is made statutory law. Consequently, Norwegian courts would take jurisdiction over any case where the defendant is domiciled in Norway. Further, in tort cases such as product liability cases, Norwegian courts would take jurisdiction if the defendant is domiciled within the EU and either (i) Norway is the place where the damage occurred, or (ii) Norway is the place of the event giving rise to the damage, *cf.* EU Case C 189/08 *Zuid-Chemie vs Philippo's Mineralenfabriek*. Insurance companies domiciled in the EU can also be brought within the jurisdiction of Norwegian courts regardless of place of damage, if the claimant is domiciled in Norway. The claimant's domicile is not relevant under the Lugano Convention.

In product liability cases involving non-EU jurisdictions, Norwegian courts would normally take jurisdiction if the defendant is domiciled in Norway or the damage occurred in Norway, subject to the matter having "sufficient connection" to Norway. The court might hold the claimant's domicile relevant in a broader consideration, but this would not be decisive.

Finally, according to the Dispute Act, a defendant may request that a claimant who is not domiciled in Norway provides security for its potential liability for legal costs.

5 Time Limits

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

Yes, see question 5.2 below.

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

Claims 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. Under no circumstance will the time limit 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, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction.

There have been no statutory amendments and few Norwegian product liability cases recently.

More often than before, injured parties and insurance companies claim recourse for damage to property falling outside the scope of the PLA, e.g. damage to professional property, even where there is no proof of fault/negligence. We are not aware of any precedence relating to strict product liability for damage to professional property. On the contrary, in January 2016, the Court of Appeal acquitted a Norwegian distributor of household appliances after one of their products caused damage to a municipal apartment building. Being advised by Advokatfirma Ræder, the distributor and its insurer had acknowledged that the damage was caused by a defect in the product, but refused liability for any damage falling outside the scope of the PLA on the argument that there was no proof of negligence on part of the distributor, a fact which was not contested. The Court of Appeal held that the distributor was not liable on the basis of strict liability neither under the PLA nor case law.

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.en.raeder.no

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 a hundred product liability cases, and frequently represents leading producers and importers, especially within the electronics industry.

Kyrre W. Kielland
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.en.raeder.no

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 65 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 have built an extensive network of cooperative partners across national borders. Ræder is represented in the board and as members of several chambers of commerce. Our international network and experience mean that we can provide prompt assistance to all our clients, including those situated outside of Norway.

We focus on each client and concentrate on building trust by providing good advice based on solid, specialist legal knowledge and commercial understanding. Our organisation is built on a foundation that is characterised by orderliness, commitment, quality and respect.

Chapter 25

Singapore

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 contracts against sellers/suppliers.

Establishing a case in negligence involves proving the existence of a duty of care, a breach of that duty and that the breach caused the damage to the consumer. What amounts to negligence depends on the facts of each case. Where there is a duty to exercise care, reasonable care must be taken to avoid acts or omissions which can be reasonably foreseen to be likely to cause physical injury to the persons or property. Liability for death or personal injury resulting from negligence cannot be excluded. Other liability for negligence may be excluded if such restriction is reasonable.

A right to claim damages under contract is predicated on the claimant having entered into a contract with the supplier of the product and the supplier having breached a term of the contract, e.g. by supplying defective products. Liability is strict where the contract has been breached and will depend on the terms agreed between the parties or implied into the contract.

Standard conditions are implied into all contracts for the sale of goods under the Sale of Goods Act (Cap. 393) (SOGA) and Supply of Goods Act (Cap. 394) (SGA). Products sold in the course of business must be of satisfactory quality, and comply with the description applied to them or a sample supplied. The seller will not be liable for faults drawn to the buyer's attention prior to the contract, or which should have been revealed by the buyer's examination of the goods. As against a person acting as a consumer, the Unfair Contract Terms Act (Cap. 396) prevents the exclusion or restriction by contract of the seller's implied undertakings as to conformity of goods with a description or sample, or as to their quality or fitness for a particular purpose.

There are also various statutes that foster consumer protection. When a consumer enters into a consumer transaction involving an unfair practice in relation to goods and services, he has a right of action against the supplier under the Consumer Protection (Fair Trading) Act (Cap. 52A) (CPFTA). Section 4 CPFTA states that:

It is an unfair practice for a supplier, in relation to a consumer transaction –

(a) to do or say anything, or omit to do or say anything, if as a result a consumer might reasonably be deceived or misled;

(b) to make a false claim;

(c) to take advantage of a consumer if the supplier knows or ought reasonably to know that the consumer –

(i) is not in a position to protect his own interests; or

(ii) is not reasonably able to understand the character, nature, language or effect of the transaction or any matter related to the transaction; or

(d) without limiting the generality of paragraphs (a), (b) and (c), to do anything specified in the Second Schedule.

The Second Schedule sets out specific unfair practices, including:

- Representing that goods or services have sponsorship, approval, performance characteristics, accessories, ingredients, components, qualities, uses or benefits that they do not have.
- Representing that goods or services are of a particular standard, quality, grade, style, model, origin or method of manufacture if they are not.
- Representing that goods are new or unused if they are not or if they have deteriorated or been altered, reconditioned or reclaimed.
- Representing that goods have been used to an extent different from the fact or that they have a particular history or use if the supplier knows it is not so.
- Representing that a service, part, repair or replacement is needed or desirable if that is not so, or that a service has been provided, a part has been installed, a repair has been made or a replacement has been provided, if that is not so.
- Using small print to conceal a material fact from the consumer or to mislead a consumer as to a material fact, in connection with the supply of goods or services.

The CPFTA defines "supplier" as:

a person who, in the course of the person's business –

(a) provides goods or services to consumers;

(b) manufactures, assembles or produces goods;

(c) promotes the use or purchase of goods or services; or

(d) receives or is entitled to receive money or other consideration as a result of the provision of goods or services to consumers,

and includes any employee or agent of the person.

Liability only arises if the unfair practice arose in relation to a "consumer transaction", i.e.:

(a) the supply of goods or services by a supplier to a consumer as a result of a purchase, lease, gift, contest or other arrangement; or

(b) an agreement between a supplier and a consumer, as a result of a purchase, lease, gift, contest or other arrangement, in which the supplier is to supply goods or services to the consumer or to another consumer specified in the agreement.

Hence, for example, if a manufacturer makes a misrepresentation in his sale to the retailer, but does not address that misrepresentation directly to the consumer, the unfair practice may not be considered to relate to a consumer transaction.

Whether conduct has been misleading or deceptive under sections 4(a) and (b) CPFTA is tested objectively, in relation to one or more sections of the public. However, the state of mind of the supplier may be relevant to whether his conduct conveyed a misleading or deceitful meaning. Some of the specific unfair trade practices listed in the Second Schedule expressly require the establishment of actual or imputed knowledge. The implication is that the other representations which do not specify knowledge do not require knowledge to be established. It is not possible to contract out of the provisions of the CPFTA.

Sections 12A to 12F of the CPFTA came into effect on 1 September 2012 to protect consumers against defective goods that fail to conform to contract, or meet satisfactory quality or performance standards at the time of purchase. Sections 12A to 12F are set out below:

Interpretation of this Part

12A. –(1) In this Part, unless the context otherwise requires –

"applicable contract" means –

(a) a contract of sale of goods;

(b) a contract for the transfer of goods; or

(c) a hire-purchase agreement;

"contract for the transfer of goods" has the same meaning as in the Supply of Goods Act (Cap. 394);

"contract of sale of goods" has the same meaning as in the Sale of Goods Act (Cap. 393);

"delivery" has the same meaning as in the Sale of Goods Act;

"goods" —

(a) in relation to a sale, has the same meaning as in the Sale of Goods Act; and

(b) in relation to any other transfer, has the same meaning as in the Supply of Goods Act;

"hire-purchase agreement" has the same meaning as in the Hire-Purchase Act (Cap. 125);

"repair" means, in cases where there is a lack of conformity in goods within the meaning of subsection (4), to bring the goods into conformity with the contract;

"transferee" –

(a) in relation to a contract of sale of goods, means the buyer within the meaning of the Sale of Goods Act;

(b) in relation to a contract for the transfer of goods, has the same meaning as in the Supply of Goods Act; and

(c) in relation to a hire-purchase agreement, means the hirer within the meaning of the Hire-Purchase Act;

"transferor" –

(a) in relation to a contract of sale of goods, means the seller within the meaning of the Sale of Goods Act;

(b) in relation to a contract for the transfer of goods, has the same meaning as in the Supply of Goods Act; and

(c) in relation to a hire-purchase agreement, means the owner within the meaning of the Hire-Purchase Act.

(2) References in this Part to dealing as consumer are to be construed in accordance with Part I of the Unfair Contract Terms Act (Cap. 396).

(3) For the purposes of this Part, it is for a transferor claiming that the transferee does not deal as consumer to show that he does not.

(4) For the purposes of this Part, goods do not conform to –

(a) a contract of sale of goods if there is, in relation to the goods, a breach of an express term of the contract or a term implied by section 13, 14 or 15 of the Sale of Goods Act;

(b) a contract for the supply or transfer of goods if there is, in relation to the goods, a breach of an express term of the contract or a term implied by section 3, 4 or 5 of the Supply of Goods Act; and

(c) a hire-purchase agreement if there is, in relation to the goods, a breach of an express term of the contract or a term implied by section 6A, 6B or 6C of the Hire-Purchase Act.

(5) The following provisions shall not apply to this Part:

(a) the definitions of "consumer" and "goods" in section 2(1);

(b) section 2(2); and

(c) the provisions in Part IV.

Application of this Part

12B. –(1) This Part applies if –

(a) the transferee deals as consumer;

(b) the goods do not conform to the applicable contract at the time of delivery; and

(c) the contract was made on or after the date of commencement of section 6 of the Consumer Protection (Fair Trading) (Amendment) Act 2012.

(2) If this section applies, the transferee has the right –

(a) under and in accordance with section 12C, to require the transferor to repair or replace the goods; or

(b) under and in accordance with section 12D –

(i) to require the transferor to reduce the amount to be paid for the transfer by the transferee by an appropriate amount; or

(ii) to rescind the contract with regard to the goods in question.

(3) For the purposes of subsection (1)(b), goods which do not conform to the applicable contract at any time within the period of six 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 regulate goods such as components of the liquefied petroleum gas system, gas cookers, hairdryers, audio products, etc., where the supply of any registered controlled goods is prohibited, SPRING Singapore, as the Safety Authority, may require the Registered Supplier to effect a recall of the goods. Supply of such goods may be prohibited for various reasons, e.g. that the goods do not conform to safety requirements.

Under the Wholesome Meat and Fish (Processing Establishments and Cold Stores) Rules (Cap. 349A, Rule 3), which regulate the slaughtering of animals and the processing, packing, inspection, import, distribution, sale, transhipment and export of meat and fish products, where any meat or fish product that has been processed in a licensed processing establishment is adulterated, contaminated or otherwise unfit for human consumption, the Agri-food and Veterinary Authority (AVA) may require the licensee to recall all stocks and to cease the sale, supply or distribution, of the product.

The AVA may also direct local importers and retailers to recall food products which have been voluntarily recalled overseas by their manufacturers.

It is an offence to fail to comply with any notice for recall issued under statute.

1.6 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 has to show that the product malfunctioned in a way that does not meet the standard that a reasonable person would regard a product to be in order to be satisfactory. This inquiry is an objective one from a reasonable person placed in the buyer's position armed with his knowledge and background, and

considering at every stage any and all factors that may be relevant to the hypothetical reasonable person (*Compact Metal Industries Ltd v PPG Industries (Singapore) Ltd* [2006] SGHC 242).

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

In such a case, the claimant cannot satisfy its evidential burden and the claim is likely to be dismissed.

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

Failure to warn may give rise to potential liability under statute and the tort negligence. In the event that death is caused, there could also be ramifications under the Penal Code (Cap. 224).

Under the CPFTA, it is an unfair practice for a supplier, in relation to a consumer transaction, to do or say anything, or omit to do or say anything, if, as a result, a consumer might reasonably be deceived or misled. Hence, silence on the part of the supplier can result in a breach. Misrepresentations made to intermediaries, which are not addressed directly to the consumer, may not be considered unfair practices relating to the consumer transaction.

Under the Penal Code, a person may be imprisoned and/or fined for causing death by doing any rash or negligent act not amounting to culpable homicide. The failure to warn, or the conscious avoidance of an obvious risk, may constitute a "rash" act.

In negligence, manufacturers and suppliers owe consumers a duty of reasonable care to provide adequate warnings with their products. There is no duty to warn of risks that are obvious or a matter of common knowledge.

