THE PRODUCT REGULATION AND LIABILITY REVIEW

Fourth Edition

Editors
Chilton Davis Varner and Bradley W Pratt

THE LAWREVIEWS

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PREFACE

In today's global economy, product manufacturers and distributors face a dizzying array of overlapping and sometimes contradictory laws and regulations around the world. A basic familiarity with international product liability is essential to doing business in this environment. An understanding of the international framework will provide thoughtful manufacturers and distributors with a strategic advantage in this increasingly competitive area. This treatise sets out a general overview of product liability in key jurisdictions around the world, giving manufacturers a place to start in assessing their potential liability and exposure.

Readers of this publication will see that each country's product liability laws reflect a delicate balance between protecting consumers and encouraging risk-taking and innovation. This balance is constantly shifting through new legislation, regulations, treaties, administrative oversight and court decisions. But the overall trajectory seems clear: as global wealth, technological innovation and consumer knowledge continue to increase, so will the cost of product liability actions.

This edition reflects a few of these trends from 2016. Notably, many jurisdictions saw an increase in both mandatory and voluntary product recalls across various industries. In India, for instance, several global car manufacturers initiated voluntary recalls of vehicles owing to various product defects, such as emissions systems that violated environmental norms. This unprecedented rise in voluntary vehicle recalls spawned legislation known as the Motor Vehicles Amendment Bill, currently pending approval in the Indian Parliament, that would for the first time mandate vehicle recalls under certain conditions. Several jurisdictions also saw a proliferation of class actions in product liability contexts. In July, the Collective Claims Act came into force in Japan, enabling small consumer claims to be aggregated and pursued by 'certified organisations', which are required to disburse to consumers 50 per cent or more of the claims recovered from business operators. This edition also highlights how certain countries' product liability laws have grappled with novel issues in the modern economy, ranging from e-commerce (e.g., the Brazilian Superior Court of Justice's conclusion that internet search providers cannot be held liable for defective products marketed through their websites) to emerging technologies (e.g., Australia's interim ban on self-balancing scooters or 'hoverboards'). Although these changes and trends may be valuable in their own right, they also create a need for greater vigilance on the part of manufacturers, distributors and retailers.

This edition covers 22 countries and territories and includes a high-level overview of each jurisdiction's product liability framework, recent changes and developments, and a look forward at expected trends. Each chapter contains a brief introduction to the country's product liability framework, followed by four main sections: regulatory oversight (describing the country's regulatory authorities or administrative bodies that oversee some aspect of

product liability); causes of action (identifying the specific causes of action under which manufacturers, distributors or sellers of a product may be held liable for injury caused by that product); litigation (providing a broad overview of all aspects of litigation in a given country, including the forum, burden of proof, potential defences to liability, personal jurisdiction, discovery, whether mass tort actions or class actions are available and what damages may be expected); and the year in review (describing recent, current and pending developments affecting various aspects of product liability, such as regulatory or policy changes, significant cases or settlements and any notable trends).

Whether the reader is a company executive or a private practitioner, we hope that this edition will prove useful in navigating the complex world of product liability and alerting you to important developments that may affect your business.

We wish to thank all of the contributors who have been so generous with their time and expertise. They have made this publication possible. We also wish to thank our colleagues Madison Kitchens and Jordan Raymond, who have been invaluable in assisting us in our editorial duties.

Chilton Davis Varner and Bradley W Pratt
King & Spalding and The Pratt Law Firm
United States
March 2017

Chapter 1

ARGENTINA

Ignacio Flores and Gonzalo García Delatour[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

Product liability in Argentina is largely regulated by the Consumer Protection Law 24,240 (LDC) – a rule of national scope passed in 1993 and which was the subject of important modifications in 1998 (Law 24,999) and 2008 (Law 26,361) – since the vast majority of the claims observed in practice are brought by consumers. These consumers can be considered as such in the strict sense, as well as the 'bystanders',[2] and they can be both individuals and legal entities.

According to the LDC, a consumer relationship exists between a professional supplier of a product and a consumer as 'final recipient, for his own benefit or his family or social group' (Article 1), and the interpretation of the Argentine courts has admitted in several cases that an entrepreneur or commercial company acquiring a product for its production chain does so as final recipient.

Relatively few cases fall outside the scope of the LDC, but such cases will be governed by the recently adopted Civil and Commercial Code (CCC) (as of 1 August 2015).

The civil and commercial courts also have an important role regarding consumer product liability claims. Generally these claims are settled on the national and federal levels as well as in the provincial courts where the LDC and the CCC are applied. In addition, consumer associations may initiate collective consumer actions, even those of a strictly pecuniary nature.

Consumer protection has been enshrined since 1994 in the National Constitution (at Article 42), which specifically establishes the guarantee for the protection of the consumer's health, safety and economic interests, as well as adequate and true information, freedom of choice and conditions of fair and dignified treatment.

The LDC provides for both judicial and administrative remedies, including conciliation instances and establishment of penalties before administrative bodies. The national and provincial states have issued rules for consumer protection.

In addition, the LDC regulates consumer associations, which have assumed a major role mainly in the proliferation of class actions.

The Criminal Code establishes penalties for those who cause injury owing to negligence or malpractice as well for those who endanger health by poisoning or adulterating drinking water, or food or medicinal substances, or goods dangerous for health.

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1 Ignacio Flores is a junior partner at Estudio Beccar Varela, and Gonzalo García Delatour is a partner at Estudio Beccar Varela.

2 Any person that is not a direct part of the contractual consumer relationship but he is also injured or affected by the defective product or service.

II REGULATORY OVERSIGHT

The consumer legal framework includes a few general obligations that overlap with those involving product regulations, for example, specific duties of information for products that may be considered 'dangerous', or general safety obligations. For this reason, agencies that have enforcement powers related to consumer regulation may impose certain remedies (e.g., fines) for breaching consumer regulations related to product liability.

Beyond these general obligations, there are no other consumer agencies that deal with any kinds of products.

There are, however, regulatory agencies that issue and enforce specific regulations regarding specific kinds of products (e.g., ANMAT, the food and drug regulator) and that may have points of contact with product liability.

ANMAT's main areas of responsibility include:

a control of the manufacturing, production, packaging, distribution, commercialisation, import and export of medicines, medical technology, food and cosmetic products;

b registration of medicines, medical technology, food and cosmetic products before their manufacturing, import, distribution and commercialisation;

c control of all clinical trials performed in Argentina; and

d control of manufacturing and commercialisation of household cleaning products.

Each of Argentina's 23 provinces also has a local health authority with concurrent jurisdiction to ANMAT on health matters. Persons and entities carrying out activities in connection with products involving health issues in any of those jurisdictions are subject to the control of both ANMAT and, depending on the specifics of each case, the local health authority where the activity is performed.

ANMAT can order the recall of a product and impose and enforce penalties detailed in local regulations, and manufacturers can defend and challenge penalties. The penalties include warnings; monetary fines; total or partial, temporary or definitive closure of the premises in which the breach occurred; suspension or barring of the activity performed by the laboratory; seizure of products in breach; and cancellation of the authorisation to manufacture or commercialise products.

III CAUSES OF ACTION

Product liability arises owing to a defect of a product that entails harmful consequences and that may be owing to defects in design, manufacture or absence of adequate information. Also there may be the event of default of the seller for failure to comply with contractual stipulations pertaining to the sale as well as breaches of the manufacturer or sellers regarding administrative rules concerning the products.

As mentioned before, the great majority of product liability claims are brought under the LDC, the remainder being governed by the common rules of the CCC regarding civil liability for a breach of the obligation not to harm (consumers always have the option to bring an action according to the provisions of the CCC, which are not excluded by the application of the LDC).

Contractual breaches are also governed alternately by the LDC or by the CCC.

Consumers can also report non-compliance with a contractual or legal provision to the authorities as well as the existence of a defect in the product, and they may even claim compensation for material damage (direct damage).

Non-compliance with governmental regulations (see Section II, *supra*) is subject to penalties by the relevant national or provincial authorities.

Finally, the Criminal Code (Article 84) establishes penalties of one to five years' imprisonment for those who cause the unintentional death of a person owing to negligence or lack of skill in their art or profession or non-compliance with the regulations for their duties. Should there be more than one victim, the minimum is two years' imprisonment.

In the case of unintentional damage to the body or health (physical injury), the penalty will be of one month to three years' imprisonment or a fine of 1,000 to 15,000 pesos (in aggravated cases, a minimum of six months' imprisonment and a fine of 3,000 pesos).

The Criminal Code also provides for penalties between three and 10 years' imprisonment for those who intentionally endanger health through drinking water, food or medicinal substances intended for public use. Such penalties may rise to between 10 and 25 years' imprisonment in the event of death. For cases of negligence or malpractice, fines range between 5,000 pesos and 100,000 pesos, and penalties of six months to five years' imprisonment are provided for cases of illness or death.

There are also many types of criminal offence concerning the trade of medical products or the violation of rules relating to animal health.

IV LITIGATION

i Forum

Product liability claims can be filed directly before the courts, but some jurisdictions (including the city of Buenos Aires, Buenos Aires province, Córdoba and others) require mandatory mediation before bringing the case to court.

The court that will intervene will normally be of a civil and commercial nature consisting in a judge of first instance whose decisions may be appealed before a court of appeal. There is the possibility of extraordinary appeals before supreme provincial courts and before the National Supreme Court for certain special cases.

Upon becoming aware that a product is dangerous, the supplier must report it to the relevant governmental authorities immediately[3] and to consumers through advertising.

Claimants sometimes report the case to a consumer authority before moving into the courts, usually to try to reach a quick settlement, otherwise if not, the authority would study the matter and can impose a fine of up to 5 million pesos and order this decision to be published.

In addition, the LDC provides for the closing down of a business for up to 30 days and the loss of administrative privileges, but such sanctions are not very usual.

An administrative claim does not prevent the commencement of legal actions.

Suppliers may not agree to arbitration with consumers. Suppliers are only allowed to register before the 'arbitration courts of consumption', which operate within the scope of the Secretariat of Commerce.

ii Burden of proof

According to the LDC, the consumer only has to prove the defect of the product and a causal relationship with the damage, without the need to prove the defendant's negligence or intent.

3 Article 4 of the regulatory decree of the LDC.

The defendant may only seek to break the causal link, proving that he or she was unrelated to the cause of the damage, a fact that generally takes place by proving the victim's fault.

The LDC establishes that the Attorney General's office (*Ministerio Público Fiscal*) shall be joined to the proceedings to ensure consumers' protection. It also establishes that suppliers shall produce all the evidence in their possession, according to the characteristics of the good or service, providing the necessary assistance to clarify the issue in dispute, which requires proactive behaviour of the defendants to prevent the judge from issuing a judgment presuming that there was a concealment that sought to cover up the fault of the supplier.

In addition, many rules state that the interpretation shall be made in favour of the consumer.

Likewise, although in common trials it is the burden of each party to prove the facts alleged thereby, such burden is subject to the theory of shifting burdens, according to which the burden of proof is borne by whoever is in a better position to prove a particular fact.

iii Defences

The limitation term of the legal action to claim damages is three years for a consumer[4] and for any other damages claim derived from civil liability.[5]

When the consumer claims in court compliance with the provisions of the LDC that do not involve a civil liability claim (i.e., concerning the non-compliance of a contract of sale), the limitation term is the generic term of five years provided for in the CCC.[6]

In case of malfunctions or defects of any kind in the product (even if they were obvious or manifest at the time of the contract) there is a legal guarantee of six months from delivery, which decreases to three months if the product is used,[7] as long as they concern the correspondence between the product offered and product delivered, or its proper functioning.

In the event of malfunction owing to hidden defects in the product that are not included in a consumer relationship, there is a limitation period of one year[8] to initiate a legal action, which necessarily entails compliance with the burden of reporting the defect to the seller within 60 days of the occurrence of the defect[9] and provided that this reporting occurred within six months from the date of receipt of the product or the date when the product was operated (three years in the case of real property), according to Article 1055 of the CCC.

There are grounds for interruption of the limitation, such as the initiation of a claim or the acknowledgement of responsibility, as well as grounds for suspension of the limitation through an extrajudicial communication or through the initiation of a pretrial mediation.

Article 40 of the LDC provides that only the supplier 'proving that he was not related to the cause of the damage' will be totally or partially released, which leads to the consideration of possible defences to demonstrate such lack of relationship.

As regards a non-manufacturer seller, he or she may claim not being aware of a defect that is attributable exclusively to the manufacturer; for example, in the case of a manufacturing or

4 Article 50 of the LCD.
5 Article 2561 CCC.
6 Article 2560.
7 Article 11 of the LDC.
8 Article 2564 of the CCC.
9 Article 1054 of the CCC.

design defect that he or she could not have known using due diligence. But this is controversial and currently a minority position, considering the joint and several liability established by Article 40 of the LDC.

Legal scholars and case law have established that when dealing with different companies that are linked by what is known as 'related contract systems' (i.e., a system of credit cards), although each acts autonomously, they all are participants in the business and profit from it, so they are not considered third parties potentially leading to joint and several liability. Currently, related contracts systems are defined in the new CCC, Article 1073.

Regarding product brands, the fact that these create trust in the consumer is considered decisive. For example, *Ivess*[10] was a case where the owner of a brand that had terminated a contractual relationship with a beverage manufacturer prior to the harmful event was held liable, owing to the mere presence of the brand in the packaging. One possibility for brand owners to escape liability in the event of termination of relationship prior to the damage occurring is to show that they extensively advertised the termination.

Another possible defence is to prove the lack of causation between the damage and the defect of the product.

The defence most commonly raised in practice is that of 'fault of the victim', for example, failure to perform the service of a car, the use of non-original spare parts, the lack of proper handling of a bottle or the poor conservation of food. To prove this, it is desirable to produce evidence to demonstrate that the manufacturing process complies with all applicable safety standards and that quality control prior to product release is strict, not to demonstrate lack of fault – which is irrelevant in a context of strict liability – but, rather, to make certain doubtful aspects about the more plausible facts.

With regard to the 'risk taking' by the victim in certain activities, it may constitute a defence but it must be taken into account that its effectiveness will be relative to the existence of the safety obligation expressly established by the LDC.

It is also possible to raise the defence of *force majeure* or act of God. This is an event that could not be foreseen, or that even foreseen, could not be avoided.

In this regard, it should be pointed out that invoking 'development risk', consisting in the possibility of non-detectable defects in the light of technical and scientific knowledge at the time the product was released, has been considered as a contingency of the risk of the activity developed by the producer, and therefore not an act of God.

Regarding the 'theory of the expert intermediary' – according to which warnings about the use of a medical product must be provided by the manufacturer to the physician and not to the patient – it has been considered in some cases inadmissible under Argentine law, taking into consideration the obligation to inform the consumer (free of charge), according to Article 4 of the LDC and also to Article 42 of the National Constitution, which enshrines the constitutional right of the consumer to 'adequate and true information', which prevents the manufacturer that has provided wrong or insufficient information from hiding behind a physician to excuse his or her responsibility.

It has been also understood that if the product was approved by the state authority, it will not serve as an exemption in a claim for damages.[11]

10 CNCiv., Sala F, *Iuele de Pinotti, Bárbara Lina vs. Soda Profesional S.A. y otro re/ damages claim*, 18-05-2007, RCJ: 3642/2007.

11 Article 1757 of the CCC.

Finally, it should also be considered that in the Argentine market there are insurers that cover the risks of product liability.

iv Personal jurisdiction

With regard to damages arising from defective products, Article 40 holds responsible all the members of the marketing chain and also those who brand the product.

On the other hand, it has been judicially recognised that consumers may bring a claim in the jurisdiction of their own domicile or that of the place of accomplishment of the act of consumption or execution of the contract, at their choice, the jurisdiction prorogation clauses being invalid.

v Expert witnesses

In judicial proceedings, it is possible and very common to propose expert evidence on controversial issues. The parties shall provide accurate questionnaires that shall not contain leading questions.

Such evidence is provided by an expert appointed by the court from the existing official lists and by drawing lots. Judges sometimes appoint universities or prestigious technical entities as experts in the absence of experts in a particular speciality or owing to the complexity of the subject.

Each party may offer a 'technical consultant', who shall be entitled to participate in the interventions of the official expert and to submit his or her own written report together with that of the expert.

Since the procedure is mostly written, it is rare for the judge to call the experts to give oral testimony. Nor is a judge bound by the findings of the expert report.

Experts' costs are normally borne by the losing party at the end of the trial, but the consumer may litigate *in forma pauperis*, so it is possible for the supplier to have to pay 50 per cent of the cost even in the case of being the winning party, without proving that the consumer had sufficient solvency.

vi Discovery

In Argentina, there is no US-style discovery. Documentation may be requested from a counterparty through a request for preliminary diligence on the basis there is uncertainty about a certain aspect of the future claim that is necessary to clarify beforehand, and that it is impossible to obtain such information without obtaining judicial relief. An anticipated evidence measure may also be requested on the basis that there is danger that the information could be lost. Judges tend to be quite restrictive when granting such measures.

vii Apportionment

Mainly, the LDC places on the part of the 'supplier' an express safety 'obligation',[12] stating that: 'The goods and services must be supplied or provided in such a way that, when used under foreseeable or normal conditions of use, they do not present any risk for the health or physical integrity of consumers or users.'

Likewise, the LDC establishes the obligation to provide the consumer with free, clear and detailed information on everything related to the essential characteristics of the goods and services provided, and the conditions of their commercialisation, and unless expressly stipulated otherwise, in physical medium.[13]

The above-mentioned is supplemented in its Article 40, stipulating strict liability for the risk or defect of a product (or service), for all members of its marketing chain and also for the individual who brands it ('the producer, the manufacturer, the importer, the distributor, the supplier, the seller and the individual who brand the product or service'), all of which are equally bound to the consumer as 'supplier', without prejudice to the repetitive actions that correspond among them.

Joint and several liability and its total compliance may be required from any of the debtors simultaneously or successively at its election, simply based on belonging to the same marketing chain or because its brand is placed on the product.

The consumer should only demonstrate the product's defect and its causal link with the damage occurred.

Such damage, according to some authors, must have transcended the product itself and propagated to the consumer or to other goods of the consumer, since if the damage is limited only to the defect of the product, they consider that it is only claimable to the direct supplier, in that solidarity that allows action against all members of the marketing chain is only justified owing to the requirement of safety of the product and not the exact compliance with the obligations assumed by the direct supplier.

Nevertheless, it is observed in practice that such distinction is rarely applied, and the judgments usually apply Article 40 of the LDC mechanically to all consumer claims, which end up collecting from the most solvent parties.

Lastly, the rules on defective or risky products that cause damage[14] and for hidden defects[15] are applied on non-consumer product liability claims.

In the first case, Article 1757 of the CCC establishes strict liability, and administrative authorisation or compliance with the prevention techniques are not liability exclusions. Once the defect of the product is demonstrated by the claimant, the defendant holds himself or herself free of liability by proving the interruption of the causal link (i.e., he or she was not related to the cause of damage, that being the fact or fault of the victim, a fact of a third party for whom it is not necessary to respond or an act of God not related to the product or activity).

Regarding hidden defects, liability is excluded if it is established that defects did not exist at the time of acquisition or that they were known or should have been known by the buyer.[16]

12 Article 5.

13 Article 4.

14 Article 1757 of the CCC.

15 Article 1051 and subsequent ones of the CCC.

16 Article 1053 of the CCC.

viii Mass tort actions

These kinds of proceedings are not regulated; therefore, it is usual to observe multiple associations competing with each other to take legal action with the same cause with respect to the same defendant before various courts, and even in different jurisdictions. That is why the Supreme Court had to establish procedural guidelines to regulate some aspects of the processes and to try to avoid the proliferation of cases with the same subject matter and possible contradictory judgments.

The Supreme Court of Argentina set out a concept of 'collective incidence rights aimed at individual homogeneous interests' in the case of *Halabi* (2009) in which the following requirements had to be met: (1) a common cause; (2) request for the same subject matter; and (3) claims not being sufficiently large to justify an individual claim.

In the past 15 years, there has been a huge increase of collective consumer actions, especially in the area of services, mainly banking and financial services; nevertheless, there were product liability claims, but in relation to the latter it is more difficult to verify the requirement of a common cause or little economic significance.

Collective actions require verification of the suitability of the association to carry them forward.

ix Damages

Judgments ordering the payment of compensation for damages issued both in actions deriving from the LDC and civil law will always provide that the compensation is quantified by taking into account only compensatory (non-punitive) criteria, except for one specific possibility of 'punitive damages' established by the LDC.

The scope of non-punitive remedy includes both the direct and the indirect consequences that could have been foreseen by the responsible person.[17] That is to say, indirect non-foreseeable damage is not compensable.

According to Article 1727 of the CCC:

> *The consequences of a fact that are used to happen according to the natural and ordinary course of things are called 'direct consequences' in this Code. The consequences that result only from the connection of a fact with a different event are called 'indirect consequences'. . . .*

One of the heads of damages is spiritual suffering (not material or physical, either because of the physical pain suffered or because of the worries or irritations caused by the damage), which it is left to the discretion of the judge to fix, although overly burdensome penalties under this head of damages does not occur often.

Damages are available for physical damage (including psychological and aesthetic damage) suffered by the consumer, with reference to the harm suffered by the consumer as per the incapacity chart (*baremo*) used by medical experts, and the impact of this disability on the possibilities of generating income of the claimant, whether permanent or temporary, and how it affects the claimant's life chances.

In case of death, close relatives may claim the 'life value' that is given by the economic aid from which they were deprived owing to the victim's death.

17 Article 1726 of the CCC.

Transfer and hospital expenses and fees of the different medical specialities that have intervened, medicines, prosthetics, not covered by civil insurance, social security or prepaid medical insurance may also be claimed (in which case those who made the payments are joined in the action against the defendants).

Likewise, compensation for damage to the consumer's material assets is also available.

Should the claimant fail to obtain a profit as a result of defective product, after demonstrating that the existence of real possibilities in such sense, there will be an obligation to compensate for the loss of opportunity or loss of profit.

Interest is paid on all items, in principle, from the harmful event.

Likewise, after a reform made in 2008 to the LDC (by Law 26,361), Argentine law that had previously considered damages claims as solely compensatory, incorporated 'punitive damages'. The expected legal maximum is 5 million pesos.

> *Punitive Damages. The supplier that fails to comply with his legal or contractual obligations to the consumer, at the instance of the victim, may be ordered by a judge to pay civil fine in favour of the consumer, which will be calculated based on the gravity of the fact and other circumstances of the case, regardless of other compensation that may be payable. When more than one supplier is responsible for the breach, they will all be jointly and severally liable to the consumer, without prejudice to the corresponding reimbursement actions. The civil fine shall not exceed the maximum fine imposed in Article 47, paragraph b) of this law.*[18]

Relatively few judgments have applied punitive damages because, although several years have elapsed, the judges have been prudent and restrictive in their application.

The requirements for the application of punitive damages, which are not specified by the LDC or any other rule, have not yet been fully outlined by Argentine doctrine and legislation. For example, it has been said that they would not be applied in a case of strict liability, requiring the supplier's wilful misconduct.

In that sense, the current president of the Argentine Supreme Court, Ricardo Lorenzetti, has also stated, as an author, that an inherent requirement would be the necessary demonstration of 'economic benefits' owing to the wrongful act.[19]

However, there have been no high penalties for punitive damages.

During the judicial proceeding, and in certain circumstances (that is, a favourable first instance court pronouncement but being appealed, or when the alleged right is plausible and there is a serious risk based on the delay on arriving at a final decision), claimants may request from the judge a monetary attachment or other kind of injunction ordered against the defendant and its assets.

In addition to money judgments, a judgment may also impose other types of obligations to give, to do or to omit to do, provided that they have been requested and the judge considers them appropriate to avoid damage. Article 1710 of the CCC imposes the duty on any individual, as much as it depends on him or her, to take reasonable measures to avoid or remedy harm, so it is not to be ruled out that a judge considers it his or her duty to provide such a measure even if it had not been requested based on said legal obligation.

In this regard, Article 1711 of the CCC allows the bringing of 'preventive action' to any individual with a reasonable interest, to avoid damage. This is foreseen to be resolved without

18 Article 52 *bis*.

19 Ricardo Lorenzetti, *Las normas fundamentales del derecho privado*, Edit. Rubinzal Culzoni, 1995, p. 391.

having to prove a factor of attribution, such as the fault, it being enough to demonstrate the illegality of the damage. The measures may be both final and provisional. Such measures should be adopted with the least restrictive criteria and the best means to ensure efficiency in achieving the purpose.

The LDC also provides fines to be imposed by the administrative authorities for penalties for breach of obligations of suppliers. These may even reach the same amount of punitive damages (5 million pesos).

Also, Article 40 *bis* of the LDC provides that administrative authorities subject to requirements such as technical specialisation, independence and impartiality and subject to subsequent judicial review may provide for compensation for 'direct damage', which is detrimental to the consumer, subject to pecuniary appreciation, immediately caused on his or her property or on himself or herself, excepting any kind of non-pecuniary consequences.

Also take into account the criminal consequences (fine or imprisonment) referred to in Section III, *supra*.

To avoid unreasonable punishment, Article 1715 of the CCC empowers the civil or commercial judges to review and reduce the penalties.

V YEAR IN REVIEW

We do not believe there have been too many relevant developments in the past year. For a couple of years, many of the collective judicial proceedings have been practically stopped owing to frequent changes of establishment between different courts and divisions of the courts of appeals, owing to the necessity of determining criteria of the filing of cases before the same court that avoid the increase of legal processes with identical purpose and the issuance of contradictory judgments.

Liability trials for more numerous products appear to be those for automotive and technological products and pharmaceutical companies, as well as bottling and food processing companies. There are many administrative claims and mediations, which are not reflected in a legal claim, seeming to show that in many cases they are not genuine claims.

Recently ANMAT announcements have been issued on certain products, the movement of which was prohibited, as well as recall of automotive components.

Chapter 2

AUSTRALIA

Colin Loveday and Sheena McKie[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

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 caused by a product may commence an action for compensation on the following bases:

a the common law tort of negligence;

b contract; and

c breach of a number of consumer protection legislative provisions, the main one being the Australian Consumer Law (ACL).

The ACL is a federal (also known as Commonwealth) law that came into effect on 1 January 2011. It applies to transactions occurring on or after that date. The ACL replaces a collection of federal and state consumer protection legislation with a single law that applies in all jurisdictions. The ACL is found in Schedule 2 to the Competition and Consumer Act 2010 (Cth) (CCA), which until 2011 was the 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 that are said to have a 'safety defect' and statutory guarantees imposed on suppliers and 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 multiple causes of action variously based on negligence and breaches of numerous provisions of the ACL.

II REGULATORY OVERSIGHT

In broad terms, there are three federal regulatory authorities in Australia that oversee areas relevant to product liability issues affecting consumers.

The Australian Competition and Consumer Commission (ACCC) has a number of important investigation and enforcement powers under the ACL. Relevantly, the ACCC is empowered to institute proceedings in relation to certain provisions of Parts 3-5 (defective

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goods actions) and 5-4 (remedies relating to guarantees), either in its own right or on behalf of those who have suffered or are likely to suffer loss as a result of contraventions of the ACL. The ACCC is also responsible for overseeing product recalls and the mandatory reporting of deaths, serious injuries or illnesses associated with consumer goods (and has published extensive guidelines addressing both of those requirements). The penalty for non-compliance with either is substantial.

The ACL requires that a person taking action to recall consumer goods must notify the Minister (practically achieved by notifying the ACCC) within two days of taking that action. In practice, however, the ACCC (and any applicable industry-specific or state-based regulator) will expect to be engaged at an early juncture before steps to recall goods (including advertising a recall) have been taken. Unless the ACCC is properly notified and satisfied with the strategy adopted by the manufacturer or distributor, it takes a very proactive role in managing product recalls.

In addition, the mandatory reporting requirement mentioned above requires a supplier to notify the Minister (usually via an online form) within two days of becoming aware of any death, serious injury or serious illness (as defined in the legislation) associated with or thought to be caused by use or foreseeable misuse of a consumer good.

The Therapeutic Goods Administration (TGA) is Australia's regulatory agency for therapeutic goods including medicines, medical devices, blood and blood products. The TGA administers the Therapeutic Goods Act 1989 (Cth), and regulates therapeutic goods through: pre-market assessment; post-market monitoring and enforcement of standards; licensing of Australian manufacturers; and verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.

The Australian Securities and Investments Commission (ASIC) oversees Australian corporations and financial markets. In particular, ASIC regulates the provision of consumer credit, financial products and financial services; however, this chapter will focus on product liability for non-financial consumer products.

In addition to the above, there are a number of state-based regulators with responsibility for administration of industry-specific regulation, for example. food or consumer electrical goods.

III CAUSES OF ACTION

There is a range of potential causes of action under which manufacturers, distributors or sellers can be held liable for injury to consumers.

i Forum

It is well 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 that the manufacturer delivers in sealed containers that 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 that 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.

ii 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 in the supply chain with which it has a contractual relationship.

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 statutory causes of action. Since 1978, consumer protection provisions have existed to allow for claims where there was no privity of contract, which are now included in the ACL. The ACL has also affected the relationship between contract and product liability by introducing provisions that render void any unfair term in a standard form contract. It also creates 'statutory guarantees' that exist independently of any contract of supply (see below).

iii Statutory warranties and guarantees

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

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

Privity of contract is no barrier to relief.

The operation of these statutory warranties and guarantees applies to the supply of goods, in trade or commerce, to a 'consumer'. This includes where the amount paid or payable for goods did not exceed A$40,000 (or greater amount as prescribed by regulations), or the goods were of a kind ordinarily acquired for personal, domestic or household use or consumption, or the goods were a vehicle or trailer acquired for use principally in the transport of goods on public roads. However, a person does not acquire goods 'as a consumer' if the person acquired (or purported to acquire) the goods for the purposes of resupply or for the purpose of using them up or transforming them in trade or commerce (either in production or manufacturer or in repairing or treating other goods or fixtures on land).

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. The definition of 'manufacturer' under the ACL is extremely broad and potentially includes anyone in the supply chain.

Following the Federal Court decision in *Courtney v. Medtel Pty Ltd*, a consumer product may sometimes be considered defective if it is subject to a higher-than-expected risk of premature failure or risk. This means that manufacturers may be liable where the product does not demonstrate any signs of failure, but where the manufacturer has indicated, often by taking product recall action, that the product may have a future or potential risk of failure.

Certain conduct in relation to the supply of defective products by corporations and their officers may be subject to criminal sanctions under the ACL.

iv Statutory causes of action for financial services

The providers of financial services products are subject to strict regulations. In the event that those providers act inappropriately in providing financial advice to their clients or selling them inappropriate products, those clients may have several statutory causes of action against the provider.

Most of the causes of action and the available remedies are contained in Chapter 7 of the Corporations Act 2001 (Cth) and the Australian Securities and Investments Commission Act 2002 (Cth). In general, a person is prohibited from:

a making a false statement which is likely to cause a person to apply for or acquire;
b inducing another person to deal in financial products by making a misleading statement;
c engaging in dishonest conduct while carrying on a financial services business; and
d engaging in unconscionable conduct (which would include taking unfair advantage of a customer's inferior knowledge about a product or service).

If a provider breaches any of those prohibitions, and that breach results in a customer suffering a loss, the customer may recover that loss in damages. In addition, if a term of a contract between a provider and customer is unfair to the customer, he or she can apply to have that term declared void.

v Product recalls

At common law, manufacturers and suppliers of products owe a continuing duty to purchasers and foreseeable users to take reasonable care to prevent a product from causing harm, including after the product is sold. Failure to recall a product that may cause harm may amount to negligence and give rise to the obligation to pay compensation to persons suffering injury, loss and damage as a result.

The issues that will be considered in deciding whether recall action is necessary include:

a the magnitude of the potential harm involved;
b the probability of such harm occurring;
c the availability and effectiveness of alternative remedial action; and
d the degree of knowledge of the potential harm.

The ACL does not require a supplier of consumer goods to obtain the ACCC's approval before a voluntary recall can be initiated. However, if the recall action is being taken because the consumer goods (or a reasonably foreseeable use or misuse) will or may cause injury to any person, the goods do not comply with a prescribed safety standard, or the goods are subject to an interim or permanent ban, the supplier must notify the ACCC of the recall action within two days of that action being taken. As a matter of practice, the ACCC (and any other industry-specific regulator) is often proactive in discussing with suppliers the structure and implementation (including advertisement) of a recall action.

In addition, the product safety provisions of Part 3-3 of the ACL contain a regime for the compulsory recall of consumer goods including where it appears to the responsible Minister that one or more suppliers of such goods have not taken satisfactory action to prevent the goods causing injury to any person.

IV LITIGATION

i Forum

Product liability litigation is usually commenced in either the Federal Court of Australia or the Supreme Court of the relevant state or territory. Civil proceedings in Australia are generally heard by a judge sitting without a jury; however, there are provisions in the various court rules for some matters to be heard by jury.

As a matter of practice, juries are usually not available in matters before the Federal Court. However, juries are not uncommon in the state of Victoria.

ii Burden of proof

The claimant bears the burden of proof, requiring it to prove all facts essential to its claim. In civil cases, the required standard of proof is the 'balance of probabilities' (i.e., that the claim is more probable than not). The defendant bears the onus of establishing any affirmative defence, and must also prove this on the balance of probabilities.

In negligence, contract and under some of the provisions of the ACL, the claimant has the burden of proving that the product was defective. 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 the outcome could not have happened without negligence.

The statutory consumer guarantees and the defective product causes of action under the ACL are often referred to as 'strict liability' provisions. In claims 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., that they 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:

a that loss or damage has been suffered;

b that the relevant conduct is either in breach of a common law duty, in breach of contract or contravenes one of the provisions of the ACL; and

c that the loss or damage was caused by the defendant's conduct.

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

Prior to reforms to the law of negligence that 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 two principal requirements for causation in negligence:

a first, that the negligence was a necessary condition of the occurrence of the harm (referred to as 'factual causation'); and

b 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 (in Victoria, an 'appropriate' 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 a consumer would suffer such loss or damage as a result of the failure to comply with a consumer guarantee.[2]

Australian courts have not embraced the view that a claimant 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.

In cases where there are two or more possible causes of the damage suffered, the High Court of Australia in *Amaca Pty Ltd v. Ellis* held that a claimant must establish that the relevant product that is the subject of the claim more probably than not was a cause of the damage suffered. Proving that it was merely a possible cause is not enough.

iii Defences

Negligence

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

a *volenti non fit injuria* (voluntary assumption of risk);
b contributory negligence; and
c 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. However, for medical products that 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. It will be important for a manufacturer to establish that it provided appropriate information and warnings to those learned intermediaries.

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:

2 Part 5-4 of the ACL.

a 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; and

b 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.

Part 3-5 of the ACL

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

a the defect alleged did not exist when the goods were supplied by the manufacturer;

b the goods were defective only because there was compliance with a mandatory standard (discussed further below);

c 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 (discussed further below); or

d 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.

'State-of-the-art' or 'development risk' defence

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.

Compliance with regulatory or statutory requirements

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 that, under law, must be complied with when goods are supplied, and which carries a penalty for non-compliance. A standard that 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 purposes for which goods of that kind are commonly bought as it is reasonable to expect.

Statutes of limitation

Time limitations on issuing proceedings exist under common law and statute. Since limitation statutes are largely state-based (noting that the ACL also has its own applicable limitations periods), this is an area of complexity given the myriad of different statutory provisions that might apply.

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 concealed. In those circumstances the limitation period is deemed to have commenced from the time the cause of action or defendant was discovered or the time that it would have been discovered by a plaintiff exercising reasonable diligence. Throughout all Australian jurisdictions, the courts have various discretionary bases for extending the time period where it is just and reasonable to do so.

Contract and tort

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 some states limitation periods run from when a plaintiff's cause of action first accrues, which is when compensable injury has first been suffered. Other states employ a discovery rule.

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:

a 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

b 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 that impedes them from properly managing their affairs.

ACL

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 of the goods by the manufacturer.

An action for non-compliance with a consumer guarantee[3] 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.

3 Part 5-4 of the ACL.

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.[4]

iv Personal jurisdiction

Whether an Australian court has jurisdiction in a product liability matter depends on whether the defendant can be validly served with initiating process. The court rules in most major Australian jurisdictions permit service outside Australia if the plaintiff has suffered some disadvantage or detriment in Australia as a result of the tort or breach of the ACL.

Ordinarily, a foreign defendant submits to the Australian jurisdiction, 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 a dispute about the proper forum for hearing of a claim.

The choice of law rules dictate that the appropriate law for a tortious action is, generally speaking, the *lex loci delicti* (law of the place where the wrong occurred). Where a product liability claim is made against a foreign manufacturer and the allegation is that the manufacture or design was negligent, the location of the manufacture or design is the place where the tort was committed. However, where the negligence alleged is a failure to warn an Australian claimant, the cause of action arises in Australia (where it is alleged the warning ought to have been given or was inadequately given).