The "learned intermediary" doctrine (as described above) has not been specifically recognised in Singapore.

3 Defences and Estoppel

3.1 What defences, if any, are available?

Under the CPFTA, the onus falls on the supplier to argue that his statements were unreasonably relied upon by the ordinary consumer, to avoid a finding of "unfair practice".

In the tort negligence, the tortfeasor can raise a defence that the claimant voluntarily agreed to the risk in full knowledge of the nature and extent of the risk. Contributory negligence may be relied on to limit liability where the claimant's conduct fails to meet the standard of care required for his own protection, and is a contributing cause in bringing about the damage.

Under the SOGA, the buyer's primary remedy is a rejection of the goods. However, the buyer will be deemed to have accepted them when he intimates to the seller that he has accepted them, or when the goods have been delivered to him and he does any act in relation to them which is inconsistent with the ownership of the seller, or when after the lapse of a reasonable time he retains the goods without intimating to the seller that he has rejected them.

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

A "state of the art/development risk defence" (as described above) has not been specifically recognised in Singapore.

In the tort negligence, the state of scientific and technical knowledge can be relevant to the determination of the scope of the duty of care that should be exercised by the manufacturer in the circumstances. However, in all tort actions, a defendant must take his victim as he finds him. Under the "egg shell skull rule", which normally applies to personal injuries, this concept is adapted to allow recovery even for unforeseeable damage. The "egg shell skull rule" applies in circumstances where, due to a claimant's innate physical susceptibility to illness or injury, he suffers extreme and unforeseeable damage which is triggered by the initially foreseeable damage caused by the defendant's negligence (*Smith v Leech Brain & Co Ltd* [1962] 2 QB 405). Hence, the defendant is made to bear all risks where physical injury to the primary victim is concerned, and the state of scientific and technical knowledge may only be a limited defence.

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

Compliance with regulatory and/or statutory requirements is generally not a defence, although in some circumstances, compliance with such requirements can establish that a manufacturer took adequate care in production.

In negligence, if a manufacturer intends his products to reach the consumer in the form in which they left him, with no reasonable possibility of intermediate examination, and with the knowledge that the absence of reasonable care in the preparation or putting up of the products will result in injury to the consumer's life or property, he owes a duty to the consumer to take reasonable care.

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

Under the doctrine of *res judicata*, parties are estopped between themselves from re-litigating issues determined by final judgment or award of any competent court or tribunal. The narrower principle of issue estoppel prevents the prosecution from calling into question issues determined in the accused's favour in an earlier proceeding.

While different claimants may be able to re-litigate issues in separate proceedings, a claimant could be prevented from re-litigating an issue decided in a previous proceeding, not involving the same parties, on the grounds of abuse of process by re-litigation. Where the doctrines of *res judicata* and abuse of process do not apply, the prior findings of another court based on similar facts can be persuasive.

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

The Civil Law Act (Cap. 43) provides that any person liable in respect of any damage suffered by another person may recover contribution from any other person liable in respect of the same damage (whether jointly with him or otherwise). Order 16 rule 1 of the Rules of Court (ROC) provides that a third-party notice may be issued by a defendant against a person who is not already a party to the action.

Such claims can be brought in either the same or subsequent proceedings. For subsequent proceedings, the claim should be brought within two years from the date of judgment or settlement of the claimant's claim.

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

See the response to question 3.1.

4 Procedure

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

The trial is by Judge. In Singapore, the jury system was abolished in 1970.

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

Order 40 rule 1 ROC allows the court to appoint an independent expert at any time, on its own motion or on the application of any party, in any cause or matter in which any question for an expert witness arises, to inquire and report upon any question of fact or opinion not involving questions of law or of construction.

It is more common, however, for the parties to engage their own experts to give or prepare evidence for the purpose of court proceedings. Under Order 40A rule 1, the court may limit the number of expert witnesses who may be called at the trial. If a material issue arises between evidence from the parties' own experts and a report from a court-appointed expert, the experts may be cross-examined.

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

Order 15 rule 12 ROC provides that the represented group must consist of "numerous persons" who have the "same interest" in the proceedings. One or more of the parties may represent all or all except one or more of them in the proceedings. Although the class members are not required to come forward individually, it is usual for the purpose of costs, the presentation of evidence and other litigation issues that the members of the class are ascertained and invited to join the action. The person who wishes to initiate the representative action may take whatever steps he considers necessary to communicate with the other members of the class.

Representative actions are not commonly brought in Singapore. However, the Court of Appeal considered the application of the representative action rule in the case of *Koh Chong Chiah and others v Treasure Resort Pte Ltd* [2013] SGCA 52, where it underlined a two-stage test. The threshold requirement of demonstrating the "same interest" would first need to be met, and only then would the Court exercise its discretion as appropriate in the circumstances of the case.

With regard to the first part of the test, the Court held that the following legal principles should be applied:

- The class of represented persons must be capable of clear definition.
- The proposed representative(s) must adequately represent the interests of the entire class, and must capably prosecute the interests of the class.
- There must be significant issues of fact or law common to all 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 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.

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

Order 33 rule 2 ROC provides that the court may order any question or issue arising in a cause or matter, whether of fact or law or partly of fact and partly of law, and whether raised by the pleadings or otherwise, to be tried before, at or after the trial of the cause or matter, and may give directions as to the manner in which the question or issue shall be stated. The court may try preliminary issues of law and fact.

4.7 What appeal options are available?

The High Court exercises both original and appellate civil and criminal jurisdiction. It hears appeals from the District and Magistrates' Courts.

The Court of Appeal hears appeals from decisions of the High Court made in the exercise of its original and appellate civil and criminal jurisdiction.

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

See the response to question 4.2.

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

There is no procedure for taking pre-trial depositions. Witnesses are required to reduce their evidence in chief to an affidavit which is filed and served on the opposing party about six weeks before trial. The witness must be present in court for cross-examination before his affidavit is admitted by the trial judge as evidence.

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

Under Order 24 rule 1 ROC, the court may at any time order any party to give discovery by making and serving on any other party a list of the documents which are or have been in his possession, custody or power, and may also order him to make and file an affidavit verifying such a list and to serve a copy thereof on the other party. The duty to give discovery continues throughout the proceedings.

It is possible for a party to make an application for an order for the discovery of documents before the commencement of proceedings under Order 24 rule 6. The order may be conditional on the applicants giving security for the costs of the person against whom it is made.

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

The main modes of alternative dispute resolution (ADR) practised in Singapore are negotiation, mediation and arbitration. The leading ADR institutions in Singapore are the Singapore International Arbitration Centre (www.siac.org.sg) and the Singapore Mediation Centre (www.mediation.com.sg). Consumers may lodge a complaint with the Consumer Association of Singapore (CASE), which may then invite the retailer and consumer to take part in mediation when the matter has reached a deadlock, or when both parties are agreeable to come forward for mediation.

ADR is not required to be pursued before litigation, although the courts have encouraged parties to consider ADR. In the State Courts, all civil cases are automatically referred to ADR unless one or more party opts out. Refusal to use ADR for reasons deemed unsatisfactory by the registrar may result in cost sanctions under Order 59 rule 5 of the Rules of Court. In the High Court, a party wishing to attempt ADR may serve an "ADR offer". The High Court will take into account the ADR offer and the response to the offer in deciding on appropriate costs orders under Order 59 rule 5 of the Rules of Court.

Section 35B of the Supreme Court Practice Directions provides that it is the professional duty of advocates and solicitors to advise their clients about the different ways their disputes may be resolved using an appropriate form of ADR.

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

Under section 16(1) of Supreme Court of Judicature Act (Cap 322) and section 19(3) of the Subordinate Courts Act (Cap 321), any party may invoke the jurisdiction of the court of first instance, or become amenable to the court's jurisdiction provided only that the defendant has been properly served with the necessary process.

Any plaintiff (Singaporean or non-Singaporean) will be able to commence proceedings in the Singapore Court if he can establish that a cause of action arises and connecting factors enable a Singapore court to take jurisdiction in a matter.

Before commencing an action, a plaintiff should consider if Singapore is the appropriate forum to commence proceedings or risk having the action stayed on the ground that there is clearly a more appropriate forum outside Singapore. A party who wishes to stay an action on such a ground will have to show that it is in the interests of the parties and of justice to try the case in another forum. The court will have to determine whether the other forum has the most real and substantial connection to the dispute, taking into account factors such as the governing law of the transaction, place of manufacture, place of sale, the location of witnesses, etc. In addition, the court will also consider whether there are circumstances which militate against a stay, including whether substantial injustice will be caused in sending the plaintiff to a foreign court.

The court may grant leave to a plaintiff to serve a writ on a defendant outside Singapore. Before a court grants leave, it must be satisfied that the plaintiff has a good arguable case falling under one of the limbs of Order 11 rule 1 ROC which, *inter alia*, include instances where relief is sought against a person who is domiciled, ordinarily resident or carrying on business or who has property in Singapore and/or an injunction is sought ordering the defendant to do or refrain from doing anything in Singapore and/or the claim is founded on a tort, wherever committed, which is constituted, at least in part, by an act or omission occurring in Singapore, and/or the claim is brought in respect of a breach committed in Singapore of a contract made in Singapore. The court has to be satisfied that there are serious issues to be tried. If leave is granted, service outside Singapore has to be in accordance with the laws of the country in which service is effected.

The recipient of an Order 11 service may also apply to set aside such service on the basis that Singapore is not the most appropriate forum to try the dispute.

5 Time Limits

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

Yes, there are.

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

Under the CPFTA, a consumer may not commence an action for unfair practice against the supplier later than two years from the date of the occurrence of the last material event on which the action is based, or the earliest date on which the consumer had knowledge that the supplier had engaged in the unfair practice, whichever occurs later.

Under the Limitation Act (Cap. 163), for actions founded on a contract or tort, the limitation period is generally six years from the date on which the cause of action accrued. There are exceptions to this rule in the case of actions where the damage claimed consists of latent injuries and damage. For personal injury claims for damages in respect of negligence, nuisance or breach of duty, the claim must be brought within three years from the date on which the cause of action accrued, or the date of knowledge by the claimant of certain facts. In actions for damages for negligence, nuisance and breach of duty which do not involve a claim for personal injury, the claim must be brought within six years from the date on which the cause of action accrued, or three years from the date of knowledge by the claimant of certain facts.

If on the date when the right of action accrued, the person to whom it accrued was under a disability, the action may be brought any time before the expiration of six years, or, in the case of personal injury claims for damages in respect of negligence, nuisance or breach of duty, three years from the date when the person ceased to be under a disability or died, whichever event first occurred. Under the Limitation Act, a person is deemed to be under a disability if he is a minor or lacks capacity to conduct legal proceedings.

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

Where an action is based upon fraud or the right of action is concealed by fraud, the period of limitation only begins to run when the plaintiff has discovered the fraud, or could with reasonable diligence have discovered it.

6 Remedies

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

Under the CPFTA, a court may order the following types of relief:

(a) restitution of any money, property or other consideration;

(b) damages;

(c) specific performance;

(d) direct the supplier to repair or replace goods or provide parts for goods; or

(e) vary the contract between the supplier and the consumer.

The CPFTA also provides that where there are reasonable grounds for believing that a supplier has engaged, is engaging or is likely to engage in an unfair practice, a specified body, e.g. CASE, may invite the supplier to enter into a voluntary compliance agreement (VCA). The VCA includes an undertaking that the supplier will not engage in a certain unfair practice, and may require the supplier to compensate any consumer who has suffered loss or damage as a result of an unfair practice. If the supplier is unwilling to enter into the VCA, or breaches the VCA, the specified body may obtain a declaration or an injunction.

The court may also make a declaration that a supplier is engaging in an unfair practice or grant an injunction restraining a supplier from engaging in the unfair practice, and require the supplier to advertise the particulars of any declaration or injunction granted.

Under the SOGA, the buyer's primary remedy for a defective product is the rejection of the goods in question, for example, the buyer rejects the goods because of a breach of any conditions that have been implied by the application of the SOGA or the SGA. After rejection, the buyer is also entitled to recover the purchase price and any loss of bargain occasioned by the breach i.e. loss of damage.

However, the buyer may elect to treat any breach on the part of the seller as a breach of warranty. The buyer will then not be able to reject the goods by reason only of such breach of warranty, but may claim against the seller for a diminution or extinction of the price, or maintain an action for damages for the breach of warranty.

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

Damages for a breach of contract are awarded in a quantum which places the innocent party in the position which he would be if the contract was performed according to its terms. The damages claimed must be for losses which were within the reasonable contemplation of the parties at the time of the contract. Unusual losses must have been communicated to the other party at the time of the making of the contract before a claim can be brought to recover such losses. The innocent party may not recover compensation for losses which would not have been suffered if he had taken reasonable steps to reduce his losses or which were caused by unreasonable steps which increased the loss suffered.

Damages in tort are made with the intention of placing the plaintiff in the position he would have been if the tort had not been committed. Damages are subject to the rules of remoteness namely that the loss recoverable will not exceed that which was reasonably foreseeable as liable to result from the breach. Damages are recoverable for physical injury, damage to property or death. There have been developments which improve the innocent party's right to sue for pure economic loss.

Under the CPFTA, the tortious measure of damages is usually applied.

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

No, they cannot.

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

The Court of Appeal has held that the general rule is that punitive damages cannot be awarded for breach of contract (*PH Hydraulics & Engineering Pte Ltd v Airtrust (Hong Kong) Ltd and another appeal* [2017] SGCA 26). The Court of Appeal noted that there are a number of other possible alternative remedies (including the award of damages for mental distress for breach of contract) that could also be invoked by the court to do practical justice while respecting the compensatory function of damages for breach of contract. However, the court also recognised that the instances in which a breach of contract can occur are manifold, and did not rule out the possibility that there might be a "truly exceptional case" to persuade the court that punitive damages should be awarded for breach of contract.

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

Under the CPFTA, the "amount of claim" shall not exceed the current prescribed limit of S$30,000.

With contractual/tortious claims there is no maximum limit on the damages that are recoverable.

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

Under Order 22A rule 7 ROC, a party under disability (a minor or a person lacking capacity) may make, withdraw and accept an offer to settle, but no acceptance of an offer made by him and no acceptance by him of an offer made by another party is binding on him until the settlement has been approved by the court. The court may take into account the settlement terms or the fact that settlement has been reached.

For class actions, the court will have to be satisfied that all aspects of the action have been settled in relation to all parties.

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

No, they cannot.

7 Costs / Funding

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

Assessment of costs is at the court's discretion. In civil proceedings, the losing party will generally be ordered to pay the reasonable legal costs and disbursements of the successful party. Costs are normally awarded on a "standard" basis, as opposed to an "indemnity" basis. Where costs are taxed on a "standard" basis, a reasonable amount in respect of all costs reasonably incurred shall be allowed. On an "indemnity" basis, all costs shall be allowed unless they are of an unreasonable amount or have been unreasonably incurred.

In criminal proceedings, any compensation made to victims may operate as a mitigating factor.

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

The Legal Aid Bureau (www.lab.gov.sg) provides legal aid and advice for civil matters. There is no government-funded legal aid for criminal matters.

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

Legal aid is available to Singapore citizens or permanent residents in Singapore.

Applicants for legal aid must satisfy the means and merits tests. Under the 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 Board is of the opinion that the applicant has reasonable grounds for taking, defending, continuing or being a party to the legal proceedings.

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

No, it is not.

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

Third-party funding arrangements may be unenforceable if they are found to be champertous, i.e. where one party agrees to aid another to bring a claim on the basis that the person who gives the aid shall receive a share of what may be recovered. However, the courts have acknowledged that where the third-party funder has a genuine commercial interest in enforcing proceedings, funding may not be champertous.

In January 2017, the Singapore Parliament passed the Civil Law (Amendment) Bill 2016, which allows third-party funding but only in the field of international (but not domestic) arbitration and related proceedings, and does not apply to court-based litigation. Such related proceedings include:

(a) court proceedings arising from or out of the international arbitration proceedings;

(b) mediation proceedings arising out of or in connection with international arbitration proceedings;

(c) application for a stay of proceedings referred to in section 6 of the International Arbitration Act; and

(d) proceedings for or in connection with enforcing an award or foreign award under the International Arbitration Act.

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

One way in which the Court helps to manage costs is through holding regular pre-trial conferences (PTCs) to monitor the progress

of the case. At PTCs, the Registrar will usually seek an update on the status of an action. Directions will then be given for the parties to progress the action in an expeditious and fair manner, e.g. the filing of interlocutory applications and the timelines therein. An action may go through several PTCs. Parties who reach a settlement at a PTC may record the settlement before the Registrar. Otherwise, trial dates will be given for matters that cannot be settled.

Parties are also encouraged to offer to settle any one or more of the claims in proceedings, to save costs and time for both the litigants and the courts. Under Order 22A rule 9 ROC, a party who rejects a reasonable offer from the other party will, upon being awarded judgment less favourable than the terms of the offer to settle, be penalised with certain adverse costs orders, while the other party will correspondingly be rewarded with such costs.

8 Updates

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

In *TV Media Pte ltd v De Cruz Andrea Heidi* [2004] 3 SLR(R) 543, the plaintiff consumed a weight loss drug and subsequently suffered impending liver failure. The plaintiff sued to recover damages for pain and suffering and medical expenses incurred. The High Court held the importing company, its director, and the sole distributor of the drug liable. The director and sole distributor appealed. The Court of Appeal upheld the High Court decision and found that a distributor or wholesaler owes a duty of care to the ultimate consumer to take reasonable care in ensuring the safety of its products. Also, despite a company being a separate legal entity, a director may be held personally liable for negligent acts.

As mentioned in the response to question 1.1 above, a "lemon law" was introduced (Sections 12A to 12F of the CPFTA) to protect consumers against defective goods that fail to conform to contract, or meet satisfactory quality or performance standards at the time of purchase. This provides for the additional remedies of repair and replacement, beyond just rejecting the goods and getting a refund. This ensures that consumers buy products of good quality, improves the image of the retail industry in Singapore and fosters good business practices among retailers.

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 leads the Intellectual Property practice at Allen & Gledhill.

Stanley specialises in all forms of IP litigation and information technology disputes, and is also a commercial litigator. He also maintains a strong advisory practice for IP management and strategy, serving a broad spectrum of clients. In the biomedical and pharmaceutical sectors, Stanley has substantial experience in advising on healthcare and medical IP and regulatory issues concerning medicines, generics, bio-similars, medical devices, clinical trials, product recalls and product liability.

Stanley is currently the Chairman of the Intellectual Property Office of Singapore, and a member of the Singapore International Arbitration Centre IP Arbitration Panel and Singapore Copyright Tribunal. He is also a director of Singapore Technologies Engineering Ltd, and an Adjunct Professor in the Faculty of Law at the National University of Singapore. Stanley serves as a Principal Mediator of the Singapore Mediation Centre, and is the first Singapore-born lawyer to have been conferred a Ph.D. in Law from the University of Cambridge, UK. He was appointed Senior Counsel in 2010.

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 matters.

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.

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Spain

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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?

In Spain, the general regime on liability for defective products or services is established in Royal Legislative Decree ("RLD") 1/2007, of 16 November, approving the consolidated text of the General Law on the Protection of Consumers and Users and other complementary regulations. Such regime is found in articles 128 to 146, both inclusive, of RLD 1/2007.

Article 136 of RLD 1/2007 defines which types of products are subject to the regime on product liability, namely any movable asset, even when this is combined or incorporated into another movable or immovable asset, as well as gas and electricity. The concept of "any movable asset" is very broad and comprises practically all equipment and consumer goods.

The regime for product liability established in RLD 1/2007 is of a strict nature.

The actions available under RLD 1/2007 do not affect any other right to damages, including moral damages, that the injured party may have as a consequence of contractual liability, based on the lack of conformity of the goods or services or any other cause of non-performance or defective performance of the contract, or of any non-contractual liability that may apply.

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

The regime on product liability established in RLD 1/2007 does not foresee any scheme of compensation for particular products.

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

The responsibility for the defect is borne by the manufacturer or by the importer who introduces the product into the European Union.

In the event that the manufacturer cannot be identified, the supplier of the product (the distributor or the "retail" supplier) shall be considered as such, unless he informs the injured party of the identity of the manufacturer or of the person who supplied the product to him, within a term of three months. This same rule applies in the case of imported products, in the event that the product does not indicate the name of the importer, even if it indicates the name of the manufacturer.

However, the supplier of the defective product shall be liable towards the injured party as if he were the manufacturer in the event that he supplied the product knowing that the defect existed. In such case, the supplier may enforce his right of recovery against the manufacturer.

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

Under the general regime on liability for defective products or services established in RLD 1/2007, the responsibility for the defective product is only borne by the manufacturer or by the importer who introduces the product into the European Union. Therefore, as the regulatory authority is neither a manufacturer nor an importer, 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 is included as an offence in the Criminal Code and the damage caused is protected by such Criminal Code.

2 Causation

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

The injured party seeking the compensation of damages has the burden of proving the defect, the damage and the causal relationship between the two.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

The regime on product liability places the burden to prove the existence of the defect, the damage and the causal relationship between such defect and damage upon the claimant. In order to establish the causal relationship between the defect in the product and the damages suffered, the claimant must provide solid and substantial evidence that supports such link, and the damages must be an appropriate and sufficient result of the defect.

However, occasionally, the Spanish Courts also accept that the causal relationship may be proven by means of presumption or circumstantial evidence.

In Spain, the principle of generic causation, i.e. that in order to prove the causal relationship it would be sufficient to demonstrate that a product is capable of causing an alleged injury, is not applied. The Spanish Courts have established that the mere fact that a product is capable of causing damage is not sufficient to establish the defective nature of such product. In order to prove that a product is defective, the claimant must prove that the damages that he or she claims to have suffered are effectively caused by the defective product. It is sufficient that the claimant proves the existence of the defect, but it is not strictly necessary that the claimant provides evidence of the specific defect of the product. We can thus conclude that in Spain the proximate causation principle operates.

On 5 March 2015, the Court of Justice of the European Union issued a ruling on 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 manufacturer who compensated the injured party shall have the right to claim recovery from the other manufacturers, depending on their involvement in causing the damages.

However, the manufacturer of a part that is integrated into a finished product shall not be liable, if he proves that the defect is attributable to the design of the product into which the part manufactured by him was integrated, or to the instructions provided by the manufacturer of the finished product.

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

In accordance with Spanish doctrine and case law, there are three large groups of defects that products may suffer from: i) manufacturing defects; ii) design defects; and iii) information defects.

The absence of the necessary warnings or instructions for use, or the inappropriateness of such information, may give rise to an information defect. As a consequence, when the information that accompanies a product is inappropriate or insufficient, then such product may be considered to be defective and may give rise to liability in the event that the product causes damages.

The information is considered to be appropriate when it allows for the identification, assessment or reduction of the announced risk. The information is also considered to be appropriate when there is a balance between the information on the safety of the product in possession of the manufacturer, and the information made available to consumers.

Moreover, the manufacturer or importer shall only be held liable for the lack of information on reasonably foreseeable risks, i.e. risks that he is aware of or should be aware of through the exercise of reasonable diligence. Within the framework of the special regime for product liability established in RLD 1/2007, a defect is defined as "the lack of safety that could legitimately be expected from the product, i.e. based on the criterion of the consumer's reasonable expectations". Further, within the scope of the consumer's legitimate expectations, only the information that was known to the manufacturer or that, in accordance with the state of scientific and technical knowledge, should have been known by him at the moment of placing the product on the market must be included.

In principle, the information and the warnings that shall be taken into account in order to determine whether a product suffers from an information defect shall be the information provided directly to the user of the product.

However, for certain types of product for which the intervention of an intermediary is required, the Courts may take the information provided to the intermediary into consideration, in order to determine whether the information provided to the consumer is sufficient and appropriate.

Specifically, in the case of medicinal products, Basic Law 41/2002, of 14 November, governing patient autonomy and rights and obligations as regards clinical information and documentation, establishes that it is the doctor's duty to guarantee that the patient has the necessary information to decide freely on the therapeutic strategy prescribed by the doctor. As a consequence, the information provided by the manufacturer to the doctor shall be taken into consideration in order to assess the set of information provided to the patient.

Lastly, we must point out that RLD 1/2007 does not expressly foresee the referred "learned intermediary rule", pursuant to which the supply of information to the learned intermediary discharges the duty owed by the manufacturer to the ultimate consumer to make appropriate product information available.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The manufacturer or importer shall not be liable if he can prove:

a) That he did not put the product into circulation.

b) That, given the circumstances of the case, it may be presumed that the defect did not exist when the product was put into circulation.

c) That the product had not been manufactured for sale or for any other form of distribution with an economic purpose, nor that was it manufactured, imported, supplied or distributed within the context of a professional or entrepreneurial activity.

d) That the defect is due to the fact that the product was elaborated in accordance with existing mandatory rules.

e) That the state of scientific and technical knowledge existing at the time the product was put into circulation did not allow for the discovery of the existence of the defect.