The ACL regulates the conduct of corporations, including foreign corporations carrying on business in Australia, and individuals.

The term 'manufacturer' is defined broadly under the ACL to include both the actual manufacturer, as well as certain entities that are 'deemed' manufacturers for the purposes of the ACL. For example, where the actual manufacturer does not have a place of business in Australia, the importer is deemed to be a manufacturer of the goods. Similarly, if goods are imported into Australia 'on behalf of' a person, that person is taken to have imported the goods into Australia under the ACL. Thus, a local importer of overseas manufactured goods may, in some cases, be exposed to liability under the ACL.

v Expert witnesses

As a matter of course in Australian litigation, parties adduce evidence from appropriate expert witnesses who give evidence concerning specialised areas of knowledge arising from their training, study or experience. The nature and extent of expert evidence, including the number of experts that might be called by any party in a particular area of expertise, is subject to the discretion of the court. In many jurisdictions, practice notes provide guidance on the way in which experts may be engaged and the content of their expert reports. Most recently, in October 2016, a new Expert Witness Practice Note was issued by the Federal Court.

The courts may also require the experts instructed by opposing parties to meet and sometimes to prepare a joint report before giving evidence in court, to narrow the issues in dispute.

An expert who is to give evidence as a witness in litigation has an overriding duty to assist the court impartially, and not to be an advocate for a party.

4 Section 87F of the CCA and Part VIB of the CCA, more generally.

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; however, court experts are rarely appointed and it is more common for the parties to adduce expert evidence from their retained independent experts.

vi Discovery

The procedural rules relating to documentary discovery vary considerably from court to court and have undergone numerous changes in recent times. All these changes (usually in the form of practice directions) have been intended to streamline the process. In product liability litigation, documentary discovery continues to be a very onerous process for defendants. In some courts there is a rule (either formal or in practice) that discovery only be given after lay and expert witness statements have been exchanged, to reduce the burden of discovery.

In general terms, 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 that are relevant to a matter in issue in the proceedings. Discovery occurs at the pretrial 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 that are no longer in the party's possession, custody or power, but that 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.

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.

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, the parties' lists verified by affidavit 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. Often, discovery is given electronically, by exchange of documents formatted to an agreed technical protocol.

Parties may apply for preliminary discovery before the substantive proceedings, to determine whether or not they have a claim against a prospective defendant or to gain information from third parties.

Depositions of the parties and witnesses are not taken before trial.

In some jurisdictions, most notably the Federal Court of Australia, pretrial 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, however, becoming more commonplace for a Federal Court judge to prefer to hear lay evidence, in particular, given orally.

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.

vii Apportionment

Defendants are permitted to rely on a statutory right to contribution from other concurrent tortfeasors (whether joint or several). A defendant must demonstrate that the person from whom contribution is sought would have been held liable for the same damage had they been a party to the proceedings. Alternatively, defendants may seek to rely on a contractual right of indemnity.

Rights of contribution or indemnity 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.

While 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. In such cases, 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.

viii Mass tort actions

There is a detailed class action procedure in the Federal Court of Australia and the Supreme Courts of Victoria and New South Wales. In November 2016, the Queensland Parliament also passed legislation enacting a new Part 13A to the Civil Proceedings Act 2011 (Representative proceedings in Supreme Court) aimed at facilitating class action proceedings in the Queensland Supreme Court. That legislation is expected to commence in early 2017. There are also representative action procedures in other state jurisdictions.

A class action (called a representative proceeding) can only be commenced in the Federal Court where it attracts federal jurisdiction, for example, if it involves a claim under the ACL, which is federal legislation.

Generally speaking, a class action can be commenced 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 question 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, it being an 'opt-out' rather than an 'opt-in' system.

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 through advertising and the like. 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. 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.

Similarly, the representative plaintiff may only withdraw from the proceedings or settle his or her individual claim with the leave of the court.

Court approval is also required for claims brought by infants or people suffering from a legal disability.

Australia is generally a 'loser pays' system. However, of significance for successful defendants, only the named representative plaintiff is liable for costs if the class action fails. The amount of costs recoverable is not usually on an indemnity basis and therefore often only represents a fraction of the actual costs incurred.

ix Damages

Monetary compensation is available for both pecuniary and non-pecuniary loss. The following damages are available for claims of bodily injury:

a general damages, including pain and suffering, loss of amenity and loss of expectation of life; and

b special damages, including loss of wages (both past and future), medical and hospital expenses and the like.

The Tort Reform Process and the introduction of the ACL 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.

Under the ACL, a person other than an injured party may also claim compensation where that person suffers loss as a result of another 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.

Damages are also recoverable for damage to mental health 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.

Exemplary, punitive or aggravated damages can be awarded by the courts, although they are extremely rare and are not available 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.

There is generally no maximum limit on the damages recoverable from one manufacturer, distributor or seller. 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. As a general rule, damages for the costs of medical monitoring in the absence of any established injury or loss are not recoverable.

In addition, courts may grant injunctions, including interim injunctions, to restrain breaches or attempted breaches of the consumer protection provisions of the ACL. 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.

Breaches of the ACL's criminal offences are subject to criminal fines of a maximum of A$1.1 million for a body corporate and A$220,000 for a person other than a body corporate for many of the offences.

V YEAR IN REVIEW

During 2016, the ACCC continued to be active in its supervision of consumer product recalls, as well as monitoring 'hot topic' issues in product safety. In particular, following an interim ban in place between 19 March and 16 July 2016, a new mandatory standard was introduced to set out minimum requirements for self-balancing scooters (e.g., hoverboards) (Consumer Goods (Self-balancing Scooters) Safety Standard 2016). The standard came into effect on 17 July 2016.

In September 2016, all ACL regulators (including the ACCC and state-based regulators) launched a National Strategy for improving the safety of button battery consumer products 2016-18. This Strategy is designed to develop evidence to inform regulatory and other approaches to improve button battery safety, and is supported by a series of voluntary industry actions and educational activities. (Voluntary) industry-based actions are set out in the Industry Code for Consumer Goods that Contain Button Batteries was developed by retailers, associations and product safety consultants together with state and federal regulators.

There are presently a range of interim bans in force across states and territories nationally in respect of decorative alcohol-fuelled burners, following reports of serious burn injuries and house fires. In addition, a national proposed ban notice was proposed by the Minister for Small Business in December 2016.

The ACCC has also been pressing for increased penalties under the ACL by appealing first judgments to the Full Federal Court.

A review of the ACL (initiated by Consumer Affairs Australia and New Zealand (CAANZ)), which formally commenced on 31 March 2016, is ongoing. An Interim Report was published in the second half of 2016. A final report is expected to be released in March 2017.

Chapter 3

AUSTRIA

Eva Spiegel and Gabriele Hintsteiner[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

i The Product Liability Act

In Austria, a statutory liability regime that governs product liability is the Product Liability Act,[2] which implemented the European Directive 85/374/EEC on Liability for Defective Products into national law. In line with the European Directive, the Product Liability Act provides for a strict (i.e., no-fault) liability scheme. Liability for damages under the Product Liability Act can neither be excluded nor limited in advance.

Under the Product Liability Act primary liability for damages caused by a defective product is placed on the entrepreneur who either manufactured the product (the producer), or imported the product into and put it into circulation in the European Economic Area (the importer).

As per the definition provided in the Product Liability Act, the producer is the person who has manufactured the finished product, a raw material or component part. Further, any person who presents itself as the producer by putting its name, trademark or other distinguishing feature on the product is regarded as the producer.

Where the producer or, in the event of products imported into the European Economic Area, the importer cannot be identified, any supplier who has put the product into circulation is liable, unless it informs the injured party within a reasonable period of the identity of the producer or the importer or the person who supplied it with the product (the preceding supplier).

The liability regime of the Product Liability Act covers liability for death, injury to body or health, and for damage to items of property resulting from the defect of a product. Damage to the defective product itself is not covered. Further, damage to an item of property is only compensable if it was not suffered by an entrepreneur who used the item of property predominantly in its business. Thus damages to items of property are basically only to be compensated as far as such damage was suffered by a consumer. In any case there is a deductible amount of €500 for damage to items of property, meaning that only the part exceeding €500 is compensable. There are, however, no caps on liability.

The Product Liability Act contains (in Section 5(1)) a definition of the term 'product defect'. A product is deemed defective if it does not provide the safety which, taking all

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2 Federal Act of 21 January 1988 Governing the Liability for a Defective Product, BGBl. No. 99/1988, as amended.

circumstances into account, could reasonably be expected, in particular with respect to (1) the presentation of the product; (2) the use to which it can reasonably be expected that the product will be put; and (3) the time the product was put into circulation. However, a product cannot be considered defective for the sole reason that an improved product is subsequently put into circulation.

According to case law of the Austrian Supreme Court, for the assessment of whether a product is to be deemed defective an objective standard is to be applied based on the safety expectations of an average product user. Expectations in the safety of a product are in general only justified if the product user also meets its own individual responsibility, meaning that for unforeseeable or downright absurd uses product liability usually is not triggered. However, a certain actual, even if improper, use may have to be equitably expected, for instance if a product is intended for use by children (such as toys or playground equipment).[3]

'Presentation' of a product is any activity by which a person subject to liability introduces the product to the public or the individual user, including advertisement, product descriptions, directions for use, instruction sheets, etc.[4]

In general, the producer has the duty to instruct users on how to safely use the product and to warn of hazards involved in the use of the product, and under some circumstances, to even warn against a possible improper use. However, these duties also depend on the need for protection of (possible) users of the product. Where a product might reach the hands of persons who are not familiar with the risks involved in the use of a product, or if a product is addressed to different profiles of users, the content and extent of the instructions must be aimed at the least informed and thus most endangered group of (possible) users.[5]

Whether a product is defective is to be assessed according to the time the individual product was put into circulation. A product is deemed to have been put into circulation once the entrepreneur has transferred it to another person into the latter's power of disposition or for the latter's use. In the case of a series of products, the point in time at which the individual product causing the damage was put into circulation is decisive.

The Austrian Supreme Court, in a case concerning the explosion of a glass bottle of carbonised mineral water causing personal injury, held that the producer of serial products must pay due regard to experience gained after the series was first launched on the market and to take these experiences into account in the further production, such as by modifying the construction, changing the production process or improving instructions to the product users.[6]

ii Other bases of liability

Apart from the Product Liability Act, liability for a defective product notably may arise out of general tort law, contract law and from the concept of 'contract with protective effect for third parties'. Liability under both general tort law and contract law as well as under said concept is fault-based.

The producer is usually a legal entity. Liability based on general tort law would require that either the producer's statutory bodies or other persons in a leading or supervisory

3 Austrian Supreme Court, Case No. 1 Ob 62/11 of 28 April 2011.

4 Welser/Rabl, *Produkthaftungsgesetz*, p. 102f.

5 Austrian Supreme Court, Case No. 7 Ob 49/01h of 30 March 2001; Austrian Supreme Court, Case No. 1 Ob 216/11p of 24 November 2011.

6 Austrian Supreme Court, Case No. 6 Ob 215/11b of 13 September 2012.

position are at fault.[7] For the conduct of other persons whom the producer employs or engages the producer is only liable towards third persons within very narrow limits, namely if such persons are habitually unable or unfit for the assigned work.

Under contract law the counterparty is responsible for damage caused by fault of its employees or any other persons used to fulfil its duties as if it acted itself and there is a presumption of fault in the event of non-fulfilment of a contractual obligation, in which case the burden of proof shifts to the defendant to prove the absence of fault.

Since it is characteristic for many product liability cases that no contract exists between the person suffering damage and the producer, relying on liability under contract law might often not be possible.

However, according to doctrine and case law developed prior to the introduction of the Product Liability Act in 1988, the contract between the producer and the first purchaser of the product unfolds protective effects through a chain of contracts towards the end customer with the consequence that the end customer (as well as persons deemed to belong to its sphere, such as family members or employees) may seek redress against the producer as if they were in a contractual relationship. Thus, the producer is responsible for damage caused by fault of its employees or any other persons used to fulfil its duties as if it acted itself and the end-customer benefits from the reversal of the burden of proof (i.e., the producer has to prove absence of fault).

Since the introduction of the Product Liability Act said concept of 'contract with protective effect for third parties' has practical relevance mainly in cases where damages are not compensable under the Product Liability Act (such as in particular damages to property suffered by entrepreneurs) or where claims under the Product Liability Act have already become time-barred.

Liability could also arise out of the violation of a 'protective law'. For instance, the Product Safety Act is deemed as a 'protective law' by scholars.[8]

II REGULATORY OVERSIGHT

The European Directive 2001/95/EC on General Product Safety was implemented into Austrian law by enacting the Product Safety Act,[9] which serves as the general source of law for product safety.

The Product Safety Act regulates safety requirements to be met by products, obligations of persons putting products into circulation and measures to be taken by government authorities with the aim of protecting human life and health from danger by hazardous products. Legislation governing product safety on the one hand and product liability on the other have a complementary function: the first instrument shall ensure that only safe products are put into circulation (preventive function); the second instrument establishes the rules under which personal injury and damage to property caused by a defective product are compensated (compensation function).[10]

7 Austrian Supreme Court, Case No. 6 Ob 108/07m of 27 February 2009.

8 Welser/Rabl, *Produkthaftungsgesetz*, p. 7f.

9 Product Safety Act 2004, BGBl I No. 16/2005, as amended.

10 Report from the Commission of the European Communities (COM(2000) 893 final) on the Application of Directive 85/374 on Liability for Defective Products, 21, 31.

In addition to the Product Safety Act there exists regulatory legislation for specific products, such as the Pharmaceutical Products Act, the Medical Devices Act, the Food Safety and Consumer Protection Act, and the Chemicals Act. Product safety and product monitoring requirements under these laws are generally stricter than under the Product Safety Act. However, as looking into these various regulations would go beyond the scope of this chapter, in the following only the Product Safety Act is addressed.

Under the Product Safety Act, the competent authorities are the Federal Ministry for Social Security, Generations and Consumer Protection and the provincial governors.

If producers, importers and suppliers know or should know from information available to them within the scope of their business activities that a product put on the market by them poses a danger to consumers that is incompatible with the safety requirements of the Product Safety Act,[11] they must notify one of the competent authorities without delay. This also applies for measures, particularly product recalls, taken by producers, importers, and suppliers. Failure to meet these notification obligations constitutes an administrative offence for which fines of up to €3,000 can be imposed.

Pursuant to the Product Safety Act, producers and importers have a duty to monitor products after putting them on the market, by taking measures that enable them to recognise dangers arising from the products and to take appropriate measures to avert such dangers. Such measures may, if necessary, include withdrawing the products from the market, giving reasonable and effective warnings to consumers and, if need be, recalling the products. Suppliers are required to contribute to monitoring the safety of the marketed products, such as by passing on indications of dangers that may be posed by a product and by cooperating with measures by the producers and competent authorities to avert danger.

If the producer or importer fails to take (appropriate) measures, the Federal Ministry for Social Security, Generations and Consumer Protection can resort to take appropriate measures, including the ordering of a product recall. Contravention of such measures constitutes an administrative offence for which fines of up to €25,000 can be imposed.

Further, in this context, based on general civil law principles producers (and as the case may be also importers and suppliers) have a product monitoring duty after the product was put on the market, entailing the duty to avert dangers thus discovered by taking appropriate measures. A violation of the monitoring duty may thus give rise to civil liability if persons suffer damages owing to such violation.

The nature and level of risks associated with a detected danger are to be taken into account when assessing which measures are appropriate in a given case to avert danger (principle of proportionality).

Further, if deemed a 'protective law', violations of the Product Safety Act or measures ordered by competent authorities thereunder could directly give rise to civil liability.

11 Pursuant to Section 4 of the Product Safety Act a product is deemed safe, when, provided that it is put to its proper or any reasonably foreseeably use, it harbours no dangers or dangers of such a low level as is acceptable for human safety with a view to its use and to safeguarding a high level of protection.

III CAUSES OF ACTION

Causes of actions for product liability claims in general have their basis in civil law, such as the Product Liability Act, general tort law, contract law and the concept of 'contract with protective effect for third parties' described above. Further, a product liability claim may also be based on a violation of a 'protective law'.

The placing of a defective product on the market or violations of product safety requirements may also constitute a criminal offence under the Austrian Criminal Code, if for instance this causes bodily injury or death of a person, (substantial) environmental damage, or danger to life and health to a larger number of persons, or danger to another's property to significant extent. Apart from the responsible individual or individuals in Austria, legal entities can also be liable for criminal offences under certain conditions (as set out in the Austrian Corporate Criminal Liability Act).

Damaged persons may join criminal proceedings as private parties, which gives them the advantage to gain access to the criminal file (although access to certain documents may be restricted) and use the documents in (subsequent) civil proceedings. In rare cases damages are awarded by the criminal court in the course of criminal proceedings. Also, in a civil proceeding damages might be awarded more easily and swiftly if the claim can be based on a criminal conviction.

IV LITIGATION

i Forum

Product liability claims are determined in civil court proceedings before state courts by professional judges. Austria does not have jury trials in civil proceedings.

Provided there is an arbitration agreement between the parties involved, product liability (related) claims may also be determined in arbitration proceedings. Under Austrian arbitration law, arbitration agreements between an entrepreneur and a consumer can only be validly concluded for disputes that have already arisen. Consumers normally assert product liability claims in civil proceedings before state courts.

ii Burden of proof

If the claim is based on the Product Liability Act the plaintiff has to prove the damage, the defect and the causal relationship between the defect and the damage. As liability under the Product Liability Act is based on strict liability, the issue of fault is of no relevance.

If the defendant raises the defence that it has not put the product into circulation or not acted as entrepreneur, the burden of proof for that rests with it. Further, if the defendant relies on the defence that the defect that caused the damage did not exist at the time it put the product into circulation, it has to show that with regard to all circumstances this is plausible (*prima facie* evidence).

If the claim is based on liability in tort the plaintiff has to prove the damage, causation, unlawfulness, that the conduct causing the damage was unlawful, and that the conduct causing the damage was at least negligent. The same holds if the claim is based on breach of contract or on 'contract with protective effect for third parties', with the exception that the defendant has to prove the absence of fault (negligence or intent).

In civil proceedings the general standard of proof is 'highly probable'.

For causation the *conditio sine qua non* test is applied, by asking the hypothetical question of whether the damage would have occurred irrespective of the conduct (respectively product defect) at issue. If this were the case the conduct (respectively product defect) was not causal. However, doctrine and case law in addition apply the theory of 'adequate' causation, meaning that damages that are the result of a totally atypical and extraordinary chain of circumstances of cause and effect are excluded from liability.

On the other hand, *prima facie* evidence may serve to the benefit of the plaintiff. If facts are established that according to general experience allow conclusions on a certain course of events, such as the existence of a product defect and the causal relationship between defect and damage, the judge may regard this as proven, unless the defendant can show that the damage may have occurred owing to an atypical course of events.[12]

iii Defences

Under the Product Liability Act, liability can be excluded by proving:

a that the defect can be attributed to a specific mandatory legal provision or official instruction with which the product had to comply;

b that the state of scientific and technical knowledge at the time the product was put into circulation by the person against whom an action is brought was not such as to enable the existence of the defect to be discovered (state-of-the-art defence); or

c that – if the person against whom an action is brought has produced merely a raw material or a component part – the defect was caused by the design of the product in which the raw material or component part was fitted, or by the instructions given by the producer of the product.

Further defences available to the defendant are that it did not put the product into circulation or did not act as entrepreneur, or that the defect that caused the damage did not exist at the time it put the product into circulation.

Outside the Product Liability Act, the defendant can invoke any defences that may serve to disprove the allegations of the plaintiff and fault.

A further defence both under and outside the Product Liability Act is contributory fault by the damaged party or a person for whose conduct the damaged party is responsible, which – if successful – may lead to a reduction of the damage the defendant has to compensate.

Further, the defendant may plead the statute of limitation.

There are relative and absolute statutes of limitations. The relative statute of limitations is three years and begins to run from the time the damaged party became aware (or at least could reasonably have become aware) of the damage and the person causing the damage. The absolute limitation period under the Product Liability Act is 10 years, starting from the time the party liable for compensation put the product into circulation. For damage claims outside the Product Liability Act the absolute statute of limitation is 30 years, starting from the time the damage occurred.

12 Fitz/Grau/Reindl, *Produkthaftungsgesetz*, p. 257.

iv Personal jurisdiction

Austrian jurisdiction for product liability(-related) claims is an issue if the defendant does not have its seat in Austria, or (as is the case in most product liability cases) there is no contractual relationship between the damaged party and the defendant from which Austrian jurisdiction (e.g., because of a jurisdiction clause in favour of Austrian courts) derives.

If the defendant has its seat outside the European Union[13] or not in a state party to the Lugano Convention[14] (i.e., in a 'third state') the question of Austrian (international) jurisdiction is to be determined on basis of the Austrian Jurisdiction Law. Pursuant to Section 92a of the Law, Austrian jurisdiction for damage claims is given if the act causing the damage occurred in Austria. According to the Austrian Supreme Court, within the meaning of this provision, if the place where the act causing the damage and the place where the damage occurred are not identical, solely the place where the act causing the damage occurred is of relevance.[15] In product liability cases this is basically the place where the defective product was manufactured. This is without prejudice to any liability of the importer of the product.

Notwithstanding the above, jurisdiction for claims against a producer based in a third state might be given in case of a 'joinder of parties', for instance, if the producer is sued together with the importer who has its seat in Austria. A precondition for the establishment of a place of jurisdiction based on 'joinder of parties' is that the parties in the joinder are joined parties within the meaning of Section 11 of the Austrian Code of Civil Procedure, meaning that they are linked by equal legal or factual grounds, or that they are jointly and severally liable. In such a case the applicable law may also have to be looked into. According to Regulation (EC) No. 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II), the law applicable to a non-contractual obligation arising out of damage caused by a product shall be: (1) the law of the country in which the person sustaining the damage had its habitual residence when the damage occurred, if the product was marketed in that country; or, failing that, (2) the law of the country in which the product was acquired, if the product was marketed in that country; or, failing that, (3) the law of the country in which the damage occurred, if the product was marketed in that country. However, the law applicable shall be the law of the country in which the person claimed to be liable is habitually resident if it could not reasonably foresee the marketing of the product, or a product of the same type, in the country the law of which is applicable under (1), (2) or (3).

As regards claims against a defendant domiciled in a Member State of the European Union, the provision that a person domiciled in a Member State may be sued, in another Member State, in matters relating to tort, delict or quasi-delict 'in the courts for the place where the harmful event occurred or may occur' is of main relevance in product liability cases lacking a contractual relationship between the damaged party and the defendant. Regulation

13 If the defendant is domiciled within the European Union, to proceedings instituted after 10 January 2015 Regulation (EU) No. 1215/2012 of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (recast) applies, and to proceedings instituted before 10 January 2015 its predecessor, Council Regulation (EC) No. 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters is applicable.

14 The Lugano Convention on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters applies in relation to Switzerland, Norway and Iceland.

15 Austrian Supreme Court, Case No. 7 Ob 541/92 of 23 April 1992, and Case No. 2 Ob 157/04h of 1 July 2004.

(EU) No. 1215/2012 of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (recast) contains this provision in Article 7(2), its predecessor, Council Regulation (EC) No. 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters in Article 5(3). Likewise, the Lugano Convention (in Article 5(3)) refers to the courts of the place where the harmful event occurred or may occur.

According to the interpretation of the European Court of Justice (ECJ), in a case where the place of occurrence of the event that may give rise to liability in tort, delict or quasi-delict and the place where that event results in damages are not identical, the expression 'place where the harmful event occurred' must be understood as being intended to cover both the place where the damage occurred and the place of the event giving rise to it, so that the defendant may be sued, at the option of the plaintiff, in the courts for either place.[16]

The Austrian Supreme Court, in a decision of 28 November 2012,[17] made a request for a preliminary ruling to the ECJ regarding the determination of the 'place of the event giving rise to the damage' in relation to product liability, by posing the question of whether this is the place where (1) the producer is established; (2) the product was put into circulation; or (3) the product was acquired by the end-user. The case underlying this request involved a dispute between a bicycle producer based in Germany and an Austrian plaintiff (a consumer) who had bought the bicycle from an Austrian-based company. While riding this bicycle in Germany the plaintiff suffered a fall and was injured. He subsequently sued the German producer for damages under the Product Liability Act before a court in Austria. According to the plaintiff his fall from the bicycle was caused by the fact that the fork ends had detached themselves from the wheel fork owing to a manufacturing defect. For the purpose of establishing jurisdiction of the Austrian court the plaintiff relied on Article 5(3) of Regulation No. 44/2001, claiming that the place of the event giving rise to the damage would be located in Austria as the bicycle was bought there, in the sense that the product was made available to the end user by way of commercial distribution.

In its judgment of 16 January 2014, the ECJ ruled upon said request by the Austrian Supreme Court that Article 5(3) of Regulation No. 44/2001 must be interpreted as meaning that, where a producer faces a claim of liability for a defective product, the place of the event giving rise to the damage is the place where the product in question was manufactured.[18] Given that Article 7(2) of Regulation No. 1215/2012 is identical to Article 5(3) of Regulation No. 44/2001, it seems safe to say that the same interpretation applies. This also holds for Article 5(3) of the Lugano Convention.

v Expert witnesses

The judge can appoint experts at its discretion to assist in establishing the facts of the case. In product liability cases, it is usual that the judge appoints an expert. The parties may propose experts and reject an expert on the grounds of bias; however, the final decision rests with the judge.

16 European Court of Justice, Case C-51/97 (*Réunion Européenne*); Case C-189/08 (*Zuid-Chemie*).

17 Austrian Supreme Court, Case No. 7 Ob 187/12v of 28 November 2012.

18 European Court of Justice, Case C-45/13 (*Andreas Kainz*).

The parties may present private expert opinions but courts regard a private expert opinion only as a private document attesting to the author's opinion. A private expert opinion might serve as an instrument to question or to raise doubt as to the court-appointed expert's opinion.

vi Discovery

Austrian law does not provide for (pretrial) discovery proceedings.

In Austrian civil proceedings, it is each party's responsibility to produce the evidence necessary to support its case. There are only very limited conditions under which a party may be obliged to disclose certain evidence upon the other party's request. These conditions are specified in the Austrian Code of Civil Procedure according to which documents are subject to disclosure if (1) the opponent itself relied on the document in the course of the proceedings; (2) the opponent is obliged to hand the document over by a substantive law; or (3) the document is qualified as a 'joint deed' between the parties.

Joint deeds are documents created in the interest of the party requesting disclosure, documents that contain information regarding reciprocal rights and obligations between the parties, or any documents that are in fact written negotiations between the parties.

The party requesting disclosure has to clearly specify the evidence (i.e., the document or documents) it wishes to see; requests to produce 'all relevant' documents are prohibited. If the above criteria are met, the court can order the opposing party to produce the requested documents. However, a court order to the opposing party to produce documents is non-enforceable. Failure to comply with the order may only be sanctioned inasmuch as the court can take this behaviour into account in its evaluation of the entire case.

Witnesses have the duty to appear before the court and to answer truthfully. Parties (these include a company's statutory representatives, such as the CEO) are generally treated as witnesses but they are under no duty to appear before the court or to give testimony. Further, Austrian law provides for grounds of refusal by parties or witnesses to answer questions during testimony in specific circumstances (e.g., confidentiality, business or trade secrets, examination exposes the party or witness to the risk of criminal prosecution, etc.).

vii Apportionment

The Product Liability Act provides for joint and several liability where two or more persons are liable for the damage caused by a defective product. As explained in Section I, *supra*, this can be the producer of the finished product, a raw material or component part, or the person who presents itself as producer, the importer, or any supplier who did not (in a timely fashion) make the required naming for exempting itself from liability. Thus, if there is more than one person liable under the Product Liability Act the person who has suffered losses can choose whether it seeks redress against one, or all, of them. If a person liable for compensation under the Product Liability Act has paid damages, though neither the person itself nor one of its employees has caused the defect, it is entitled to claim full reimbursement from the producer of the defective finished product, raw material, or component part. If several parties are liable for reimbursement, then the liability towards the person compensating the damage is again joint and several. If several parties liable under the Product Liability Act have contributed to the defect, the extent of the claim for reimbursement of the person that has compensated the damage against the other parties depends on the circumstances, in particular on the extent to which one or the other party is responsible for the damage or to which the damage was caused by bringing about a product defect.

Outside the Product Liability Act joint and several liability may, *inter alia*, arise if two or more persons unlawfully and negligently contributed to the damage but the proportion to which each contributed cannot be determined.

Austrian law does not provide for market share liability.

The Product Liability Act does not contain a provision regarding successor liability for companies that have acquired the product manufacturer or other persons in the distribution chain. Thus, the general rules apply.

Section 1409 of the Austrian Civil Code contains a mandatory provision that provides for the statutory assumption of liabilities by the acquirer of a business or substantial part of assets for debts pertaining to such business or assets of which the acquirer knew or should have known at the time of the transfer. The acquirer becomes jointly liable with the seller for such debts; however, the acquirer's liability is limited to the market value of the acquired assets.

Pursuant to Section 38 of the Austrian Commercial Code, a person that acquires (by way of singular succession) and continues a 'business' assumes all business-related relationships of the seller, including all connected rights and liabilities, as of the date of the transfer of the business. The seller, on the other hand, remains liable for these liabilities only as far as they become due during a period of five years from the date of the transfer. The acquirer's liability is not limited; however, the acquirer and the seller may agree on exclusions of liability. Such agreement is effective in relation to third parties only if it was registered in the commercial register, or published in a commercially customary manner, or notified to the third party on an individual basis.

viii Mass tort actions

Austrian law does not (yet) provide for mass tort actions; however, the Austrian Procedural Code offers instruments that permit the bundling of a series of related claims or proceedings under certain conditions, thus enabling a number of plaintiffs to bring their claim against one defendant. Such instrument is in particular a formal joinder of parties, which presupposes that the subject matter of the claims is based on similar factual grounds and jurisdiction of the court is given for each individual claim.

Further, Austrian case law has in the preceding years developed the 'class action of Austrian style' under which, if the claims are first assigned to another person or legal entity, this person (legal entity) may then bring the claims as sole plaintiff in one action provided that the bases of the claims, as well as the questions of fact and law are in principal the same.

ix Damages

In case of personal injury both under the Product Liability Act and fault-based liability under general civil law, compensation includes medical treatment costs, loss of income, and appropriate damages for pain and suffering (which may also include mental damages and suffering owing to losses of a close relative). In the praxis of courts as measurement criteria for damages for pain and suffering certain amounts for days of severe, moderate and mild pains and sufferings are applied, which are usually calculated by a court-appointed medical expert.

As regards damages to property, under the Product Liability Act, there is a deductible amount of €500, and damages to the defective property itself are not covered. Further, under the Product Liability Act pure financial losses are not recoverable.

Austrian law does not allow for punitive or exemplary damages.

For criminal liability, see Section III, *supra*.

V YEAR IN REVIEW

The Austrian courts published no major decisions relating to product liability last year.

In one case, the Austrian Supreme Court dealt with the issue of what constitutes an end product within the meaning of the Product Liability Act, in the context of packaging a product for transport. The product (insulating material) had been fixed on transport pallets with plastic foil. This was not done properly, and the transport pallets started to slide, which resulted in injury to a person. The question in this case was whether a new – and defective – end product was created through the packing process. The Supreme Court reasoned that the end product is the product in the form in which according to general understanding it is intended for use by the customer. If the packaging of a finished product does not have any influence on the substance of the product, but merely serves the preparation of its transport and to safeguard that it is not damaged during transport, no 'new' end product is created by the packaging. The Supreme Court thus dismissed the product liability claim.[19]

19 Austrian Supreme Court, Case No. 7 Ob 175/16k of 30 November 2016.

Chapter 4

BELGIUM

Joost Verlinden and Gert-Jan Hendrix[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

Until 1991, no specific rules on product liability existed under Belgian law. Instead, persons injured by defective products claimed damages based on either the general provisions of tort law or on the rules relating to the sale of goods. On 25 July 1985, however, the then European Economic Community adopted Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (the Product Liability Directive). This Directive was transposed into Belgian law by way of the Act of 25 February 1991 concerning liability for defective products (the Product Liability Act), which entered into force on 1 April 1991, and applies only to damage caused by defective products brought into circulation after that date. It was later amended by the Act of 12 December 2000 modifying the Act of 25 February 1991 concerning liability for defective products, to bring it in line with Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999 amending Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products. The Belgian legislator has chosen to adopt the European directives on product liability in full, choosing not to derogate from their provisions even where allowed.

Since Article 13 of the Product Liability Act states that the Act does not affect any rights that the injured person may have under tort law, injured persons may also base their claims on tort law or contract law. The injured person may choose to do so in cases that do not fall entirely under the scope of the Product Liability Act, such as cases involving intangible or immoveable goods, or cases where it would like to claim damages from a party other than the producer. Tort claims in product liability cases are based on Articles 1382 to 1383 of the Civil Code, the basic articles on tort law. Contractual claims are based on Article 1641 of the Civil Code, which imposes on the seller of a good the obligation to warrant that that good is free from defects, or, in the case of consumer contracts, on Article 1649 *quater* of the Civil Code, which was created by the Act of 1 September 2004 concerning the protection of consumers as regards the sale of consumption goods and transposed Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees into the Civil Code.

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II REGULATORY OVERSIGHT

The main authorities with regard to product regulation are the Ministry for the Economy and for Consumer Affairs (the Ministry), the Consumer Safety Commission (CSC) and the Central Contact Point for Products (CCPP). The latter two were created by the Act of 9 February 1994 concerning the safety of products and services (the Product Safety Act), which implemented Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety into Belgian law, and which has since been largely replaced by Book IX of the Code of Economic Law.

The Minister can prohibit the placing of products on the markets, impose safety rules on manufacturers or order a recall of products when products are not in conformity with either specific safety rules or with the general safety rule set out in Article IX.2 of the Code of Economic Law; however, before being allowed to take any measure, the Minister must consult representatives of the manufacturers, consumer organisations and, where applicable, labour organisations.

The Minister may, however, instead of consulting any of those organisations, consult the CSC, which is the general advisory body on product safety. The CSC may further give advice to the Minister with regard to product safety policy in general, organise consultations between manufacturers, consumer organisations, and the Minister, and organise campaigns to raise awareness of product safety issues.

Article 17 of the Product Safety Act grants the CSC the power to gather all information necessary for its advice. This includes the possibility of forcing a manufacturer to produce documents that would normally be covered by trade or factory secrecy. The members of the CSC are then, however, bound by professional secrecy and may only publish the information that is directly relevant for the risk assessment of the products in question.

Finally, the CCPP only plays a coordinating role. It acts as a contact point for consumers, producers, distributors, employers, and regulatory bodies from other Member States of the European Union with regard to safety regulation questions, and sends those questions to the proper authorities. It also centralises data regarding the safety of products.

Article IX.8 Section 4 of the Code of Economic Law imposes the obligation on producers and distributors to immediately inform the CCPP of any safety risks associated with products that they have placed on the market and that would be in violation of the safety rules concerning that product. Producers and distributors must then cooperate fully with the authorities in their assessments of the risks involved. Not informing the CCPP of potential safety risks is punishable, on the basis of Article XV.102, Section 2 of the Code of Economic Law, by a criminal fine of between €208 and €200,000.

III CAUSES OF ACTION

i Claims under the Product Liability Act

Article 1 of the Product Liability Act makes a producer liable for all damage caused by a defect in its product.

Thus, any injured person, regardless of whether it had a contractual relationship with the producer of the defective good, has the right to commence proceedings for indemnification. This right is not limited to consumers, although damage to goods can only be recovered if the goods are ordinarily intended for private use and were also used as such.

A product is defined by Article 2 of the Product Liability Act as any tangible, moveable, good, even if it is part of another moveable or immoveable good. This includes electricity and,

since the Act of 12 December 2000, agricultural products and game. Though doubt could exist as to whether software would fall under the definition of product, both the European Commission and the preparatory works of the Product Liability Act have stated that software must also be considered a product for product liability purposes.

An action may be lodged against the producer of a product, which can be one of four different persons on the basis of Articles 3 and 4 of the Product Liability Act:

a the real producer (i.e., the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part);

b the apparent producer (i.e., the person who, by putting its name, trademark or other distinguishing feature on the product presents him or herself as its producer);

c the importer (the person who imports into the European Union a product in the course of its business with the intention of selling it or making it available for use by a third party); or

d the supplier of the product, where the product was manufactured within the European Union, but the identity of the producer of the product is unknown, or where the product was manufactured outside the European Union and the identity of the importer is unknown (the supplier will be released of liability, however, if it informs the injured person, within a reasonable time, of the identity of the producer or importer).