The manufacturer of a part that is integrated into a finished product shall not be liable if he proves that the defect is attributable to the design of the product into which the part was integrated, or to the instructions provided by the manufacturer of the finished product.

In the case of medicinal products, foods or foodstuffs intended for human consumption, the persons liable shall not be able to invoke the state of scientific and technical knowledge defence set out in point e) above.

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

The fact that the state of scientific and technical knowledge existing at the time the product was put into circulation did not allow for the discovery of the existence of the defect may be used as a defence. However, as pointed out in the answer to question 3.1 above, such defence cannot be invoked in the case of medicinal products, foods or foodstuffs intended for human consumption.

The manufacturer has the burden of proving that the defect could not be discovered.

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

Compliance with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product can be used as a defence, if such requirements impose the inexcusable obligation on the manufacturer to elaborate the product in strict compliance and observance of 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.

In case the damages caused by a company by means of its defective product were of criminal entity, that is, constituting an offence under the Spanish Criminal Code, such Code sets forth the possibility that legal entities are held criminally liable. Companies may be held criminally liable as a result of the behaviour of the following persons:

(a) their directors or legal representatives, if they have been appointed to perform their duties or even if they do so without a formal appointment;

(b) other persons authorised to adopt decisions on behalf of the company, including middle management, general and individual proxies, and persons to whom control and organisation functions have been delegated (including the compliance officer); and

(c) those who are subject to the authority of the above-mentioned persons, including the employees of subsidiaries and persons with a commercial relationship with the company, such as self-employed individuals or subcontracted employees, provided that they are within the company's corporate domain.

As a general rule, the company shall only be subject to criminal liability if the criminal behaviour of one of the above-mentioned persons was intentional and wilfully misconducted. Reckless behaviours may only result in the company being held criminally liable when involving crimes regarding "fraudulent insolvency", "natural resources and environment", "financing of terrorism" or "money laundering".

According to the Criminal Code and the rulings of the Spanish Supreme Court on this matter, for a legal person to be held criminally liable, the prosecution must prove that both the offence was committed and that the internal control tools deemed ideal and effective to prevent and try to prevent the criminal conduct in question at the company were either non-existent or ineffective.

To be exempted from liability, the accused company is responsible for demonstrating that the compliance system was in place and effective. In the opinion of the Spanish Supreme Court, if the prosecution is unable to demonstrate that the compliance system was non-existent or ineffective, the company cannot be held criminally liable.

In any case, the criminal liability of a legal person is a relatively new matter in Spain, on which the Spanish Supreme Court has not yet addressed this issue on a regular basis. To this end, we must carefully monitor future statements made by the Spanish Supreme Court, in addition to the interpretation, in general, of the Courts and the Public Prosecutor's Office in terms of the provisions of the Criminal Code.

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

The effects of *res judicata* produced by final judgments and consisting in the permanence over time of the efficacy of the judgment as a mechanism for legal safety and certainty have certain limits. One of those limits is the subjective limit, which means that the effects of *res judicata* only apply between the litigating parties, and therefore it is possible to bring new claims on matters of fault, defect or capability of a product to cause a certain type of damage, provided that the claimant is really different. For example, in the event of personal damages suffered by an individual during a traffic accident as a consequence of the malfunctioning of an airbag, it is possible for the injured person's insurance company to file a claim against the car manufacturer in order to recover the hospital expenses paid by such insurance company, and for the injured person him/herself to file a claim against the car manufacturer for the compensation of personal damages. Of course, such personal damages cannot include the hospital expenses paid directly by the insurance company. In this example, the claim by the insurance company would be brought under insurance law, and the claim by the injured person under the regime on product liability.

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

The manufacturer or importer against whom proceedings for product liability are brought may claim in his defence that the defect was due to the actions of a third party, but his liability *vis-à-vis* the claimant will not be reduced hereby.

Nevertheless, the manufacturer or importer who paid compensation to the injured party shall be able to claim such part from the third party as corresponds to such third party's involvement in causing the damages in subsequent proceedings. Such proceedings against the third party must be brought within a period of one year, counted from the day the compensation was paid to the injured party.

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

The liability of the manufacturer or the importer may be reduced, or even excluded, if it is proven that the damages were caused partially

or entirely due to the actions or negligent behaviour of the injured party. However, the behaviour of the injured party must be valued on a case-by-case basis, and must hold direct relation with the defect.

For example, in the example of the malfunctioning of an airbag cited in our answer to question 3.4 above, the manufacturer of the airbag cannot defend itself by arguing that the accident was caused due to the reckless behaviour of the driver (injured party).

The behaviour of the injured party may have contributed to the accident, but not to the malfunctioning of the airbag.

4 Procedure

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

In the case of court proceedings, the case shall be resolved by a judge.

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

In legal proceedings on product liability, the examination of expert evidence may only be proposed by the parties to the trial. In this type of proceeding, the Court may not *ex officio* propose the examination of expert evidence or appoint technical specialists in order to assess the evidence presented by the parties.

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.

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

When those damaged are a group of consumers or users, then the claims can be brought by associations of consumers and users and/or the Attorney General's Office, in accordance with what is set out in the answer to question 4.3 above.

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

Even though it is difficult to provide a general answer, it is rather common that a period of 14 to 18 months goes by between the filing of the claim and the rendering of the judgment in first instance.

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

The preliminary issues which, due to their very nature, represent an obstacle to the continuation of the trial and that require prior resolution by the judge, are those that refer to: i) lack of jurisdiction or competence of the Court before which the claim is brought; ii) lack of capacity or representation of the litigants; iii) *lis pendens* or *res judicata*; iv) necessary passive joinder of defendants; v) inappropriateness of the proceedings; or vi) a legal defect in the way the claim has been filed.

These preliminary issues to be decided beforehand only relate to matters of law.

4.7 What appeal options are available?

In legal proceedings on product liability, it is possible to file an appeal before the Provincial Court against the judgment rendered in first instance by the Court of First Instance.

Against the judgment on appeal rendered by the Provincial Court, there are two appeal options: i) an extraordinary appeal for infringement of procedure; or ii) a cassation appeal, provided that the amount of the proceedings exceeds the sum of 600,000 Euros or the decision on the appeal has reversal interest, because the judgment subject to appeal contradicts the Supreme Court's jurisprudence, or decides on points and issues on which contradictory case law from the Provincial Courts exists or it applies rules that have been in force for less than five years, as long as, in the latter case, no jurisprudence from the Supreme Court exists concerning previous rules of identical or similar content.

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

The proposal of the examination of expert evidence corresponds to the litigants, and the only restriction 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.

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

Witnesses are not required to present themselves for pre-trial deposition and they only declare on the day of the trial.

The reports issued by the experts must be provided by the parties, together with the document initiating the proceedings or together with the response to the claim. In the event that this is not possible, the parties must announce their intention to provide such reports in the claim or in the response to the claim. In such case, the reports shall be provided to the Court five days before the date set for the pre-trial hearing ("*Audiencia Previa*"), so that the Court may provide a copy to the other party.

Expert reports, the necessity or usefulness of which results from the statement of defence or from the allegations and pleas set forth at the pre-trial hearing (i.e., expert report, the need for which becomes apparent at a later stage of the proceedings), shall be submitted by the parties for their transfer to the counterparties at least five days prior to the trial.

If the parties so request, the experts who have prepared the reports shall intervene in the trial in order to ratify, explain or clarify their reports, and in order to respond to any question regarding their reports.

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

After the filing of the claim and the response to the claim or, if appropriate, after the pre-trial hearing, documents and instruments related to the merits of the case presented by the claimant or the defendant shall only be admitted in the following cases:

i) If they are dated subsequent to the claim or the response to the claim or, if applicable, to the pre-trial hearing.

ii) If they are dated prior to the claim or response to the claim or, if applicable, to the pre-trial hearing, provided that the party which submits them justifies not having known of their existence before.

iii) If it was not possible to obtain them before due to reasons which are not attributable to the party, provided that the party duly designated the archive, official file or place where they are located, or the registry, registry book or files of which it seeks to obtain a certification.

When a document regarding facts related to the merits of the case is presented once the acts referred to in the previous section have concluded, the other parties may, during the proceedings or hearing, allege the inadmissibility of taking them into consideration.

No document shall be accepted after the trial, except for judgments, judicial or administrative resolutions, rendered or notified on a date subsequent to the moment of submission of conclusions, and provided that they may be conditional or determining for the decision.

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

RLD 1/2007 establishes the possibility that conflicts between consumers, users and companies may be resolved through the Consumer Arbitration System, with no special formalities and in a manner that is binding and enforceable on both parties, provided that the conflict does not concern intoxication, injury, death or the existence of reasonable evidence that an offence has been committed.

It is also possible to resolve conflicts in the field of product liability through the mediation system established in Law 5/2012, of 6 July, on mediation of civil and commercial matters or through the arbitration system governed by Law 60/2003, of 23 December, on Arbitration.

The submission of the parties to any of the referred arbitration or mediation proceedings is voluntary, and therefore alternative methods of dispute resolution are not required to be pursued before initiating any court proceedings.

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

Pursuant to 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 (that recasted Council Regulation (EC) No 44/2001, of 22 December 2000), jurisdiction for product liability claims that derive from a contractual relationship between the claimant and the defendant corresponds to the Courts of the place of delivery of the defective product, unless otherwise agreed upon by the parties in the contract.

In the case of a contract with a consumer, the claim by the injured consumer against the manufacturer or importer may be brought before the Courts of the Member State in which the manufacturer or importer has its domicile, or before the Courts of the place of domicile of the consumer.

As to product liability claims that arise from non-contractual relationships, the same above-mentioned regulations establish that the Courts of the place where the harmful event occurred shall have jurisdiction.

If the claimant or defendant is not domiciled in the European Union, a case-by-case analysis will need to be carried out as the applicable bilateral or multilateral treaties will determine whether the person can be brought to Spanish jurisdiction or not.

5 Time Limits

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

The statute of limitations for proceedings for the recovery of damages caused by a defective product initiated under the regime of RLD 1/2007 is three years, counted from the date the damages were incurred by the injured party, provided that the identity of the party liable for the damages is known to the injured party.

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

In the event the claim is brought under the regime of RLD 1/2007 because of the defective nature of the product causing the damages, as defined in such regulation, the liability will always be of a strict nature, and the statute of limitations is three years. In the event of bodily injury, this statute of limitations starts to run from the moment when the final extent of the injury has been defined and established.

In the event that the claim cannot be brought under such regulation, the claim shall have to be brought under the general rules of civil law, the regime for liability of which is fault-based. In the event that the relation is non-contractual, the statute of limitations is one year.

In order to avoid a discussion on whether the product and the defects fall within the definition of RLD 1/2007 and, therefore, to avoid the debate on whether the statute of limitations of one year or three years applies, in cases of non-contractual liability we recommend initiating the proceedings within one year.

The age or the condition of the claimant does not affect the calculation of any time limit and the Courts do not have any discretion to disapply them. As noted above, legal proceedings brought under the product liability regime of RLD 1/2007 may be barred by limitation if they are initiated after a period of three years. However, the Court shall only reject the claim on this ground if the defendant raises the issue of limitation.

The prescription of the action may be interrupted by the injured party by filing a claim before the Courts or by means of an extrajudicial claim, or through any act of acknowledgment by the liable party.

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

The prescription period starts to run from the moment that the injured party has knowledge of the damages suffered and knows the identity of the person liable for such damages. We also refer to our answer to question 5.2 above 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 compensation in the form of an economic indemnity for the damages caused to him or her by the defective product.

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

The regime on product liability established in RLD 1/2007 extends to personal/bodily damages, including death and material damages, provided that such damages have been caused to goods destined to private use or consumption and that they are mainly used by the injured party in such concept.

Damages to the defective product itself are not recoverable under RLD 1/2007. However, the injured party may claim compensation for such damages under general civil and commercial law.

Moral damages may be recovered under general civil law.

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

If the defect has not been proven, no damages have been caused yet, and, as a consequence, it is not possible to establish a causal relationship between the defect and the damages. 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 respect, the previously mentioned ruling of 5 March 2015 by the Court of Justice of the European Union establishes that the Directive 85/374/CEE, regarding damages caused by defective products, should be interpreted in the sense that the surgical operation for the replacement of a defective product implanted on a patient constitutes "damage caused by death or personal injuries", for which the producer is liable, if such an operation is necessary to overcome the defect in the product in question, even though the product has not malfunctioned yet.

However, in the particular case at stake, it is important to note that the manufacturer himself noticed the defect on the products and recommended doctors to replace them by means of surgical operations, so the defect of the products was acknowledged even though they had not malfunctioned yet.

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

Under Spanish law, no punitive damages – only compensatory damages – can be recovered. However, the Courts have some discretionary powers in awarding such compensatory damages and one may expect the conduct of the defendant to have some impact on the amount of damages awarded.

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

The overall civil liability of one manufacturer for damages – death and personal injuries – caused by identical products with the same defect shall be limited to the maximum amount of 63,106,270.96 Euros.

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

Minors do not have procedural capacity and must be represented in the proceedings by their parents with parental authority, which may be exercised jointly by both parents or individually by one of the parents, with the consent of the other. If for any reason the parents have been deprived of the parental authority, the minor shall be represented in the proceedings by his or her legal guardian, but the guardian will need a judicial authorisation in order to bring the claim.

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

The possible right of Government authorities to be reimbursed in the terms set out in the question is not legally protected by the Spanish regime on product liability.

7 Costs / Funding

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

The costs of the proceedings shall be imposed on the party who has had all 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 of 7,455.14 Euros.

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

The amount of the attorney's professional fees shall be one freely agreed upon between the client and the attorney, in observance of the rules on ethics and on free competition. The form in which the fees are to be paid shall also be freely agreed upon, and may include payment of a percentage of the outcome of the claim. In any case, the client shall have to pay all expenses that may arise as a result of the assignment.

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

We are not aware of any regulation that prohibits third party funding of claims, and as a result, such third party funding is admissible. Such funding will be subject to the terms and conditions agreed upon by the parties, provided that they are not contrary to law, ethics or public order.

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

No, the Court does not exercise any kind of control over the costs to be incurred by the parties in order to check if they are proportionate or not.

8 Updates

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

In our responses to the questions we have already included the newest trends and developments as regards product liability in Spain, with special regard to the ruling by the Court of Justice of the European Union regarding implantable medical devices.

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Xavier Moliner
Faus & Moliner
Rbla. Catalunya 127
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 May 2016, the *Chambers & Partners Guide* highlighted Xavier Moliner's specialisation in the litigation sector, as well as his work in the public procurement field. They also mentioned that he is "well respected for his experience with product liability issues". 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 2016*. Faus & Moliner has earned such recognition by *Chambers & Partners* for 10 years in a row.

Clients say it is "a well-recognised firm in the field of life sciences. It has strong business orientation and can clearly communicate in a direct and understandable manner, proposing potential solutions based on legal options available". "The firm is probably the best specialist in regulatory law."

Moreover, the *Chambers & Partners Guide* highlighted that it is "recognised for its expertise in draft regulations, product liability, commercial agreements and compliance projects".

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 proof that the products have met and complied with the contemporary technical and professional standards of reasonably expected safety requirements. Nevertheless, according to Paragraph 3, Article 7 of the CPA, if a manufacturer can prove that the defect of the products was not caused by negligence, the court may reduce the compensation.

Claims initiated based on points 1 and 2 above are classified as contractual liabilities in Taiwan. In addition, for a defective product, if a manufacturer/distributor breaches his/her/its statutory obligations, such as fraud, criminal or civil liability may also be imposed on the manufacture/distributor.

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

No. There is no scheme of compensation for particular products in Taiwan.

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

According to 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 occurs, 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 Article 36 or 38 of the CPA, it shall be punished by an administrative fine of not less than NT$60,000 and not more than NT$1,500,000 and which may be imposed successively; if there 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 conducts, instead of just proving that the defendant wrongly exposed him/her to an increased risk of a type of injury known to be associated with the product.

Normally, the burden of proof is imposed upon the claimant (e.g., the claims based on 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 not a specific principle called "market-share liability" in Taiwan. However, the manufacturers would be jointly and severally liable for a defective product; therefore, a plaintiff (consumer) may claim against a group of product manufacturers for an injury caused by a defective product, even when the plaintiff does not know by which defendant the product is manufactured.

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

If the products may endanger consumers' lives, bodies, health or property, a warning, as well as the methods for emergency handling of such danger, shall be labelled at a conspicuous place (Paragraph 2, Article 7 of the CPA). Whether a particular warning should be specifically labelled depends on the nature of the subject matter of the warning, i.e., if it is a well-known use of the product, no warning is required. If a business operator (e.g. a manufacturer or distributor) fails to perform its labelling obligations in this regard, it will be held liable for the damage caused thereby (Paragraph 3, Article 7 of the CPA).

In Taiwan, if information regarding the use of a product is not well-known, the business operator shall label the warning on the product. Therefore, only information, advice and warnings provided directly to the consumer would be taken into account. Even if the product can only be obtained through the intermediary who owes a separate obligation to assess the suitability of the product for the particular consumer, if information regarding the use of a product is not well-known, a business operator cannot discharge its obligations to label a warning on the product.

There is no principle of "learned intermediary" applied in Taiwan.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The following defences are commonly asserted in a product liability action:

1. Comparative Fault or Comparative Negligence

A plaintiff's improper conduct might negate some or all of the defendant's liability for an injury. Under the comparative fault, damages are apportioned according to each party's fault. The plaintiff's recovery would be reduced in proportion to the amount of his or her negligence.

2. Lack of Negligence

If a business operator proves that the defect of the product or a missing label from the products at issue was not caused by negligence, the court may reduce its liability for damages (Paragraph 3, Article 7 of the CPA).

3. State of the Art/Development Risk Defence

According to Articles 7 and 7-1 of the CPA, an affirmative defence of "state of the art" applies in Taiwan. That is, if a manufacturer is able to prove that the products have met and complied with the contemporary technical and professional standards of reasonably expected safety requirements prior to the launching of such products for sale into the market, the manufacturer will not be held liable for the damage caused thereby.

4. Causation Defence

If the damage is not caused by a product's defect, a business operator will not be held liable for such damages.

5. Statute of Limitations

According to the CPA and the Civil Code, a person should exercise his/her right regarding product liability within two years from the date that he/she is aware of the damage and the identity of the liable person or ten years from the date of the wrongful act.

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

According to Articles 7 and 7-1 of the CPA, an affirmative defence of "state of the art" applies in Taiwan. That is, if a manufacturer is able to prove that the products have met and complied with the contemporary technical and professional standards of reasonably expected safety requirements prior to the launching of such products into the market, the manufacturer will not be held liable for the damage caused thereby. Furthermore, it is the manufacturer's obligation to prove that the fault/defect in the product was not discoverable given the state of scientific and technical knowledge at the time of supply.

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

Generally 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 in the same procedure. In such a case, the claimants who opt in cannot re-litigate the issues of fault, defect or the capability of a product to cause this certain type of damage in separate proceedings.

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

According to Paragraph 3, Article 7 of the CPA, business operators causing injury to the consumers or third parties shall be jointly and severally liable. In addition, according to Article 273 of the Civil Code, the creditor is entitled to demand one or several or all of the 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?

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 How long does it normally take to get to trial?

For a civil case, normally it takes around 10 to 12 months to obtain a judgment in the District Court, six to 10 months in the High Court, and eight to 12 months in the Supreme Court. If the amount of claim is no more than NT$500,000 or no more than NT$100,000, the summary proceeding or small-claim proceedings shall apply, respectively, and it would take less time to obtain a judgment. However, please note that the time may vary depending on the complexity of a case and whether the higher court upholds or overturns the judgment rendered by the lower court.

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

Yes. According to Article 383 in the Code of Civil Procedure, where the claims or defences presented are sufficient for the court to render its judgment, the court may enter an interlocutory judgment. In addition, where an interlocutory issue relating to the litigation proceedings is sufficient, the court may also give a ruling on such issue prior to its final judgment. The interlocutory judgment/ruling would bind the judgment of the court for the remainder of the trial. Both matters of law and issues of fact can be determined by the court preliminarily. Given that there is no jury system in Taiwan, the judge would decide the preliminary issues.

4.7 What appeal options are available?

According to Article 437 of the Code of Civil Procedure, a judgment rendered by the District Court can be appealed to the High Court. In addition, a final judgment rendered by the High Court can be appealed to the Supreme Court as long as the amount of the claim is NT$1,500,000 or more. However, an interlocutory judgment or a ruling made during litigation proceedings cannot be appealed independently. Thus, the parties may only appeal against the interlocutory judgment or ruling after the final judgment is rendered.

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

Yes. Expert testimony is usually presented in product liability actions because the determination of relevant factual and legal issues often requires professional knowledge toward a specific product. Therefore, the court may need the assistance of expert testimony to clarify relevant issues in a product liability case. According to Paragraph 1, Article 326 and Article 328 of the Code of Civil Procedure, an expert shall be a person with special knowledge or experience in giving expert testimony, and shall be appointed by the court. Besides, according to 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.

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

The Code of Civil Procedure provides the preparatory proceeding which is similar to the system of pre-trial deposition.

According to Paragraph 2, Article 270 and Article 268 of the Code of Civil Procedure, the court can order the parties to present evidence in the preparatory proceeding. If the court deems that the preparation for oral arguments is not completed, the presiding judge may order the parties to submit a preparatory pleading or defence with complete reasons and also order them to specify or state in detail the evidence which they propose to invoke regarding a certain issue/matter.

Given such, assuming that an expert witness is able to clarify relevant issues in a product liability case, the court may ask the parties to present or exchange witness reports in the preparatory proceeding.

The parties can select an expert to provide his professional opinion in a product liability case in both the first and second instance. According to Point 5 of the Expert Counselling Directive, when a complicated case involves a professional field, the court can counsel the expert when it sees it is necessary. For the same reason, the court can ask an expert witness to present in the preparatory proceeding.

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

According to 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.

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

According to Paragraph 1, Article 403 of the Code of Civil Procedure, if the dispute arises from proprietary rights where the price or value of the object in dispute is not greater than NT$500,000, the matter shall be subject to mediation by the court before the relevant action is initiated.

In addition, parties may utilise various forms of alternative dispute resolution, including arbitration, mediation, negotiation and conciliation. Based on Article 1 of the Arbitration Act, parties may enter into an arbitration agreement to resolve a dispute through arbitration. Also, according to the 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).

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

In civil cases, parties may, by agreement, designate a court of first instance to exercise jurisdiction over a dispute between the parties, provided that such agreement relates to a particular legal relationship. Meanwhile, the agreement shall be evidenced in writing.

Without both parties' agreement, persons that are not domiciled in Taiwan may be brought within the jurisdiction of Taiwan courts either as a defendant or as a claimant, provided that the concerned dispute has a connecting factor with Taiwan. However, whether the connecting factor is sufficient enough is subject to determination by the courts on a case-by-case basis.

5 Time Limits

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

According to the CPA and the Civil Code, a person should exercise his/her right regarding product liability within two years from the date that he/she is aware of the damage and the identity of the liable person or 10 years from the date of the wrongful act.

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

The time limit does not vary depending on whether the liability is fault-based or strict.

The age or condition of the claimant does not affect the calculation of time limits and the court does not have 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 by any of the following causes: (1) a demand for the satisfaction of the claim; (2) an acknowledgment of the claim; or (3) an action brought for the satisfaction of the claim.

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

The concealment or fraud does affect the running of any time limit.

6 Remedies

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

In product liability actions, compensation shall be limited to the injury actually suffered and the loss of expected profits based on a fixed plan. In most cases, the plaintiff claims for monetary compensation. However, according to Article 538 of the Code of Civil Procedure, where it is necessary for the purposes of preventing material harm or imminent danger or other similar circumstances, a petition may be made for an injunction maintaining a temporary *status quo* with regard to the legal relationship in dispute. Moreover, according to Article 53 of the CPA, consumer ombudsmen or consumer protection groups may petition to the court for an injunction to discontinue or prohibit a business operator's conduct which has constituted a material violation of the provisions of the CPA relating to consumer protection.

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

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 plaintiff customer has suffered actual physical injury.

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

Punitive damages are available in product liability actions. According to Article 51 of the CPA, in consumer protection-related cases, the consumer may claim for punitive damages up to five times the amount of actual damages as a result of injuries caused by the wilful act of misconduct of business operators; however, if such injuries are caused by gross negligence or negligence, punitive damages up to three times or one time the amount of the actual damages may be claimed, respectively. It is worth noting that a customer is required to prove that the business operators maliciously, wilfully, intentionally or negligently caused injury.

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

There is no cap on damages recoverable from a single manufacturer for claims arising out of a single incident or accident.