The definition of producer is thus fairly broad and is interpreted broadly by the courts as well.

ii Tort claims

An injured party may also base its claim on the law of torts, contained in Articles 1382 to 1383 of the Civil Code. However, Belgian law only allows for claims to be based on the law of torts where no contractual relationship exists between the tortfeasor and the injured party. Thus, a consumer cannot hold the entity that sold him or her the defective product liable on the basis of tort law. He or she will, in that case, have to either rely on the Product Liability Act or on the law of contracts. However, once outside the contractual domain, an injured party may sue any person in torts, no matter how remotely removed they are from each other.

iii Contractual claims

Where the injured party was in a direct contractual relationship with the seller of the good, it may also base its claim on Article 1641 of the Civil Code.

While the law of contracts would normally not allow the injured party to claim damages from entities higher up the production chain with which it was not in a contractual relationship, courts have nonetheless allowed such 'direct claims', to circumvent the sluggish process of having each entity in the production process sue its direct contractual counterparty. Thus, where the defect can be traced back to the producer of the raw materials, the end user of the good may directly sue that producer of raw materials based on Article 1641 of the Civil Code.

As regards consumer contracts, Article 1649 *quater* of the Civil Code requires that the person lodging the claim is a consumer, which is defined by Article 1649 *bis* as any natural person who is acting for purposes that are not related to his or her trade, business or profession. The consumer may, on the basis of that article, hold a seller liable for any lack of conformity in the goods sold.

iv Criminal charges

The producer of a defective product could be prosecuted for the crime of unintentionally killing or injuring a person, defined by Articles 418 to 420 of the Criminal Code. These articles make punishable the act or omission performed without the intention of harming or killing a person, which owing to a lack of due care or precaution results in the death or injury of another person.

Criminal proceedings will usually be started by the public prosecutor, who will always be the opposing party in those proceedings, but may also be started by an injured party by filing a complaint with the investigating magistrate.

Where criminal proceedings have been started, an injured party may lodge its claim in tort directly with the criminal court, which will then render a judgment on that claim in its judgment on the criminal charges. Where an injured party chooses to lodge its claim in tort before a civil court, all civil proceedings will be stayed until after the rendition of the judgment on the criminal charges. The civil court will then be bound by the interpretation of the facts given by the criminal court in that judgment.

IV LITIGATION

i Forum

Product liability cases are tried before the general civil court system in Belgium. This court system consists of four distinct levels of ordinary courts:

a the justice of the peace courts;
b the courts of first instance, the labour courts and the commercial courts;
c the courts of appeal; and
d the Court of Cassation.

The justice of the peace courts are the lowest civil courts. Since they only have jurisdiction over local matters and claims below €2,500, they will only deal with minor product liability cases. Judgments rendered by the justice of the peace courts can only be appealed if the value of the claims concerned exceeds €1,860. Appeals against judgments of a justice of the peace are generally heard by the courts of first instance, unless where both parties are merchants under Belgian law, in which case appeals are heard by the commercial courts.

The courts of first instance are Belgium's general courts, and are divided into a section for cases regarding minors and family law, a criminal section, known as the criminal court, which has jurisdiction over certain criminal offences, and a civil section, which has general jurisdiction over all civil claims not exclusively attributed by law to other courts.

The commercial courts only deal with disputes between or against enterprises (i.e., persons who permanently pursue an economic goal), which by definition includes most commercial enterprises. The main benefit of appearing before the commercial courts is that the court is partially composed of lay judges, who are themselves business people and therefore have more knowledge of commercial practice.

Appeals against decisions by the courts of first instance and the commercial courts are heard by the courts of appeal, unless the value of the claim concerned does not exceed €2,500, in which case the judgment becomes final immediately. Appeal judgments of the courts of first instance or the commercial courts against judgments of the justice of the peace courts

cannot be appealed any further. The courts of appeals may, within the limits of the appeal lodged by the appellant, re-examine the facts, and are thus not bound by the interpretations made by lower courts.

Against a judgment in second instance, a party may commence proceedings before the Court of Cassation, the highest court in civil and criminal matters. The Court of Cassation's scope of review is limited to procedural issues and the correct application of substantive law. As such, the Court of Cassation must accept the facts it is presented with as they are set out in the appeals judgment. If a judgment is quashed by the Court of Cassation, it is referred back to a court at the same level as the court that rendered the judgment.

ii Burden of proof

The general evidentiary rule of Article 870 of the Judicial Code states that each party should furnish evidence of the facts it relies on.

Claims under the Product Liability Act

The Product Liability Act created a system of faultless liability, meaning that a producer will be liable as soon as it is proven that damage has resulted from a defect present in its product, regardless of whether it committed a fault.

According to Article 5 of the Product Liability Act, an injured party may prove that a product is defective by proving it does not provide the safety that a person is entitled to expect, taking all circumstances into account. Thus, a product may be considered defective even though it operates in accordance with its design, but where it is presented in such a way that the user of the good may expect it to be safer than it is in reality; however, a product cannot be considered defective for the sole reason that a better product is subsequently put into circulation. The determination of the presence of a defect will thus be heavily fact-driven. However, where it is found that products belonging to the same group or forming part of the same production series have a potential defect, it is possible to classify as defective all products in that group or series, without there being any need to show that the product in question is defective.[2]

Apart from proving the presence of a defect, an injured party will also have to establish that a sufficient causal link existed between the defect and the damage suffered, such that the presence of the defect was a necessary condition for the damage to arise. Finally, an injured party will have to prove the damage it suffered.

Tort claims

As opposed to liability under the Product Liability Act, liability under tort law is not faultless. Articles 1382 and 1383 of the Civil Code, the legal basis for the tort of negligence, states that a person will be held to repair the damages caused by his or her fault or omission. A fault can generally be proven by demonstrating that the tortfeasor violated either of two standards: either it violated an obligation imposed on it by the law, or it neglected to behave as a normal, careful, and prudent person placed in the same situation would have.

The process of proving such a fault is, in some circumstances, made easier by the implementation of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety into Belgian law. Article IX.2 of that Code

2 Cases C-503/13 and 504/13 *Boston Scientific Medizintechnik GmbH* [2015], paragraph 41.

of Economic Law contains the obligation for producers to place only safe products on the market. A violation of that obligation could be considered a fault under Article 1382 of the Civil Code. However, as a recent judgment of 22 March 2016 of the Police Court of Antwerp, section Turnhout, shows, that is not necessarily the case. In that judgment, the Police Court held that mere proof that a product is defective does not suffice to hold a producer liable on the basis of Article 1382 of the Civil Code.

Similar to the claims under the Product Liability Act, an injured party will also have to prove that the fault was a necessary condition for the damage to arise and that it suffered harm.

Contractual claims

To sufficiently prove its claim in contract, an injured party will have to prove that a defect existed in the good that is the subject of the contract of sale. The standard of proof that the buyer has to meet in this regard is that a characteristic of the good makes it unsuitable for the purpose for which it is intended or less suitable for that purpose, to the extent where the buyer would not have bought the good had he or she known the characteristic. The buyer will also have to prove that that characteristic was already present in its incipiency at the time of the sale.

A claim lodged for breach of a consumer contract, based on Article 1649 *quater* of the Civil Code, requires the consumer to establish that the product was not in conformity with the contract of sale. One instance where such non-conformity is present is the situation where the good is not of the quality that is normal in goods of the same type and that the consumer could reasonably expect, given the nature of the goods.

The injured party will again have to prove that a sufficient causal link existed between the breach of contract and the damage, and that it suffered harm.

iii Defences

Claims under the Product Liability Act

Article 8 of the Product Liability Act states that a producer cannot be held liable when it proves that:

a it did not put the product into circulation;[3]

b having regard to the circumstances, it is probable that the defect that caused the damage did not exist at the time the product was put into circulation by it, or that the defect came into being afterwards;

c the product was neither manufactured by it for sale or any form of distribution for economic purpose nor manufactured or distributed by it in the course of the producer's business – this effectively requires the producer to prove that the production of the product was both non-commercial and non-professional in nature;

d the defect is owing to compliance of the product with mandatory regulations issued by public authorities;

3 The European Court of Justice has held that this defence covers cases where a person other than the producer has caused the product to leave the process of manufacture, where the product was used contrary to the producer's intention, or where the product is used for private purposes or in similar situations (Case C-127/04 *O'Byrne* [2006] ECR I-1330, paragraph 24; see also: Case C-203/99 *Henning Veedfald* [2001] ECR I-3569, paragraph 16).

e the state of scientific and technical knowledge at the time when the producer put the product into circulation was not such as to enable the existence of the defect to be discovered;[4] or

f 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.

Article 10, Section 1 of the Product Liability Act prohibits the producer from contractually creating additional grounds of defence.

Article 12 of the Product Liability Act provides a limitation period of three years for claims, starting on the day on which the injured person becomes aware, or should have been aware, of the damage, the defect and the identity of the producer, and in any event upon the expiry of a period of 10 years from the date on which the producer put the product into circulation.

Tort claims

Against a claim in tort, a producer can only defend itself by proving that its fault was owing to force majeure (i.e., an unforeseeable and irresistible event that made it impossible for the producer to not behave in the way it did).

Tort claims are time-barred, on the basis of Article 2262 *bis* of the Civil Code, five years after the day on which the injured person became aware of both the damage and the identity of the tortfeasor, and in any event 20 years after the day on which the tort was committed. Tort claims are therefore subject to a longer limitation period than claims under the Product Liability Act.

Contractual claims

A producer might similarly defend itself against a claim in contract by proving force majeure. The statute of limitations on contractual claims expires after 10 years.

iv Personal jurisdiction

For proceedings brought before 10 January 2015, the international jurisdiction of Belgian courts is determined on the basis of Council Regulation 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (the Brussels I Regulation). For cases brought, however, after 10 January 2015, international jurisdiction is determined on the basis of Regulation 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 (recast) (the Brussels I Recast), which superseded the Brussels I Regulation, but leaves much of its rules for establishing jurisdiction untouched.

Claims against persons domiciled within the European Union must, on the basis of Article 2 of the Brussels I Regulation and Article 4 of the Brussels I Recast, be brought before the courts of the Member State of domicile of that person; however, exceptions to this general rule exist.

4 The state of scientific and technical knowledge has to be assessed objectively, meaning that it includes all knowledge that the producer should have been aware of, and not only that knowledge of which it was effectively aware.

First, if the injured party is in a contractual relationship with the producer of the product, Article 5.1(a) of the Brussels I Regulation and Article 7.1(b) of the Brussels I Recast allow it to sue before the courts of the Member State where the defective product was delivered. Furthermore, Article 16.1 of the Brussels I Regulation and Article 18.1 of the Brussels I Recast allow the injured party, should it be a consumer, to sue the party with which it contracted before the Member State of its own domicile, if its counterparty pursues commercial or professional activities in that Member State, and the contract falls within the scope of those activities.

Second, if the injured party is not in a contractual relationship with the producer of the product, Article 5.3 of the Brussels I Regulation and Article 7.2 of the Brussels I Recast allow it to lodge a claim in tort before the courts of the Member State where the harmful event occurred.

For claims falling outside the scope of the Brussels I Regulation (those against a producer not domiciled within the European Union), the Belgian Code of Private International Law is applicable. Article 5 of that Code again states the general rule that a defendant should be sued before the courts of its domicile. However, if a contractual relationship exists between an injured party and the producer of a defective product, the injured party may sue before the Belgian courts if the contractual obligation concerned was created in Belgium or was to be performed in Belgium. Where no contractual relationship exists between the injured party and the producer, the producer may be sued in tort before the Belgian courts if either the tort was committed or the damage occurred in Belgium.

v Expert witnesses

Expert witnesses are frequently appointed by courts, especially in product liability cases, which by their nature concern technical or specialist issues. Courts are rather reluctant to rely on the findings of experts who conduct their inquiries at the request of one of the parties alone, as they are suspected of bias. Courts will therefore usually appoint independent court experts, which they can do at their own motion. These court experts will allow the parties to comment on a draft report, adduce evidence they consider necessary and ask additional questions, to ensure that each party's viewpoint is taken into account. In the majority of cases, the final report of a court expert is accepted by the court.

vi Discovery

Belgian law does not provide for the possibility of discovery or depositions as they are known in common law jurisdictions. Parties have to adduce those documents that they consider necessary to substantiate their claims themselves, and are not under an obligation to produce any documents that would contradict their claims.

Belgian law does know one exception to this rule. Article 877 of the Judicial Code allows a court, at its own motion or at the request of one of the parties to the dispute, to order the production of a document, regardless of whether it is held by a party to the dispute or a third party, where there are serious, precise and concurring presumptions that that party is in possession of the document and that the document contains evidence of a fact that is relevant to the case.

vii Apportionment

Where multiple parties would be held jointly and severally liable by a court for the same error or for separate errors that caused the damage to the injured person, the injured party may claim payment of his or her entire damage from one liable party.

That party may then claim contribution in that payment from the other liable parties, each having to contribute in proportion to the gravity of the contribution of their fault to the causation of the damage. The risk of insolvency of one of the liable parties is borne by the other liable parties, such that where one of the liable parties defaults on his or her contribution in the damages, the others will have to distribute this loss among themselves. Thus, where multiple parties are held liable, the injured party is protected against the insolvency of one of the liable parties, since it can claim full payment from the most solvent liable party.

viii Mass tort actions

Class actions became available under Belgian law by the entry into force on 1 September 2014 of the Act of 28 March 2014 on the insertion of a Title 2 'Actions for collective redress' into Book XVII of the Code of Economic Law. Class action proceedings are only available to plaintiffs whose claims are based on specific statutes, and only for cases where the cause of the collective harm occurred after 1 September 2014. Pursuant to Articles XVII.36 and XVII.37 of the Code of Economic Law, the Product Liability Act is included in this list of specific statutes on which a class action may be based.

Whether the class action requires plaintiffs to opt in or opt out is, for Belgian plaintiffs, left up to the discretion of the court; however, an opt-in system must always be used for foreign plaintiffs. A class action can only be brought by a class representative, which may be either a recognised consumer organisation, the Federal Ombudsman for Consumer Affairs, or any organisation authorised by the Minister. In a recent judgment of the Constitutional Court of 17 March 2016, this limitation was declared unconstitutional and annulled to the extent that class representatives from other EU and EEA Member States complying with the requirements of point 4 of Recommendation 2013/396/EU could not bring a class action. Until the legislator amends this statutory provision, the courts will therefore allow claims brought by such representatives from other EU and EEA Member States.

Before the court assesses the class' claim on its merits, it must first set a time period during which the class representative and the defendant must negotiate on a collective settlement. If a settlement is reached and receives court approval, it becomes binding on the entire class. Only when no such settlement can be reached will the court hear the case on its merits.

In addition to the possibility of a class action, actions brought separately by different persons but having the same object may be joined where the court considers it beneficial.

ix Damages

Belgian law turns on the principle that damages should place the injured party in the same position it would have found itself in had the event causing the damage not occurred. This includes not only damages for costs that have actually been incurred owing to the injury, such as hospitalisation and recovery costs, but also non-economic (moral) damages for pain, suffering and disfigurement. Punitive damages, however, cannot be awarded. There is no cap as to the amount of damages recoverable under Belgian law.

Under the Product Liability Act, damages for personal injury are subject to the general principles of Belgian law (i.e., that both costs incurred and moral damages must be awarded),

but damages suffered to goods may only be awarded if the goods are ordinarily intended for private use or consumption and are used by the injured person mainly for his or her own private use or consumption. Even when damage to goods satisfies these two conditions, damages may only be awarded for the amount exceeding €500, so that the injured party must bear the first €500 in losses itself.

V YEAR IN REVIEW

2016 only saw two published judgments concerning product liability and safety claims, both of which entailed straightforward applications of the rules set out above, with no major surprises. 2016 was therefore a relatively quiet year in terms of product liability and product safety cases.

A first judgment, of the Court of Appeal of Liège, concerned a man losing three fingers owing to a defective circular saw. The saw that caused the harm was already the second one of that type that the victim owned. He had exchanged the first one for a new saw after it turned out to be defective. The Court of Appeal held that this exchange did not prove that the victim should have been aware that the saw was unsafe. Furthermore, the Court of Appeal applied a very factual test to determine whether a company could qualify as the 'importer' under Article 4, Section 1 of the Product Liability Act.

A second judgment, of the Police Court of Antwerp, section Turnhout, concerned a bicycle tyre that exploded, causing its owner to fall. The court rejected the claim based on the Product Liability Act against the producer of the tyres, since it was proved that the defect was not already present in the tyre when it was manufactured. The bicycle salesman, however, did not manage to prove that the defect was not yet present when he put it into circulation, and was therefore held liable. The claim against the bicycle salesman based on Article 1382 of the Civil Code was rejected, since the victim did not sufficiently prove a fault.

Finally, the Constitutional Court rendered an important judgment in the field of class action suits on 17 March 2016, by holding that the limitation of the right to bring a class action to certain entities was unconstitutional to the extent that it excluded class representatives from other EU and EEA Member States complying with the requirements of point 4 of Recommendation 2013/396/EU. Until the legislator amends this statutory provision, those EU and EEA class representatives will be able to bring class action suits.

Chapter 5

BRAZIL

Fabio Teixeira Ozi and Murilo Castineira Brunner[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

In Brazil, consumer laws were enacted primarily to protect consumers from problems arising from products or services suppliers. The first bill of law for this specific purpose came about in the country in 1977, but the codification of consumer rights took place 11 years later with the enactment of the 1988 Federal Constitution.

The Constitution was responsible for establishing three important principles for consumer protection: protecting consumer rights;[2] ensuring its imperative within the economic order;[3] and, in the Act of Transitory Constitutional Provisions, making these protective rules mandatory, both in private and public law, by creating the Consumer Protection Code (CDC).[4] The CDC was approved in 1990 by the National Congress, and became effective on 11 March 1991.

The enshrinement of the CDC within the Constitution vests consumer protection with extreme importance within Brazilian private law in terms of its social function;[5] the protection granted to the consumer goes beyond the mere economic and encompasses the protection of life, health and safety.[6]

The CDC protects consumer rights both in terms of products and services. Although the CDC is the primary statute, it is not the sole legislative source of rights and obligations applicable to consumer relationships. It is also possible to apply general laws (such as the Civil Code) to fill in gaps in the CDC. Furthermore, there are various other federal laws applicable to specific industries, such as consumer relations involving insurance, telecommunications, the internet, private health services, financial services, and the creation and maintenance of databases. The CDC also has implications for procedural law, especially Law No. 9,099/1995, which created and governs civil and criminal special courts, before which a significant number of consumer lawsuits are heard.

The CDC is thus considered a law of hybrid nature: it contains rules that are civil, administrative and criminal in nature, in addition to rules of procedural law.

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2 Article 5(XXXIII) of the Federal Constitution.

3 Article 170 of the Federal Constitution.

4 Article 48 of the ADCT.

5 Bessa, Leonardo Roscoe. 'National System for Consumer Protection'. In Benjamin, Antônio Herman V; Marques, Cláudia Lima; Bessa, Leonardo Roscoe. Manual de Direito do Consumidor. São Paulo: Revista dos Tribunais, 2008.

6 Article 6, Item I of the Consumer Protection Code.

Article 2 of the CDC defines 'consumer' as an end-user of a product or service, without differentiating between individuals and legal entities, nor between purchasers and users. In practice, the CDC grants equal protection to consumers and to all those that have been victims of defect-related accidents or of any abusive practices listed in Articles 17 and 29.

As far as legal opinions are concerned, there are two theories to define a 'consumer': maximalist[7] and finalist.[8] According to the former (maximalist), a consumer is understood as a person who actually removes an item from the market, irrespective of the purpose of such act, thus encompassing professionals. According to the latter (finalist), the consumer is considered the factual and economic recipient of a product who does not make use of it professionally, thus excluding intermediate consumption, in which the product returns to the production chain.

The Superior Court of Justice (STJ)[9] has adopted the finalist theory, but this theory has been applied with moderation in relation to legal entities in a process referred to as 'deepened finalism', authorising the application of the CDC even when the consumer is not the final recipient of the product or service but is still vulnerable to actions of a supplier (technical, legal, factual or informational vulnerability).[10]

The CDC is not applicable when neither party is considered a consumer, as described before. Instead, the general rules set out in the Civil Code will apply, which grants the egalitarian treatment to sellers and purchasers of products and services. The considerations submitted herein mind the application of the CDC's specific rules.

It must also be emphasised that the Constitution[11] establishes concurrent jurisdiction between the federal government, the states and the Federal District to legislate on production and consumption matters. So, as well as federal laws, state and district laws also apply to consumers, the application of which are restricted to the territories of the federative entities in which they were enacted.

II REGULATORY OVERSIGHT

The CDC authorised the creation of the National Consumer Defence System (SNDC).[12] This network is made up of private entities and federal, state and municipal agencies, and agencies of the Federal District, including public consumer protection foundations (known as Procons), civil consumer protection associations and the Public Prosecutor's Office.

There are many public and private entities that form the SNDC, and in order to promote cooperation between them, the Department of Protection and Consumer Defence (DPDC), a federal agency under the Ministry of Justice, was created. Many of the responsibilities of this department were assumed in 2012 by the National Consumer Office (Senacon), also subordinated to the Ministry of Justice.

7 Benjamin, Antônio Herman V; Marques, Claudia Lima; Bessa, Leonardo Roscoe. *Manual de Direito do Consumidor*, 4th edition, reviewed and extended, São Paulo: Editora Revista dos Tribunais, 2012, p. 91.

8 Ibid., pp. 89–90.

9 A federal court that tries cases at final level in which violation is alleged of federal laws or discrepancies in the construal and application of such laws.

10 Special Appeal No. 1.195.642/RJ, Third STJ Panel, Reporting Justice Nancy Andrighi, tried on 12 November 2012.

11 Article 24, item V of the Federal Constitution.

12 Article 106 of the Consumer Protection Code.

Senacon carries out activities such as the maintenance of the National Consumer Protection Information System (Sindec), which ensures broad access to consumers and suppliers to information related to the industry so as to allow more transparency in consumer relations.

Senacon is also in charge of managing and inspecting product recalls, as set out in Article 10 of the CDC, paragraphs 1 and 2 of which compel suppliers to communicate to authorities and consumers any possible risks associated with the use of the product identified after its introduction to market. Currently, Ordinance No. 487 of 15 March 2012, enacted by the Ministry of Justice, regulates Article 10 of the CDC and establishes that 'the supplier of products and services that, subsequent to their introduction on to the consumer market, learns of any hazard such products may have, must immediately notify': (1) the DPDC (Senacon); (2) a Procon; and (3) any competent regulatory agency.

Senacon also advises consumers on their rights and receives complaints or suggestions submitted by representative entities or public or private legal entities; it further determines whether any consumer rights have been violated and applies administrative penalties in cooperation with the Procons.

As previously noted, Procons are public foundations dedicated to the protection of consumers. The creation of a Procon depends on the administration of each of the states and municipalities. The states and the Federal District have the foundations of the Procons already in place, with offices in the state capitals and also in other important urban centres. A Procon's main purpose is to harmonise relations between consumers and suppliers by means of the planning, coordination and performance of national and state policies of consumer protection and defence. This takes place at an administrative level without any direct subordination to the judicial branch.

Procons also process consumer claims in which suppliers should attempt conciliation and closure of any potential litigation. Such complaints may also lead to an administrative proceeding. If the existence of any violation of consumer rights is confirmed, the Procon may enforce administrative sanctions on suppliers such as fines, the removal of products or services from the market, cancellation of registration and authorisation to sell such products or services with the competent agency, and prohibition of manufacture or importation of products.

The civil consumer protection associations are non-profit private entities. They are engaged in parallel to public agencies in the protection of individual or class consumer rights. Once they have been in existence for more than a year, the CDC authorises them to file class actions on behalf of consumers.[13]

The Public Prosecutor's Offices are authorised, through the establishment of the Consumer Protection Justice Prosecution Offices, to investigate any violations of consumer law and to file lawsuits to ensure collective rights.

III CAUSES OF ACTION

The main causes of action under which suppliers of products and services may be held liable for losses suffered by consumers are the existence of deficiencies or defects in the products and services provided, faults in the provision of clear information to consumers, and misleading advertising or advertising in violation of the rules set out in the CDC.

13 Article 82, item IV of the CDC.

A product is deemed defective when it does not offer the safety that it is lawfully expected to offer, taking into account the following aspects:[14]

a the presentation of the product;

b the use and risks that can reasonably be associated with it; and

c the time it was put into circulation.

Specifically, a product may be deemed defective as a result of faults in its design, manufacture, assembly, use, presentation or packaging, or of insufficient or inadequate information about its use and risks.[15] In such a case, the law establishes that its domestic or foreign manufacturer, producer, builder and importer are liable for the losses suffered by the consumer, regardless of fault. Merchants are only held liable for such consumer losses when the manufacturer, builder, producer or importer is unknown or when the product is supplied without clearly identifying the manufacturer, builder, producer or importer, or when the product is not properly stored and looked after.[16]

Likewise, a service is deemed defective when it does not offer the safety that it is expected to offer, taking into account material circumstances, such as the manner of its provision, the result and risks that can be reasonably expected from it, and the duration of the service.[17] In such a case, the law establishes that the service provider is liable for the losses suffered by the consumer, regardless of fault.[18]

In addition to compensation for losses caused by defective products and services, the law provides protection to consumers in the event of faults in products or services. Quality and quantity faults are those that make the product improper or inadequate for its intended consumption, or diminish its value in some way. A fault in the product will also exist in the case of any disparity between the indications in its container, packaging, labelling or advertisement and the product itself.[19]

Consumers may demand remediation of faults within 30 days. After such period, if the fault is not remedied, consumers may alternatively, at their discretion, demand the replacement of the product by another of the same type that is in perfect working order, the immediate refund of the amount paid, as adjusted for inflation, in addition to any damages, or a proportional price rebate.[20]

Similarly, in the event of dissatisfaction with the quality of a service, which diminishes its value, as well as in the event of any disparity between the services provided and the description of such in its offer or advertising, the law entitles consumers to the right to demand: a re-performance of the service at no additional charge; an immediate refund of the amount paid, as adjusted for inflation, in addition to any damages; or a proportional price rebate.[21]

14 Article 12, paragraph 1 of the CDC.

15 Article 12, main provision of the CDC.

16 Article 13, main provision of the CDC.

17 Article 14, paragraph 1 of the CDC.

18 Article 14, main provision of the CDC.

19 Article 18, main provision of the CDC.

20 Article 18, paragraph 1 of the CDC.

21 Article 20, main provision of the CDC.

It should be noted that suppliers must be given the right to rectify any faults existing in products and services. Contract termination, with reimbursement of the monies paid, is authorised only when the supplier is not successful in such rectification within the deadline set by the law.

In addition to the aforementioned claims, consumer lawsuits based on product defects or deficiencies usually also include moral damages. The courts usually grant such claims, but such damages are usually only given in small amounts.

The CDC is the main basis for product liability claims, as informed at the first paragraph of this section.

Finally, product and service provider's officers may be subject to criminal liability, as set out in Articles 61 to 80 of the CDC. Criminal liability may be imposed only against natural persons and based on their fault. Crimes prescribed in the CDC are related to the violation of consumer rights and penalties range from the application of fines up to two years' imprisonment.

IV LITIGATION

i Forum

The CDC entitles consumers to pursue their rights through any type of action, the only condition being that such action must be able to provide adequate and effective protection of consumer rights.[22]

A consumer has the right to file a civil liability action against a supplier of products and services in the jurisdiction of his or her own domicile.[23] In addition, choice-of-jurisdiction clauses in consumer contracts may have their validity challenged by the consumer, provided that the bringing of an action in the agreed-upon jurisdiction would impede or hamper the defence of consumer rights. In most cases, courts declare the nullity of choice-of-jurisdiction clauses in consumer contracts, thus giving preference to the filing of actions in the jurisdiction of the domicile of the consumer.

Moreover, clauses inserted in consumer contracts establishing mandatory arbitration are automatically null and void, as expressly provided for in Article 51, item VII of the CDC.

Cases involving consumers and suppliers are processed before civil state courts. Ordinary proceedings are followed by the case being heard by a trial court, when defences and evidence may be submitted. The decision issued by such court may be appealed to the State Court of Appeals, whose appeal, as a rule, stays the effects of the trial court decision. The Court of Appeals, through a collegiate body (composed of three judges), renders a decision, either unanimously or by majority, upholding, annulling or reversing the decision of the trial court. Such decision may be appealed to the STJ or the Federal Supreme Court. The hearing of such appeals by the superior courts depends on certain specific requirements being met, and the vast majority of appeals is not even heard by either court.

In addition, there are small claims courts, which are jurisdictional bodies the purpose of which is to reconcile, adjudicate and enforce less complex cases in a more expeditious manner. Actions filed before the small claims courts must follow the procedure set out in Law No. 9099 of 26 September 1995, and claims may not exceed an amount equal to 40 times the

22 Article 83 of the CDC.

23 Article 101, item I of the CDC.

minimum wage in the country. In the small claims courts, it is not necessary to advance court costs, and no costs for loss of the suit may be awarded against either party if there is no appeal against the decision. Such measure is intended to facilitate the defence of consumer rights.

Whether to file a civil liability action against suppliers with a court of general jurisdiction or with a small claims court is at the discretion of consumers. Actions filed with small claims courts do follow a simplified proceeding to the extent that, *inter alia*, the filing of interlocutory appeals is not allowed, the production of complex evidence is prohibited and the intervention of third parties is not allowed. The decision issued by a small claims court may be appealed, without a staying effect, to a panel of three judges, who may, either unanimously or by majority, uphold, annul or reverse the decision of the small claims court.

ii Burden of proof

The general rule in Brazilian procedural law is to place upon each of the parties to a dispute the burden of proving the allegations they have presented in the case. The shifting of the burden of proof in certain circumstances is, however, possible; for instance, when the claim involves a consumer on one side and a supplier on the other. Article 6 of the CDC provides the facilitation of the defence of a consumer's rights in the courts, including by shifting the burden of proof in his or her favour in civil cases. The recently enacted new Code of Civil Procedure also establishes the possibility of the court determining the shifting of the burden of the proof.

Such shifting is not automatic by operation of law, and depends on the discretion of the court, which must check whether the consumer's claim is honest and whether there is indeed vulnerability before the supplier. In addition, it must also examine whether such shifting will benefit the production of the evidence.[24]

The courts and the legal community were split over what constitutes an appropriate time for shifting the burden of proof over the course of proceedings. In May 2012, the STJ issued a (non-binding) precedent stating that the shifting of the burden of proof relates to the evidentiary stage, not the adjudication; thus, the court should order its application when the proceeding is still at its initial stage, not when it is adjudicating the case.[25] The new Code of Civil Procedure, in force since March 2016, determines that the eventful shifting of the burden of the proof shall be determined before the beginning of the evidentiary stage of the proceeding (Article 357', III).

iii Defences

The liability of the supplier for losses caused to consumers by its products or services is strict, and the consumer must simply demonstrate the existence of the loss and its causal connection with the deficiency or fault to necessitate compensation, regardless of any proof of fault of the supplier.

To avoid being held liable, the supplier of products must rely on one of the exclusions set out in Article 12, paragraph 3 of the CDC.

In the first instance, the supplier may prove that it was not responsible for placing the defective product on the market. This exclusion cannot be relied upon even if the supplier

24 Article 6, item VIII of the CDC.

25 Second Division, EREsp No. 422.778-SP, original Reporting Justice: João Otávio de Noronha, *ad hoc* Reporting Justice: Maria Isabel Gallotti (Article 52, IV, b of the Internal Regulations of the Superior Court of Justice), trial date 29 February 2012.

has placed the product on the market only in order to test it. Likewise, a supplier that had its product introduced by an agent or representative cannot rely on this to exempt itself from liability.

In the second instance, the supplier will not be held liable if it can prove that the alleged defect does not exist.

Finally, the supplier will not be held liable for damages if the loss has been caused by improper use of the product by the consumer or by a third party. The exclusion of liability of a service provider occurs in similar events. Under Article 14, paragraph 3 of the CDC, the liability of the supplier is excluded if it proves that the defect does not exist or that the loss resulted entirely from the fault of the consumer or of any third parties.

The statute of limitations applicable to consumer claims for damages based on product or service liability is five years[26] from the date on which the consumer becomes aware of the loss and of the liability for such loss. General statute of limitation rules set out in Brazilian law allow the interruption of the period only once and only in limited events.[27]

In addition, the CDC provides that consumer claims for apparent or easy-to-find defects is barred by pre-emption within 30 days, in the case of a non-durable service or product; or within 90 days, in the case of a durable service or product. This pre-emptive period begins to run from the date of delivery of the product or completion of the service.[28]

iv Personal jurisdiction

From the point of view of jurisdiction, Brazil is a unitary state. Thus, it is a single jurisdiction that has authority over all federated states. Article 21 of the Code of Civil Procedure provides that the Brazilian courts have jurisdiction when: (1) the respondent, regardless of nationality, is domiciled in Brazil, in which case a foreign legal entity that maintains an office, branch or subsidiary in the country is deemed domiciled in the country; (2) the obligation is to be performed in Brazil; or (3) the action originates from something occurring or action taken in Brazil.

In short, all suppliers that have businesses in the country, either directly or through representatives, are subject to Brazilian jurisdiction. As already explained, clauses establishing any jurisdiction other than the domicile of the consumer as the competent jurisdiction may be deemed null and void if they hamper or impede the defence of his or her rights in court.

26 Article 27 of the CDC.

27 Article 202 of the Civil Code: 'The interruption of the statute of limitations, which may only occur once, shall occur: I Upon an order from a court, even if it lacks jurisdiction, ordering that process be served, if the interested party provides such service within the time and in the form set forth in procedural law; II Upon protest, in the same conditions set forth in the preceding item; III Upon protest of a negotiable instrument; IV Upon submission of the negotiable instrument to the probate court or in a bankruptcy proceeding; V Upon any judicial act that puts the debtor in default; or VI Upon any unambiguous act, albeit extrajudicial, that implies acknowledgement of the claim by the debtor. Sole paragraph: Such interrupted statute of limitations resumes from the date of the act that interrupted it or of the last act of the process that interrupted it.'

28 Article 26, main provision and paragraph 1 of the CDC.

v Expert witnesses

When 'proof of a fact depends on technical or scientific knowledge, the court shall be assisted by an expert in accordance with the provisions of Article 156' of the Brazilian Code of Civil Procedure. In cases involving product liability, expert evidence is usually produced to determine the actual existence and causes of the alleged problems.

Upon granting the production of expert evidence, the court will appoint an expert it finds reliable to act as an expert witness, as well as allowing the parties to appoint their own retained experts and formulate questions in order to settle the disputed issue.

Retained experts appointed by the parties may participate in all of the production of expert evidence by attending the hearing and then submitting a technical opinion containing their findings on the opinion of the court-appointed expert.

The parties may also request, after the production of expert evidence, that the expert witness be heard at a hearing to provide clarification. The testimony of such expert witness is not, however, regarded as testimonial evidence, but as a continuation of the expert evidence previously started.

On the other hand, the opinion submitted by the expert witness is just another element available to the court, and the court does not need to limit its findings to such evidence if it understands that it is not sufficient. The court may even decide against using expert evidence if justified by other evidence in the case.

It should, however, be mentioned that nothing prevents the court from using other types of evidence to make its findings, as it is not limited to any type of evidence produced in the proceedings. Furthermore, opinions of expert witnesses, although prepared by experts, are often inconclusive.

vi Discovery

Brazilian procedural law, the same as many other civil law jurisdictions, does not provide for a discovery phase in proceedings. Evidence is usually produced during the course of the proceeding itself.

There are few exceptions to such rules, but they are applicable only in cases in which the interested party demonstrates urgency in the need for production of the evidence before filing the claim. In product liability claims, this exception usually applies in cases in which an expert examination is necessary, but waiting until the filing of the claim and the beginning of the evidentiary phase may frustrate the analysis by the expert owing to the perishing of the allegedly defective product. Parties may also request a court order to compel the opposing party to provide documents in court.

Plaintiffs may claim for the disclosure of documents or disclosure of an object that must be examined; however, this precautionary request can be filed only if the plaintiff demonstrates that without the disclosure of such document or object the claim may not be processed. In other words, plaintiffs must prove that the examination of the document or object is essential for the comprehension and acknowledgment of the matter under analysis.

In Brazilian procedural law, the acceptable types of evidence are (1) depositions by the parties, (2) confessions, (3) discovery of a document or item, (4) documentary evidence, (5) testimonial evidence, (6) expert evidence and (7) judicial inspections.

In cases of claims involving liability for allegedly defective products, all means admitted in law are applicable, but in most cases, given the nature of such matters, technical opinions clarifying disputed issues regarding an alleged manufacturing defect are essential.

As such, certain types of evidence may be subject to certain limitations, such as depositions of the parties and testimonial evidence, which are commonly used for clarification of factual – but not necessarily technical – situations. Accordingly, expert evidence and documentary evidence become of paramount importance to illuminate the issues raised by the parties.