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

Because the settlement proposal shall be made by the court, court approval is substantially required for settlements made at the court proceedings, including class actions.

According to Paragraph 1, Article 54 of the CPA and Paragraph 1, Article 41 of the Code of Civil Procedure, if a mass of parties get injured out of the same consumer relationship, they can select one or more persons to bring an action for damages from themselves on behalf of the appointing parties and the appointed parties.

In addition, pursuant to Paragraph 1, Article 51 of the Code of Civil Procedure, in cases involving minor or incompetent persons, the legal guardian can represent him/her when conducting litigation or the court will appoint a special representative for minors or incompetent persons.

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

National Health Insurance is founded for people with Taiwanese nationality. According to Paragraph 2, Article 1 of National Health Insurance Act, this health insurance is compulsory social insurance. Benefits shall be provided during the insured term under the provisions of this Act, in case of illness, injury, or maternity occurred to the beneficiary. The insurance is funded by the Government and the insurance premiums are paid by the insured. Benefits provided to the insured by the Government in respect of the injury allegedly caused by the product are not recoverable from a third party.

7 Costs / Funding

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

According to Article 78 of the Code of Civil Procedure, the losing party shall bear the litigation expenses, including the cost of filing a suit, appeal, rehearing proceeding, re-appeal and petition for payment order, etc. Therefore, court fees and other incidental expenses could be recovered from the losing party. However, based on Article 82 of the Code of Civil Procedure, if the successful party has failed to present means of attack or defence in a timely manner, or to meet a specified date or period, or otherwise delayed the proceeding, the court may order the successful party to bear all or part of the litigation expenses incurred from the delay.

With regards to their own legal costs of bringing the proceedings, such as attorney fees, for the first and second instance, the litigation expenses do not include attorney fees, so the successful party cannot recover such expenses from the losing party. For the third instance, attorney fees are included as a part of the litigation expenses and can be recovered from the losing party, notwithstanding that the amount shall not exceed NT$500,000.

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

Based on Paragraph 1, Article 107 of the Code of Civil Procedure, except in cases where there is manifestly no prospect for a party to prevail in the action, where a party lacks the financial means to pay the litigation expenses, the court shall, by ruling on a motion, grant litigation aid. However, the litigation aid only covers court costs and other incidental expenses; attorney fees are not included in litigation aid. In addition, the Legal Aid Foundation may provide legal services for low income individuals or those who need such assistance, as determined by the Legal Aid Foundation, and the whole or part of the attorney fees would be remitted.

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

For low income individuals, for example, to be eligible for the public funding by the Legal Aid Foundation, a single person living in Taipei shall have a monthly disposable income not exceeding NT$28,000 and shall not have disposable assets with an equivalent value of more than NT$500,000.

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

No, it is not.

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

Pursuant to Article 30-2 of the Regulation of Lawyer Ethics, an attorney shall not accept the third party funding for attorney fees unless the client's informed consent has been obtained and unless such arrangement will not influence the independent professional judgment of the attorney.

An attorney shall avoid receiving attorney fees from a third party in order to prevent ethical issues and conflicts of interest, or the violation of the duty of confidentiality and of attorney-client privilege.

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

No. According to the Code of Civil Procedure, the court cost shall be levied on the basis of the price or value of claim proportionately; however, the Court does not exercise any control over the costs to be incurred by the parties.

8 Updates

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

The Consumer Protection Committee, Executive Yuan, approved the amended Mandatory and Prohibited Provisions of Standard Form Contracts for Instant Messaging Service ("**Regulations**"), which will take effect on May 1, 2018. The aim of the Regulations is to reduce consumer disputes in relation to accounts being hacked or suspended, or in-app purchases (e.g., stickers) disappearing. Pursuant to the Regulations, business operators have to disclose the following items to users: (i) their corporate names and contact details; (ii) the content of contracts and services; (iii) the ground(s) on which business operators may terminate the contract and suspend offering services; and (iv) the consumer dispute resolution mechanism(s). In the event that a consumer's account is hacked, the business operator must notify the consumer and discontinue his/

her account, and then re-open the account after the consumer has changed his/her password. Moreover, if a consumer's account is deleted due to the consumer changing his/her terminal device or the account being hacked, the business operator has to aid the consumer in recovering his/her account, prepaid amount and in-app purchases (e.g., stickers).

In recent years, owing to a series of food safety scandals in Taiwan, consumer protection groups initiated many product liability class action lawsuits. In October 2013, the Consumer Protection Association of Taiwan was delegated by 3,776 consumers to file a class action lawsuit against a local edible oil producer that was found guilty of adulterating cheaper cottonseed oil into higher-end cooking oil to increase profits. On 18 December 2017, the court rendered a judgment ordering the dishonest producer to pay compensation of around NT$91 million (approximately US$3 million) to 2,840 victims, the amount of which shattered the previous record regarding class action lawsuits for food product liability in Taiwanese judicial history.

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 a senior associate at Lee and Li. His primary areas of practice include food safety, mergers and acquisitions, product liability, commercial transactions, general corporate matters, and 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 obtained his LL.B. from the National Taiwan University, and holds an LL.M. degree in international law from Columbia Law School and an LL.M. degree in global health law from Georgetown University Law Center.

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 100 Taiwanese lawyers, patent attorneys, technology experts, and specialists in other fields.

Chapter 28

Turkey

Noyan Turunç

Esin Çamlıbel

TURUNÇ

1 Liability Systems

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

The rules regarding product liability are regulated under the Turkish Code of Obligations, Law No. 6098 (the **"COO"**) and the Law of Consumer Protection, Law No. 6502 (the **"LCP"**). Furthermore, the Law on the Preparation and Implementation of Technical Legislation Products, Law No. 4703 (the **"Technical Legislation Law"**) may also be applicable in a product liability case depending on the circumstances of the matter. Furthermore, secondary legislation relating to product liability consists of regulations such as Regulation of Liability for Damages arising from Defective Goods (the **"Product Liability Regulation"**) and Market Surveillance Regulation.

Under Turkish Law, it is a controversial issue whether there is strict liability for product liability cases, in large part because liability is regulated only by an article of the Product Liability Regulation and not by statute. The referenced article states that in case the defective product causes a person's death or injury or causes damage to a property, the manufacturer is obliged to indemnify such damage irrespective of the negligence of the manufacturer. While the Supreme Court has held that there is no strict liability for the manufacturer, the manufacturer must take every possible precaution to eliminate the risks.

Because the LCP defines the consumer as a real or legal person who acts for non-professional or non-commercial purposes, a potential dispute that arises between a trader and the seller because of a defective good will be settled as per the provisions of the COO. Claiming compensation for material or moral damage from the manufacturer or seller (or both) will also be a matter of contractual liability under these general provisions.

As for criminal liability, the Turkish Criminal Law foresees the liabilities in cases of selling, supplying or keeping food materials or drugs that endanger human health, as well as producing or selling medical or other substances that endanger human life.

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

The state does not operate any schemes of compensation for particular products. A direct connection between the damage caused and the specific defect must be firstly proven in order to declare direct responsibility.

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

The LCP does not contain a special provision regarding the damages incurred due to the defective products. Rather, it refers to the COO for compensation claims listed in Article 11 related to the defective products.

As per the Product Liability Regulation, where two or more persons are liable for the damage, they will be jointly liable. The LCP foresees joint and several liability for the manufacturer, seller and importer for the optional rights of the consumer**,** in case a damage has occurred because of a defective product.

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

Pursuant to the Technical Legislation Law, the regulatory authority authorises Conformity Assessment Offices, which appoint Notified Bodies to supervise the market. The Technical Legislation Law includes administrative fines up to TRY 135,000 in the event these offices fail to comply with their obligations and allow defective products to be released onto the market.

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 products should possess the requirements set forth in the technical regulations. Producers, on the other hand, are obliged to investigate if there are any complaints related to their products and perform tests to resolve any problems. As part of their surveillance, regulators conduct tests to ensure that such products have been produced in accordance with applicable regulations. If it is understood that a product is not safe, regulators have the power to require the manufacturer to recall the product. Furthermore, producers must notify the distributors of the products as well, and take every possible precaution, such as applying product recalls and destroying the affected products, if it is not possible to rectify the problem following the complaints. If producers fail to comply with the recall process, an administrative fine of up to TRY 285,000 will

be imposed. If a consumer detects a defective product that shall be subject to recall, he/she may file an individual case within the scope of the LCP.

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

Criminal liability may arise under certain conditions in the event of injury or death due to the products or services. Article 186 of the Turkish Criminal Code sets forth that "selling, supplying or keeping food materials or drugs that endanger human health are sentenced to imprisonment of one year to five years and a judicial fine corresponding to up to 1,500 days is imposed". Article 187 establishes that persons producing or selling medical products that endanger human life and health can be sentenced to imprisonment from one to five years and a judicial fine is also imposed. Finally, under Article 194, imprisonment of six months to one year is foreseen for those who provide or present substances for consumption which endanger human health.

2 Causation

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

In principle, under Turkey's legal framework, plaintiffs bear the burden of proof unless there is a specific statutory provision.

As such, per Article 6/2 of the Product Liability Regulation, the plaintiff is required to prove the defect in the product, the damage it suffered, and the causal link between the defect and the damage. However, pursuant to Article 10/1 of the LCP, defects detected within six months of the date of delivery are deemed existent at the time of delivery, thus the burden of proof lies on the defendant in such cases.

2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

A direct connection between the damage caused and the specific defect must be established by the claimant. Expert and documentary evidences are admitted to prove causation. Testimonial evidence is generally not because the dispute is related to a technical issue, and it is normally not legally feasible to prove controversial technical details based on oral testimony.

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

In principle, where more than one person is responsible for the same damage, their liability towards the person injured is joint and several. A party who is exposed to the claims of the consumer shall use its recourse right against the other liable persons as per their internal relationship *pro rata* to their contribution to the defect.

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

In case the manufacturers fail to provide adequate warnings for open and obvious risks, this can give rise to their liability. If the use of a product is not safe for the consumer, this fact must be made known. Turkish Law does not apply the "learned intermediary" theory. In case of a defect, all producers, importers and dealers/distributors are jointly liable for losses incurred due to the defective product. The Product Liability Regulation provides that in the event that producers, importers and dealers/distributors duly inform the consumers and successfully complete the recall process, all will be released from liability.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The manufacturer shall not be liable if it proves any of the below:

a. that the product was not launched into the market by the manufacturer;

b. that the product was not produced for selling, or was not manufactured during commercial or professional activities;

c. that, having regard to the circumstances, the defect which caused the damage did not exist at the time when the product was supplied to the market;

d. that the defect was caused due to the compliance of the product with applicable technical regulation; or

e. that the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the existence of the defect to be known.

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

There is a state of the art defence, as noted above under question 3.1 (point e), and it is for the manufacturer to prove that the fault/defect was not discoverable.

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

Under Article 5/4 of the Technical Legislation Law, the manufacturer can be released from liability if it can prove that it did not supply the unsafe product to the market, or the unsafe product derived from following the relevant technical regulations, as is the case with the Product Liability Regulation Article 7.

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

Every court reviews each specific case within its own conviction. If a separate court has already tried on the same defect, such judgment would be persuasive, provided they share the similar facts. There is no issue of estoppel preventing a different claimant from bringing an action against a defendant in separate proceedings.

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

Regardless of being a player in the product supply chain, indemnification can be claimed by the defendant in subsequent proceedings through the right of recourse. Consumers may file a case against all involved in the chain of production. Thus, if the responsible third party for the damage has relation to the product supply, indemnification can be required during the same proceedings.

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

Per Article 6 of the Product Liability Regulation, the liability of the manufacturer may be reduced or removed, if it is proven that the damage is caused by the consumer or any person for whom the consumer is responsible.

4 Procedure

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

There is no jury system under Turkish Law. Disputes, including product liability claims, are tried by civil courts and all decisions are made 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, if the court finds that the issues to be proven require special technical knowledge, technical expert assessors may carry out the work involved for pursuing these purposes. The court may appoint one or more experts.

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

The LCP has some specific provisions related to class actions or representative proceedings. Consumer organisations, relevant public authorities and the Ministry of Customs and Trade have the right to file a lawsuit for the suspension of production and sale of the defective product, and for the collection of these products from third parties which possess such products for sale. However, class actions are rarely used in Turkey.

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

Yes (see above under question 4.3).

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

A complex product litigation takes approximately between 18 and 24 months following its filing, and the justified decision is issued one to three months after the final hearing. The above-mentioned periods generally depend on the courts workload. If the justified decision is appealed to Regional Court of Justice and Supreme Court, respectively, by one of the parties, the period may extend over four years, on average.