In relation to documents in a foreign language, local court precedents[29] and applicable law[30] have settled that their procedural use depends on their translation into Portuguese by a certified translator. Therefore, there is no restriction on the use of such documents relating to liability for defective products, provided the requirements for their admissibility are met.

Finally, with respect to evidence produced in similar cases, court precedents[31] support the understanding that such evidence is admissible, although it remains subject to certain requirements, such as the submission of such evidence for adversarial testing[32] and a minimum level of similarity between the relevant cases.

vii Apportionment

The CDC establishes strict liability on suppliers,[33] through which all suppliers in the consumption chain are responsible for any defects or faults in products or services, irrespective of the proof of fault. Therefore, consumers faced with a fault or defect in a product may direct its claim for redress of moral or property damages to any of the entities of the consumer chain.

In addition, according to the CDC, it is not possible to share liability for damages between suppliers with respect to one particular consumer in the same proceeding. As liability is joint, the sued supplier must respond in full to the consumer, except when there exists a right of recourse in relation to the responsible party in a specific action.

When a company that has engaged in a relationship with consumers has been acquired, the successor company can be sued to repair any damages arising from faults or defects in products or services provided by the former company.

Finally, as a rule, liability is limited to the supplier's legal entity. Partners and managers can only be held liable, exceptionally, in the event of abuse of the corporate entity. According to Article 50 of the Civil Code, cases of such abuse, characterised by the changing of purpose or patrimonial confusion with regard to the corporate structure, a judge may extend obligations to the private assets of the managers or partners of the corporate entity. Specifically in the consumer sphere, Article 28 of the CDC provides express authorisation for a judge to determine such abuse in the event of supplier insolvency, regardless of fulfilment of the requirements of Article 50 of the Civil Code.

29 Superior Court of Justice (STJ), 3rd Panel, REsp No. 606393, Reporting Justice: Humberto Gomes de Barros, trial date 19 May 2005.

30 Article 192 of the Code of Civil Procedure.

31 São Paulo State Court of Appeals (TJSP), 9th Chamber of Private Law, Interlocutory Appeal No. 0018700-10.2012.8.26.0000, Reporting Judge: Piva Rodrigues, trial date 24 April 2012.

32 STJ, 2nd Panel, AgRg no AREsp No. 455198, Reporting Justice: Mauro Campbell Marques, trial date 18 March 2014.

33 Article 12 et seq.

viii Mass tort actions

The CDC determines, in Articles 81 to 104, that class actions may be brought if disparate interests or rights, collective interests or rights, or individual homogeneous rights are in question.[34]

The following are qualified to file class actions:[35]

a the Public Prosecutor's Office;
b the federal government;
c states;
d municipalities and the Federal District; and
e public authorities, associations and foundations for consumer protection.

In terms of location, the CDC states that, except in cases applicable to the Federal Court, the action must be filed either at a local level in the court of the place where the damage occurred or, for national or regional damages, in the judicial district of the city and state or the Federal District, with the rules of the Code of Civil Procedure applying to cases of concurrent jurisdiction.[36]

ix Damages

In actions founded on the civil liability of the supplier of products and services, the consumer may claim full compensation for any damages suffered, which include not only what has actually been lost, but also reasonable loss of profits. Monetary reinstatement and default interest plus contractual fines will also form part of the damages. Moreover, as already stated, the law ensures the possibility of compensation for moral damages.

The award to defendants in indemnity actions of the payment of punitive damages is not foreseen in Brazil, nor is there legislation setting out indemnity amounts. In order to prevent or reduce any damages caused to consumers, the court may determine the adoption of specific measures such as early relief under penalty of sanctions in the event of non-compliance.

Article 56 of the CDC provides an exhaustive list of administrative penalties that may be applied by entities that are part of the SNDC, in the event of violation of the rules set out therein. They are:

a fines;
b seizure of the defective product;
c product destruction;
d cancellation of registration;
e product manufacturing prohibition;
f suspension of supply;
g temporary suspension of business,
h revocation of concession or permission of use;
i repeal of licence or closure of the business;
j administrative intervention; and
k counter-advertising.

34 Article 81 of the CDC.
35 Article 82 of the CDC.
36 Article 93 of the CDC.

These penalties may be applied on a cumulative basis by the authorities, including by means of an injunction, before or during an administrative proceeding to investigate breaches of consumer laws.

The CDC also provides, in Articles 61 to 74, crimes against consumer rights. Such crimes, although considered of a lesser degree, can be punished by the imprisonment of the officers, directors or representatives of the suppliers for up to two years, plus a fine.

V YEAR IN REVIEW

Recently, legislative proposals, case law and also administrative discussion have been focusing on the collective protection of rights. As a result, we highlight the increase in the number of recall procedures, especially in the automotive sector and food industry.

Moreover, the new Code of Civil Procedure, in force from March 2016, enhances the existing system of judgment of overlapping actions based on the ruling of a binding precedent. The new procedural law authorises courts to judge overlapping actions and form their own binding precedents, applicable in their respective jurisdiction.

Internet and e-commerce is also in focus in the current year. For example, in October 2016 the Brazilian Superior Court of Justice rejected the liability of internet search engines for defective products shown on their websites.[37] Internet and e-commerce issues have been increasing over the years, mainly because of the advance of social media, and they will likely be a matter of attention in 2017. Special attention should be given to the legislative measures intended to limit access to the internet, by authorising internet suppliers to cease their services if consumers exceed their internet data plans.

The application of government's Provisional Measure No. 764, of 27 December 2016, will be a highlight in 2017. This Provisional Measure allows product suppliers to give discounts depending on the payment method elected by consumers. According to current Brazilian courts precedents, giving discounts for immediate payments, rather than through instalments, is misconduct because it allows suppliers to charge imputed interest. Following the Provisional Measure it is now a lawful commercial practice, and the Brazilian courts' understanding will have to adapt to this new legislation.

37 STJ, 3rd Panel, REsp No. 1444008, Reporting Justice: Nancy Andrighi, trial date 25 October 2016.

Chapter 6

CHINA

Ariel Ye, Yue Dai and Xinyu Li[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

In China, a combination of laws, regulations and rules issued by administrative departments together form a complicated legal framework for product liability with civil, administrative and criminal dimensions.

Product liability in a civil context concerns situations where defective products cause loss or harm to another, and the manufacturers or sellers, or both, bear responsibility for infringement of the victim's rights. The key laws on product liability include:

a the General Principles of Civil Law;
b the Tort Liability Law (TL);[2]
c the Product Quality Law (PQL);[3] and
d the Laws on the Protection of Consumer Rights and Interests (PCRI).[4]

These laws set up a legal framework governing issues such as how to determine whether a product is defective, how to commence product liability litigation and who bears responsibility for product liability.

Additionally, the Supreme People's Court has issued a series of judicial interpretations in relation to specific issues that have arisen in product liability cases. One such example is the Interpretation of the Supreme People's Court of Some Issues concerning the Application of Law for the Trial of Cases on Compensation for Personal Injury,[5] which sets out the levels of compensation for a personal injury incurred by a defective product.

In addition to civil liability, the PQL and the PCRI also set out the approaches and powers of the administrative authorities to supervise product liability and to issue administrative penalties. Furthermore, the PRC legislative institution has issued laws and regulations regarding the manufacturing and circulation of certain products to ensure their safety and quality, such as the Food Safety Law[6] and the Pharmaceutical Administration Law.[7]

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1 Ariel Ye is a senior partner, Yue Dai is a partner and Xinyu Li is an associate at King & Wood Mallesons. The authors want to acknowledge other associates at King & Wood Mallesons, Tianren Li, Dong Feng, Stephen Johnson and Songyuan Li, who also contributed to this chapter.

2 Effective as of 1 July 2010.

3 Effective as of 1 September 1993, amended on 27 August 2009.

4 Effective as of 1 January 1994, amended on 25 October 2013.

5 Effective as of 1 May 2004.

6 Effective as of 1 June 2009, amended on 1 October 2015.

7 Effective as of 1 December 2001, amended on 24 April 2015.

In China, product liability may also give rise to criminal liabilities. Chapter 3 of the PRC Criminal Law[8] contains a section titled 'Crimes of Manufacturing and Selling Fake and Shoddy Goods'. This specifically provides strict criminal penalties in respect of manufacturing and selling fake or defective products that severely infringe the consumers' interests. These provisions in the Criminal Law seek to safeguard and reinforce product safety in China.

As China is a civil law country, the principle of *stare decisis* does not apply in product liability litigation proceedings. However, judges may still be guided by precedent cases previously decided by courts, particularly if there are judgments of the Supreme People's Court or other superior courts addressing similar facts or legal issues, or if the area of law is unsettled.

II REGULATORY OVERSIGHT

The General Administration of Quality Supervision Inspection and Quarantine (GAQSIQ) and its attached agency, the Defective Product Administration Centre, oversee product safety and product recalls in China. The Standardisation Administration Committee is in charge of the promulgation of mandatory standards of product safety and sanitation. The State Administration for Industry and Commerce, together with the China Consumers' Association, supervise product quality and protection of consumer rights after products have entered into circulation.

In relation to certain specific categories of products (including automobile, children's toys, medical appliances and food, etc.), there are specific regulatory authorities that are responsible for the supervision and management of their safety. For example, the General Administration of Food and Drugs supervises the safety of food and drugs in all stages, such as manufacturing, circulation and consumption.

Under the current regulatory system in China, manufacturers and sellers of products bear the obligation to continuously pay attention to possible defective products. If the product is discovered to be defective after it has entered into circulation, the manufacturer and the seller are obliged to take proper remedies, such as issuing warnings or recalling the product. If they fail to take appropriate remedies in a timely manner or to take insufficient remedies, thereby causing damage, the manufacturer and seller will be liable to tort liabilities. Since the formal implementation of the Provisions on the Administration of Recall of Defective Auto Products (ARDAP) on 1 October 2004, legislators and regulators have gradually established an effective product recall system. Since then, the product recall system has played an increasingly important role in protecting consumers' rights. In 2016, the GAQSIQ had published 169 auto product recall notices and recalled 11,794,850 defective auto products. Over 200 models of vehicles in 45 automobile brands were involved in those recalls, including Honda, Chevrolet, Buick, Volkswagen, Volvo, etc.

In China, the China Consumers' Association and other consumer associations play important roles in protection of consumer rights. The consumer associations are social organisations with Chinese characteristics, which are established across the country and pursuant to the laws and regulations in order to conduct public supervision over products and protect consumer rights and interests. The consumer associations can perform many community duties such as: (1) providing consumption information and advisory services to consumers; (2) participating in formulation of laws, regulations, rules and mandatory

8 Effective as of 1 October 1997.

standards relating to consumer rights and interests; (3) participating in supervision and inspection of goods and services by the relevant administrative authorities; (4) accepting consumer complaints, and carrying out investigation and mediation into the complaint matters; (5) for acts that harm the legitimate consumer rights and interests, supporting aggrieved consumers to file lawsuits or filing lawsuits by itself pursuant to the law; and (6) publicly advocacy regarding acts that may harm the legitimate consumer rights and interests.

III CAUSES OF ACTION

Under PRC law, a manufacturer or seller, or both, will be liable under tort if they have manufactured or sold a product that has caused harm to a person's life or property. 'Product' refers to property that is manufactured for sale. Real estate does not fall within the scope of product. In general, product liability contains three elements: (1) the issue of whether the product is defective; (2) the damage or loss suffered; and (3) the causal relationship between the defective product and the damage.

The most important element is whether a product is defective. Product defects are categorised as design defects, manufacturing defects and inadequate warning or instructions. According to Article 46 of the PQL, there are two tests to determine product defects, namely, the statutory standard and the unreasonable danger standard. Under the statutory standard, a product will be defective if it fails to meet the applicable national or industrial standards in respect of the safety and sanitation of that product. However, meeting statutory standards does not necessarily mean that the product is without defects. PRC courts will still apply the unreasonable danger standard to determine whether the product unreasonably endangered the life or property of the consumer, or both. Hence, even if a product meets the relevant national or industrial standards, it still may be considered defective if it does not meet a reasonable person's expectations regarding product safety.

Apart from the tort liability, a consumer can also bring a warranty claim in respect of product flaws. Under PRC laws[9], a product must conform to the quality standards or specifications as presented by the manufacture and seller. If a product fails to conform to such warranties, the consumer can sue the seller for breach of warranty even if the product might not constitute a defective product under the product liability law.

In addition to the tort liability discussed above, administrative penalties might also be imposed on manufacturers and sellers of defective products. For example, if the product manufactured or sold is not in conformity with the national and industrial standards regarding the safety or sanitation, the regulatory authorities can stop the manufacture and sale of defective products, confiscate the defective products, impose fines on the manufacturer and seller and even revoke their business licences. In addition, the manufacturer and seller might also be administratively penalised if they do not perform their obligations to recall the defective products. For instance, where an automobile manufacturer breaches the ARDAP, for example, for failing to stop manufacturing the products, selling or importing defective auto products, withholding information of the defects or refusing to implement a recall as ordered, the regulatory authorities will order it to make correction, impose a fine between

9 See Article 148 of the Contract Law (effective as of 1 October 1999), Article 40 of the PQL, Articles 40(1) and 48 of the PCRI.

1 per cent to 10 per cent of the monetary value of defective auto products and confiscate any illegal income of the manufacturer. Furthermore, the regulatory authorities may revoke the manufacturing licences of the manufacturer if the circumstances of violation are serious.[10]

Lastly, the *Criminal Law* contains nine crimes relating to the manufacture and sale of defective products. As a result, the manufacturers and sellers will face criminal penalties in severe cases.

IV LITIGATION

i Forum

In accordance with Article 47 of the PQL, when there is a civil dispute regarding product quality, the parties may resolve their dispute by negotiation, mediation, arbitration or litigation. In practice, the most common forum is litigation.

In the PRC civil system, there is a two-tiered trial system under which a party has the right to appeal a decision at first instance to an appellate court. In general, the second instance judgment is final and binding. However, under special circumstances, a party may also apply for a retrial. However, the standards to initiate the retrial are very strict, and it is within the court's discretion whether to grant a request for a retrial. In practice, it is very rare for a court to grant a retrial.

If a product liability dispute is relatively simple and with a small amount in dispute, a summary procedure or small claims procedure may apply to the litigation. These two types of procedures are more flexible and quick, and the small claims procedure does not allow the parties to appeal.

In civil litigation proceedings, a party may also resolve the dispute by negotiation or settlement. A settlement judgment issued by the court has the same effect as a civil judgment. If one party fails to perform its obligations under the settlement judgment, the other can apply to court for enforcement.

In China, any contractual or other disputes over property rights and interests between citizens, legal persons and other organisations can be submitted to arbitration. Since arbitration procedure relies on the parties' agreement, it may be more applicable to a seller's contractual disputes arising from defective products, rather than product liability disputes.

ii Burden of proof

In product liability proceedings, the plaintiff has the burden of proving: (1) the product is defective; (2) damage or loss owing to the defective products; and (3) a causal relationship between the defect and the damage suffered.

However, in practice, the plaintiff, as an individual, usually has limited technical knowledge about the product in dispute. As a result, courts do not generally impose too stringent a burden of proof on the plaintiff. As long as the plaintiff has *prima facie* evidence (such as the inspection report from a professional inspection institution) that the product has problems, the burden of proof will be shifted to the manufacturer or seller. The manufacturer or seller will then have to prove that the product does not have any defects. It will thus have

10 See Article 24 of the Regulation on the Administration of Recall of Defective Auto Products (effective as of 1 January 2013).

to prove that the product meets the national and industrial standards (if any), and does not have any reasonably foreseeable danger that may threaten a person's health or damage a person's property.

In practice, the inspection procedure plays an important role in determining whether the product is defective. A party may apply to a court for inspection in order to determine whether a product is defective (in particular, whether there is a design defect or manufacturing defect). The inspection will be conducted by inspection institutions with appropriate qualification or by judicial inspection institutions. The parties may agree to appoint a specific inspection institution; if not, the court can appoint one. Furthermore, even if the parties do not apply for inspection, if necessary, the court may itself decide to appoint an inspection institution to determine whether the product is defective.[11] The inspection fees are relatively high and the process is time-consuming, and there may be technical issues that are beyond the expertise of certain inspection institutions, which may present some obstacles for the plaintiff.

Furthermore, it may be difficult to prove that there is a causal relationship between the defect and the damage incurred. In general, a court would not require the victim to prove that the injury or damage was in fact caused by the defective product. The victim only needs to prove that there is connection between the injury or damage and the defective product. Lastly, courts usually take a 'presumptive approach' when determining whether there is a causal relationship. This means that, if a product is defective and other possible causes of injury have been ruled out, the causal relationship is therefore presumed to be established.

iii Defences

Under PRC law, the defences include procedural defences and substantive defences.

Relying on a statute of limitations is a procedural defence. The statute of limitations for product liability claims is two years from the date when the party concerned is notified or should have become aware that his or her rights have been infringed. Under no circumstances may a case be brought more than 10 years from the time a defective product was first delivered to the user or consumer. However, as an exception, if the product expressly specifies a safe use period, a tort claim can still be brought as long as the safe use period has not been exceeded.[12]

In relation to substantive defences, there are three statutory defences under which a manufacturer may avoid liability.[13] First, a manufacturer may avoid liability if the products have not been put into circulation. For example, this defence may be available if a manufacturer is about to destroy some defective televisions stored in the warehouse; however, a thief steals one and then sells it to a person who is subsequently injured when using it. Notwithstanding the person's injury, the person could not claim compensation from the television manufacturer. Secondly, a manufacturer may avoid liability where the defects do not exist when the products are put into circulation. In other words, the manufacturer could demonstrate that the defect was caused by the victim. Thirdly, the scientific and technological standard at the time the product was put in circulation has not reached a level to enable the manufacturer to discover the defect in the product. The manufacturer will bear the burden of proving the above three statutory defences.

As outlined above, the plaintiff has to meet its burden of proving three elements in a product liability claim (i.e., defects, injuries or damage and causal relationship). If a

11 See Article 76 of the Civil Procedure Law (effective as of 9 April 1991, amended on 31 August 2012).

12 See Article 45 of the PQL.

13 See Article 41(2) of the PQL.

defendant successfully challenges the plaintiff's proof in respect of any of these three elements, the defendant will not be found liable. Of these three elements, the defendant usually challenges the 'defects' and 'causal relationship'. For example, in a case where the explosion of a microwave oven caused injuries, if the plaintiff wants his or her claims for compensation to be supported, the plaintiff shall prove that the microwave oven was defective resulting in the explosion; the plaintiff was injured owing to the explosion; and there was causal relationship between the injury and the defects. In this case, the defendant might challenge the existence of the defects on the basis that the microwave oven's design and manufacture satisfy the relevant compulsory national or industrial standards. The defendant might deny the causal relationship by proving that the plaintiff improperly used the products.

iv Personal jurisdiction

The PQL applies to all manufacturing and marketing activities within the territory of China.[14] Accordingly, the PQL regulates both manufacturers and sellers with businesses operating within China, including a seller who imports products manufactured outside China and sells such products within China. Any violation of provisions in this law may lead to aforementioned civil, administrative and even criminal liabilities.

In accordance with the Civil Procedure Law, as a tort case, product liability claims are under the jurisdiction of the court at the place where the tort occurs or at the place of domicile of the defendant.[15] The place where the tort occurs includes the place where a tortious conduct is committed and the place where the consequence of a tortious conduct occurs.[16] If the manufacturer and seller are domiciled in China, the PRC courts will without doubt have jurisdiction over the proceedings. Even if the manufacturing and selling were committed outside of China, if the damage occurs within China, the manufacturer and seller outside China may still fall under the jurisdiction of the PRC courts.

v Expert witnesses

The Chinese legal system recognises the role of expert witness in disputes. Any party can apply to a PRC court for an expert to testify at court on certain issues of fact that are within his or her expertise. Where an application of a party is permitted by a PRC court, the party making the application will bear the costs of the expert witness' attendance. The judge hearing the proceedings or any party may cross-examine the expert. Where permitted by the court, experts may address each other during proceedings in relation to issues arising in the proceedings.[17]

vi Discovery

Contrary to the common law jurisdictions, there is no general process of discovery in Chinese civil litigation. Except where the burden of proof has shifted (as outlined above), each party has the evidentiary burden of proving its claims.[18] However, if there is evidence that a party

14 See Article 2 of the PQL.

15 See Article 28 of the Civil Procedure Law.

16 See Article 24 of the Interpretation of the Supreme People's Court on the Application of the Civil Procedure Law of the People's Republic of China (effective as of 4 February 2015).

17 See Articles 122 and 123 of the Interpretation of the Supreme People's Court on the Application of the Civil Procedure Law of the People's Republic of China.

18 See Article 64 of the Civil Procedure Law.

and its representative are unable to collect, the party may apply to the court for investigation and collection.[19] For example, if a vital inspection report regarding product defects was kept by the product manufacturer, and the consumer is unable to obtain it, the consumer could apply to the court to collect this evidence from this manufacturer. In addition, there may be a situation in which there is evidence demonstrating that a party possesses certain evidence, but that party refuses to provide it without any proper justification. In such case, if the other party claims that the evidence is unfavourable to the party that possesses it, a court may infer that the claim is established.[20]

vii Apportionment

Where any harm is caused by a defective product, the victim may seek compensation from the manufacturer or the seller. That is, for the victim, both the manufacturer and the seller assume liability. Between the manufacturer and the seller, after any party assumes liability, this party may be entitled to be reimbursed by the other. However, when a manufacturer seeks reimbursement from a seller, it will have to provide evidence that the product's defect was caused owing to the fault of the seller.[21]

viii Mass tort actions

To date, the Chinese legal system does not provide for class actions as they exist, particularly in the United States. However, where the subject matter of action is same or is of the same kind, courts may allow the parties to hear the case concurrently.[22] However, 'collective action' is uncommon in product liability cases. In addition, where the subject matter of a claim is of the same kind in nature, but the number of potential plaintiffs is unclear when the claim is initiated, courts may publish a notice to describe the case and claims and notify right holders to register with the court within a certain period of time. The parties that have registered with the people's court may recommend a representative or representatives to participate in the litigation. The judgment or ruling issued by the court will bind all right holders that have registered with the court. Such a judgment or ruling will also apply to actions instituted during the statute of limitation by rights holders that have not registered with the court.[23]

ix Damages

Under PRC law, where a defective product causes any harm to another person, the manufacturer or seller, or both, will assume tortious liability.[24] Where a person suffers personal injury owing to a defective product, damages will often include: medical treatment expenses; funeral service fees; compensation for mental distress (if applicable); and other economic compensation. Where a person suffers damage to his or her property owing to a defective product, a court will often order the tortfeasor to remedy the damage or pay

19 See Article 94 of the Interpretation of the Supreme People's Court on the Application of the Civil Procedure Law of the People's Republic of China.

20 See Article 75 of the Some Provisions of the Supreme People's Court on Evidence in Civil Procedures (effective as of 1 April 2002).

21 See Article 43 of the TL, Article 43 of the PQL.

22 See Article 52 of the Civil Procedure Law.

23 See Article 54 of the Civil Procedure Law.

24 See Articles 41, 42 of the TL.

compensation in an amount equal to the remediation costs.[25] Where the defect of a product endangers the personal or property safety of another person, the victim shall be entitled to require the manufacturer or seller to assume tortious liability by removing the obstruction or eliminating the danger.[26]

In addition, there is punitive compensation under PRC law. Under the TL, where a manufacturer or seller is aware that a product is defective and continues to manufacture or sell the product, and the defect causes death or serious damage to the health of another person, the victim may be entitled to obtain punitive compensation.[27] Under the PCRI, business operators that fraudulently provide commodities or services will, as required by consumers, increase the compensation for consumers' losses. The increase in compensation will be three times the payment made by a consumer for the commodity purchased or the service received or it will be 500 yuan if the increase calculated above is less than 500 yuan. Where business operators knowingly provide consumers with defective commodities or services that cause death or serious damage to the heath of consumers, the victims have the right to claim punitive compensation of no more than two times the amount of losses incurred.[28] Under the Food Safety Law, in addition to claiming damages, a consumer may require a manufacturer of a food produect that fails to meet food safety standards or a trader knowingly dealing in such food to pay an indemnity of 10 times the price paid or three times the loss. If the amount of the additional compensation is less than 1,000 yuan, it will be 1,000 yuan, except for a defect in the labels or instructions on the food that does not impair food safety or mislead consumers.[29]

V YEAR IN REVIEW

In 2016, there were two main developments in product liability law. One was to enhance the recall system of defective products. The other was the further development of consumer-related public interest litigation.

The product recall system began from the issuance of the ARDAP on 12 March 2004. Subsequently, several supervision authorities issued certain specific recall provisions, such as the Administrative Provisions on the Recall of Children's Toys (effective as of 27 August 2007), the Administrative Measures for Drug Recalls (effective as of 10 December 2007) and the Provisions on the Administration of Food Recall (effective as of 27 August 2007). However, other than recall provisions for these specific products, no recall provisions were provided for general consumer goods, which meant that consumers buying general products could not be effectively protected.

On 21 October 2015, the GAQSIQ issued the Measures for the Administration of the Recall of Defective Consumer Goods (the Measures), which became effective as of 1 January 2016. The Measures addressed the gap in the law mentioned above, and completed the establishment of an effective recall system for defective consumer goods. The Measures have the following key features.

25 See Article 16 of the TL; Article 44 of the PQL; Article 49 of the PCRI.

26 See Article 45 of the TL.

27 See Article 47 of the TL.

28 See Article 55 of the PCRI.

29 See Article 148 of the PRC Food Safety Law.

First, the Measures specially define the concepts of 'consumer goods', 'defect', 'recall' and 'manufacturer'. In accordance with the Measures,[30] 'consumer goods' means the products purchased and used by consumers for living needs. 'Defect' means non-compliance with state or industrial standards regarding protection of personal or property safety or any other unreasonable risks to personal or property safety caused by design, manufacturing or warning labelling that generally exist in the same batch, model or type of consumer goods. 'Recall' means the measures taken by consumer goods manufacturers concerning defective consumer goods to eliminate defects or reduce or remove safety risks. 'Manufacturer' means an enterprise legally formed within the territory of China that manufactures consumer goods and in whose name a certificate of product inspection is issued. Enterprises that import consumer goods from outside the territory of China and sell such products within the territory of China or authorised institutions formed by overseas enterprises within the territory of China are also deemed as manufacturers in the Measures.

Secondly, the Measures define the parties responsible for recall and their associated liabilities. The Measures clearly provide that manufacturers are the parties responsible for the recall of defective consumer goods and assume the primary liabilities for recall. Furthermore, the Measures also clearly provide for the obligations and procedures in recall proceedings, such as the manufacturer's obligations for collection and analysis of information, reporting of defect investigations, accepting supervision from authorities, challenges and appeals, recording of the recall plans and reporting of recall measures.

Lastly, the Measures establish a catalogue administration system for consumer goods. Consumer goods recalled in accordance with the Measures are to be subject to cataloguing according to the degree of risk of the damage or potential safety hazards in the relevant consumer goods. The catalogue is developed and administered by the GAQSIQ.[31] Children's products and electronic appliances were the first to be subject to catalogue administration, including 11 types of children's products and nine electronic appliances. The Measures also provide that, where any other consumer goods that have not been listed in the catalogue need to be recalled, the Measures may apply.[32]

In addition, consumer-related civil public interest litigation has been further developed in 2016. In relation to consumers, the PCRI provides that, for infringement of the lawful rights and interests of widespread consumers, the China Consumers' Association has standing to file lawsuits in the people's courts.[33] The Interpretation of the Supreme People's Court on Several Issues Concerning Application of Laws in the Hearing of Consumer-related Civil Public Interest Litigation issued in April 2016 by the Supreme People's Court details five circumstances under which consumer-related civil public interest litigation can be initiated:

a where there are defects in the goods or services provided, damaging the lawful rights and interests of numerous non-specific consumers;

b when the goods or services provided may endanger consumers' personal or property safety without giving clear warnings or marking the correct methods to use the goods or accept the services, as well as the methods for preventing the relevant hazards; or false or misleading statements about the quality, performance, purpose and validity period of the goods or services provided;

30 See Article 3 of the Measures.

31 See Article 5 of the Measures.

32 See Article 5 of the Measures.

33 See Article 47 of the PCRI.

c where there are risks in business locations such as hotels, shops, restaurants, banks, airports, transport stations, ports, theatres, scenic areas or entertainment venues that endanger consumers' personal or property safety;

d where unfair and unreasonable provisions for consumers are established that exclude or restrict consumers' rights, reduce or exempt the liability of business operators and increase consumers' liability by means of standard clauses, or circulars, statements or salesroom bulletins; and

e in relation to other practices that damage the lawful rights and interests of numerous non-specific consumers, endanger consumers' personal or property safety, or harm the public interest. In addition to consumer associations, this interpretation also expands the scope of parties with standing to commence public interest litigation to 'agencies and social organisations authorised by laws or by the National People's Congress and its standing committee.'[34]

34 See Articles 1, 2 of the Interpretation of the Supreme People's Court on Several Issues Concerning Application of Laws in the Hearing of Consumer-related Civil Public Interest Litigation (effective as of 1 May 2016).

Chapter 7

ENGLAND & WALES

Fiona East[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

As a Member State of the European Union, English law relating to product liability changed significantly following the implementation of the legislation emanating from the European Commission. Directive 85/374/EEC was introduced in July 1985 in order to approximate the laws of the Member States in relation to liability of the producer for damage caused by defective products.[2] It introduced a system of liability without fault on the part of the producer and was implemented in the United Kingdom through the Consumer Protection Act 1987, adding to the existing rights under the UK law of contract and tort.[3]

The European Directive seeks to protect victims and promote improvement in product safety. At the same time it aims to strike the correct balance between consumer protection and producers' interests. This chapter provides an overview of how the English legal system attempts to achieve this, with reference to relevant case law and developments where appropriate.

On 1 October 2015, the long-awaited Consumer Rights Act 2015 (CRA) came into force. The purpose of this new legislation is to clarify, update and consolidate the various pieces of legislation that governed consumer rights including the Sale of Goods Act 1979, the Supply of Goods and Services Act 1982 and the Unfair Terms Act 1977. It is considered to be 'the biggest overhaul of consumer law for a generation'.[4]

II REGULATORY OVERSIGHT

The EU has created directives that govern certain products, for example, the Toy Safety Directive 2009/48/EC governs toy safety and the Cosmetics Directive 76/768/EEC ensures that cosmetic products within the EU are safe for consumers.[5] For products that are not governed by a specific Directive, the General Product Safety Directive 2001/95/EC (GPSD) applies. Under the GPSD, producers are under an obligation to provide information on risks to consumers, monitor risks, recall dangerous products and respond to emergency safety risks.

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1 Fiona East is a partner at Weightmans LLP.

2 European Commission – Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee – 8.9.11.

3 Article 13 of Directive 85/374/EEC.

4 www.gov.uk/government/news/biggest-overhaul-of-consumer-rights-in-a-generation.

5 www.cosmeticseurope.eu/safety-and-science.

RAPEX is the EU rapid alert system for dangerous consumer products with the exception of food, pharmaceutical and medical devices that are covered by other mechanisms. RAPEX allows 31 participating countries and the European Commission to exchange information on products (subject to EU harmonisation) that pose a risk to health and safety of consumers. This system ensures that relevant authorities or businesses are informed quickly so that they can takes measures to reduce the risk, for example, through recalls, warnings or withdrawal of the product.

Within the United Kingdom, there are a number of investigative bodies responsible for overseeing the safety of different consumer products. The Health and Safety Executive regulates workplace products, Trading Standards regulates consumer products, the Environmental Health Department regulates food and the Medicines and Healthcare products Regulatory Agency (MHRA) regulates pharmaceuticals and medicines. If there are concerns regarding the safety of a product, it should be reported to the appropriate body. Each regulatory body has a range of powers; for example, Trading Standards can demand a recall, prosecute or order products not to be sold.

Part 3 of the CRA[6] enhances certain investigatory and enforcement powers. It gives powers to the Competition and Markets Authority, which can consider a complaint about a term in a consumer contract.[7] The regulator may now take a more proactive approach to traders it considers are less than scrupulous in their dealings with consumers.

III CAUSES OF ACTION

There are three causes of action under which a manufacturer, distributor or retailer may be held liable for injury to persons or property caused by the supply of a defective product:

i Breach of contract

The normal principles of contract law apply to the sale of defective goods. The Sale of Goods Act 1979 continues to apply to business-to-business contracts where there is an implied term that the goods supplied under a contract of sale are of 'satisfactory quality'. Consumer contracts are now governed by the CRA and the requirement of 'satisfactory quality', namely what 'a reasonable person would regard as satisfactory'[8] is a term of the contract.

Under contract law, only the purchaser of the product can bring a claim against the immediate seller or supplier. A third party who has suffered injury or damage as a result of the defective product will be unable to bring a claim under this cause of action (no privity of contract) and will have to turn to the Consumer Protection Act 1987 (CPA) or pursue a claim in negligence.

Strict liability is applicable under the CRA. A seller may be found liable even though there was no fault on its part and the fault in the product could not have been discovered by reasonable inspection. The consumer simply has to show that the product failed to comply with the conditions of sale, and that as a result of this breach injury, loss or damage was suffered.

6 Section 70; Schedule 3(1) and (2) and Schedule 5 of the CRA.

7 www.gov.uk/government/uploads/system/uploads/attachment_data/file/450440/Unfair_Terms_Main_Guidance.pdf.

8 Section 9(2) of the CRA.

If a seller is found liable, consideration should be given to the supply chain in order to determine whether an indemnity can be sought from another party. It is important that retailers ensure that any contracts with suppliers include enforceable indemnity provisions that enable them to recover any loss. Furthermore, prudent retailers should have product liability insurance.

Remedies

If a breach of contract is established, under the CRA there is a new hierarchy of remedies available aimed to give clarity and further protection to consumers. In brief, the tiered remedies are (1) a short-term right of a 30-day period when certain faulty products can be rejected; (2) a right to have faulty goods repaired or replaced; and (3) a possible right to a price reduction or refund or a final right to reject.

Damages that result from the natural and probable consequence of the breach can be claimed.

ii Negligence

While there is this cause of action, consumers are more likely to bring a claim under the CPA in light of the principle of strict liability afforded under the Act.

A claim in negligence can be brought against anybody in the supply chain who owes a duty of care to the buyer, but a claimant must prove that the manufacturer or supplier owed that duty of care and that there was an act of negligence that caused the injury or loss.[9]

The duty is to take reasonable care to ensure a product does not cause injury or loss to a consumer.

In contrast to bringing a claim under the CRA, a claimant does not need to be the purchaser of the product. This broadens the scope of potential claimants, but the principle of strict liability does not apply. A claimant has to show that the manufacturer or supplier was at fault, it has failed to take sufficient care and was negligent. This frequently makes bringing a claim in negligence more difficult.

Remedies

The principle behind the remedies in negligence is to put the claimant in the same position as he or she would have been, had the negligent act not occurred.

iii Claims under the CPA

Part 1 of the CPA implemented the Product Liability Directive 85/374/EEC. In 2004, the Director General for Health and Consumer Protection stated: 'the safety of products is a high priority for the EU. Our objective is to ensure a consistently high level of protection for each and every citizen.'[10] By the introduction of strict liability, the CPA has eased the burden on claimants in proving their case.

9 *Howmet Ltd v. Economy Devices Ltd* [2014] EWHC 3933; this case involved a factory fire in which the factory owner brought a claim in negligence and breach of statutory duty. It was held that the manufacturer had breached its duty of care but there was insufficient evidence on causation. The case was upheld on appeal ([2016] EWCA Civ 847). Weightmans LLP acted for Howmet.

10 http://europa.eu/pol/pdf/flipbook/en/consumer_en.pdf.

Relevant law

Section 2 of the CPA states: 'where any damage is caused wholly or partly by a defect in a product, every person to whom subsection 2 applies shall be liable for the damage.'

What is a product?

Section 1(2) defines 'product' as: 'any goods or electricity and [...] includes a product which is comprised in another product, whether by virtue of being a component part or raw material or otherwise.'

Who is liable?

Section 2(2) defines the individuals who may be liable. The definition extends far beyond the manufacturer. Essentially, the CPA sets out four groups of individuals who may be liable:

a the producer[11] of the product (importantly, this will include the manufacturer and assembler of a finished product made from brought in components);

b any person who holds him or herself out to be the producer of the product (through using a trademark or by putting his or her name on the product);

c the first importer of the product into a Member State (from a place outside the Member State);[12] and

d the supplier may be held liable if the claimant requests the supplier to identify the individuals mentioned above within a reasonable period of time after the damage occurred and the supplier fails to comply with the request.[13]

There is a wide number of potential parties to sue, affording better protection for consumers.

What is a 'defective' product?

Section 3 of the CPA defines 'defect'. It states that: 'there is a defect in a product if the safety of the product is not such as persons generally are entitled to expect.'

When determining what individuals are generally entitled to expect a range of circumstances are taken into account, for example the marketing of the product (including packaging, labelling, instructions, warnings and intended use) and the relevant EU or UK standard or code of practice.[14] This is an objective test. The question arises over what the public is entitled to expect. 'The safety is not what is actually expected by the public at large but what they are entitled to expect.'[15]

The burden lies with the claimant to prove on the balance of probabilities that the product is defective.

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11 Section 1(2) defines the producer as the person who manufactured the product; in the case of a substance which has not been manufactured, the person who won or abstracted the product; or if the product has not been manufactured, won or abstracted but essential characteristics of the product are attributable to an industrial, or other process, the person who carried out this process. This means that a claimant can bring a claim against someone who obtained defective raw materials, a person who manufactured the product or a defective component.

12 This must be in the course of business and for the purpose of supplying it to another (Section 2(2)(c) of the CPA).

13 Section 2(3) of the CPA.

14 Section 3(2) of the CPA.

15 *A and Others v. The National Blood Authority and Others* [2001] 3 All E.R. 289.

In *Michelle Buckley v. Henkel Ltd*[16] the claimant suffered a severe allergic reaction to a hair dye product. The product contained a chemical permitted under the EU Cosmetics Regulation 1223/2009 capable of causing an allergic reaction in some people. It was accepted that certain products carry an inherent risk and that some people generally could not be entitled to expect that certain products would be completely risk-free. The majority of people would not have experienced a reaction using the hair product. This product was accompanied by a leaflet with instructions and a warning that a severe allergic reaction might be experienced.[17] The judge concluded the hair dye was not defective. The decision highlights the importance for cosmetic manufacturers to provide clear instructions and warnings to consumers sufficiently informing them of the risks associated with their products.

In the recent case of *Boston Scientific*[18] the European Court of Justice was asked to determine whether a medical device was defective if it was in a group of products with a potential to be defective. Notwithstanding the absence of proof of the individual product in question having a defect, it was held that all the devices in the group could be classified as defective.

Who can bring a claim?

A claim may be brought by any person injured by the defective product, regardless of whether the product was purchased by the injured person.

A fundamental difference between a claimant bringing a claim under the CPA and in negligence is the principle of strict liability. In common with a claim under the CRA, there is no need for the individual to prove fault on the part of the producer. The claimant simply has to show that the product was defective and that the defect caused the damage suffered.

iv Criminal action

Under the General Product Safety Regulations 2005,[19] no producer shall place on the market, supply or offer or agree to be placed on the market a product unless it is safe (Regulation 5). Definitions of 'safe product', 'producer', and 'product' are defined within the Regulations.

Criminal action may be brought either against an individual or a corporation if these Regulations are breached; the burden of proof is beyond all reasonable doubt. The power to investigate and prosecute for an alleged contravention falls to a number of authorities stated in Regulation 10(4). In England, this includes county councils, district councils and London borough councils. The maximum penalty is 12 months' imprisonment or a fine of £20,000 (or both).

The Product Safety and Market Surveillance Package (PSMS) continues to be considered in the European Parliament, which will replace the GPSD. The PSMS comprises the Consumer Product Safety Regulations (CPSR) and the Market Surveillance of Products Regulations. The CPSR will incorporate the GPSD but also impose greater obligations, for

16 25 November 2013, St Helens County Court, DDJ Ranson.

17 DDJ Ranson said: 'The detailed instructions for the use of the hair product are contained in the leaflet and it is intended and expected that these would be read by the user. In this case I find the instruction leaflet in the hair product is clear. It is therefore clear from the instructions that there is a risk of an allergic reaction and a number of warnings and precautions are highlighted.'

18 *Boston Scientific Medizintechnik GmbH v. AOK Sachsen-Anhalt* – Die Gesundheitskasse (C-503/13), March 2015.

19 Implementing the General Product Safety Directive 2001/95/EC.

example, detailed documentation and notification requirements to ensure consumer products are more traceable and easily identifiable. There will be extended and additional powers given to market surveillance authorities in order to enforce the Regulations. The Regulations do not govern civil liability; breach of the CPSR occurs when a 'dangerous product' is placed on the market whereas under the CPA the product has to be 'defective'; however, a breach of the Regulations will be useful evidence in a civil claim. Deadlock remains over the wording of the Regulations, and while the EU Parliament adopted the proposals in 2014, the European Council has blocked them. The main area of disagreement is in relation to the issue of the country of origin marking (i.e., 'made in') of consumer products.

IV LITIGATION

i Forum

Many product liability claims in the UK are determined without going to trial. Notwithstanding issues in respect of liability, the defendant will often take into account customer relationships, supplier relationships and business responsibilities; the producer will be keen to minimise publicity and avoid reputational harm.

Who can bring a claim?

In the event that a matter proceeds to trial then the issues are determined by the judge in the light of the evidence presented to the court.

The English legal system encourages parties to engage in early neutral evaluation, mediation or joint settlement meetings to explore the possibility of settlement in preference to a trial.

ii Burden of proof

Generally, the burden of proof is on the claimant to show on the balance of probabilities that the product is defective and that there is a causal relationship between the defect and the damage suffered.

Earlier cases of *Ide v. ATB Sales*[20] and *Lexus Financial Services v. Russell*[21] suggested that it was not an onerous task for claimants to overcome this burden. On occasion, the court may accept proof by inference. It is open to a judge to find a product defective if it failed in its use and no other plausible explanation is available.

In *Ide v. ATB Sales*, where the handlebars on a bike fractured, the claimant was unable to identify the particular nature of the defect; however, the judge was willing to accept that a manufacturing or design defect was 'not improbable' and therefore found for the claimant.

Claimants frequently argue that the complexities of products make it almost impossible to prove a specific defect. It can also be extremely costly for claimants to obtain expert evidence. Producers believe it is essential for the burden to remain with the claimant in order to strike a balance between the producers' and consumer interests.

More recent cases arguably go some way to demonstrating that the burden does remain with the claimant to prove that the product is defective, albeit on the balance of probabilities.

20 [2008] EWCA Civ 424.

21 [2008] EWCA Civ 424.

In *Love v. Halford*[22] the claimant brought a claim against a supplier on the basis that the steerer tube of the bike had fractured causing the claimant to fall. The judge considered that there was no evidence of any type of failure of the steerer tube and therefore dismissed the claim. He felt that there must have been a prior event in which the steerer was damaged and not repaired properly and that the probable cause of the final fracture was the result of a second accident – notwithstanding that the judge could not reach a conclusion as to how it happened.

Meanwhile, in *Hufford v. Samsung Electronics*,[23] a case involving a fridge freezer that caught fire, the claimant argued that the fire originated inside the appliance. The defendant argued that it was combustible material outside of the fridge freezer that caught fire, which subsequently spread to the appliance. The court accepted the opinion of the defendant's expert. The judge held that the claimant had failed to discharge the burden of proof, which required evidence that (1) there was a defect in the product or (2) the fire had started in the appliance.

The judge in *Hufford* clarified that the burden of proof remains on the claimant throughout. However, the claimant does not have to identify the precise defect in the product and it is enough to prove that there was a defect in broad or general terms.

It remains to be seen what impact the decision in the *Boston Scientific* case will have on claims under the CPA in relation to the burden of proof.

The recent Court of Appeal judgment in *Howmet*[24] is a useful reminder of the clear principle – already stated in earlier cases but reaffirmed – that if a user of a product knows it is defective but continues to use it, then the manufacturer may no longer be liable if a claim for compensation for injury or loss follows as there has been a break in causation. As Jackson LJ stated, '[o]nce the end user is alerted to the dangerous condition of a chattel, if he voluntarily continues to use it thereby causing personal injury or damage, he normally does so at his own risk'.

iii Defences

If the claimant proves there is a defect in the product that caused damage there are some limited defences.

It was considered by the European Commission that such defences should be available to give balance to the producers' interests. They can be found in Section 4(1) of the CPA and cover the following:

a The development risk or state-of-the-art defence: 'the state of scientific and technical knowledge at the relevant time was not such that a producer […] might be expected to have discovered the defect […] in his products'. This defence is the subject of fierce debate especially in the pharmaceutical industry.

b The defect did not exist in the product when supplied. Some products suffer wear and tear, need servicing or are misused. As long as the defendant has provided appropriate instructions and warnings and can prove that the product was not defective when it was supplied, they can successfully defend the claim.

c The product was neither supplied in the course of business nor with a view to profit.

22 [2014] EWHC 1057 (QB).

23 [2014] EWHC 2956 (TCC).

24 [2016] EWCA Civ 847.

d The producer did not at any time supply the product to another, for example, the product was stolen or was a counterfeit.

e The defect was owing to compliance with any requirement under any enactment or with any Community obligation.

f If a supplier produced only a component of the product it will have a defence if the defect was in the subsequent product and was owing to the design of the subsequent product.

What is clear is that it is no defence to say that the manufacturer took all reasonable care to ensure there was no defect in the product.

Limitation

Under the CPA, claims for personal injury and property damage should be brought within three years of the date from which the cause of action arises (under the Limitation Act 1980).[25] If the damage was not discoverable at the time that it happened, the three-year limitation period will run from the date that the claimant discovered or should reasonably have discovered that the harm was attributable to the defective product. The court has discretion to extend this period when they consider it is equitable for them to do so.[26]

Under Section 4 of the CPA, a 10-year long stop applies (i.e., an individual loses the right to bring a claim 10 years from when the product was first put into circulation, if proceedings have not been started). It is, however, not always possible to know when the product was put into circulation. If the product has a life expectancy of less than 10 years, provided the producer gives instructions on the need to service/renew/dispose within that period, they may not be liable for a product that develops a fault beyond its life expectancy.

The time limit for contractual claims for property damage (i.e., claims under the Sale of Goods Act 1979 or CRA) is six years from the breach of contract.

iv Personal jurisdiction

A first importer into a Member State may be found liable under Section 2(2)(c) of the CPA. The purpose of this is to ensure that consumers are not disadvantaged by having to bring a claim in another jurisdiction that may have more difficult barriers to satisfy. This will not prevent the manufacturer from bringing a claim for an indemnity from the manufacturer abroad.

A significant development is the decision in *Allen and Ors v. DePuy International Ltd*,[27] which concerned a group of 10 claimants from countries outside the EU. The claim arose out of alleged personal injuries from prosthetic hip implants manufactured in the UK. The claimants had their implants in New Zealand, Australia and South Africa. The court determined that Private International Law (Miscellaneous Provisions) Act 1995 (PILA) should be used to determine the applicable law. Under Section 11 of PILA, the general rule is that the relevant law is the law in country where the injury was sustained. Section 11(2) can

25 Section 11A.

26 Section 33 of the Limitation Act 1980.

27 [2014] EWHC 753 (QB).

be displaced in exceptional cases under Section 12(2), but this is only in rare circumstances. In this case it was held that Section 11(2) had not been displaced and therefore the relevant law was that of New Zealand and South Africa.

The court has also considered whether the CPA extended to injuries caused outside the UK in situations where English law did apply. The judge held that even in cases where English law did apply, the claims fell outside of the territorial scope of the CPA where injuries were sustained outside the UK.[28] There is nothing in the statute that suggests it applies outside of the UK/EEA.

v Expert witnesses

The UK allows evidence from expert witnesses. The role of an expert is to explain industry requirements and evolving safety considerations and to inform the judge of the state of the art in relation to product safety. Product liability cases can involve highly complex products and decisions are often determined based upon which expert gives more convincing evidence. The cases of *Love* and *Hufford* demonstrate the importance of obtaining robust expert evidence.

vi Discovery

If a defendant denies liability prior to proceedings, it should disclose documents in its possession that are material to the issues between the parties in order for the claimant to assess whether there is sufficient evidence to progress a claim. If necessary, the claimant may apply to the court to seek an order for the proposed defendant to disclose documents with a view to assisting the dispute to be resolved without proceedings.

Once proceedings have been commenced, the parties will be obliged to disclose all documents upon which they rely, which must include those that may adversely affect their own case, another party's case or indeed support another party's case. Parties are under an obligation to carry out a reasonable and proportionate search for these documents. Each party is entitled to have copies or inspect the documents that are not subject to legal professional privilege.

vii Apportionment

Section 2(5) of the CPA makes it clear that where two or more persons are liable, their liability is joint and several. A party is entitled to bring a claim against another party if it is felt that another party has contributed to the defect. It is important that when a claim is brought, the defendant considers its relationship with other parties in the supply chain. Contracts should be considered, and, where there are no contracts in place, it is necessary for parties to consider whether an indemnity can be obtained from another party.

28 'In my judgment wherever one draws the line, consumers who suffer damage outside the EEA and who have no connection with the EEA, and where marketing and supply of the defective product was outside the EEA are not within the scope in difficult cases will have to be determined upon the facts of those cases. There will often be difficulties with the territorial limits of any statute/directive.'

viii Mass tort actions

Group actions are permitted in the UK. There are two main types of collective redress mechanisms: group litigation orders (GLOs)[29] and representative actions.[30] GLOs are made by the court where numerous claims give rise to common issues of law or facts. A GLO is an order by the court for the claims to be managed together. Individual claimants must enter themselves on a group register. It is not necessary for the same solicitor or law firm to conduct the case for all the individual claimants.

Representative actions are made where there is more than one person bringing a similar claim against the same defendants. Each claimant has to opt-in to be considered as part of the action. Any court order made binds the persons represented as a party.

Collective redress mechanisms for consumers have been increasingly considered by policymakers. The European Commission adopted a 2013 Recommendation setting out common principles to be applied by Member States to be implemented by July 2015. However, they are not binding and it is clear that Member States have differing views.

ix Damages

Section 5 of the CPA entitles consumers to sue for compensation, death, personal injury and damage to private property (not business) if the amount of the damage to property is valued in excess of £275. It is not possible to recover for pure economic loss. The damages awarded fall into two main categories: general and special damages.

General damages

This seeks to compensate claimants for pain, suffering and loss of amenity. In order to make an assessment, the court will wish to consider medical evidence to support this claim.

The appropriate award of damages is determined by the judge. The Judicial College Guidelines are now a well-known source of information for both judges and practitioners when considering the level of awards. The Guidelines set out a wide variety of types of injury within monetary brackets. Their purpose is to achieve consistency between awards; however, review of previous reported cases remains an important tool to assist in the exercise.

Special damages

This covers financial loss and expenses (past and future) arising from the injury. It covers areas such as loss of earnings, the cost of care, travel and miscellaneous items. The claimant is under a duty to mitigate his or her loss.

The claimant is not allowed to recover losses that are considered to be too remote. It must be a consequential loss that is within the reasonable contemplation of the parties.

Under the CPA, in contrast with the CRA, there is no entitlement to recover the cost of the defective product itself; for example, if a kettle has an electrical fault and catches fire causing damage to the kitchen – there can be no claim for the kettle but a claim does lie in respect of the damage to the kitchen.

29 CPR 19.11.

30 CPR 19.6.

V YEAR IN REVIEW

English product liability law has been heavily shaped by a myriad of European Regulations and Directives, and following the 2016 vote in the UK to exit the European Union, much has been written about the status of existing English law that has been derived from Europe. While the position will fall to be finalised as part of the withdrawal process, it appears that the intention behind the Great Repeal Bill (which is to be introduced in the next Queen's Speech in spring 2017) will be to encompass all EU laws that are in force as of the moment the UK leaves the EU within domestic legislation, and, therefore, the status quo will be preserved in relation to product liability law in England and Wales. Thereafter, it will be for Parliament to determine which laws governing product liability will remain, be amended or be repealed.

The PIP breast implant 'scandal'[31] has continued to be in the news, having been the subject of a preliminary ruling by the Court of Justice of the European Union (CJEU) in February 2017 in the case of *Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH*.[32] The CJEU has confirmed that the purpose of notified bodies under the Medical Products Directive is to protect end users. However, it has been left up to national courts to decide if this creates a direct liability.

Product recalls can result in the destruction of an excellent reputation of a manufacturer. If you are going to do a recall, it is vital to ensure that you have the correct fix and sufficient product to meet the demand of the recall. A proper recall procedure should be in place, and good contacts with suppliers should be maintained, including a dialogue on how recalls will be managed. In 2016, Samsung had to recall the Galaxy Note 7. This particular recall shows the power of social media, as from the launch customers were posting their experiences of overheating batteries on the phone, fires and explosions. An exchange programme was initiated, and newer models of the Note 7 were provided to customers. However, a replacement model caught fire in October 2016, and Samsung launched a product recall; the Note 7 was then permanently discontinued. Several airlines banned the Note 7 on planes, and a number of customers experienced difficulties trying to return their device to Samsung as some postal forces would not deliver them. The recall is likely to cost Samsung a significant sum in financial terms, and the cost of any loss of reputation remains to be seen.

If the PSMS passes through the European Parliament, manufacturers, distributors and importers will find themselves facing greater obligations, for example, the requirement to draw up technical documents containing details of any risk management that was undertaken.[33] In contrast to the Product Liability Directive, the Regulations have direct effect, and, therefore, they will not need implementing in the UK. For manufacturers, distributors and importers, it is, therefore, vital to understand the proposed changes now and to take precautionary measures so they are prepared.

In July 2017, the European Commission will assess the practical impact of the Recommendation regarding Collective Redress and determine whether further measures should be proposed.

31 http://www.nhs.uk/Conditions/PIP-implants/Pages/Introduction.aspx – PIP breast implant.

32 Preliminary ruling in Case C-219/15.

33 Product Safety and Market Surveillance Package, Com (2013) 78 Final – Brussels, 13 February 2013.

Chapter 8

FRANCE

Christophe Hénin[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

Before the adoption of the Product Liability Directive No. 85/374/EEC (the Directive), French jurisdictions used to implement general civil liability, whether tortious, based on Article 1240 of the French Civil Code (FCC),[2] or contractual, based on Article 1231-1[3] of the FCC.

The Directive was adopted in the European Union on 25 July 1985 to protect consumers against damages caused by defective products. It allows injured persons to seek compensation with regard to defective products put into circulation within the internal and single market. Companies are then required to deliver products free from defect or danger to users (i.e., products that offer the level of safety that can reasonably be expected). EU Member States were required to implement the Directive by 30 July 1988. As France failed to transpose the Directive within the time frame imposed, the Commission opened infringement proceedings under former Article 171 of the EC Treaty[4] against France, following the 13 January 1993 ruling by the European Court of Justice (ECJ).[5]

Notwithstanding such a default on the part of France, the French jurisdictions decided *proprio motu* to interpret the existing general civil liability framework in the light of the Directive provisions. In a ruling dated 3 March 1998,[6] the French Supreme Court applied the Directive provisions and dismissed the provisions of the FCC.[7]

Finally, on 19 May 1998,[8] France transposed the Directive, and the FCC has included an exhaustive set of regulations in this respect: the new Title IV *bis*, 'Liability for defective

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2 Article 1240 of the FCC as modified by Ordonnance No. 2016-131 of 10 February 2016: 'Every act whatever of man that causes damage to another obliges him by whose fault it occurred to repair it.'

3 Article 1231-1 of the FCC as modified by Ordonnance No. 2016-131 of 10 February 2016: 'A debtor is condemned, where appropriate, to the payment of damages either on the ground of the non-performance or a delay in performance of an obligation, unless he justifies this on the ground that performance was prevented by force majeure'.

4 Article 171 of the EC Treaty: 'If the Court of Justice finds that a Member State has failed to fulfil an obligation under this Treaty, the State shall be required to take the necessary measures to comply with the judgment of the Court of Justice.'

5 ECJ, 3 January 1993, *Commission of the European Communities v. French Republic*, Case C-293/91.

6 Supreme Court, civ I, 30 July 1998, *Laboratoires Léo v. M. Scovazzo*, No. 96-12078.

7 Supreme Court, civ I, 10 December 2014, *X v. Royal and Sun Alliance*, No. 13-14314 – in this more recent case, the Supreme Court decided to explicitly dismiss Article 1382 of the FCC and to again apply the Directive provisions.

8 Law No. 98-389 of 19 May 1998 on Product Liability.

products',[9] just after the chapter relating to general civil liability rules. It should be noted, however, that in 2002,[10] the ECJ ordered the French Republic to amend its existing law, which incorrectly transposed the Directive. The ECJ ruled that the French legislation that exposed suppliers and distributors to legal claims on the same basis as producers was illegal. Again, in 2006,[11] the ECJ ordered France to pay a fine because of its failure to take the necessary measures to fully comply with the previous judgment of 2002.[12]

On 26 January 2016, Law No. 2016-41 for the modernisation of our healthcare system was enacted[13] and introduced into French law the class-action mechanism within the healthcare sector. The law entered into force on 26 September 2016 with Decree No. 2016-1249.[14]

II REGULATORY OVERSIGHT

In France, the Directorate-General for Competition, Consumer Affairs and Prevention of Fraud is heavily involved in the prevention of accidents occurring in everyday life and has, in this regard, a general competence in dealing with matters of safety of industrial products. It also publishes a list of recall notices of product and several reporting forms of risk products for professionals. There are also several authorities that have specific expertise in certain industrial sectors.

For instance, the French Agency for Food, Environmental and Occupational Health Safety essentially contributes to ensure health and safety in the areas of environment, labour and food. More specifically, it helps to ensure the protection of the health and welfare of animals, the protection of plant health, and the assessment of food quality, food safety and nutritional properties. It also has competence over veterinary medicinal products. In its field of competence, the Agency, at the request of other public and administrative authorities, may provide the relevant expertise as well as the scientific and technical support necessary for the development of laws and regulations.

In the health products sector, as a second example, it should also be noted that in accordance with the EU directives, the conditions for granting a marketing authorisation for medicinal products for human use (for innovated products as well as for generics), either nationally or through the European centralised or decentralised procedure, are contained and detailed within the French Public Health Code (PHC).[15] In this regard, the French National Agency for Medicines and Health Products Safety (ANSM) plays a key role. Indeed, applications for marketing authorisation are submitted to the ANSM, which scientifically

9 Articles 1245 to 1245-17 of the FCC as modified by Ordonnance No. 2016-131 of 10 February 2016.

10 ECJ, 25 April 2002, *Commission of the European Communities v. French Republic*, Case C-52/00.

11 ECJ, 14 March 2006, *Commission v. France*, Case C-177/04.

12 The ECJ, in a ruling of 14 March 2006, *Commission v. France*, Case C-177/04 stated that: 'by continuing to regard the supplier of a defective product as liable on the same basis as the producer where the producer cannot be identified, even though the supplier has informed the injured person within a reasonable time of the identity of the person who supplied him with the product, the French Republic had not taken all necessary implementing measures set out in the judgment of 25 April 2002.'

13 Official Journal of the French Republic, 27 January 2016, No. 0022, Text No. 1. It is relevant to underline that the French Constitutional Council in its Decision No. 2014-690 DC dated 13 March 2014 decided that the class-action mechanism does not breach any constitutional rules and principles.

14 Official Journal of the French Republic, 27 September 2016, No. 0225, Text No. 5.

15 Articles L5121-8, L5121-10, R5121-5 and R5121-21 et seq. of the PHC.

assesses the marketing authorisation file according to scientific criteria regarding quality, safety and efficacy. A new product must provide a benefit/risk ratio at least equivalent to the existing products. The application is thus reviewed by the committees of the Agency (and in particular by the commission in charge of the initial assessment of the benefit/risk balance of the health products) if a deeper examination and a supplementary peer opinion for such a case is required. Three outcomes can arise: a favourable opinion, a request for further information or an unfavourable opinion. Once the marketing authorisation has been granted, manufacturers must comply with a set of rules set out by EU directives,[16] and by the PHC under Article L5121-9-2 et seq.[17] The manufacturer of medicinal products for human use must also comply with the good manufacturing practices[18] laid down with the intention of providing minimum requirements that a manufacturer must meet while manufacturing these products, in order to ensure they are in compliance with requirements of safety, quality and efficacy included in the medicinal product master file. It is also relevant to note that, downstream, good distribution practices[19] should also be observed. The safety of medicinal products is thus ensured by the ANSM, which has a general competence, under certain circumstances, to suspend or withdraw a marketing authorisation[20] or to order the recall of any lot or batch of a medicinal product,[21] as well as to carry out an inspection on the manufacturing site.

III CAUSES OF ACTION

As defined by general French civil liability rules,[22] the producer is liable for any loss or damage caused by a defective product[23] put into circulation, whether or not the producer has a contract with the injured person. In order to make a claim against the producer, the injured person must prove an actual damage, a defect of the product and a causal link between the defect and the damage.[24]

16 Directive 2010/84/EU of the European Parliament and of the Council dated 15 December 2010, amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use.

17 Article L5121-9-2 of the PHC provides that 'the undertaking or the operator of a medicinal product shall immediately inform the ANSM of the withdrawal or restriction imposed by the competent authority of any country in which the product is marketed, and of any other new information which may affect the assessment of the benefits and risks of the medicinal product or the product concerned. Where appropriate, the ANSM conducts immediate reassessment of the risk-benefit balance of such product and of all products with the same mechanism of action or a similar chemical structure'.

18 Volume 4 of 'The rules governing medicinal products in the European Union' contains guidance for the interpretation of the principles and guidelines of good manufacturing practices for medicinal products for human and veterinary use laid down in Commission Directives 91/356/EEC, as amended by Directive 2003/94/EC and 91/412/EEC, respectively.

19 Ibid.

20 Article L5121-9 of the PHC.

21 Article L5312-1 of the PHC.

22 Article 1245 et seq. of the FCC.

23 On this point, see Court of Appeal, Versailles, 13 October 2016, No. 14/05586, *UCB Pharma* where for the first time the judge ruled that regardless of the absence of the patient's medical dossier, the evidence of the use of the medicinal product was demonstrated.

24 Article 1245-8 of the FCC.

Pursuant to Article 1245-3 of the FCC, a product is defective 'when it does not provide all the safety that can be legitimately expected from it'. There have been several opportunities for defining the content of a 'defect' in French case law. It should be noted, for instance, that the fact that certain active ingredients for therapeutic use are dangerous do not characterise *de jure* the defectiveness of the product.[25] Similarly, the defectiveness of a medicinal product cannot be inferred from the simple fact that the medication triggered the damage alleged by the patient,[26] or from the fact that the marketing authorisation listed the possible defect as an adverse reaction.[27] On the contrary, such a listing provides the consumer or patient 'the safety that can be legitimately expected from the product'.[28]

Concerning the causal link between the defect and the damage, at first, the French jurisdictions required an actual, direct and certain causal link. The certainty of the causal link should be understood as a scientifically proven causal link between the defectiveness of the product and the occurrence of the injury;[29] however, patients were facing some major difficulties in providing the necessary scientific evidence to prove the causal link between their damages and the defect of the product. Therefore, the actual case law has admitted 'proof by presumption', when these presumptions are 'serious, precise and concordant'. Several elements form the basis of the judges' assessment, such as the fact that the product, under the acquired scientific data, could be a material cause of the damage, the time between the occurrence of the damage and the medication, and the absence of other causes that could explain the occurrence of the injury to the patient.[30]

On 22 October 2015, in the *Mediator* case,[31] judges admitted the fulfilment of these three criteria – even if in one case, the medical history of the patient led the Court to partly exclude the liability of the manufacturer. This decision was confirmed by the Court of Appeal of Versailles on 14 April 2016.[32]

25 Supreme Court, civ I, 5 April 2005, No. 02-11.947 and 02-12.065; see article by Christophe Hénin and Anne-Catherine Maillols, 'La responsabilité des médicaments: à la recherche d'un équilibre entre rigueur et pragmatisme' [Medicinal products liability: looking for a balance between rigour and pragmatism], *Les Petites Affiches*, 21 June 2005 No. 122 pp. 9–15.

26 Court of Appeal, Bordeaux, 18 March 2015, No. 13/03029, *Société Merck Sharp & Dohme-Chibret*.

27 Supreme Court, civ I, 24 January 2006, No. 03-19.534, *Société Aventis Pasteur MSD v. Mme X et autres*; Tribunal of First Instance, Nîmes, 1 February 2016, No. 14/03320, *Laboratoire GlaxoSmithKline, Laboratoire Boehringer, Société Lilly France*.

28 Supreme Court, civ I, 24 January 2006, No. 02-16.648, *Société les Laboratoires Servier SA v. Mme X et autres* – see article by Christophe Hénin and Anne-Catherine Maillols, 'La responsabilité du fait des médicaments: nouveautés et exigences' [Medicinal product liability: innovations and requirements], *Décideurs*, April 2006, No. 74–75, p. 166.

29 Supreme Court, civ I, 23 September 2003, No. 01-13.063, *Laboratoires GSK*.

30 Court of Appeal, Versailles, 25 November 2005 No. 04/03953, *Laboratoires GSK*. See also article by Christophe Hénin and Anne-Catherine Maillols, 'La responsabilité du fait des médicaments: de quelques rappels nécessaires sur ses fondements et conditions' [Medicinal product liability: a necessary recall of the conditions and the basis of liability], *Les Petites Affiches*, 19 May 2006, No. 100, pp. 6–20; Supreme Court, 22 May 2008, No. 05-20.317 and 06-10.967, *Société Sanofi Pasteur MSD*.

31 See Section V, *infra*.

32 Tribunal of First Instance, Nanterre, 22 October 2015, No. 12/07/07723 and No. 13/06176, *Société Laboratoires Servier SAS* confirmed by Court of Appeal, Versailles, 14 April 2016, No. 15/08232 and No. 15/01593.

Nevertheless, the Supreme Court remains particularly demanding when it comes to admitting the existence of such presumptions.[33]

The various interpretations of the Supreme Court on the method of proof have recently pushed the jurisdiction, in a case regarding the hepatitis B vaccine, to refer to the ECJ the question of the validity of serious, precise and concordant presumptions, notwithstanding the absence of scientific proof, as to prove the link of causation.[34]

The victim could also bring criminal legal proceedings against the manufacturer, either by summoning him or her to appear before the criminal court or by filing a criminal complaint with an application to join in the proceedings. The public action aims to have the criminal offence publicly determined and punished. But, a victim who has been 'personally' harmed by the criminal offence and who seeks compensation may start a civil action,[35] which may be brought before the same criminal court.[36] For example, if the patient dies as a result of the medication, the manufacturer may be sued for manslaughter[37] or for an active or passive deceptive product.[38]

IV LITIGATION

i Forum

In France, product liability claims are usually brought before civil and criminal courts. However, alternative procedures do exist in certain cases. For example, within the healthcare sector, the Law of 4 March 2002[39] establishes an autonomous alternative compensation scheme in relation to medicinal liability. The aim is to resolve the difficulties encountered by victims of serious medical accidents, such as iatrogenic disorders,[40] or of a defective medicinal product, by allowing them to obtain quick and easy access compensation.

In this regard, the National Compensation for Medical Accidents Office was established in order to compensate victims of therapeutic hazards, medical accidents, iatrogenic diseases and nosocomial infections.

33 Supreme Court, 22 January 2009, No. 07-16.449, *Laboratoire GlaxoSmithKline*; 24 September 2009, No. 08-16.097, *Société Aventis Pasteur MSD*; 25 November 2010, No. 09-16.556, *Société Sanofi Pasteur MSD*; 28 April 2011, No. 10-15.289, *Laboratoire GlaxoSmithKline*; 26 January 2012, No. 10-28.195, *Société Sanofi Pasteur MSD*; 28 June 2012, No. 11-14.287, *Société Sanofi Pasteur MSD*; 29 May 2013, No. 12-20.903, *Laboratoire GlaxoSmithKline*.

34 Supreme Court, 12 November 2015, No. 14-18.118, *Société Laboratoires Servier SAS* – see also Supreme Court, 22 September 2016, No. 15-20,791, *Société Laboratoires Servier SAS,* which ruled that since the decision of the ECJ will influence the solution of the appeal before the Supreme Court, it is appropriate to stay the proceedings until such a decision is rendered.

35 Article 2 of the French Code of Criminal Procedure (CCP).

36 Article 3 of the CCP.

37 Article 221-6 of the CCP.

38 Article 213-2 of the Consumer Code. A product should be actively deceptive whenever the allegations, for example, affixed to the leaflet and/or to the immediate or outer packaging do not exactly correspond to the technical or marketing authorisation file. The same product could also be passively deceptive whenever relevant information in order to protect public health is missing.

39 Law of 4 March 2002 No. 2002-303 concerning the patients' rights and the quality of the national health system.

40 Disorder or adverse effect resulting from the medical treatment, owing to the use of medicinal product or to the intervention of a healthcare professional.

Thus, pursuant to Article L1142-4 et seq. of PHC, the victim of a medical accident may refer to the Commission for Conciliation and Compensation (CCI). Depending on the seriousness of the injury,[41] this procedure aims at reaching conciliation or an amicable settlement. The procedure of conciliation applies to an injured person whose seriousness is below the damage threshold considered as serious, whereas the procedure of amicable settlement applies when the injury is above the threshold of seriousness.

The President of the CCI acknowledges receipt of the request and will require any missing documents. When the file is complete, the Commission has a period of six months to issue its opinion.

If the application is deemed admissible, the President of the CCI should appoint an expert or a body of experts, and set a deadline for submission of the expert report. Then, a copy of this report is sent to each party, who is summoned before the CCI and may be assisted or represented by a person of their choice. Following the meeting, the Commission should issue a notice signed by the President and sent to the parties, which is accompanied by documents required for an offer of compensation.

If the parties concerned disagree on the compensation proposed, the case should then be brought before the regular courts.

ii Burden of proof

It is particularly obvious that questions and procedural issues relating to the burden of proof, which falls on the plaintiff[42] are seen by the different parties to be of real practical significance.

Pursuant to Article 145 of the French Code of Civil Procedure (CPC), it is possible, prior to any trial, to obtain the necessary and relevant information, to establish proof of the facts or request the admissible investigation measures – including upon request.

The plaintiff may ask the judge to appoint an expert to draft an expert's report, on the condition that a legitimate reason for doing so is given. The assessment of whether a reason is legitimate requires examination in particular of the utility of the measure sought in regard to the further litigation,[43] and the relevance of the investigations requested.

Conversely, such a measure will be refused if it is considered 'unnecessary'. Thus, the judges refuse to order an expert to issue a report when they consider that there is sufficient evidence to rule, or when the measure sought is not likely to enable them to settle the dispute.[44]

Furthermore, on the basis of established practice and case law, judges consider that if the action based on the future litigation is time-barred, there is no legitimate reason to order

41 Article D1142-1 of the PHC:
the threshold of seriousness is determined by the following criteria:
- *the damage must have caused permanent damage to physical and mental integrity above 24%;*
- *or have resulted in a work disability or temporary functional deficit of at least 6 consecutive months, or 6 months on a non-consecutive 12-month period.*

42 Article 1245-8 of the FCC (Article 4 of the Directive), ECJ, 20 November 2014, *Novo Nordisk Pharma GmbH v. S*, Case No. 310/13.

43 Tribunal of First Instance, Rouen, Referee's Order of 6 December 2001, *Laboratoire Bayer v. X*, Tribunal of First Instance, Toulouse, Referee's Order of 11 December 2003, *Société Aventis Pasteur MSD v. Carine Barbier*.

44 Supreme Court, com, 17 March 1987, No. 85-11.130; Supreme Court, com, 18 February 1986, No. 84-10.620; Court of Appeal, Paris, 17 December 2003, No. 2003/13837.

the measures sought on the basis of Article 145 of the CPC.[45] In practice, Article 145 of the CPC is frequently used to seek an expert report in order to clearly establish the existence of the damage and its extent.

Concerning the burden of proof in regard with the defect of the product, pursuant to Article 1245-3 of the French Civil Code a product is defective 'when it does not provide all the safety that can be legitimately expected from it'.[46]

Article 1245-3 also provides that the safety of a product, which can be legitimately expected, has to be assessed through all the circumstances concerned, including the presentation of the product, the reasonably expected use of the product and the time when the product was put into circulation. A product should not be considered defective for the sole reason that a better product has been subsequently put into circulation.

The burden of proof in relation with the causal link between the damage and the defect of the product concerns the certainty of the causal link. The French jurisdictions previously required a direct and certain causal link, but judges now admit 'proof by presumption' when these presumptions are 'serious, precise and concordant'.[47] The French courts definitively acknowledge that mere non-concordant presumptions cannot establish the existence of a causal link, no more than a mere possibility of a causal link.[48]

iii Defences

As mentioned above, 'the safety that can be legitimately expected from the product' is notably assessed in the light of the product's presentation. Indeed, this information will influence the legitimate expectation of the user about the safety of the product, and must therefore be regarded as inseparable from the product in the assessment of the defectiveness. In this respect, the more information provided to consumers, the lower the chances of characterising the defect of the product. Therefore, concerning medicinal products, pharmaceutical companies have a strong incentive to provide exhaustive information in the summary of the product characteristics (SPC) and in the package leaflet.