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

Yes, the court can try preliminary issues that relate to the law at the time of the main trial.

4.7 What appeal options are available?

A new appellate process was introduced a short while ago. There are two types of appeals in Turkey: a) examination of the Turkish Regional Court of Appeal; and b) examination of the Supreme Court. Thus, the Regional Court of Appeal will function as a "court of cassation". In principle, final decisions concerning material rights may be appealed; however, actions for amounts under TRY 3,560, for 2018, are final and not appealable.

Decisions which are appealed before the Turkish Supreme Court hereinafter will firstly be subject to the examination of the Turkish Regional Court of Appeal, which will have the jurisdiction to examine the decision on procedural grounds and merits of the case, and will be able to repeat certain procedural steps, as opposed to the Supreme Court, which can only examine the case over the file. Under the current system, if the claim amount is lower than TRY 47,530, the decision of Turkish Regional Courts of Appeal is not appealable before the Supreme Court.

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

Both parties can rely on expert opinion evidence. The court is also entitled to rule for an expert opinion for technical matters that require specialist knowledge. The court may decide to listen to the expert who prepared the written opinion. However, if the expert does not accept the invitation, the report will not be taken into consideration. The Turkish Code of Civil Procedure, Law No. 6100 (**"CCP"**), states that the judge cannot decide to have an expert opinion on legal issues and the outcome of the expert report is not binding on the judge. In addition, the parties may submit expert/technical reports supporting their claims to the court.

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

There is no pre-trial in the Turkish procedural system. Factual and expert witnesses may be required to present themselves at the hearing or trial.

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

Pursuant to current practice, each party submits two petitions to the court including their claims and arguments before the investigation phase of the case. In the preliminary investigation hearing, the court will order the parties to submit their evidence that they have not yet submitted within two weeks. Any party failing to submit its evidence shall forfeit the right to submit additional evidence and the court shall immediately proceed to the "investigation" phase, whereby it would evaluate the parties' petitions/evidence collectively and subsequently make its judgment.

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

Arbitration, which has long been recognised, has only recently become a more familiar method of alternative dispute resolution in Turkey. Mediation, on the other hand, was not recognised as a method in Turkey until the Law on Mediation for Civil Disputes, Law No. 6325 came into force in 2012. Accordingly, parties can choose mediation or arbitration as the means for resolving their disputes. However, for product liability cases, it is not obligatory for the parties to pursue arbitration or mediation prior to filing a lawsuit.

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

Pursuant to the CCP, if a party is not domiciled in Turkey, courts located at the habitual residence of the party have jurisdiction. However, if the party does not have a habitual residence, courts located where the damage is alleged to have occurred have jurisdiction.

5 Time Limits

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

Yes, please see question 5.2.

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

Unless a longer period is agreed between the parties, the claim should be brought before the courts within two years starting from the time of delivery of the goods to the consumer, and in any case, the claim would be time-barred 10 years after the damage occurs.

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

If the defect is hidden from the consumer due to the seller's fault or negligence, the statute of limitations periods do not apply.

6 Remedies

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

In case of a defect, the consumer is entitled to choose among the rights provided alternatively under the Article 11 of the LCP, which are: (1) the right to ask for free repair; (2) the right to ask for the replacement of the good with a defect-free one; (3) the right to terminate the contract; and (4) the right to demand a discount from the sale price in proportion to the defect. The plaintiff-consumer can also ask to be compensated both for the material and immaterial damages if the required conditions set forth by the COO are met.

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

Within the scope of material damages, treatment costs, funeral costs, damages incurred, including those to be incurred, as a result of the loss or impairment of the injured party's ability to work and loss of earnings can be claimed. Within the scope of moral damages, an appropriate compensation will be ruled by the court considering the circumstances of the matter for the plaintiff's psychological/mental damages.

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

If a causal link between the defect and the damage exists, the costs may be recovered.

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

No, they are not recoverable.

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

According to Turkish Law, the compensation amount cannot exceed the plaintiff's actual damage since as a general rule, compensation cannot be enriching.

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

Parties may partially or entirely settle the dispute before trial or during the litigation, up until the final judgment is rendered. During the preliminary investigation, the court encourages parties to settle or mediate. If the parties choose not to exercise these options, the court will continue to try the case. Settlement is legally binding and equivalent to a final judgment.

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

No such claim by government authorities is contemplated under Turkish Law.

7 Costs / Funding

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

The successful party may recover litigation expenses from the losing party in proportion to the amount awarded. The legal fees to be reimbursed to the successful party shall be determined according to the minimum attorney fee tariff issued by the Turkish Bar Association. With regards to the attorney fees, the litigation expenses do not include attorney fees, so the successful party cannot recover such expenses from the losing party.

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

Yes, articles 334–340 of the CCP set out the provisions regarding public funding by the state for people who experience financial difficulties.

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

Legal aid may be granted to low-income citizens who are unable to afford the required legal expenses.

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

Pure contingency fees are not acceptable in Turkey. It is possible to determine the amount of the legal fee based on a certain ratio up to 25% of the total amount to be ruled by the court.

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

Turkish Law does not provide any specific regulations regarding third-party funding; however, litigation funding by third parties is not forbidden in Turkey. Claimants who have a strong case but limited finance to pursue it, or simply prefer to seek external funding, can apply for litigation funding to finance their case.

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

No, it does not.

8 Updates

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

In line with Turkey's efforts to harmonise its laws with EU legislation, the LCP resembles relevant Directives and places significant emphasis on consumer protection. The scope of the LCP covers all consumer transactions and all other consumer-related practices. It aims at specifically regulating certain acts and practices of private/public commercial or professional entities prior to or after their conclusion of any agreement with consumers. Secondary legislation promulgated under the LCP and recent court decisions also indicate an increased level of consumer rights and protection, again, in line with EU practices.

Noyan Turunç
TURUNÇ
Tesvikiye Caddesi 19/11
Tesvikiye 34365
Istanbul
Turkey

Tel: +90 212 259 45 36
Email: nturunc@turunc.av.tr
URL: www.turunc.av.tr

Noyan Turunç is the Firm's founding partner. Mr. Turunç has decades of experience advising multinational and domestic corporations in a wide variety of industries including automotive, banking, consumer goods, energy, industrial goods, insurance and reinsurance and telecommunications across many jurisdictions including Turkey, the EU, the United States, Asia and Latin America.

Mr. Turunç's experience covers a wide spectrum of areas, including banking and finance, product liability, mergers and acquisitions, insolvencies, project finance, competition (antitrust), labour and employment, and tax. Mr. Turunç also has extensive experience in litigation with respect to corporate issues.

Before founding TURUNÇ, Mr. Turunç was general counsel at Boeing Services (Turkey) and The Coca-Cola Export Corporation (Turkey). He has also served as an independent board member and chairman of the audit committee of Aksigorta, a publicly listed company and one of the largest insurance companies in Turkey.

Mr. Turunç is also the author of numerous publications.

Esin Çamlıbel
TURUNÇ
Tesvikiye Caddesi 19/11
Tesvikiye 34365
Istanbul
Turkey

Tel: +90 212 259 45 36
Email: ecamlibel@turunc.av.tr
URL: www.turunc.av.tr

Dr. Çamlıbel is an expert in commercial law, competition law, European Union law, intellectual property law, and international trade and WTO laws. Dr. Çamlıbel has extensive experience in advising domestic and multinational clients in a wide variety of industries on these topics.

Dr. Çamlıbel is also an assistant professor of law at **Dokuz Eylül University**, where she is the head of the Commercial Law Branch of the Business Administration Department in the Faculty of Economics and Administrative Sciences, and the deputy head of the Graduate Department of EU Studies there. She is also the coordinator for the Jean Monnet Module on "Strengthening the Competition Culture During the Accession Process", a teaching program co-funded by the European Commission. Dr. Çamlıbel has also written and lectured extensively on a wide range of topics.

TURUNÇ

Founded in 1990, TURUNÇ is a leading law firm providing a broad range of cutting-edge legal services to a global clientele through three integrated offices in each of the three largest cities in Turkey.

In addition to its core commercial, corporate governance, transactional practices, TURUNÇ delivers advice on all specialised areas, e.g., competition law, intellectual property and labour law, making corporate governance and transactions cost-efficient for clients.

TURUNÇ complements its corporate practice with a matching force in its dispute resolution department, which litigates several hundred cases each year in various industries across a wide spectrum of areas including tort and product liability defence, corporate and commercial disputes, competition litigation, finance litigation, insolvency, administrative disputes, and customs and tax litigation. TURUNÇ also represents clients in the enforcement of foreign judgments and arbitral awards.

United Arab Emirates

Hamdan AlShamsi

Hamdan AlShamsi Lawyers & Legal Consultants

Omar Kamel

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 strict in particular for the regulations found with department or the consumer protection. The articles of the law allow for 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 and the definition of a provider under the UAE Federal Consumer Protection Laws are 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 who supplies goods and services to the 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 to go 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 to 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 breach. The primary sanction is a fine of between AED 10,000 and AED

1,000,000 for a wide range of offences, including:

1. displaying, offering, promoting or advertising any goods or services which may inflict damage on the consumer in the course of ordinary usage;
2. labelling the product other than in compliance with legal requirements;
3. failing to provide appropriate warnings to consumers as to the risks associated with the product;
4. failing to comply with approved standard specifications; and
5. artificially creating 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 the 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 which was 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.

The ADQCC and Dubai Municipality have the power to take samples of products and arrange for them to be tested against the applicable standards set by ESMA. When a breach is discovered, the supplier is notified and given an opportunity to undertake their own investigations, and, where agreed, may obtain their own test report. After the outcome of further testing, additional reports may be commissioned by the regulator and a decision is then made as to whether the defect merits a recall. If that is the case, as neither the ADQCC nor the Dubai Municipality have the necessary enforcement powers, the MOE is asked to authorise the recall based upon the available evidence. The MOE usually accepts the recommendations of the ADQCC or Dubai Municipality that a product should be recalled, unless the supplier successfully negotiates an alternative solution.

The incidence of product recalls in the UAE is on the increase. As the ESMA continues to set applicable standards for a wider range of products, the opportunity for investigation and testing increases, and once a *prima facie* case of non-compliance is established, the regulators are under a duty to act in the interests of consumer safety. Both the Dubai Municipality and the ADQCC have been active in recalling products from the market, and, of course, once one Emirate has ordered a recall, it is almost inevitable that the supplier will be required to recall the product in neighboring Emirates. The ADQCC have recalled thousands of products since its establishment in 2009, primarily following testing which proved that the product did not comply with standards set by the ESMA. Recently recalled items include an array of electrical appliances (where there are obvious safety concerns), including juicers, blenders, rice cookers and deep-fat fryers.

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 concept liability; 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 in the details in a 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 respecting labeling 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 the traders and distributers.

3 Defences and Estoppel

3.1 What defences, if any, are available?

The defences that a defendant can have are 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 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 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 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 by 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 How long does it normally take to get to trial?

In product liability disputes an application can be brought before a judge and parties properly served in approximately three months, thereafter the judge and parties will submit responses and evidences to the courts, or otherwise the courts appoint experts and makes orders, until the courts eventually deliver judgment.

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

The courts may by law try preliminary issues like jurisdiction; however, generally the courts will deliver one judgment at the end which will deal with all the matters or otherwise a preliminary matter.

4.7 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.

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

Yes, the court usually appoints one or more expert to provide their opinion regarding the disputed matters, parties are able to rely on expert opinion evidence. 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.

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

The 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 practise 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.

4.10 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.

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

There is no general requirement for alternative methods of dispute to be followed before the suit, and only in exceptional cases does the law require parties to follow an alternative dispute resolution before claiming before the courts.

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

The law on jurisdiction in the UAE can entertain a case against a person that is domiciled outside 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 of price; 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 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 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, in no more than 300 words, a summary of any new cases, trends and developments in Product Liability Law in your jurisdiction.

Answer not available at time of print.

Hamdan AlShamsi
Hamdan AlShamsi Lawyers & Legal Consultants
Office 1611, 16th Floor, Al Manara Tower
Al Abraj Street, Business Bay
Dubai
UAE

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.