Another legal defence may consist in contesting the causal link between the damage and the defect of the product, with the support of the world scientific literature related to the occurrence of the disease. This literature can help prove that the product, under the acquired scientific data, could not be a cause of the damage suffered.[49]

Moreover, Article 1245-10 of the FCC provides several grounds of exoneration for the manufacturer. The producer or the distributor cannot be found liable if he or she proves that he or she did not put the product into circulation, or that the product was neither manufactured by him or her for sale or any form of distribution. He or she can also argue that the defect is owing to compliance of the product with mandatory regulations issued by the public authorities.

45 Court of Appeal, Paris, 26 September 2012 No. 11/23165; Court of Appeal, Paris, 11 October 2012, No. 11/23194.

46 See Section III, *supra*.

47 See Section III, *supra*.

48 Supreme Court, civ I, 23 September 2003, *Laboratoire GlaxoSmithKline v. Mme Morice*; Supreme Court, civ II, 31 March 1983, bull, civ, 1983 II, 89.

49 See, for example, Tribunal of First Instance, Nanterre, 13 February 2014, *Leleux v. Zambon France*.

Finally, the manufacturer can also prove, alternatively or in addition, that the defect that caused the damage did not exist at the time the product was put into circulation, or that the state of scientific and technical knowledge at the time the product was put into circulation did not allow the manufacturer to discover or identify the defect concerned.

The ECJ clarified that the state of scientific and technical knowledge must be examined through an objective assessment of the most advanced level of knowledge, regardless of the industrial sector concerned.[50]

iv Personal jurisdiction

Article 1245-5 of the FCC provides that a producer of a finished product should be defined as the producer of any raw material or of any component part and any other person who, by attaching his or her name, trademark or other distinguishing feature on the product presents him or herself as the producer.

Without prejudice to the liability of the producer, any person who imports into the European Union a product for sale, hire, leasing or any form of distribution in the course of his or her business is deemed to be a producer and should be responsible as a producer.[51]

In addition, where the producer of the product cannot be identified, each supplier of the product is treated as a producer unless he or she informs the injured person of the identity of the producer or of the person who supplied him or her with the product within three months of the date the victim notified the claim.[52]

It should also be borne in mind that pursuant to Article 1245-7 of the FCC, where two or more persons are liable for the same damage, they will be liable jointly and severally,[53] without prejudice to the provisions of national law concerning the rights of contribution or recourse.

In this respect, Article 1245-15 of the FCC provides that the rights conferred upon the injured person against the producer expire 10 years from the date the product was put into circulation, unless the injured person has, in the meantime, brought a case against the producer.

Moreover, Article 1245-16 adds that a limitation period of three years applies to proceedings for the recovery of damages. The limitation period begins to run from the day on which the plaintiff became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer.[54]

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50 ECJ, 29 May 1997, *Commission of the European Communities v. United Kingdom of Great Britain and Northern Ireland*, Case C-300/95.

51 The 'producer' might thus have several meanings. Such a terminology obviously refers to the manufacturer but can also include within its scope other actors such as a parallel importer, Supreme Court, civ I, 4 June 2014, *Europhyto v. SwissLife Insurance and Axa Belgium*, No. 13-13558.

52 See, also, ECJ, 9 February 2006, *Declan O'Byrne v. Sanofi Pasteur MSD*, Case C-121/04; ECJ, 2 December 2009, *Aventis Pasteur v. OB*, Case C-358/08.

53 Supreme Court, civ I, 26 November 2014, *Ceramtec v. Wright Medical France*, No. 13-18819.

54 Court of Appeal, Grenoble, 27 June 2011, *Robveille v. GlaxoSmithKline*; Court of Appeal, Toulouse, 24 January 2012, *El Hannoui v. GlaxoSmithKline*; Court of Appeal, Paris, 4 September 2012, *Bitton v. Sanofi-Aventis France*; Court of Appeal, Paris, 26 September 2012, *MSD France v. Bitton*; Court of Appeal, Paris, 11 October 2012, *Blouzat v. Sanofi Aventis France*; Court of Appeal Lyon, 21 January 2013, *Vignes v. SNC Sanofi Pasteur*; Court of Appeal, Rennes, 23 January 2013, *Raoul v. GlaxoSmithKline*; Court of Appeal, Lyon, 12 February 2013, *Mazotti v. Expanscience*; Tribunal of First Instance, Versailles, 4 April 2013, *Devoucoux v. Sanofi Pasteur MSD*; Court of Appeal, Versailles, 12 September 2013, *Sophie*

With regard to the coordination of the two expiration periods, it is worth mentioning that the three-year limitation period is included in the 10-year period in which the liability of the manufacturer can be sought.[55]

However, it follows from the principle of non-retroactivity that, when the defective product entered into circulation after the expiry of the time limit for the transposition of the Directive, but prior to the entry into force of the Law of 19 May 1998,[56] an action for damages is subject to a different period, which is a time limit of 10 years from the consolidation of the damage as it was previously provided under French law.[57]

In addition, Law No. 2016-41 for the modernisation of our healthcare system set forth that claims brought before the ONIAM are now barred 10 years from the consolidation of the damage.[58] The 10-year limitation also applies to claims resulting from a contamination with the hepatitis B or C virus or human T-lymphotropic virus,[59] human immunodeficiency virus[60] caused by transfusion of blood products or injection of blood derivatives, to actions for compensation for damage directly related to mandatory vaccination[61] and those resulting from the intervention, in exceptional circumstances, of a professional, an institution, a service or an organisation outside the scope of its activity of prevention, diagnosis or treatment.[62]

Where the product is manufactured in a foreign country and sold in the French jurisdiction, this sale within the French territory is sufficient to expose the manufacturer or producer to liability before the French jurisdictions. Indeed, Article 14 of the FCC states that the foreign party may be summoned to appear before the French courts for the enforcement of the obligations contracted either in France or in foreign countries, with a French citizen. In addition, and more substantially, Article 5 of the EU Regulation No. 44/2001 of 22 December 2000, on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters,[63] allows and recognises the French jurisdiction, especially when the damage is suffered in France.

French criminal law is also applicable to offences committed within the French jurisdiction. A criminal offence should be deemed to be committed within the French territory as long as one of the facts constituting the offence concerned is located within

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X v. GlaxoSmithKline; Court of Appeal, Reims, 12 November 2013, *Vallois v. SAS Carrefour and SAS Unilever France*; Court of Appeal, Aix-en-Provence, 16 January 2014, *Pierrette X v. SAS Abbott France*; Tribunal of First Instance, Nanterre, 13 February 2014, *Leleux v. Zambon France*; Tribunal of First Instance, Paris, 3 March 2014, *Naouri v. GlaxoSmithKline*; Court of Appeal, Versailles, 28 May 2014, *Saguet v. AstraZeneca*; Supreme Court, 18 June 2014, *Y v. Expanscience*; Tribunal of First Instance, 1 July 2014, *Osset v. GlaxoSmithKline*; Court of Appeal, Bastia, 3 September 2014, *Dayez v. Sanofi Pasteur MSD*.

55 Court of Appeal, Versailles, 22 January 2015, No. 13/08038; Court of Appeal, Versailles, 28 May 2014, No. 13/07340; Tribunal of First Instance, Paris, 3 March 2014, No. 12/09780; Tribunal of First Instance, Narbonne, 1 July 2014, No. 13/00352.

56 See Section I, *supra*.

57 Supreme Court, 15 May 2015, No. 14-13.151 P.

58 Article L1142-28 of the PHC.

59 Article L1221- 14 of the PHC.

60 Article L3122-1 of the PHC.

61 Article L3111-9 of the PHC.

62 Article L3131-4 of the PHC.

63 JOUE, L-12/1, 16 January 2001 – see also, from 1 January 2015, EU Regulation No. 1215/2012 of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, JOUE, L-351/1, 20 December 2012.

France. French criminal law is also applicable whenever the victim is of French nationality at the time of the offence, regardless of whether the crime was committed by a French national or a foreign national, and even if the offence took place outside the French jurisdiction.[64]

v Expert witnesses

In proceedings before the civil courts, as mentioned in Section IV.ii, *supra*, Article 145 of the CPC is frequently used by French judges in practice, in order to obtain an expert report that should identify the damage, its extent and the existence of a causal link between the damage suffered and the alleged defect of the product.

Both parties are permitted to retain industry or subject-matter experts as a part of their defence. The victim can present an expert from his or her insurer, for example, while pharmaceutical companies, for instance, could use an expert report compiled by their own experts as part of their defence.

The French criminal courts also permit testimonies or evidence from expert witnesses, including during procedures connected with a crime where a jury is mandatory.

vi Discovery

One of the main differences between the rules of procedural law in common and civil law systems lies in the faculties that correspond both to the parties and to the judicial authority in the application of discovery in finding material evidence. Indeed, in civil law systems, there is no need to apply discovery, given that proceedings tend to be written rather than oral, and therefore there is no tacit or strategic advantage to be gained from applying the element of surprise. Even though a phase similar to that of pretrial (beginning with the allegations or pleading) does exist in civil law systems, the investigative powers offered to the parties are minimal when compared with those corresponding to the parties in common law systems. In this regard, there are no such available discovery methods regarding product liability cases before the French jurisdictions.

vii Apportionment

In situations where several persons are liable for the same damage, the protection of the consumer requires that the injured person should be able to claim full compensation for the damage from any one of them.

A fair apportionment of risk between the injured person and the producer or the distributor implies that the producer should be able to free him or herself from liability if he or she furnishes proof as to the existence of certain exonerating circumstances. Therefore, the liability of the producer remains unaffected or may be reduced by acts or omissions of other persons having contributed to cause the damage. The contributory negligence of the injured person may also be taken into account to reduce or disallow such liability.

viii Mass tort actions

As mentioned in Section I, *supra*, Law No. 2016-41 was enacted on 26 January 2016 and embraces class actions The law entered into force on 26 September 2016.[65]

64 Article 113-2 and 113-7 of the FCC.

65 Official Journal of the French Republic, 27 September 2016, No. 0225, Text No. 5.

The French class action model enables an accredited association, for the defence of users of the French health system, to sue manufacturers, suppliers or providers using health products that fall within the sphere of competence of the ANSM[66] and liability insurers. Such an action is brought before a civil or administrative court (depending on the defendant) in the name of several plaintiffs in order to obtain compensation for the damage suffered by individual consumers placed in a similar or identical situation. The law applies to any breach of a legal or contractual obligation that caused physical injuries.

In such a case, the court will directly determine within the judgment the criteria to be met in order to join the group as well as the publicity measures to be implemented. After the exhaustion of domestic remedies, the publicity measures will be implemented. The deadline to join the group (late opt-in system) will be determined by the judge (between six months and five years) and the claim for compensation will be directly addressed to the defendant.

In case of refusal or improper offer to compensate, the members of the class action will have to introduce an individual legal action before the initial judge. This will considerably delay the final decision.

Such a procedure does not seem well-adapted to the health sector as cases will obviously not be handled in a timely and efficient manner. Indeed, the time to settle a complex case is expected to exceed 10 years.

However, if the new legislation does not simplify the judicial process for the patients, it will clearly facilitate the expansion of French business litigation with a specialisation of certain French law firms in mass torts as it already exists in the US.[67]

ix Damages

The damages potentially recoverable against the manufacturer for product liability mainly concern the impairment of physical integrity (death or injury), and all the resulting damages whether or not they have economic consequences. Damages can include medical or pharmaceutical expenses, expenses related to requiring assistance from a third person, moral prejudice (pain and suffering,[68] compensation for disfigurement and loss of amenity), direct material prejudice (work disability), and indirect material prejudice (revenue loss of subsidies). They also include the damage to goods and property (damage resulting from the destruction or deterioration of goods, economic damages, operating losses, loss of use, loss of profit, expenses caused by the damage to goods, etc.).[69]

66 It would appear possible to include clinical trials and, as such, medicinal products without marketing authorisation (e.g., the Phase I clinical trial conducted in Rennes in 2016 during which several accidents occurred), in the future class action.

67 Taking into due account that Decree No. 2014-1251, 28 October 2014 regarding lawyers' means of communication allowed lawyers to do advertising through flyers, posters, movies, radio or television; Council of State, 9 November 2015, No. 386296 and No. 384728 stated that such a provision complies with Directive 2006/123/EC.

68 In this regard, the French Supreme Court recently confirmed that a victim can obtain compensation for post-traumatic stress; Supreme Court, Crim, *X v. Y*, 21 October 2014, No. 13-87669.

69 Damages resulting from injury to the product itself are excluded from product liability, but may be apprehended by the guarantee against hidden defects (Article 1641 et seq. of the FCC). Damages resulting from non-compliance of the good to the intended use are subject to the obligation of conformity (Article L211-1 et seq. of the COC).

In French civil law, damages are strictly limited to compensation. For this reason, punitive damages are not used since they are deemed to be in contrast with the principle of compensation, which has been promoted as a fundamental and mandatory principle governing the civil liability system.

However, there may be criminal penalties in certain circumstances. For example, if a victim of a defective product dies, as mentioned above, the manufacturer may be sued for manslaughter.

As an example, the maximum penalty for manslaughter, pursuant to Article 221-6 of the FCC is three years' imprisonment as well as a €45,000 fine. If a prudential obligation has been voluntarily breached the maximum penalty increases to five years' imprisonment and a €75,000 fine. Pursuant to Article 222-19 of the FCC, the maximum penalty for unintentional impairment to physical integrity is two years' imprisonment as well as a €30,000 fine. If a prudential obligation has been voluntarily breached, the maximum penalty increases to three years' imprisonment and a €45,000 fine.

V YEAR IN REVIEW

In France, and in particular within the healthcare sector, litigation has increased considerably in the past two years, and should be reinforced by the adoption of the class-action mechanism.

Indeed, since the *Mediator* case[70] involving an anti-diabetic medicinal product, marketed since 1976, which was prescribed off-label as an appetite suppressant and caused several cases of valvular disease, patients and authorities have brought several actions, in particular in 2013.

The victims were able to seek remedy either from the manufacturer[71] or from the state. Indeed, several judgments rendered by the Administrative Court of Paris in 2014 held that given the legal and material privileges of the ANSM, the absence of the suspension or withdrawal of the medicine's marketing authorisation should be regarded as a wrongful failure that constitutes a ground for liability on the part of the state.[72]

Three new judgments of the Administrative Court of Appeal of Paris dated 31 July 2015[73] have confirmed such a principle: the state – but not the ANSM[74] – can be sued before the administrative judge on the ground of a simple negligence, while maintaining a right of action by way of subrogation against the manufacturer. In the *Mediator* case, questions were also raised about a possible compensation for patients who were simply afraid of developing a valvular disease after the medicine was taken. Unlike the judicial judge,[75]

70 Out of a total of 8,942 claims addressed to the ONIAM, 1,942 have so far succeeded for the plaintiffs.

71 See Section III, *supra*. The Tribunal of First Instance of Nanterre compensated the victims of the Mediator on the basis of liability for defective products, Tribunal of First Instance, Nanterre, 22 October 2015, No. 12/07/07723 and No. 13/06176, *Société Laboratoires Servier SAS*. Although the compensation has been judged derisory (€27,000 and €10,000), Servier filed an appeal against the decision. Court of Appeal of Versailles, on 14 April 2016, No. 15/08232 and No. 15/01593 confirmed the first instance decision.

72 Administrative Court, Paris, 3 July 2014, No. 1312345/6; 7 August 2014, No. 1312469/6; 12 September 2014, No. 1312391/6.

73 Administrative Court of appeal, Paris, 31 July 2015, No. 14PA04082, 14PA04083 and 14PA04146.

74 Article L5322-2 of the PHC, according to which the Director-General of the agency makes, on behalf of the state, the decisions that fall under its scope of competence.

75 The Supreme Court admitted first the compensation for the prejudice of anxiety caused by the exposure to asbestos dust: Supreme Court, 11 May 2010, No. 09-42.241; 3 March 2015, No. 13-20.486.

it was well-known that the administrative judge has always been reluctant to establish a principle of compensation for the prejudice of anxiety.[76] In line with its previous case law, the Council of State recently circumscribed such a possibility of compensation to the existence of three criteria: the awareness of the disease; the seriousness of the risks and the specificity of contaminations by transfusions.[77]

Such a dissension between the judicial and the administrative judges has been reflected in the *Mediator* case, where the Administrative Court of Appeal of Paris, in a series of judgments dated 2 July 2015[78] confirmed by the Council of State on 9 November 2016[79], chose not to indemnify 'concerns that could not be legitimately proven' while the presiding judge of the Court of Nanterre ruled differently.[80]

Beyond the *Poly Implant Prosthesis (PIP)* case, and the abnormal level of PIP breast implant ruptures, or the recall of the Ceraver orthopaedic prostheses, the French government and the ANSM contributed to a 'contraceptive pills scandal' widely publicised through the media in early 2013. In January 2013, the ANSM suspended the marketing authorisation of Diane 35, and its generic treatments against acne, also prescribed off-label as an oral contraceptive, given the risk of venous or arterial thrombosis. However, the European Commission decided on 15 July 2013 that, contrary to the French Authority's decision, the risk-benefit balance remained favourable, but that the prescription should be restricted. Following the decision of the European Commission, the ANSM initiated a procedure to inform pharmaceutical laboratories that the marketing authorisation's suspension had been withdrawn. A similar legal and regulatory imbroglio focused on the third and fourth generation of pills with the same result. However, these regulatory and legal actions have seen litigations before the courts initiated by a large number of patients.

The ANSM, again, in June 2013, issued a general alert on a possible error of the diuretic medicinal product furosemide's packaging, which was suspected to contain sleeping pills, based on a single report. The Agency decided to recall every batch of the medicinal product as a 'precautionary measure' and to stop the corresponding manufacturing lines. This case was given broad media coverage, despite the fact that, after several months, the investigation concluded that it was a possible error on the part of the patient concerned and of the pharmacist involved.

In October 2013, several complaints for manslaughter were filed against a new oral anticoagulant medicinal product, suspected of causing life-threatening bleeding, which is, however, an expected side effect of the medicinal product concerned.

In December 2013, victims of the alleged adverse effects of Gardasil, a vaccine against cervical cancer, have filed complaints for unintentional impairment to physical integrity. The victims claimed that they had contracted severely debilitating diseases in the weeks and months following vaccination without having any medical history.

76 Action relating to asbestos; Council of State, ass., 3 March 2004, No. 241150.

77 Council of State, 27 May 2015, No. 371697.

78 Administrative Court of Appeal, Paris, 2 July 2015, No. 14PA04137, No. 14PA04138, No. 14PA04139, No. 14PA04140, No. 14PA04141, No. 14PA04142, No. 14PA04143 and No. 14PA04156.

79 Council of State, 9 November 2016, No. 393108.

80 Tribunal of First Instance, 28 January 2016, *Servier*.

Very recently, in December 2016, a French class action was initiated against Sanofi before the Tribunal of first instance of Paris, as regards medicinal products based on valproate and derivatives (Dépakine, Micropakine, Dépakote, Dépamide and generics) that may have created malformations and developmental disorders at birth.

Such consequences have become a political issue, to which French public authorities replied by the creation of another compensation fund.[81]

Beyond the rise in civil and criminal litigations in 2013 and 2016, which can be considered as a key and central new legal fact, particularly within the health sector, the ability to now embrace the class-action mechanism in France will undoubtedly increase the risk of litigation across all the industrial sectors; this should lead companies to adopt renewed and protective behaviours or to reinforce them, in terms, for example, of internal compliance and audit, which will have to duly consider the whole spectrum of regulation in the sector concerned (regulatory obligations, transparency rules or conflict of interests, for example).

81 Article 150 (V) of the French Finance Law for 2017.

Chapter 9

GERMANY

Christoph Wagner[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

Product liability in Germany is understood as civil liability for all direct and collateral damages resulting from the use or application of a specific product.[2] Civil liability may be based on contractual[3] or legal provisions.[4] Relevant and primary sources of law are the Law of Torts as set forth in Section 823 et seq. of the German Civil Code (BGB)[5] as well as the German Product Liability Act (ProdHaftG),[6] the latter coming into effect on the basis of a transposition of Council Directive 85/374/EEC into national law.[7] Contrary to the liability provisions of the BGB, in case of damage to an item of property the ProdHaftG shall only apply if the damage was caused to an item of property other than the defective product and this other item of property is of a type ordinarily intended for private use or consumption and was used by the injured person mainly for his or her own private use or consumption.[8] Furthermore, the liability for personal damages under the ProdHaftG is limited to a maximum amount of €85 million.[9] Finally, any damage to an item of property is subject to an accidental damage excess of €500.[10]

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2 Tobias Lenz in Tobias Lenz, *Produkthaftung*, 2014, Section 3 Rn. 1.

3 E.g., material damages liability under an asset purchase agreement.

4 Liability under the Law of torts and liability regardless of culpability ('Strict Liability').

5 Section 823 – Liability in damages –, Book 2 – Law of Obligations –, Division 8 – Particular types of obligations –, Title 27 – Torts –, German Civil Code in the version promulgated on 2 January 2002 (Federal Law Gazette [*Bundesgesetzblatt*] I, p. 42, 2909; 2003 I, p. 738), last amended by Article 4 paragraph 5 of the Act of 1 October 2013 (Federal Law Gazette I, p. 3719); www.gesetze-im-internet.de/englisch_bgb/index.html; liability under the Law of Torts; see also Sections 826 and 831 BGB.

6 Act on Liability for Defective Products – Product Liability Act – of 15 December 1989 (Federal Law Gazette I, p. 2198), last amended by Article 9(3) of the Act of 19 July 2002 (Federal Law Gazette I, p. 2674); www.gesetze-im-internet.de/englisch_prodhaftg/index.html; liability regardless of culpability ('Strict Liability').

7 Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products; Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999 amending Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.

8 Section 1(1)2 ProdHaftG.

9 Section 10(1) ProdHaftG: In such case as personal injuries have been caused by a product or by identical products with the same defect, the party liable to pay damages shall be liable only up to a maximum amount of €85 million.

10 Section 11 ProdHaftG: In the case of damage to property, the injured party shall pay for damages up to an amount of €500 himself or herself.

In addition to the aforesaid the regulatory product safety laws comprising a wealth of provisions have to be observed. These provisions, in particular the German Product Safety Act (ProdSG)[11] as the core piece of legislation, transpose the European New Legislative Framework (NLF) into national law. Directives (EC) No. 764/2008[12] and No. 765/2008[13] are in immediate and final effect in all EU Member States throughout Europe and binding in their entirety.[14] Decision No. 768/2008/EG[15] forming an integral part of the NLF was adopted into German law as an integral component of the provisions of the ProdSG. In addition to these a number of other European rules and regulations regarding product safety[16] were transposed into German law.[17]

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11 Act on making products available on the market (Product Safety Act – ProdSG) of 8 November 2011 (Federal Law Gazette I, p. 2178; 2012 I, p. 131), www.gesetze-im-internet.de/englisch_prodsg/index.html.

12 Regulation (EC) No. 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No. 3052/95/EC.

13 Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93.

14 Article 288(2) of the Treaty on European Union and the Treaty on the Functioning of the European Union.

15 Decision No. 768/2008/EC – a common framework for the marketing of products in the EU.

16 Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93; Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93; Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to Medicinal Products for human use; Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary Medicinal Products; Council Directive 93/42/EEC of 14 June 1993 concerning medical devices; Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices; Council Directive 96/98/EC of 20 December 1996 on marine equipment; Regulation (EU) No. 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC; Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits; Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys; Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009 relating to simple pressure vessels; Council Directive 90/396/EEC of 29 June 1990 on the approximation of the laws of the Member States relating to appliances burning gaseous fuels; Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment; Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC; Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC; Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres; European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts; Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers; Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment.

17 Act implementing Regulation (EU) No. 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and with

Finally, product liability is also considered in criminal law in Germany. In addition to the core provisions of the German Criminal Code (StGB)[18] special provisions regarding criminal product liability have been established.[19] These provisions are applicable upon breach of product-specific obligations,[20] in particular,[21] but not limited to provisions relating to general food law,[22] medicinal products law[23] and medical devices law.[24],[25]

II REGULATORY OVERSIGHT

Market surveillance in Germany is exercised by the respective competent authorities in the 16 German federal states,[26] and responsibility for the enforcement of the ProdSG therefore lies with the 16 German federal states.[27] Notwithstanding the foregoing, the German federal administration is also partially competent for market surveillance, for example:

regard to the implementation and application of other legislative acts of the European Union regarding construction products (Act on Construction Products – BauPG); Medicinal Products Act (the Drug Law – AMG), www.gesetze-im-internet.de/englisch_amg/index.html; Act regarding the Use of Nuclear Energy for Peaceful Purposes and the Protection against its dangers (the Atomic Energy Act); Act on Genetic Engineering (GenTG); Medical Devices Act (MPG); Decree on Ship Safety (SchSV); First Decree to the ProdSG (Decree regarding the Provision of Electrical Equipment for the Use within Defined Voltage Limits – 1. ProdSV); Second Decree to the ProdSG (Decree regarding Toy Safety – 2. ProdSV); Sixth Decree to the ProdSG (Decree regarding the Provision of Simple Pressure Vessels – 6. ProdSV); Seventh Decree to the ProdSG (Decree regarding Consumer Installations – 7. ProdSV); Eighth Decree to the ProdSG (Decree regarding the Provision of Personal Protective Gear – 8. ProdSV); Ninth Decree to the ProdSG (Decree regarding Machinery – 9. ProdSV); Tenth Decree to the ProdSG (Decree regarding the Provision of Pleasure Craft and Related Traffic – 10. ProdSV); Eleventh Decree to the ProdSG (Decree regarding Explosives – 11. ProdSV); Twelfth Decree to the ProdSG (Decree regarding Elevators – 12. ProdSV); Thirteenth Decree to the ProdSG (Decree regarding Aerosol Packaging – 13. ProdSV); Fourteenth Decree to the ProdSG (Decree regarding Pressure Equipment – 14. ProdSV).

18 German Criminal Code in the version promulgated on 13 November 1998, Federal Law Gazette I, p. 3322, last amended by Article 1 of the Law of 24 September 2013, Federal Law Gazette I, p. 3671 and with the text of Article 6(18) of the Law of 10 October 2013, Federal Law Gazette I, p. 3799; www.gesetze-im-internet.de/englisch_stgb/index.html.

19 Tobias Lenz in Tobias Lenz, *Produkthaftung*, 2014, Section 2 Rn. 1 and 59 et seq.; Kühne, *Strafrechtliche Produkthaftung in Deutschland*, NJW 1997, 1951.

20 Tobias Lenz in Tobias Lenz, *Produkthaftung*, 2014, Section 2 Rn. 59.

21 Sections 39 and 40 of the Act on making products available on the market (Product Safety Act – ProdSG) of 8 November 2011 (Federal Law Gazette I, p. 2178; 2012 I, p. 131), www.gesetze-im-internet.de/englisch_prodsg/index.html.

22 Section 58 et seq. of the Foodstuffs and Consumer Goods Law (LFGB); Section 38 et seq. of the GenTG; Section 48 et seq. of the Wine Act (WeinG).

23 Section 95 et seq. AMG.

24 Section 40 et seq. MPG.

25 Tobias Lenz in Tobias Lenz, *Produkthaftung*, 2014, Section 2 Rn. 59; Kühne, *Strafrechtliche Produkthaftung in Deutschland*, NJW 1997, 1951.

26 The Working Committee Market Surveillance (LASI) coordinates supervisory activities and publishes a user's manual called *Handlungsanleitung für die Ausführung der Marktüberwachung in Deutschland*: http://lasi-info.com/uploads/media/LV_36_2014.pdf.

27 See Article 24(1)1 ProdSG and Decree of the Baden-Württemberg Department of the Environment on jurisdiction in the field of Product Safety (ProdSZuVO) issued 13 February 2012, GBl. BW Nr. 2, S. 62.

a the German Federal Institute for Drugs and Medical Devices[28] takes part in the supervision of medicinal products and medical devices;[29]

b the Federal Motor Transport Authority[30] is the competent authority for market supervision regarding motor vehicles and trailers operated on public roads;

c the Federal Network Agency for Electricity, Gas, Telecommunications, Post and Railway[31] is the competent federal authority for the implementation of the Act on Electromagnetic Compatibility of Equipment and the Act regarding Radio and Terminal Equipment; and

d the Federal Institute for Occupational Safety and Health[32] provides support on market surveillance to other authorities.[33]

Any potential criminal product responsibility is investigated by each of the 16 German federal states' district attorney's offices as well as the police departments fully independent from other authorities' activities.

Market surveillance in Germany for the most part is aimed at consumer protection with the express aim of minimising risks as far as possible.

III CAUSES OF ACTION

Civil liability claims come into existence upon unlawful and either wilful or negligent causation of damages, in particular a person's death, injury to his or her body or damage to his or her health, his or her personal liberty, damage to an item of property or to any other right.[34] Contrary to the liability claims based on the BGB, liability on the basis of the ProdHaftG is limited insofar as a defective product has to have caused a person's death, injury to their body or damage to their health, or damage to an item of property.[35]

Infringements of regulatory product safety laws may lead to market surveillance authorities taking the adequate measures. The authorities will take action if they suspect the respective product not to meet the necessary statutory requirements and are expressly authorised and empowered to place a ban on the sale of products of this kind.[36]

Criminal product responsibility may be considered upon breach of product-specific obligations.[37] The principles of criminal product responsibility are applicable in case of the manufacturer's use of a mark that could be confused with a GS or CE mark as far as a person's life or his or her health or items of property of significant value are endangered.[38]

28 Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), www.bfarm.de/EN/BfArM/_node.html.

29 Section 32(1) MPG; Section 64(2) AMG.

30 Kraftfahrt-Bundesamt (KBA), www.kba.de/EN/Home/home_node.html.

31 Bundesnetzagentur, www.bundesnetzagentur.de/cln_1432/EN/Home/home_node.html.

32 Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA), www.baua.de/en/Homepage.html.

33 Article 32(2) and (4) ProdSG.

34 Section 823(1) BGB.

35 Section 1(1) ProdHaftG.

36 Article 26(2) Nr. 6 ProdSG.

37 Tobias Lenz in Tobias Lenz, *Produkthaftung*, 2014, Section 2 Rn. 59.

38 Articles 40, 39(1) Nr. 9, 22(4) ProdSG.

IV LITIGATION

i Forum

Ordinary contentious jurisdiction in Germany comprises civil as well as criminal courts. Administrative courts are part of the 'special courts'. The 16 German federal states and the federal administration operate ordinary as well as special courts, the former with several instances. As a general rule and, in particular, depending on the amount in dispute three instances are available to the persons seeking justice. The first two instances are (regional) courts of the respective federal state; however, the court of last resort is a federal court.

Instances of the ordinary contentious jurisdiction are the district (or local) courts, the regional courts either as courts of the first instance or, if courts of the second instance, as appellate courts, the courts of appeals and the Federal Court of Justice. The administrative court system also provides three instances: the administrative courts, the higher administrative courts and the Federal Administrative Court.

A constitutional complaint to a constitutional court[39] offers the opportunity to enforce all civil rights and liberties granted by the Constitution against the Federal Union and the 16 German federal states. The constitutional complaint is not meant to provide an extension of the appeal stages but a prerogative writ limited to the investigation of a potential breach of specific provisions of constitutional law.[40]

The European Court of Justice, *inter alia*, rules on the interpretation of the treaties entered into among the 28 Member States of the European Union by way of preliminary rulings as well as the validity and interpretation of a measure (in particular a regulation, directive or decision) adopted by an institution, body, office or agency of the European Union. The national courts may, and sometimes must, refer to the European Court of Justice and ask it to clarify a point concerning the interpretation of EU law, so that they may ascertain, for example, whether their national legislation complies with that law. If the need for a preliminary ruling is related to an imprisoned person the European Court of Justice will rule without undue delay.[41]

As a general rule civil product liability claims will be tried, heard and ruled at the civil courts composed of professional judges. Jury trials are not provided for under the German Code of Civil Procedure (ZPO); the same applies for (US-style) class actions. Civil claims resulting from criminal offences may be pursued in a separate civil law proceeding ('adhesive procedure') forming an integral part of the criminal proceedings.[42]

Disputes pertaining to regulatory product safety laws are tried and heard before the administrative courts. These courts, with the exception of the Federal Administrative Court, are composed of both professional and lay judges with a professional judge presiding.

39 The Federal Constitutional Court or constitutional courts of the 16 German federal states.

40 Basic Law for the Federal Republic of Germany, www.gesetze-im-internet.de/englisch_gg/index.html, and Contitutions of the 16 German federal states.

41 Article 267 of the Treaty on European Union and the Treaty on the Functioning of the European Union.

42 Section 403 et seq. of the Code of Criminal Procedure (StPO) in the version published on 7 April 1987 (Federal Law Gazette Part I, p. 1074, 1319), as most recently amended by Article 3 of the Act of 23 April 2014 (Federal Law Gazette Part I, p. 410), www.gesetze-im-internet.de/englisch_stpo/englisch_stpo.html.

Criminal product responsibility is tried at the criminal courts with at least one professional judge presiding. Lay judges may be involved in proceedings both at the district and regional court level.[43]

ii Burden of proof

As a threshold matter, there are no generally accepted rules regarding the onus of proof applicable to both civil and administrative proceedings.[44] Therefore, at least in most cases, the general rule as to the onus of proof will be applied. On the basis of this general rule a fact remaining uncertain is deemed to be non-existent and non-proven. As a result of the foregoing, the claimant has to establish full proof of the facts his or her claim is based on and the opposing party is obliged to establish proof for the subsequent loss of the claimant's right or its estoppel.[45]

The ZPO lays down certain exceptions treating constitutive facts as equal to being void and in doing so shifts the onus of proof to the respective opposing party.[46] In the case of claims based on the Law of Torts, wide-reaching rules have been established with respect to the reversal of the onus of proof regarding breaches of duty and, in particular cases, with regard to defects that caused the damage not existing at the time when the producer put the product into circulation. The reversal of the onus of proof is particularly established by taking into consideration the injured claimant's lack of evidence regarding knowledge of the producer's internal processes and the related inability to establish and prove a defect and the producer's breach of duty.[47] The injured party, therefore, has to establish and prove all facts within the own reach of responsibilities which may be proven by the accepted means of evidence (e.g., the state of scientific and technical knowledge at the time when the producer put the product into circulation)[48] or any facts obligating the producer to warn or instruct.[49] The injured person bears the onus of proof and has to establish the defect, the damage and the causal relationship between defect and damage.[50] The principles of the reversal of the onus of proof applicable for claims under the Law of Torts remain unaffected by concurrent contractual claims.[51]

Based on Section 1(4) ProdHaftG the injured person bears the burden of proving the defect, the damage and the causal relationship between defect and damage. If it is disputed whether the obligation to pay compensation is excluded pursuant to Section 1(2) or (3) ProdHaftG, the producer bears the burden of proof. According to Section 3(1) ProdHaftG,

43 District court: court of lay assessors; regional court: criminal and second criminal division, second criminal division as assize court.

44 BVerwG, Decision dated 31 August 1961 – II C 117.58, BVerwGE 13, 36.

45 Dawin in Schoch/Schneider/Bier, *Verwaltungsgerichtsordnung*, 31. EL Oktober 2016, Section 108 Rn. 96.

46 Foerste in Musielak/Voit, ZPO, 13. Auflage 2016, Section 286 Rn. 35 f.

47 BeckOK BGB Section 823 Rn. 552, also see: BGH, Decision dated 26 November 1968 – VI ZR 212/66, NJW 1969, 269.

48 BeckOK BGB Section 823 Rn. 552; also see: OLG Düsseldorf, Decision dated 31 May 1996 – 22 U 13/96, NJW-RR 1997, 1344.

49 BeckOK BGB Section 823 Rn. 552; also see: BGH, Decision dated 17 March 1981 – VI ZR 191/79, NJW 1981, 1603.

50 BeckOK BGB Section 823 Rn. 552, also see: BGH, Decision dated 8 December 1992 – VI ZR 24/92, NJW 1993, 528.

51 BeckOK BGB Section 823 Rn. 552, BGH, Decision dated 19 November 1991 – VI ZR 171/91, NJW 1992, 1039.

a product has a defect when it does not provide the safety that one is entitled to expect, taking all circumstances into account, in particular its presentation, the use to which it could reasonably be expected that it would be put, and the time when it was put into circulation. A product is not defective, however, for the sole reason that a better product is subsequently put into circulation.[52]

In all cases regarding regulatory product safety law the onus of proof is also affected by the respective relief sought by the claimant. In actions for annulment of an administrative deed involving a burden the onus of proof lies with the agency with regard to all facts substantiating and justifying the deed.[53] The same basically applies if the agency denies the applicant a permit in cases of a preventive ban with reservation on the granting of such permit.[54]

The following applies in criminal proceedings: in order to establish the truth, the court shall, proprio motu, extend the taking of evidence to all facts and means of proof relevant to the decision.[55] The court shall decide on the result of the evidence taken according to its free conviction gained from the hearing as a whole.[56] Deviations from this principle are based on either exclusion of evidence including improperly obtained evidence or rules of evidence binding a criminal court with regard to certain third-party findings.[57]

iii Defences

Civil claims under the Law of Torts, Section 823 BGB et seq., become time-barred after three years (Section 195 BGB). The standard limitation period commences at the end of the year in which the claim arose and the obligee obtains knowledge of the circumstances giving rise to the claim and of the identity of the obligor, or would have obtained such knowledge if he or she had not shown gross negligence (Section 199(1) BGB). Limitation of action with regard to claims against the company does not necessarily coincide with the limitation of claims against the company's management.[58]

Contrary to the foregoing, claims under the ProdHaftG become time-barred three years from the date the claim arose and the obligee obtains knowledge of the circumstances giving rise to the claim and of the identity of the obligor, or would have obtained such knowledge if he or she had not shown gross negligence.[59]

With regard to the regulatory product safety law it has to be stated that claims of public agencies, both proprietary and non-pecuniary, may become time-barred.[60]

52 Section 3(2) ProdHaftG.

53 Dawin in Schoch/Schneider/Bier, Verwaltungsgerichtsordnung, 31. EL Oktober 2016, Section 108 Rn. 102.

54 Dawin in Schoch/Schneider/Bier, Verwaltungsgerichtsordnung, 31. EL Oktober 2016, Section 108 Rn. 102; a law reservation of authorisation can be found in Section 20(1)1 MPG.

55 Section 244(2) StPO.

56 Section 261 StPO.

57 Ott in Karlsruher Kommentar zur Strafprozessordnung, 7. Auflage 2013, Section 261 Rn. 34.

58 Vgl. BGH, Decision dated 12 December 2000 – VI ZR 345/99, NJW 2001, 964.

59 Section 12(1) ProdHaftG.

60 Section 53 of the Administrative Procedure Act (VwVfG); vgl. Bader/Gerstner-Heck in *Bader/Ronellenfitsch Beck'scher Online-Kommentar VwVfG*, 30. Edition, Stand: 1 January 2016, Section 53 Rn. 6 et seq.; Ossenbühl: *Verzicht, Verwirkung und Verjährung als Korrektive einer polizeilichen Ewigkeitshaftung*, NVwZ 1995, 54.

The statute of limitation also applies to criminal product responsibility and the related criminal and administrative offences; after limitation occurs the related punishment is precluded. The respective limitation periods relate to the respective threat of punishment.[61]

In addition to the foregoing both claims under civil and public law may be forfeited, in particular, but not limited to cases of *venire contra factum proprium*, meaning that a right or claim may no longer be enforced when the opportunity to enforce the right or claim has not been exercised for a long period of time and the belated exercise of a right constitutes a breach of good faith. This is the case if the obligor based on a certain behaviour of the obligee relied on the non-action of the right or claim and made arrangements in this regard so that any belated exercise of the rights and claims would be likely to cause unreasonable damage to the obligee.[62] In any case, all legal prerequisites for forfeiture have to be reviewed and verified individually.

Under the ProdHaftG the producer's liability obligation may be excluded by proving that:

a he or she did not put the product into circulation;

b under the circumstances it is probable that the defect which caused the damage did not exist at the time when the producer put the product into circulation;

c the product was neither manufactured by him or her for sale or any other form of distribution for economic purpose nor manufactured or distributed by him or her in the course of his or her business;

d the defect is due to compliance of the product with mandatory regulations at the time when the producer put the product into circulation; or

e the state of scientific and technical knowledge at the time when the producer put the product into circulation was not such as to enable the defect to be discovered.[63]

The obligation to pay damages of the producer of a component part is also excluded if 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. The first sentence shall apply to the producer of a raw material *mutatis mutandis*.[64]

Where fault on the part of the injured person contributes to the occurrence of the damage, Section 254 BGB shall apply; in case of damage to property, the fault of the person who exercises actual control over the item of property is deemed to be equal to the fault of the injured person. The liability of the producer shall not be reduced when the damage is caused both by a defect in the product and by the act or omission of a third party.[65]

In accordance with Section 15(1) ProdHaftG the provisions of the Act shall not apply to medicinal products if damage was caused as a result of the administration of a medicinal product intended for human use, which was distributed to the consumer within

61 Section 78(3) StGB – from three to 30 years.

62 Ossenbühl: *Verzicht, Verwirkung und Verjährung als Korrektive einer polizeilichen Ewigkeitshaftung*, NVwZ 1995, 54; Bundesverwaltungsgericht, Decision dated 20 January 1977 – V C 18/76, VerwRspr 1978, 243.

63 Section 1(2) ProdHaftG.

64 Section 1(3) ProdHaftG.

65 Section 6 ProdHaftG.

the purview of the Drug Law (AMG). Liability claims may only be brought based on Section 84 et seq. AMG – strict liability – or under the Law of Torts, Section 823 BGB et seq.[66]

iv Personal jurisdiction

The conflict of laws in the field of product liability was harmonised by the Regulation (EC) No. 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (the Rome II Regulation). The application of the Rome II Regulation is not limited to conflicting legislation of two or more Member States of the EU but also in conflicts with legislation of a non-Member State.[67] If damage occurs in Germany caused by a product imported from Canada in accordance with Article 3 of the Rome II Regulation the applicable law has to be determined in accordance with Article 5 of the Regulation. However, one needs to consider that subject to Article 14 of the Regulation the parties to a dispute are free to agree on the applicable law both by an agreement entered into after the event giving rise to the damage occurred or where all the parties are pursuing a commercial activity, also by an agreement freely negotiated before the event giving rise to the damage occurred.

Agreements regarding the choice of law with at least one party being a consumer are only valid after the event giving rise to the damage occurred.

The following has to be checked with regard to the applicable law on the basis of the Rome II Regulation:[68]

a choice of law: Article 14(1);

b habitual residence in the same country: Articles 4(2) and 5(1)1;

c habitual residence if product was marketed in that country: Article 5(1)1 lit. a, and foreseeability for the producer: Article 5(1)2;

d country in which the product was acquired if the product was marketed in that country: Article 5(1)1 lit. b, and foreseeability for the producer: Article 5(1)2;

e country in which the damage occurred, if the product was marketed in that country: Article 5(1)1 lit. c, and foreseeability for the producer: Article 5(1)2;

f habitual residence of the producer if the product was not marketed in the country the damage occurred and the producer did not foresee the marketing: Article 5(1)2; and

g delegated jurisdiction: Article 5(1), excluding choice of law, on the basis of a manifestly closer connection with another country: Article 5(2).

From a procedural perspective and due to the qualification of product liability forming a part of the Law of Torts the place of jurisdiction is established in accordance with Section 32 ZPO.[69] For civil proceedings based on the Law of Torts, 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 (EuGVVO) offers a choice of several venues within the EU, both at the place of habitual residence of the

66 Section 91 AMG.

67 Article 3 of the Rome II Regulation.

68 Tobias Lenz in Tobias Lenz, *Produkthaftung*, 2014, Section 6 Rn. 74; Wagner in *Münchener Kommentar zum BGB*, 6. Auflage 2013, ProdHaftG Einleitung Rn. 23 f.

69 'For complaints arising from tort, the court in the jurisdiction of which the tortious act was committed shall have jurisdiction.'

defendant (Article 4(1) EuGVVO) and the place the damage and the direct consequences have occurred (Article 7 No. 2 EuGVVO), taking potential conflict of laws at the competent venue into consideration.[70] The injured party is offered a choice between several venues unless specific connections limit the injured party's choice to either the country the product was marketed in or the direct consequences have occurred.[71]

The ProdHaftG and the United Nations Convention on Contracts for the International Sale of Goods are applicable concurrently.[72]

v Expert witnesses

An expert witness is one of several means of evidence made available to the parties to a court procedure under the ZPO and other rules of procedure. It is the expert witness's task to assist the court deemed ill-informed in a certain field with regard to special knowledge in such field. In brief, the expert witness passes on his or her expertise to the court.

vi Discovery

Neither German law in general nor the ZPO in particular provide for US-style discovery. Orders and requests to produce documents or data forming part of a discovery may not be enforced against a German company under the Convention of 18 March 1970 on the Taking of Evidence Abroad in Civil or Commercial Matters as Germany, in accordance with its Article 23,[73] has declared not to execute letters of request issued for the purpose of obtaining pretrial discovery of documents as known in common law countries. If a party to a court proceeding violates his or her obligation related to a pretrial discovery this violation may both be sanctioned by the foreign court and may also serve as a basis for a negative ruling by this court.

Deviating from the foregoing a legal right to obtain information is established under Section 84 et seq. AMG for medicinal products. This right to information may be enforced against both the pharmaceutical manufacturer and the competent agency in case of any damages potentially caused by a medicinal product. The legal right to information is limited if the requested information has to remain confidential owing to legal provisions or the non-disclosure is based on either the manufacturer's or any third party's interest worth being protected.[74]

Further, in German civil cases a secondary onus of proof may be established to the disadvantage of the party not bearing the (primary) onus of proof. This applies in all matters

70 Junker in *Münchener Kommentar zum BGB*, 6. Auflage 2015, Preliminary remarks to Article 1 Rome II Regulation Rn. 26.

71 Wagner in *Münchener Kommentar zum BGB*, 6. Auflage 2013, ProdHaftG Einleitung Rn. 26.

72 Tobias Lenz in Tobias Lenz, *Produkthaftung*, 2014, Section 6 Rn. 53 et seq.; BGH, Decision dated 28 November 1994 – VIII ZR 44/94, IPRax 1996, 124.

73 'The Federal Republic of Germany declares in pursuance of Article 23 of the Convention that it will not, in its territory, execute Letters of Request issued for the purpose of obtaining pre-trial discovery of documents as known in common law countries.'

74 Section 84a AMG.

where a party is obliged to produce information due to the fact that the other party primarily bearing the onus of proof has no detailed knowledge of the determining factors and the other party may be expected to produce the information requested with reasonable effort.[75]

Where, according to the allegation made by the party tendering evidence, the record or document is in the hands of a public agency or of a civil servant in the narrower sense of the term, evidence shall be offered by filing the petition with the court that the public agency or the civil servant be requested to provide the record or document.[76]

In administrative disputes regarding regulatory product safety matters, obligations to provide information may exist and be in effect.[77]

In criminal procedures relating to criminal product liability all criminal investigations are conducted by applying the accepted ways and means to obtain evidence including but not limited to securing and seizing objects and searching the body, the property or the private and other premises of a person.[78]

vii Apportionment

Obligors under the ProdHaftG are both all persons controlling and supervising the production process who have produced the final product, a raw material or a component part and also anyone who imports or takes into the area of application of the Agreement on the European Economic Area a product for sale, hire, leasing or any form of distribution with an economic purpose in the course of his or her business. The protection of an injured person under the ProdHaftG is much more pronounced compared to the Law of Torts under Section 823 BGB et seq. This is owed to the fact that all obligations of producers as well as distributors are based on the potential obligor's respective activities and are, therefore, *de facto* limited. The ProdHaftG does not differentiate between persons having produced the final product, suppliers and raw material producers and who is in breach of his or her respective duty of care. The resulting 'accumulation' of obligors adds to the protection of the injured person and is meant to facilitate the enforcement of claims by avoiding the difficult need for the obligor to identify the real obligee within the network of interacting producers of the final product, component part producers and distributors.[79] Where the producer of the product cannot be identified, each supplier of the product shall be deemed to be its producer unless he or she informs the injured person within a month of his or her receipt of a demand to this effect of the identity of the producer or of the person who supplied him or her with the product.[80]

75 Bacher in *Vorwerk/Wolf, Beck'scher Online-Kommentar ZPO*, 23. Edition, Stand: 1 December 2016, Section 284 Rn. 85.

76 Section 432 ZPO.

77 See also Section 26(3) No. 4, (5) MPG.

78 Section 94 et seq. StPO.

79 Wagner in *Münchener Kommentar zum BGB*, 6. Auflage 2013, Section 4 ProdHaftG Rn. 1.

80 Section 4(3) ProdHaftG.

If two or more producers are liable to pay damages for the same damage, they shall be liable jointly and severally. In the relationship of the parties liable to pay damages, liability in damages as well as the extent of compensation to be paid depends, unless otherwise specified, on the circumstances, in particular to what extent the damage is caused mainly by one or the other party.[81]

viii Mass tort actions

German law does not provide for mass tort and class actions in the field of product liability. However, proceedings may be filed against multiple persons (co-parties) if the respective obligation is based on the same legal and factual grounds[82] or if claims or potential obligations are brought to court on similar, or for the most part similar, legal and factual grounds.[83] Identity of legal grounds is also assumed, in particular, if various claimants claim for damage compensation under the Law of Torts resulting from the same offence but with varying amounts in dispute.[84] Notwithstanding the foregoing, 'connected' proceedings of co-parties described above are rarely to be found in Germany owing to the lack of a legal obligation to act uniformly as co-parties and the resulting fact that most co-parties tend to act independently in the proceedings.

ix Damages

On the basis of Section 823(1) BGB, the liable party has to compensate the injured person for all damages illegitimately and culpably caused. The party liable for damages must restore the position that would have existed had the circumstance obliging him or her to pay damages not occurred. Where damages are payable for injury to a person or damage to a thing, the obligee may demand the required monetary amount in lieu of restoration. Liability to compensate for damage resulting from a tort directed against the injured person extends to the disadvantages the tort produces for the livelihood or advancement of the injured person. The party liable for damages is also responsible for compensation of any indirect damages[85] and intangible damages, in particular, but not limited to damages for pain and suffering.

Liability under the ProdHaftG is limited where personal injuries have been caused by a product or by identical products with the same defect; in this scenario the party liable to pay damages shall be liable only up to a maximum amount of €85 million. Should the combined indemnification to be paid to several injured parties exceed the maximum amount specified above, then the individual compensation shall be reduced *pro rata* to the maximum total given.[86] In addition, in the case of damage to property, the injured party shall pay for damages up to an amount of €500 himself or herself.[87]

81 Section 5 ProdHaftG.

82 Section 59 ZPO.

83 Section 60 ZPO.

84 See BayObLG, Decision dated 20 October 1998 – 1Z AR 75-98, NJW-RR 1999, 1010.

85 Sections 823, 249 et seq. and 842 et seq. BGB.

86 Section 10 ProdHaftG.

87 Section 11 ProdHaftG.

V YEAR IN REVIEW

The European Commission strives to improve product safety and better market surveillance for products in the European Single Market. With these aims, the Commission introduced a bill for a 'Product Safety and Market Surveillance Package'.[88] Sessions regarding enacting of the Package took place; however, the efforts of the European Commission to bring the package into effect as of 1 January 2015 failed for undisclosed reasons. It remains open, therefore, whether the Product Safety and Market Surveillance Package will come into effect at all and how the Commission intends to deal with the results of the deliberations so far.

88 Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, More Product Safety and better Market Surveillance in the Single Market for Products, 13 February 2013, COM(2013) 74 final; Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, 20 actions for safer and compliant products for Europe: a multi-annual action plan for the surveillance of products in the EU, 13 February 2013, COM(2013) 76 final; Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the implementation of Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93, COM (2013) 77 final; also see Klindt in *Klindt, Produktsicherheitsgesetz*, 2. Auflage 2015, Einführung Rn. 34 et seq.

Chapter 10

GREECE

Anthony B Hadjioannou and Maria S Kanellopoulou[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

Product Liability issues arising from the sale of products is regulated by the provisions of Articles 534–558 of the Civil Code (on sale contracts) as amended by Law 3043/2002, which was introduced for the harmonisation of the national legislation to Directive 44/1999/EC for consumer products, as amended by Directive 2011/83/EC. Further, Law 2251/1994, as amended by Law 3587/2007,[2] which is a *lex specialis* 'for the protection of consumers' regulates in more detail in its Article 6 the issue of the manufacturers' responsibility for defective products.

The Civil Code provisions are more strictly related to issues arising out of the sale of defective products, while Law 2251/1994 extends also to liability arising, *inter alia*, from abusive contractual terms, after-sale service, issues related to health and safety of consumers, responsibility of the provider of services, etc. In both cases (i.e., pursuant to both the provisions of the Civil Code and the provisions of Law 2251/1994), liability is strict.

Contractual liability does play a role in the sense that, in addition to any liability arising out of the provisions of the law, the buyer or the consumer who purchased a defective product under a contract has also the possibility to file a complaint for breach of contract.

In general, however, both the provisions of the Civil Code, as well as the provisions of Law 2251/1994, provide adequate protection to lawful interests such as one's life, health and property.

Liability for breach of the above statutory obligations can be imposed in the way described, below. Criminal sanctions, however, can only be imposed in case of fraud, for example, where the seller knew about the defect of the product and concealed it from the buyer.

II REGULATORY OVERSIGHT

The obligation to recall products is a general obligation provided by Article 540, paragraph l(i) of the Civil Code, as amended. More particularly, this Article provides that in case of liability of the seller for a real defect in the product sold or if the product is not fit for the purpose or not fit by description, and in general when the product does not comply with the pre-agreed

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2 As further amended by Laws 3844/2010, 3853/2010, 3862/2010, 4177/2013, 4242/2014 and 4314/2014.

terms or the objective of the sale and purchase agreement between seller and buyer, the buyer has the right to request from the seller the recall of the product and either the repair of its defect or replacement with a new one.

The main condition for the above Article to apply is for the defect to exist at the time of the sale, namely at the moment when the ownership over the product passed from the seller to the buyer.[3] In case the seller refuses to recall the product (or repair or replace it, as the case may be), the buyer has the right to have recourse to justice requesting from the court to order the seller to recall the product and to repair or replace it with a new one. According to the general provisions on tort of the Civil Code[4] an obligation is established for the producer to follow up and recall, if necessary, his or her product after it has been launched in the market. In case of failure to do so, then the producer is held liable as per the aforementioned provisions on tort.

Furthermore, Article 7, paragraph 5 of Law 2251/1994 (as amended) provides that producers, when disposing their products, shall comply with the rules imposed by European and Greek law, the standards imposed for the safety and health of consumers, the European Commission Recommendations and the codes of proper use and ethics regarding the safety of products. The said standards, applicable in Greece, per category of product, regarding the safety of the products, are defined by the Minister of Development (or through the common decision of the above Minister and any other competent Minister). Through a similar decision, the inspection procedures, sampling procedures, laboratory tests on the products are also defined, and any special issue and any relevant detail is ruled. Moreover, Article 7, paragraph 6 of Law 2251/1994 provides that products, which even if used within the ordinary and foreseen circumstances, may nonetheless entail serious and direct risks to the safety and health of consumers, should be recalled by the producer or may be preventively confiscated by the authorities. The procedure and the terms and conditions of the said recall shall be decreed through a decision of the above Minister (or through the common decision of the above Minister and any other competent Minister).

III CAUSES OF ACTION

The claimant must be able to establish a causal link between the damage he or she suffered and the defect in the product. It is not sufficient to prove that the product was defective and that he or she suffered damage or injury. The claimant also has the burden of proving that the defect in the product caused the specific injury or damage sustained.

If the claimant is only able to prove exposure to an increased risk of a type or injury known to be associated with the product, the seller or the producer, or both, may be released from any liability if it can produce evidence that the product was within accepted specifications when sold or launched in the market. However, if the claimant cannot establish a causal link between the defect and the damage or injury then the seller and producer cannot be held liable.

3 Article 537, paragraph l of the Civil Code.

4 See Article 914 et seq.

i The contribution of failure to provide warnings to product liability

Failure to warn the public about the defects of a product does not in itself give rise to liability. The main element in any product liability case brought before Greek justice is the existence or not of a loss or damage suffered and the causal link between the defect in the product and the damage incurred. However, the failure to warn may give rise to liability if the plaintiff can satisfactorily establish that had the defendant warned the public in time about the defect, the loss or damage would not have occurred. Further, failure to warn for defects that were known or became apparent to the defendant may be an aggravating element to be taken into consideration in the amount of damages awarded by the courts.

All kinds of information will be taken into account. For instance, if the manufacturer or producer of a product becomes aware of a defect in his product, he or she can either directly inform the ultimate consumers, or in case there is an intermediary in the supply chain between him and the consumer he or she can ask the intermediary to inform the public about it. A classic example is the one of car manufactures and local representatives. When a foreign car manufacturer becomes aware of a defect in the gearboxes of a specific model, it will inform its local representative (which may be a subsidiary or an independent entity), who will be charged to inform its clients about the withdrawal of the defective gearbox usually through both the issuance of a press release and through letters addressed to its clients directly. In the event, however, of damage suffered owing to the defective gearbox, the consumer has the possibility to file suit both against the manufacturer of the car as well as against the local representative or against whichever he or she chooses.

In relation to who is responsible if the product can only be obtained through the intermediary that owes a separate obligation to assess the suitability of the product for the particular consumer, then the issue is not one of 'a defective product' but rather of 'the wrong product'. In that case, the manufacturer (for example, a pharmaceutical company) has no liability towards the consumer (patient) because the choice of medical device used in a surgery or medicine prescribed belongs to the surgeon or doctor who can be sued for malpractice.

There is no principle of 'learned intermediary' under the Greek legal system in the sense that the manufacturer is completely discharged of any and all liability towards the consumer if the product was defective and the defect caused the damage.

IV LITIGATION

i Forum

Pursuant to the Greek civil procedural system, all trials are heard only by judges. A trial by jury in Greece will only be found in the criminal courts and only in serious cases (felonies).

ii Burden of proof

The claimant (i.e. the consumer) has the onus of proving that there is a defect in the product and that the defect is the cause of the injury or damage he or she has suffered.

The burden of proof rests on the victim (i.e. the consumer) to prove:

a that there was a defect in the product;

b that such defect resulted in the damage (caused by regular or normal use of the product); and

c the causal link between the defect and the damage.

On the other hand, the manufacturer will be exempt from liability if it can prove that:

a it did not circulate the product in the market;

b the defect did not exist at the time that the product was circulated (i.e., at the time that it left the production facility);

c it did not manufacture the product with the intention of distributing it and did not distribute the product as part of its business activity;

d the defect was because of the fact that the product was manufactured in accordance with mandatory legal requirements; or

e at the time when the product was circulated in the market, the existing scientific and technical standards did not allow for the manufacturer to diagnose the defect in the product.

iii Defences

General provisions

According to the provisions of the Civil Code on Sale of Products, the seller, besides the general defence of the claim, has the following particular defences: (1) to invite the buyer to proceed with the replacement of the product or to rescind from the contract within a reasonable period of time. If such time lapses inactive, the exercise of the respective right or rights of the buyer is time-barred (Article 546 of the Civil Code); and (2) in case of consecutive sales, and, therefore, liability of the end seller towards the buyer, the end seller has subrogate rights against the previous seller. As far as the defence of the producer against the consumer is concerned, same is analysed in the following paragraphs.

In any case, the liability of the producer or buyer (and its respective defence against the claimant) may be limited or eliminated in the event:

a of parallel liability with others; and

b of concurrent fault of the buyer or consumer (see Article 300 of the Civil Code).

In this latter case, the liability may be totally exhausted in case of an exclusive fault of the buyer or consumer (i.e., in case of use of the product against the instructions for use, etc.).

Finally, it is notable that the state does not operate any schemes of compensation for particular products. If a claimant considers that the state is responsible for damages incurred owing to a particular defective product then, in order to be compensated, he or she will have to take action against the state before the administrative courts.

Scientific and technical knowledge at the time of supply

The issue of defectiveness of products that fall within the category of 'state of the art products' or within the category of 'highly technologically advanced products' depends significantly on the scientific and technical knowledge available to the producer at the time of production of the specific product. The producer may be released if it produces sufficient evidence that at the time of placing its product in the market there was an objective lack, on the basis of the then existing standards of science and technology, of knowledge allowing it to diagnose the *a posteriori* defectiveness of the product. In this respect, there is an obligation on the producer to strictly follow up the development of science and technology in its particular field of production and to adopt any developments accordingly. For the ignorance of a potential defect to be justified it is not sufficient for the producer to refer to its own capabilities. What matters is the international standard of scientific and technical knowledge existing at that particular point in time and in that particular field of production.

The burden of proof always lies with the consumer to prove the existence of a defect. However, in the case of technologically advanced products it is for the producer to prove the level of scientific and technical knowledge available at the time in its particular field of production.

Development, manufacture, licensing, marketing and supply requirements

Article 6 paragraphs 8 and 9 of Law 2251/1994 provide the defences pursuant to which the producer of a defective product may be acquitted of its liability towards the consumer. More particularly, Article 6, paragraph 8(d) states that the producer is exempted of its liability if it can prove that the defect is because of the fact that the product was produced in accordance with the rules of *ius cogens* instituted by any public authority or pursuant to Article 6, paragraph 8(d) the producer is exempted of its liability if it can prove that when the product was placed into circulation the level of scientific and technical knowledge did not allow it to diagnose the existence of the defect.

Further, paragraph 9 of the same Article provides that the producer of a component of a product is not liable if it can prove that the defect is owing to the design of the product to which the component was embodied or to the guidelines provided by the producer of the product, in which case the producer is considered to be the producer of the product in which the component was embodied.

Time limits

All claims must be filed within the applicable time limits imposed by the statute of limitations. The general principle is that all claims based on commercial disputes are statute-barred after the lapse of five years as of the date the claim was born. However, claims based on the sale of goods provisions for defective products are statute-barred after the lapse of two years for moveable property, and after the lapse of five years for immoveable property, from the day of delivery of the product to the buyer, irrespective of whether the buyer discovered the defect immediately or some time later.

The same statute of limitations (five years) is also applicable for any claim based on tort (direct or indirect damages and moral damages) commencing as of the date the party that incurred the damage realised the existence of the damage and could also identify the liable party; in no case shall this time limit exceed 20 years as of the date the damage occurred. However, if the tort constitutes at the same time a criminal offence that provides for a longer statute of limitations then this later time limit shall prevail.

For claims by consumers against producers for damages provoked by defective products under Law 2251/1994, the statute of limitations is three years as of the date the party that incurred the damage realised or ought to have realised the following three things: (1) the existence of the damage; (2) the defect of the product; and (3) the identity of the producer.

The age and the condition of the claimant do not affect the calculation of any time limits. They do not vary depending on whether liability is fault-based or strict, and the court does not have the possibility to disapply the time limits.

iv Personal jurisdiction

According to the general provision of Article 22 of the Civil Procedural Code, one person can be subjected to the jurisdiction of the court where he resides, or, in case the one to be sued is a company, then, according to the provision of Article 25, paragraph 2 of the Civil Procedural Code, that company can be subjected to the jurisdiction of the court where the

company has its registered seat. In case of tort, the courts that have the jurisdiction are those where the event occurred or will occur.[5] However, the parties have the right to agree in writing to subject their disputes to the jurisdiction of certain courts, and such agreement is binding for the contracting parties, according to the provisions of Article 42 of the Civil Procedural Code.

v Expert witnesses

The court has the right to appoint experts pursuant to the procedure outlined in Articles 368 to 392 of the Civil Procedural Code.

When the court appoints an expert, the only restriction on the nature and the extent of the evidence it seeks is that it determines specific questions that the expert must answer in his or her respective report and for which he or she is appointed to provide his or her special knowledge and skills. Further, the court will impose on the expert a deadline by which he or she must prepare and submit the report to the court. Nonetheless, judges evaluate all kinds of evidence (even evidence presented by an expert) freely. This means that they are not bound to follow the conclusions of the expertise, although, certainly in practice an expert's opinion has a special weight.

After his or her appointment by the court, the expert takes an oath that he or she will prepare his or her expert opinion report with due diligence. The defeated party pays the expert's fee. In case of the appointment of an expert, the litigant parties are entitled to appoint their technical advisers who cooperate with the expert.

Irrespective of whether the court has appointed any expert, the litigants are also free to either submit expert opinions prepared by experts of their own choice (as exhibits to their briefs), or to invite experts to execute affidavits or to testify in court and be cross-examined as witnesses on the date of hearing. In this respect, there are no restrictions on the nature and the extent of the evidence presented to the court.

As per the procedure before the courts, in cases where the court has appointed an expert to prepare and file an expert report, the report must be filed with the secretariat of the court within the time limit imposed by the court and pursuant to Article 389 of the Civil Procedural Code. The hearing can take place only after the expiration of five days from the filling of the expert report with the court secretariat.

vi Discovery

Witnesses' affidavits

According to Law 4335/2015 (which amended the Code of Civil Procedure), the parties have the right to obtain (before either the magistrate judge or a notary public, or the Greek Consulate abroad) and submit to the court up to five affidavits when supporting their lawsuit and three when rebutting the opponents' lawsuit. The execution of the affidavit must take place prior to the submission of briefs and after proper convocation of the opponent to attend its execution. The opponent does not have the right to cross-examine the witness. However, he or she has the right to attend the execution of the affidavit only in order to obtain a copy thereof and comment upon the deposition of the witness in the briefs.

5 According to the provision of Article 35 of the Civil Procedural Code.

Submission of evidence with the court

According to said law, in cases tried before the court of first instance under ordinary procedure (either single-member or multi-member), the parties are obliged to file with the court secretariat their briefs and all documentary evidence (exhibits, affidavits, private expert opinions, etc.) within 100 days of filing of the lawsuit (and within 130 days of filing of the lawsuit when one or both litigant parties has its registered seat abroad). Within 15 days, thereafter, the parties shall file an addendum counter-arguing the allegations of the opponent. After that day, the court secretariat delivers the files to the reporting judge for his or her preparation of the trial, then the hearing date it is set and no more fillings are permitted until the date of hearing. After the hearing and in case the judge considers that it is necessary to cross-examine witnesses, he or she issues a respective court order, and the parties must prepare the witness for the ordered cross-examination.

vii Apportionment

According to the provisions of the Civil Code on sales, the liability is with the seller and with the servants, agents etc., of the seller only. In this case, the claimant shall always be the purchaser of the goods in question.

However, under the special legislation on the protection of consumers[6] the producer of the defective product is held liable for damage incurred to the consumer. Under certain circumstances (i.e., in case the producer is not known to the consumer, etc.) the same liability is extended also to the 'importer' and to the 'supplier' of the defective product, which both are equated, by the law, to producer (quasi-producers). According to the existing case law, 'importer' is anyone who imports goods from third (non-EU) countries.

Furthermore, according to Article 926 of the Civil Code in case the damage is owing to a joint action of several parties or in case there is a parallel liability on more than one party (principal, servant, etc.) for the same damage, then all the parties involved are liable *in toto*. The same principle applies also where several parties acted simultaneously or one after the other and the determination of who out of them is responsible for the damage provoked is impossible.

Following the above, if more than one producer manufactured a defective product, the claimant (buyer or consumer) may file a claim against all people involved.

Any manufacturer that ultimately pays to the claimant the amount awarded by the court has the right to take, in turn, action against the other co-defendants and request that they participate to the amount awarded to the claimant. The share of each one of them to the damages awarded shall be fixed by the court on the basis of the decree of each one's fault or, alternatively, it shall be shared proportionately among them.

viii Mass tort actions

Article 10 of Law 2251/1994 introduced for the first time in Greece the institution of 'consumer associations actions' for the protection of the general interests and welfare of consumers. Consumer associations may act either independently or jointly provided that the total number of their registered active members exceeds the minimum number of 500 members.

6 See Articles 3, 6 and 7 of Law 2251/1994.

In practice, such claims are not very common, and most of the time they are directed against banking institutions for the protection of consumers against unfair contractual terms.

Also, Law 2251/1994 recognises the existence of consumer associations and regulates the way in which they can file claims against producers on behalf of consumers. A consumer association may file a claim or participate in a claim on behalf of any one of its members. Consumer associations with more than 500 registered active members can bring claims for the protection of the interests and of the general welfare of consumers.

ix Damages

Pursuant to Article 540 of the Civil Code, the buyer has the right to take action against the seller of the defective product and request either the repair or the exchange of the product with a non-defective identical product, or the decrease of its value or even the retreat from the sale. Further, under the ordinary provisions of tort, the claimant can claim compensation for actual damage incurred (i.e., expenses incurred, damage to property) or for loss of profits under the condition that he or she can establish a causal link between the damage incurred and the defective product. These are strictly pecuniary damages that can be assessed.

Damages and compensation for bodily injury or mental damage suffered cannot be assessed in real money and, therefore, will fall under the broader category of 'compensation for moral damages'. In this case, again, the claimant will have to be able to prove the existence of a causal link between the moral damage suffered (i.e., owing to the bodily or mental injury suffered) and the defective product.

The main difference, however, between actual damages and moral damages is that the claimant does not have to assess and be able to prove the amount of moral damage suffered. Hence, there are no restrictions in claiming compensation for moral damages, and claimants can freely estimate the amount of compensation they believe appropriate. Of course, the court in deciding whether or not to award moral damages and to what extent will take into consideration not only the particular facts of the case but also the financial situation and wealth of both the claimant and the defendant, and will award the amount it deems fair and appropriate given the circumstances of each particular case. Therefore, usually the amount of moral damages awarded by the court is lower than the amount sought by the claimant. In no case, however, can the court award a larger amount of moral damages than those claimed by the claimant.

Damage to the product itself cannot be claimed under the provisions of the Law 2251/1994, but can only be claimed under the provisions of the Law on Contracts or Tort.

Moreover, as far as damage has been incurred and can be assessed and proved by the claimant, then damages can also be recovered. Hence, under the provisions of Greek law, it is impossible for someone to claim compensation for future and not-yet-incurred damage. For instance, if a person had to undergo medical treatment or medical tests, examinations and monitoring owing to the administration of a defective drug, which caused bodily damage, he or she would be entitled to claim compensation from the producer and the distributor of the drug and recover the damages incurred only if he or she was in a position to prove that the product was defective and that the defect caused the damage.

Namely, the claimant can only claim for damage incurred. However, it is impossible to claim compensation for any kind of expenses incurred where the product is not defective or did not malfunction or its defect did not cause the injury or any other kind of damage

(pecuniary or other). In short, therefore, a claimant can claim compensation for costs incurred owing to a defective or malfunctioning product only if he or she is in a position to establish the causal link between the damage incurred and the defect of the product.

Finally, it is notable that the Greek courts do not award punitive damages in the sense that the term has gained in certain jurisdictions and especially in the United States. However, in the Greek jurisdiction and as explained above, it is common practice for claimants to claim (and, in successful claims, for the courts to award) moral damages.

V YEAR IN REVIEW

The recent developments affecting product regulation and liability are mentioned in Section I, *supra*. We indicatively refer below to a specific judgment issued by Greek courts regarding the issue under review. That judgment refers to court rules on the conditions to release a producer from liability (common cases brought before the Greek courts).

In this case, heard by the Athens First Instance Court, the plaintiff had purchased a yoghurt from a supermarket. She said she had taken the yoghurt from a fridge in the supermarket and after purchasing it, placed the yoghurt in her own fridge. Later that day she sat down to eat the yoghurt in front of the television with the lights switched off. After the first spoonfuls, the consumer felt that the yoghurt had a strange taste, so she stopped eating it after having consumed a considerable quantity thereof. She switched on the lights and saw that the yoghurt had mould on its surface. Shortly afterwards, the consumer experienced acute abdominal pain and vomiting. The consumer called a doctor, who diagnosed acute gastroenteritis and recommended bed rest and the relevant treatment. The consumer filed a lawsuit against both the producer of the yoghurt and the supermarket, seeking compensation, claiming that they were jointly liable. According to the consumer's allegations, the most plausible reason for the yoghurt being rendered defective was a fault on the part of the producer when producing, storing and/or transferring the product, without excluding any storage fault on the part of the supermarket after the product had entered its sphere of influence and risk. The producer argued that: (1) its production was automatic and took place on a large scale, in conformity with EU and national regulations, and that the defect, if any, had appeared after the product left its production facility; and (2) the same defect had been found in no other product of the same or any other batch of yoghurt. The court ruled that the defectiveness of the yoghurt was not because of fault of the producer. Thus, it accepted the tortious liability of the supermarket owing to a failure in maintenance of the yoghurt. The court ruled that:

> *the limited time between the purchase of the product by the plaintiff and partial consumption thereof on the same day does not justify the development of mould (to the extent that it was manifested in the product) to be attributed to her own fault. In other words, the mould of the product is disproportionately minor if it is attributed to fault of the first defendant (producer) and rather great if it is attributed to fault of the plaintiff herself. So, the cause of defectiveness of the yoghurt bought by the plaintiff from the second defendant (supermarket) is necessarily the existence of fault of the latter during maintenance of the product in its store. Such fault is not excluded by the fact that the second defendant generally takes appropriate measures for maintenance of the products and particularly it places dairy products in fridges at a stable temperature of 2 degrees Celsius and regularly checks the good operation of its fridges, because it is always possible that single faults may happen.*

Therefore, having rejected all other possibilities, the court ruled that it was possible that the supermarket's cooling conditions were inappropriate, and that it could not be excluded that the yoghurt in question, while being stored by the supermarket, had sustained damage to its packaging. Consumers often move products from their initial shelf, and, during such movement, it is possible that damage could occur to the packaging, or the product could be placed outside the fridge or in another place where it is not cooled.