Omar Kamel
Hamdan AlShamsi Lawyers & Legal Consultants
Office 1611, 16th Floor, Al Manara Tower
Al Abraj Street, Business Bay
Dubai
UAE

Tel: +971 4 346 9262
Email: hamdan@alshamsilegal.com
URL: www.alshamsilegal.com

Holding a Master's Degree in Commercial law and a member of the Jordanian Bar since 2001, Mr. Kamel is an experienced corporate counsel possessing strong post-qualification experience in commercial practices in MEA. He is also profoundly skilled in corporate and restructuring matters, investments, corporate actions, intragroup transactions and service arrangements, specialises in general mergers and acquisition practice, strategic transactions and corporate restructurings, draft documents incidental to formation and ongoing business operations of corporations, partnerships, and limited liability companies; he advises on corporate governance matters (including resolutions, preparing board and committee meeting materials and agendas and maintaining corporate records), and has experience in cross-border transactions, real estate and commercial finance transactions covering licensure, development and supply agreement.

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, and 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 programs to compensate individuals injured by certain types of products and exposures.

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

Plaintiffs can name any entity within the distribution chain of a product as a defendant. As the entity responsible for placing the allegedly defective product into the stream of commerce, manufacturers are usually the primary target of defect claims. The extent of responsibility for fault/defect varies among states. Defences, including those known as "seller exceptions", are sometimes afforded to non-manufacturers; exceptions vary by state and often require the non-manufacturer to show that it did not contribute to the alleged defect and had no knowledge of the alleged defect.

1.4 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 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 specifies the length of time a plaintiff has to file a claim after an injury occurs or after the plaintiff should have "discovered" a latent injury. The statute of limitations for product liability cases varies by state, generally from two to six years.

Unavoidably unsafe products. Comment k of Section 402A of the Restatement Second of Torts covers products that are incapable of being made safe for their intended and ordinary use. If a product

meets this criterion, states that accept this defence require evidence that the product was properly manufactured and contained adequate warnings of the known and unavoidably unsafe propensities of the product.

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

State-of-the-art design is an absolute defence in some states and, in others, can be used as evidence of non-negligence and as evidence that a feasible alternative design did not exist at the time of manufacture. Plaintiffs often rely on expert testimony to put forth an alternative design. To rebut a plaintiff's expert and support a state-of-the-art argument, defendants may submit evidence that: (1) shows compliance with federal regulatory design standards; (2) shows the manufacture submitted relevant material to a regulatory agency before gaining government approval; and (3) shows compliance with industry standards.

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

Few states recognise compliance with regulatory requirements as a defence to products liability claims.

Also see questions 3.1 ("Pre-emption") and 3.2 above.

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

United States courts give full faith and credit to prior judgments in any state court. Claims brought by unrelated claimants are not subject to estoppel; every plaintiff has a right to litigate their claims. A prior plaintiff's case against the same defendant does not preclude a subsequent plaintiff from litigating the same product liability issues. Plaintiffs are precluded from re-litigating issues if the issue has already been the subject of final judgment on the merits, related to a single transaction or injury, and involving the same parties.

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

Contribution claims are generally apportioned among the tortfeasors relative to culpability in terms of the percentage of fault for the plaintiff's injury. Indemnity generally shifts liability completely to one party, most often up the distribution chain toward the manufacturer. Indemnification can originate from a contractual agreement or negligence on the part of a third party. In certain jurisdictions, multiple defendants in a case are considered joint and severally liable for a plaintiff's injury, which makes each defendant liable for the entire judgment. In those cases, defendants who pay more than their apportioned share generally have a right to contribution against other defendants.

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

Several jurisdictions account for such contribution by reducing the damages awarded by the percentage of fault attributed to the plaintiff's own actions in causing the accident. In addition, a plaintiff's contributory negligence can be used as evidence that the defendant's product was not the proximate cause of an accident.

Defendants can also seek to reduce damages by invoking an affirmative defence to show that the plaintiff, through his own actions, assumed the risk. (See question 3.1 "Assumption of Risk".)

4 Procedure

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

Every trial has a judge and a fact finder. A judge always rules on legal issues. The fact finder can be either the judge or a jury. Federal and state rules of procedure allow any party to demand a jury trial on any issue triable. Parties can waive this right and proceed with a bench trial, meaning the judge rules on both legal and fact issues.

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

Federal Rule of Civil Procedure ("FRCP") 53 allows a judge to appoint a special master to hold trial proceedings and, in some instances, make findings of fact on exceptional conditions. Special masters may address pre- and post-trial matters that cannot be timely addressed by the judge.

See question 4.8 below for a discussion of Federal Rule of Evidence 706.

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

FRCP 23 sets forth the following prerequisites for class certification: (1) the class is so numerous that joinder of all members of the class is impractical; (2) there are questions of law or fact common to the class; (3) the claims or defences of the class representative parties are typical of the claims or defences of the class; and (4) the representative parties will fairly and adequately protect the interest of the class. Most states have class action procedures similar to the federal rules.

A plaintiff may seek certification of a class for product liability claims that a defendant manufactured an unreasonably dangerous product. Each plaintiff must have a valid cause of action. In the case of personal injury claims, plaintiffs often have difficulty certifying the class because the extent of alleged injuries among plaintiffs can vary widely, meaning individuals of the proposed class are not representative of others in the class. The individual assessment of each plaintiff's damages and injuries reduces the frequency with which class actions are seen for products liability litigation.

In the case of products liability class actions, plaintiffs opt-out or they are bound by the outcome.

Parties can also file motions before the Judicial Panel on Multidistrict Litigation which determines whether civil actions pending in different federal districts involve one or more common questions of fact such that they should be transferred to one district for coordinated proceedings.

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

Generally, no one other than the injured party can bring a claim against a manufacturer. This includes representative bodies as they have no standing to file claims for injuries sustained by members. Rarely, claims can be brought "in the public interest" by an individual.

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

The time from filing a claim to trial varies depending upon both the case and the jurisdiction. In complex product litigation, the pre-trial process can take one to two years and sometimes longer depending on whether it is a single plaintiff with a single set of issues or a consolidation of hundreds of cases from multiple jurisdictional districts.

State courts' trial calendars also vary significantly by jurisdiction.

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

Under FRCP 42, when there are common questions of law or fact, courts can order separate trials on one or more separate factual issues, claims, crossclaims, counterclaims, or third party claims. Deciding a preliminary issue related to several actions can assist the court in avoiding prejudice or expediting and economising consolidated hearings.

Prior to trial, defendants can move for summary judgment to dispose of specific claims or the entire case where there is no genuine issue of material fact and judgment may be entered as a matter of law. During trial, a court can grant a directed verdict or judgment as a matter of law after the plaintiff's case is presented if the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the plaintiff.

4.7 What appeal options are available?

Final judgments can be appealed to a higher court, usually within 30 days after entry of judgment or order appealed from. Fed. R. App. P. 4. Appellate courts apply different standards, depending on the type of issue being appealed. Factual determinations at the trial level are rarely overturned. Questions of law are reviewed *de novo*. The appellate court will not overturn the decision unless the trial court's error was likely to have impacted the outcome. A successful appeal can result in reversal, a new trial, or remand for further proceedings in the trial court.

In rare cases, an interlocutory appeal may be made before final judgment. 28 U.S.C. §1292. State appellate procedures vary by jurisdiction but are generally similar to the federal rules.

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

Federal Rule of Evidence 706 allows a court to "appoint any expert that the parties agree on and any of its own choosing".

State evidentiary rules and Federal Rule of Evidence 702 allow parties to present an expert's testimony. Rule 702 sets forth four requirements that must be met for a witness who is qualified as an expert by knowledge, skill, experience, training or education to provide expert opinion testimony: "(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied principles and methods to facts of the case".

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 50 U.S. 579 (1993), the Court charged trial judges to act as gatekeepers in assessing the reliability of scientific expert testimony. Several factors can be used to determine whether an expert's testimony is reliable, including: (1) whether the expert's theory can be tested; (2) whether the expert's theory has been subjected to peer review and publication; (3) the known or potential rate of error of the particular scientific technique; and (4) whether there has been "general acceptance" of the expert's theory or technique.

There are often pre-trial hearings to determine the admissibility of expert evidence.

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

FRCP 26 requires parties to disclose the names and addresses of individuals likely to have discoverable information that the disclosing party may use to support its claims or defences, unless the use would be solely for impeachment purposes, as well as the identity of any witness who may be used at trial to present expert opinion evidence. Disclosure of expert witnesses, unless otherwise stipulated or ordered by the court, must be accompanied by the expert's written report.

State rules vary on the requirements of fact and expert depositions and expert report disclosure.

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

FRCP 26 requires parties to provide, as part of initial disclosures, a copy or description by category and location of all documents, electronically stored information, and tangible things that the disclosing party has in its possession, custody or control that may be used to support its claims or defences. Rule 26 also requires a party, as part of its pre-trial disclosures, to identify each document or exhibit that the party expects to offer or may offer at trial.

Parties may also serve interrogatories and requests for production of documents. Rule 33(b)(3) requires that a party provide answers and/or objections with specificity to each interrogatory, separately and fully in writing under oath. Requests for production must also be responded to either by objections, specifying the reasons for such objection, or state that copy and inspection will be permitted as requested.

If parties fail to disclose such documents as required by Rule 26(a) or respond to discovery requests pursuant to Rule 33 or Rule 34, numerous sanctions are available under Rule 37.

In the *In re: Actos (Pioglitazone) Products Liability Litigation*, a jury returned a $9 billion punitive damages award against defendant manufacturers after the jury heard evidence of the defendant's alleged destruction, or spoliation, of evidence. This verdict was later reduced to $37 million and then voluntarily dismissed pursuant to a $2.4 billion global settlement.

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

Alternative dispute resolution is available in state and federal courts. The types of arbitration available include arbitration, mediation, and negotiation. The programmes for alternative dispute resolution vary by state. Rule 26(f) of the Federal Rules of Civil Procedure requires parties to discuss settlement as part of their initial conference and judges often encourage parties to consider settlement discussions and mediation at various stages in the pre-trial discovery process. Additionally, courts in certain jurisdictions are authorised by local rules to mandate mediation between parties.

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

Persons or corporations not domiciled in the United States can be subject to suits here if personal jurisdiction exists. To establish personal jurisdiction, due process requires that a defendant has "certain minimum contacts" with the forum "such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice'". *International Shoe Co. v. Washington*. Personal jurisdiction can be established through specific or general jurisdiction.

In 2014, the Supreme Court 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 having an immediate impact on 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 Litigation is becoming increasingly common and is often used by plaintiffs in pursuing complex litigation claims.

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

FRCP 1 states that the Rules should be construed to "secure the just, speedy, and inexpensive determination of every action and proceeding". A practical manner for controlling costs is court

oversight to ensure that cases proceed expeditiously. However, not all courts focus on strict oversight as a cost control measure.

Additionally, courts are empowered to examine the proportionality of costs in considering the merits of discovery requests. Pursuant to amended FRCP 26(b)(1), information is discoverable if it is relevant to the party's claim or defence and is "proportional to the needs of the case". Proportionality factors to be considered include: the amount in controversy; parties' relative access to relevant information; parties' resources; importance of the discovery in resolving issues; and whether the burden or expense of the proposed discovery outweighs the likely benefit. Courts may deny discovery requests where the burden and cost of compliance is deemed too high; alternatively, while rare, courts may impose cost sharing to compensate for the expense of compliance.

8 Updates

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

In June 2017, the US Supreme Court limited the ability of plaintiffs to bring manufacturers into whatever jurisdiction they choose. In *Bristol-Myers-Squibb v. Superior Court*, the Court rejected California's expansion of specific personal jurisdiction to cover claims by nonresident plaintiffs against a nonresident defendant for injuries that did not occur in California. The Court held 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. This opinion has already impacted the practice of "forum shopping" with subsequent dismissals of cases brought in states by nonresident plaintiffs with no personal jurisdiction over defendants for their claims.

Also, there remains uncertainty regarding the impact of the Trump presidency on product liability litigation. The general expectation is legislative reform efforts to reduce the volume and cost of litigation. That said, the private practices of President Trump signal a potential deviation from this position. As a private businessman, Mr. Trump was an active litigant and as president he has not made litigation reform an issue.

There are indicators that the Trump administration will maintain continuity with expected tort reform positions. For example, litigation reform legislation generally falls in line with President Trump's emphasis on de-regulation, less federal oversight and diminished directives for federal agencies to utilise enforcement powers. The president has appointed and nominated judges largely supportive of de-regulation and federal preemption of certain types of tort claims.

Overall, it would be surprising if President Trump breaks with the prevailing sentiment of the business community and the Republican Party, which favours litigation reform.

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, Partner in the Products Liability & Mass Tort department of Drinker Biddle & Reath LLP, 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 programs 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 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. Dan received his J.D. from Seton Hall University School of Law while serving as one of the editors for *The Home News*.

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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