In order to reach its conclusion on the issue of liability, the court applied the theory of spheres of influence or risk source. On the basis of the extent of defectiveness, the product at issue no longer fell within the sphere of the producer and consequently no liability could be established. This consideration of the court was supported by the facts that:

a the production method applied by the producer was automatic and large scale;
b no other defective products of the same or another batch were reported; and
c the supermarket admitted that the yoghurt had been supplied to it in perfect condition.

Therefore, the court released the producer from liability.

Chapter 11

INDIA

Vivek Bajaj and Annie Philip[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

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

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

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

a the Sale of Goods Act 1930 (SGA);

b the Consumer Protection Act 1986 (CPA); and

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

Further, given that India is a common law country, courts are influenced by principles of justice, equity and good conscience, and principles of tort law such as the duty of care, negligence and strict liability (including absolute liability in exceptional circumstances) in claims dealing with product liability. The provisions of the Indian Penal Code 1860 (IPC), such as those relating to criminal negligence, fraud and cheating, may apply in cases of defective products supplied if criminal intent is ascribed to the acts of the manufacturers or suppliers. Furthermore, depending on the facts of the case, criminal liability may also arise under industry-specific statutes (discussed below).

There are also regulations such as the Bureau of Indian Standards Act 1986 (the BIS Act)[2] and the Bureau of Indian Standards Rules 1987 (the BIS Rules), which set out mandatory and voluntary standards and specifications applicable to products across different sectors and industries.

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2 The Bureau of Indian Standards Act 2016, which was has been approved by the Parliament and notified in 2016 for general information, will replace the BIS Act upon coming into force.

In addition to the foregoing, specific areas such as the food,[3] pharmaceuticals,[4] automotive[5] and electronics[6] industries, have laws that govern and regulate standards, product safety and liability in such sectors.

II REGULATORY OVERSIGHT

The regulatory authorities in India overseeing product safety fall into two categories: pan-industry regulators and industry-specific regulators. Among the pan-industry regulators, the most significant agency for product safety and development of product standards is the Bureau of Indian Standards (BIS), which was established under the BIS Act and the BIS Rules. BIS develops and sets out quality standards and certification requirements for different goods in India, some of which are mandatory, while the others remain voluntary. In cases of goods where the standards are mandatory, such as cement, identified electronic goods, pneumatic tyres and certain valves and cylinders, manufacturers as well as importers are required to ensure compliance with these standards before such goods are imported, distributed or sold in India.

In addition to the foregoing, drugs, automotive and food industries are some of the notable sectors that are governed by industry-specific regulators, which are discussed below.

i Drugs

The Central Drugs Standard Control Organisation (CDSCO) is the central authority for discharging functions assigned to the central government under the Drugs Act. Some of the major functions of the CDSCO include regulatory control (including quality control) over imported and locally manufactured drugs and setting out standards applicable to drugs and cosmetics. The CDSCO also has the power to regulate, restrict or prohibit the manufacture, sale or distribution of drugs or cosmetics that are likely to involve any risk to human beings or animals.

The implementation of these standards and related requirements under the Drugs Act and the rules framed thereunder are carried out by central and state authorities, including central and regional drug laboratories, drugs controllers, licensing authorities and inspectors.

ii Automobiles

Under the MVA, the Ministry of Road Transport and Highways is the primary authority for regulation of the automotive industry in India. It has overarching powers under the MVA including laying down of standards on automotive safety, construction and equipment of motor vehicles, which have to be complied with by automobile manufacturers. Pursuant to these powers, the Ministry of Road Transport and Highways, in consultation with the Automotive Industry Standards Committee and other committees, has set out automotive technical standards and specifications to be complied with by motor vehicles manufactured or sold in India.

3 Food Safety and Standards Act 2006 (FSSA).

4 Drugs and Cosmetics Act 1940 (Drugs Act).

5 Motor Vehicles Act 1988 (MVA).

6 Electronics and Information Technology Goods (Requirements for Compulsory Registration) Order 2012.

iii Food

The Food Safety and Standards Authority of India (Food Authority) was established under the FSSA to regulate the manufacture, storage, distribution, sale and import of food to ensure availability of safe and wholesome food for human consumption. The Food Authority has broad powers under the FSSA, including specifying and enforcing standards and guidelines in relation to food and food labelling.

III CAUSES OF ACTION

The term 'cause of action' is not defined under Indian statutes but has acquired a settled meaning based on judicial interpretation. It is largely a civil law concept and generally speaking, it refers to all circumstances or sets of facts that (1) give rise to a right to sue, or (2) if proved or admitted, would entitle the plaintiff (complainant) to the relief claimed by it.

Given the broad import of the term, various causes of action may arise in contractual disputes. For example, in a suit for damages for breach of contract, the cause of action may consist of the making of the contract, performance of the contract and of its breach. Similarly, in cases of consumer complaints under the CPA, the presence of a defect in the goods purchased or of a deficiency in services availed will constitute a cause of action to file a complaint before the relevant consumer court.

Indian courts have cautioned against extrapolation of civil law concepts such as 'cause of action' onto criminal law. The criminal procedural law in India unambiguously states that every offence shall ordinarily be inquired into and tried by a court within whose local jurisdiction it was committed. Therefore, this principle will need to be borne in mind in the event provisions of the IPC are attracted to product liability cases.

IV LITIGATION

i Forum

Depending on the facts, the goods or services involved and the category of the aggrieved party (consumer or buyer for commercial use), there are multiple fora that an aggrieved party can approach in cases relating to loss, damage or injury resulting from defects in goods or services. These include:

a jurisdictional consumer court or forum (depending on the claim amount) under the CPA;
b jurisdictional civil court in a case of a contractual breach or a tortious action;
c an arbitration tribunal in accordance with an arbitration agreement executed between the relevant parties in a case of contractual breach; or
d jurisdictional magistrate's court in the event of a criminal offence.

In addition to the foregoing, in certain circumstances, aggrieved parties can also approach a jurisdictional high court in the event that the distribution of defective products has resulted from a breach of duty or inaction by a statutory authority.

Further, in 2015, the Indian Parliament enacted the Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act 2015 (Commercial Courts Act), which seeks to streamline and fast track commercial disputes (including disputes arising out of agreements related to the sale of goods or provision of services). The Commercial Courts Act provides for the constitution of (1) commercial courts at a district level, except areas where

the High Court exercises ordinary original civil jurisdiction, and (2) commercial divisions and commercial appellate divisions in all High Courts having ordinary civil jurisdiction. These have been constituted for the adjudication and speedy disposal of commercial disputes of a specified value of not less than 10 million rupees or such other notified value within the limits of the relevant territorial jurisdiction. Although the Commercial Courts Act has come into force, commercial courts are still in the process of being set up in various Indian states.

In India, dispute resolution through adjudication by courts and arbitration are completely distinct and independent processes that rarely overlap. In cases where disputes are adjudicated before a civil court or a specially constituted tribunal, the matter is presided over by judges or presiding officers, as the case may be. India does not follow a jury system of trial. In a case of arbitration proceedings, the claims are adjudicated by the arbitral tribunal appointed by the parties in accordance with their arbitration agreement or in the manner set out in the rules of arbitration elected by the parties. Having said that, it is very common for parties to an arbitration agreement to appoint retired judges as arbitrators.

ii Burden of proof

The Indian Evidence Act 1872 sets out the law relating to burden of proof for civil and criminal cases. As a general rule, any party seeking the court's intervention as to enforcement of its legal rights must prove the facts that establish and substantiate its claim.

To establish causation in product liability cases under Indian law, every fact establishing the elements of a cause of action must be proved by the plaintiff or the aggrieved party. Therefore, in cases relating to defects in products, depending on the factual circumstances, the burden of proof will be on the aggrieved party to prove (1) presence of a defect in the goods, (2) breach of warranty or condition (implied or expressed), or (3) breach of duty of care and resulting damage (in instances involving negligence). In some cases, however, the Indian courts have held that the existence of the defect *per se* is proof of negligence.

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

iii Defences

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

a the product being compliant with requisite statutory standards prescribed;
b the product not being 'defective' as defined under the CPA;
c the purchaser of the product is not a 'consumer' as defined under the CPA;
d loss or injury is owing to negligence or misuse by the consumer or buyer including contributory negligence;
e the consumer or buyer had examined the goods prior to purchase and accepted it, being satisfied of its quality or specification; or
f contractually agreed disclaimers or limitations on warranties in terms of scope, period, recourse and amount.

In addition to the foregoing, defendants (such as manufacturers, distributors or sellers) could also contend that a civil action or complaint is barred by limitation. Limitation on filing of suits in India is governed by the Limitation Act 1963. The period of limitation for a civil proceeding for monetary compensation on account of a contractual breach is three years from the date on which the breach occurs. The CPA provides for a limitation period of two years from the date of the cause of action; however, the CPA gives the consumer court the discretion to entertain complaints filed beyond the limitation period if it is satisfied with the reasons for the delay.

Further, under the general law on limitation, some specific statutes regulating certain products expressly set out applicable periods of limitation. For example, the FSSA provides for a limitation period of one year from the date of commission of an offence, extendable up to three years at the discretion of the relevant authorities.

iv Personal jurisdiction

Usually, a civil court will have jurisdiction to adjudicate a claim if the cause of action, wholly or in part, arises within its jurisdiction. Further, the Civil Procedure Code (CPC), which sets out the relevant provisions relating to the jurisdiction of courts in civil cases, gives the plaintiff discretion to file a suit for compensation for damage done to person or moveables, in (1) the jurisdictional court of the local limits where the damage took place, or (2) the court within the local limits where the defendant resides, or carries on business, or personally works for gain.

In cases involving foreign parties, Indian courts favour the common law principle of comity. Therefore, if the facts and circumstances indicate that a foreign court has jurisdiction (for example, if the parties have agreed to subject themselves to the exclusive jurisdiction of a foreign court), subject to certain exceptions, Indian courts are reluctant to interfere and tend to direct the aggrieved party to seek redress before the relevant foreign court. Having said that, it should be noted that in certain cases Indian courts have ignored the choice of jurisdiction of the contracting parties if, among others, it is in the interests of justice to do so or if, by contract, the parties have vested jurisdiction in a court that originally lacks jurisdiction. Further, if it can be demonstrated by the aggrieved party that the situs of the contract or the cause of action (wholly or in part) arises in India, the Indian courts may assume jurisdiction, if considered appropriate to do so.

Indian law recognises the doctrine of privity of contract and, consequently, third parties are not ordinarily entitled to benefit from or sue for the breach of a contract to which they are not a party. Applying this principle to a case relating to product defects, where cause of action (wholly or in part) arises in India, a manufacturer or seller would not be liable for damages under breach of contract unless the claimant can establish existence of a valid contractual relationship with such manufacturer or seller.

However, in a considerable deviation from the position relating to contractual claims, in certain cases where aggrieved parties have alleged the tort of negligence, Indian courts have applied the principle in *Donoghue v. Stevenson*,[7] where a duty of care is imposed on a party with regard to any person who would be affected by the first party's actions or that such first party should have considered while directing its acts or omissions (irrespective of whether any contractual relationship exists), and have assumed jurisdiction over such first party upon

7 [1932] AC 562.

the request of the aggrieved party. Therefore, exercising such jurisdiction, Indian courts have attached tortious liability to sellers and distributors in addition to manufacturers in cases of defective products.

v Expert witnesses

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

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

vi Discovery

The procedure governing the discovery of documents or information under Indian law is principally governed by the CPC for civil matters and CrPC for criminal cases. Indian courts (including consumer courts) have inherent powers to call for the production of documents or information that are in the power or possession of a party to the proceeding or a third party at any time during the pendency of proceedings. Indian law does not, however, permit discovery of evidence or information prior to initiation of legal proceedings.

Discovery of information is permitted through an order for discovery of documents or through interrogatories in civil cases, or through summons in criminal cases. The granting of an order permitting discovery of information (including production of documents) is completely at the discretion of the court and, ordinarily, discovery will not be permitted unless the court is satisfied that it is necessary either for disposing of the matter fairly or in order to save costs. In the event the information or documents are not produced before the court and no legitimate reason is provided for such failure, the courts may draw an adverse inference against the party that has failed to comply.

In criminal cases, the court has the power to issue summons or a written order requiring a person to produce any document or thing believed to be in its possession or power for the purpose of any investigation, inquiry, trial or other proceeding.

vii Apportionment

Under Indian law, a decree passed in respect of payment of compensation or damages in a suit for breach of contract or tortious claims may be passed by a civil court only against persons named as defendants in such suit.

In cases of defective products that are also contractual breaches, apportionment of liability is ordinarily contractually driven and may be joint or several (or both) depending on the provisions of the contract and the facts and circumstances of such cases. In cases of tort, the Indian courts recognise the principle of joint and several liability. Under this principle, multiple parties may be held jointly liable in respect of any tortious claim by an affected person in the event that (1) such parties have, acting in concert, committed a wrongful act

resulting in loss or damage to the affected person or, (2) when not acting in concert, have, by their individual wrongful acts, caused loss or damage to the affected person. In exceptional cases, courts have apportioned the liability between multiple tortfeasors on the basis of material evidence available on record, indicating the degree of liability of each tortfeasor. Further, in consumer cases under the CPA, the relevant forum has upheld the principle of joint and several liability and held the manufacturer and dealer to be jointly and severally liable for defective goods.

viii Mass tort actions

Under the CPC, two or more plaintiffs have the right to aggregate their claims in a suit against one defendant, even if their causes of actions are separate and distinct, in the event that the right to obtain relief arises out of the same act, transaction, or series of acts or transactions, and the causes of action are of such a nature that if separate suits were filed by the plaintiffs, common questions of law or fact would arise. Additionally, the CPC also allows one or more persons to file a suit against the opposing party on behalf of, or for the benefit of, numerous persons having the same interest in such suit, with the prior permission of the court in which such suit is required to be instituted. In this regard, interest is said to be similar or common when the plaintiffs have a common grievance against the defendant and the relief sought is in its nature beneficial to all persons interested in the suit.

The CPA recognises the right of one or more consumers or a voluntary consumer association to file a complaint against a single manufacturer, dealer, distributor, etc. on behalf of, or for the benefit of, numerous consumers having the same interest. Such complainants are required to obtain prior permission from the relevant forum for adjudication of disputes under the CPA before instituting such proceedings. Additionally, the CPA provides the district, state and national fora the power to grant relief to several consumers who are unidentifiable. This power is typically exercised in the event of loss or injury being suffered by a large number of consumers as a result of defective goods or services, and such consumers cannot easily be identified.

ix Damages

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

Further, damages under contract may be either liquidated or unliquidated. Liquidated damages are such as have been agreed upon and fixed by the parties in anticipation of a breach whereas unliquidated damages must be assessed and quantified. In either case, the courts have broad discretion in the assessment of damages. Applying the reasonableness test, the court usually awards the actual amount of loss proved to have been suffered by the aggrieved party as a direct result of the breach of the contract by the defaulting party; however, if the parties have stipulated liquidated damages in the contract, the courts, subject to such stipulated amount being a genuine pre-estimate of the loss, will not grant damages in excess of the stipulated amount.

Unlike in the case of a contract where the function of damages is primarily to compensate the aggrieved party for losses sustained by it owing to breach of contract, the

function of damages in tort is to put the injured in the position in which it would have been had the tort not been committed. Further, the Indian courts have held that remedy by way of damages in tort extends to a negligent manufacturer causing monetary loss by the supply of a sub-standard product and is not restricted merely to loss of life or property of the user.

In contractual disputes, Indian courts do not normally award punitive or exemplary damages. However, applying principles of tort law, such as strict and absolute liability, exemplary damages have been awarded by the courts in cases where harm has been caused by ultra-hazardous or dangerous actions. Further, under the CPA, the courts have in the past awarded exemplary damages by way of compensation in exceptional cases where it has been established that the complainant suffered harassment and extreme pain and suffering as a result of the conduct of the manufacturer, supplier or distributor, pursuant to its claim. It must, however, be noted that the amount of exemplary damages awarded under the CPA or by a civil court is much lower than and not comparable with punitive damages that are awarded in other developed countries.

With regard to the assessment of damages, Indian law imposes on the plaintiff the duty of taking all reasonable steps to mitigate the loss consequent to the breach, and debars the plaintiff from claiming any part of the damage that is owing to its failure to take such steps. Therefore, a court may deny a plaintiff's claim to the extent that it finds that the plaintiff has failed to mitigate the loss.

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

V YEAR IN REVIEW

The Bureau of Indian Standards Act 2016 (the BIS Act 2016), which seeks to replace the BIS Act, was passed by Parliament in 2016. While the BIS Act 2016 has been passed by the Indian Parliament, it is yet to come into force. The BIS Act 2016 allows the central government to notify certain goods, articles, processes, systems or services that will need to compulsorily comply with prescribed standards and carry a standard mark. Such goods, articles, processes, systems or services will be notified by the government if it thinks them to be necessary for: (1) public interest; (2) the protection of human, animal or plant health; (3) safety of the environment; (4) prevention of unfair trade practices; or (5) national security. Further, the Bureau of Standards may recall a good or article if it is convinced that the good or article does not conform to the requirement of a particular standard. The BIS Act also provides for penal consequences including fines and imprisonment for non-conformance with prescribed standards and other acts of non-compliance.

The Union Ministry of Health and Family Welfare notified the Medical Devices Rules 2017, which are proposed to come into force on 1 January 2018. These rules will apply to substances used for in vitro diagnosis and surgical materials, blood and blood component collection bags; mechanical contraceptives, disinfectants and insecticides as notified under the Drugs Act; and devices notified from time to time under the Drugs Act. As per these rules, medical device manufacturers are required to follow the essential principles of safety

and performance of medical devices as well as conform to standards that may be specified by the Ministry of Health and Family Welfare or the Bureau of Indian Standards. Where no standards are notified by the Indian regulators, medical devices are required to conform to the standards laid down by the International Organisation for Standardisation (ISO) or the International Electrotechnical Commission (IEC), or any other pharmacopoeial standards. In absence of these international standards, the medical devices should conform to the validated manufacturer's standards.

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

Recently in the pharmaceutical sector, Sanofi recalled four batches of its painkiller 'Combiflam' in 2016 as per Class III recall (i.e., where the defective product is not likely to cause any adverse health consequences) under the Guidelines on Recall and Rapid Alert System for Drugs. This is after the CDSCO found them to be substandard since they did not pass the tests for disintegration.

The three-decade-old CPA is sought to be replaced by a new law that was introduced as the Consumer Protection Bill 2015 (the Consumer Bill) in the lower house of the Indian Parliament on 10 August 2015. The salient features of the Consumer Bill include introducing provisions relating to product liability, enhanced penalties and establishment of the Central Consumer Protection Authority (CCPA) (a regulatory agency that has wide powers to address concerns of the consumers). Some of the powers of the CCPA include (1) inquiring into and conduct of investigations into violations of consumers' rights, (2) recall of the products found to be unsafe or withdrawal of services found to be unsafe or hazardous, and (3) issuing safety notices and alerting consumers to unsafe goods or services.

The Consumer Bill also includes provisions that make the manufacturer or the producer liable for product liability action where any personal injury, death or property damage is caused to the consumer owing to marketing, packaging or labelling of any product. Further, the basis for product liability action and the evidence requirements that have to be fulfilled by the complainant have also been set out in the Consumer Bill. In certain cases such as inability to identify the manufacturer, lack of jurisdiction over the manufacturer, negligence, express independent warranty by the product seller and failure of the product to conform to such warranty could also make the product seller liable to product liability actions.

On 18 January 2017, the Union Ministry of Health and Family Welfare notified the Food Safety and Standards (Food Recall Procedure) Regulations 2017 (the Food Recall Regulations), which have not yet come into force. The objective of the Food Recall Regulations is to ensure removal of food under recall from all stages of the food chain, to disseminate information to the concerned customers and to destroy or reprocess food under recall. The Food Recall Regulations contain provisions and procedures pertaining to removal of food that is unsafe, including recalls. In the past, the Food Authority has used its inherent powers under the FSSA to recall defective or unsafe food articles. In 2015, the Food Authority ordered a recall of Maggi Instant Noodles manufactured by Nestlé India

Limited and a prohibition on the production, import, distribution and sale of these noodles owing to the presence of excess lead and for violating the labelling requirements under the FSSA. The order for prohibition was challenged by Nestlé India Limited before the Bombay High Court, which set aside the order for prohibition passed by the Food Authority. The Food Authority has challenged the judgment of the Bombay High Court, and the matter is currently pending before the Supreme Court of India.

Despite the absence of a statutory framework in place for automobile recalls in India, industry giants such as Volkswagen, Honda, Ford, Maruti Suzuki, Yamaha, Hyundai, Renault-Nissan and General Motors initiated large-scale voluntary recalls of their automobiles in 2016 owing to defects discovered in various components. Volkswagen, as part of a global recall, is currently carrying out a voluntary recall of its cars in India owing to violation of emission norms. In this respect, it has been asked by the National Green Tribunal (which is the forum set up in India for expeditious disposal of cases relating to environmental, conservation and related issues) to present a roadmap for the recall of its defective vehicles. The unprecedented rise in the number of voluntary automobile recalls in India and concerns around road safety has led to the introduction of the Motor Vehicles (Amendment) Bill 2016 (MV Amendment Bill) in the lower house of the Indian Parliament on 9 August 2016. This MV Amendment Bill seeks to amend the Motor Vehicles Act 1988 and is currently pending approval of the Indian Parliament. The MV Amendment Bill allows the central government to order the recall of motor vehicles with defects that may cause damage to the environment, driver or occupants or other road users, if such defects are reported to the central government. The MV Amendment Bill also provides that the manufacturer whose vehicles are recalled will have to (1) either reimburse the buyers for the full cost of the vehicle, or replace the defective vehicle with another vehicle with similar or better specifications, and (2) pay such fines and other dues as may be prescribed. Where the manufacturer notices defects in the motor vehicles it manufactures, the MV Amendment Bill also provides for voluntary recalls after informing the central government. In such cases, the manufacturer shall not be liable to pay the prescribed fines.

Currently, one of the mechanisms adopted by manufacturers and dealers to avoid or limit liability is voluntary product recall. Voluntary product recalls have recently been carried out across several industries despite the lack of statutory or regulatory guidance in this respect. These are generally strategic actions to limit potential liability owing to defective products, given that obligations such as duty of care under tort law and consumer protection laws continue to apply.

Chapter 12

ISRAEL

Avi Ordo and Moran Katz[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

The Defective Products (Liability) Law 5740-1980 (DPL) specifically regulates the issue of defective products that result in bodily injury. The DPL imposes strict liability on manufacturers of defective products, the liability for which is subject only to limited and specific defences, and does not require proof of fault on the part of the manufacturer, but only the existence of a defect in the manufacturer's product. Nonetheless, a prescribed cap is imposed in the DPL for non-pecuniary damages, as well as for loss of earnings and loss of earning capacity. The DPL also provides a shortened limitation period. In view of these limitations, the DPL is seldom solely relied upon and injured persons usually also utilise other causes of action that are not subject to these limitations.

Liability for a defective product may also be based on a tort claim filed in reliance on the Civil Wrongs Ordinance (New Version) 5728-1968 (CWO),[2] or on a claim for breach of contract filed in reliance on the Contracts Law (General Part) 5733-1973 (the Contracts Law), the Sale Law 5728-1968 (the Sale Law) or the Sales Law (International Sale of Goods) 5760-1999 (the International Sales Law).

Liability for failure to disclose material information relating to a product may be imposed by virtue of the Consumer Protection Law 5741-1981 (CPL) and deviation from standards governing the manufacture, distribution and sale of products may be actionable under the Standards Law 5713-1953 (SL).

II REGULATORY OVERSIGHT

i Israeli Standardisation Administration (ISA)

The ISA, which falls under the auspices of the Ministry of Economy, oversees the adoption of, and adherence to, the relevant standards under the SL. The ISA may determine that a specification of a product or certain working process be listed as an Israeli standard. The Minister of Economy may declare an Israeli standard as an official standard. Upon such declaration, no person may deal with any such product or perform such working process unless he or she complies with the requirements of such official standard.

The SL regulates the issue of product recalls of products that are subject to an official standard and, *inter alia*, authorises the Commissioner of Standardisation to impose a product recall and prescribes the circumstances under which a safety event or deviation from the

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2 For example, for negligence or breach of statutory duty.

applicable standard must be notified to the Commissioner of Standardisation. In addition, Israeli Standard 10393 adopts in its entirety international standard ISO 10393 and provides practical guidance to suppliers about consumer product recalls and other corrective actions to be taken after a product has left the manufacturing facility. Recent amendments to the SL impose new tractability obligations alongside additional changes related, *inter alia*, to quality checks and approval for the marketing of standard-subject products.

ii Product-specific regulation

Certain products are regulated by specific legislation that identifies the regulatory authority responsible for overseeing the safety of such products. For example:

a Medicinal preparations fall within the responsibility of the Pharmacy Department, a division within the Ministry of Health (MOH). All matters pertaining to medicinal preparations are largely regulated by the Pharmacists Ordinance [New Version] 5741-1981 (PO), as well as corresponding regulations and guidelines issued by the MOH. The recall of medicinal preparations is addressed in the PO, as well as in the Pharmacists Regulations (Preparations) 5746-1986 and Guideline No. 3 published by the MOH and entitled 'Notification of a Defect in Medicinal Preparations and Raw Active Ingredients'. The issue of pharmacovigilance and safety monitoring is addressed in Guideline No. 6 published by the MOH and entitled 'Reporting Adverse Events and New Safety Information'.

A recent comprehensive amendment to the PO introduced into primary legislation the obligation to immediately notify the Director General of the MOH (DG) of a defect in a preparation. Said amendment also lists the steps that the DG is authorised to take in connection with a preparation that is found to be defective, in order to safeguard public health, for example, initiating a product recall and notifying the public thereof by publishing same in the media. It is also prohibited to manufacture, market and use a preparation that was the subject of a decision given by the DG under the aforesaid authority, save in accordance with the DG's directives in connection with the said preparation.

In addition, with respect to a potentially hazardous preparation, MOH-supervised consumer product and cosmetic product, the DG is authorised to prohibit the manufacturing or marketing of such product or preparation or to order its destruction, after being convinced that the product is indeed hazardous (subject to giving the manufacturer/distributor/registration owner an opportunity to present his or her arguments in the matter).

b Medical devices fall within the responsibility of the Medical Devices Department, a division within the MOH. The Medical Devices Law 5772-2012 (MDL), which is expected to enter into effect as soon as all corresponding regulations are enacted, caters for the regulation of medical devices. The MDL addresses, *inter alia*, the issue of product recalls and provides that the MOH will publish regulations detailing the registration owner's duty to notify the MOH of events with safety implications.

Cosmetics fall within the responsibility of the Cosmetics Department, a division within the MOH. As mentioned in point *a*, above, according to the PO, the DG is authorised to take certain steps in connection with potentially hazardous cosmetics. An additional amendment to the PO, which is expected to enter into effect as soon as corresponding regulations are enacted, addresses, *inter alia*, the issue of product recalls and prescribes the steps that should be taken by a dealer who discovers that a cosmetics

product under his or her responsibility is harmful. The amendment also grants the DG broad powers with respect to harmful cosmetics, including the authority to impose a product recall, notify the public of the harmful cosmetic product, etc.

d The food sector falls within the responsibility of the National Food Service, a division within the MOH. The recently enacted Protection of Public Health (Food) Law, 5776-2015 (FL), provides regulation for the food and nourishment sector. Said law grants the DG broad powers with respect to harmful food products, including the authority to issue directives to food dealers with respect to the manner of manufacturing, packaging, transporting, storing and selling food products, imposing a product recall, instructing food dealers to publish details regarding harmful food products, notifying the public of harmful food products, etc. According to the FL, a dealer who discovers or is made aware of the fact that a food product under his or her responsibility is harmful is obliged to take, as soon as possible, reasonable steps in order to prevent use of that food product, including *inter alia*, withdrawing it from the market, notifying the public thereof, etc. The dealer is also obliged to notify the DG of any steps taken by him or her as aforesaid, comply with any directives issued by the DG after receiving such report and adhere to record-keeping duties, as prescribed by the FL. The DG is also authorised to independently take the necessary steps to protect the public from harmful food products, including, in certain circumstances, notifying the public thereof by publishing same in the media, withdrawing the harmful food product from the market, etc.

e Vehicles and transportation-related products fall within the responsibility of the Ministry of Transport and Road Safety (MOT). The recently enacted Licensing of Services and Occupations in the Vehicle Field Law, 5776-2016 (VL), provides comprehensive regulation of the vehicle sector. The said law contains provisions facilitating, *inter alia*, the recall of vehicles and transportation-related products. With respect to vehicles, the VL imposes on vehicle manufacturers, direct (i.e., authorised) importers and distributors, *inter alia*, a duty to notify the MOT, vehicle owners, the general public (if instructed by the Director General of the MOT) and the direct (authorised) importer's service garages, of any serial safety malfunction. Said dealers are further obliged to repair in their service garages any such malfunction, without consideration. Certain notification duties are also imposed on parallel and small-scale importers. Under the VL, the Minister of Transport was given the authority to enact regulations governing the recall procedure of vehicles and transportation-related products. The first set of regulations, published in October 2016 and titled 'Licensing of Services and Occupations in the Vehicle Field (Importation, Marketing and Brokerage of Private Import of Vehicles), 5776-2016' addresses, *inter alia*, the recall of privately imported vehicles and related notification, publication and reporting duties imposed on vehicle importers. Additional regulations governing the recall of vehicles and transportation-related products are expected to be enacted in the near future. The recall procedure of vehicles is further regulated by Guideline 83, published by the MOT, which sets out the period of time given to an importer to inform the Licensing Department at the MOT of the recall process, and also imposes sanctions on individual citizens who failed to perform the recall procedure in a timely manner following its publication in the press.

III CAUSES OF ACTION

i Civil liability

Tortious claims for injury can be brought based on either the DPL or the CWO. For details concerning liability under the DPL, see Section I. The main cause of action in product liability cases is based on the CWO and, in particular:

a negligence, for which the following elements must be established: the existence of a duty of care; breach of such duty by the defendant; and a causal connection between the said breach and the resultant damage; and

b breach of statutory duty, in which a plaintiff claiming breach of statutory duty will need to show the breach by the defendant of a duty imposed on it by any law or regulation, other than the CWO (e.g., the duty to meet an official standard), provided that: (1) the purpose of such other law or regulation is to protect or benefit the plaintiff; and (2) the damage caused as a result of the breach is of the nature contemplated by that law or regulation.

A manufacturer or distributor of a defective product may also be exposed to contractual claims. In addition to the provisions of the specific contract that form the contractual basis between the relevant parties, the Contracts Law, the Sale Law and the International Sales Law should also be taken into consideration. These laws include provisions to the effect that, for example, a party to a contract should not mislead the other party and both parties should perform the contract in good faith and in a customary manner. In addition, according to the Sale Law, a seller will not be deemed as fulfilling its obligations under a contract if, for example, it delivers a product that does not meet the quality required for its normal or commercial use, or for a special purpose as reflected in the contract.

Civil liability for certain acts or omissions related to a defective product may also be established by reliance on the CPL. The CPL provides, *inter alia*, that a dealer[3] should disclose to the consumer any defect or quality inferiority that materially diminishes the value of the product, as well as any feature of the product that necessitates a particular type of maintenance or use in order to avoid injury to the user, any other person or the product during ordinary use or handling.

The CPL further provides that a dealer should not do anything – whether by act or omission – likely to mislead a consumer as to any matter material to a transaction. Examples of matters that are material to a transaction, as listed in the CPL, include the quality and nature of the product or service; the use that can be made of the product and the risk associated with such use; the manner of handling the product; and the conformity of the product to a standard, specification or model.

ii Criminal liability

Criminal sanctions as regulated by the Penal Law 5737-1977 (PL), may be imposed, where death or severe injury is caused owing to negligence. Criminal sanctions may also be imposed by virtue of legislation referring to specific products that may apply in the event of the sale or distribution of defective products. In addition, the SL provides that it is a criminal offence to manufacture, sell, import or export a product that fails to comply with the requirements

3 A 'dealer' is defined as anyone who sells a commodity or performs a service by way of trade, including a manufacturer.

of an official standard (subject to the terms of said law). In addition, a dealer who misleads a consumer as to any matter material to a transaction or fails to disclose to a customer any defect, inferior quality or other feature known to it that materially diminishes the value of the product may be liable to criminal sanctions under the CPL. Similar administrative penalties such as fines and administrative warnings may also be imposed where a dealer is found to have breached the provisions of the SL or other product-specific legislation, such as the PO, the FL and the VL.

IV LITIGATION

i Forum

Product liability cases are classified as general civil law claims and, as such, are adjudicated within the framework of the general court system. The same holds true with respect to criminal proceedings with product liability aspects.

The Israeli courts of first instance may be either the magistrates' courts or the district courts, generally depending on the value of the subject matter of the case. District courts have jurisdiction over cases in which more than 2.5 million New Israeli shekels are in dispute. Appeals of judgments rendered by a magistrate's court are heard by the district court, and those of the district court (when sitting as a court of first instance) are heard by the Supreme Court in Jerusalem. A second appeal before the Supreme Court will be given in rare cases and only upon the approval of the court. The Israeli legal system does not have juries and all decisions are rendered by professional sitting judges.

Certain violations of the CPL and the SL may also be adjudicated by the relevant regulatory officials (i.e., the Commissioner of Consumer Protection and the Commissioner of Standardisation, respectively).

ii Burden of proof

As mentioned above, under the DPL there is no need to prove negligence on the part of the manufacturer – a plaintiff need only show that the product was defective and that the injury was caused as a result of a manufacturing defect. Under the DPL, a product is presumed to be defective if the circumstances of the case are more consistent with the conclusion that it was defective than with the conclusion that it was not. The plaintiff bears the burden of convincing the court that such presumption should apply and, if successful, the burden shifts to the manufacturer to prove that the product is not defective.

If, however, the manufacturer is able to show that the product passed a reasonable safety check before leaving its control, then the burden of proof shifts again and the presumption is that the product became defective after having left the control of the manufacturer. In *Phoenicia et al v. Amar et al*,[4] a landmark and precedential decision in Israeli product liability law, the Supreme Court held, *inter alia*, that sample checks are not sufficient in order to establish the presumption that the defect arose after the product left the manufacturer's control. Therefore, the manufacturer must show that the specific damaged product was reasonably checked.

Where the cause of action is based on torts or contracts, the plaintiff bears the ultimate burden of proof, based on the required standard of balance of probabilities.

4 CA 166/88.

As for the elements to be established by the plaintiff in a claim for negligence, see Section III, *supra*.

The CWO contains several rules and caters for various situations whereby the onus to prove that no negligence exists shifts to the defendant. These include:

a where the damage was caused by a dangerous object that was owned by the defendant or in respect of which the defendant was responsible, or fire, and the defendant was the owner or holder of the property where the fire erupted;

b *res ipsa loquitur*;[5] and

c where it is reasonable to assume that the defendant may have more information regarding the incident and the subject matter of the claim, then – practically – the court expects the defendant to provide evidence showing that no defect exists.

iii Defences

Under the DPL, only the following defences are available to a defendant in order to mitigate or avoid liability:

a The defect arose after the product left the manufacturer's control (see the discussion above concerning reasonable safety checks).

b Based on the state of scientific and technological development at the time the product left the manufacturer's control, it could not have known with regard to its design that the product did not meet reasonable safety standards.

c The manufacturer had not intended the product to leave its control, and it took reasonable steps to prevent the product leaving the manufacturer's control and to warn the relevant public of the associated risk.

d The injured party is more than 12 years old and knew of the defect and the associated risk and voluntarily exposed himself or herself to that risk.

Where a claim for product liability is based on the CWO or the CPL, a defendant may raise the following defences:

a no fault – in which the damage was caused by an extraordinary natural event that a reasonable person could not have foreseen and the consequences thereof could not have been prevented, even with reasonable care, or that the fault of another person was the decisive cause of the damage;

b voluntary exposure to risk (does not apply to breach of statutory duty);

c *de minimis*; and

d an act committed pursuant to any enactment (this does not apply where the cause of action is negligence).

The mere fact that a product complied with an Israeli standard does not constitute a defence, nor would that fact be sufficient to show that the manufacturer was not negligent. Nonetheless, under certain circumstances, such compliance may give rise to a refutable presumption of non-negligence. In addition, a recent district court decision recognised compliance with a regulatory authority's directives as a valid defence against a claim concerning the non-disclosure of information to the public relating to a specific product (such decision, however, does not constitute binding case law).

5 'The thing speaks for itself.'

Statutory periods of limitation are entrenched in Israeli civil law. The general rule is that the statutory period of limitation with regard to civil actions, including product liability matters, is seven years. The statutory period of limitation for causes of actions falling under the DPL is three years. In addition, an action under the DPL can only be brought within 10 years of the end of the year in which the product left the manufacturer's control. A plea of prescription for causes of action arising under any law may not be entertained by the court unless the defendant raised it at the earliest opportunity after the action was brought.

iv Personal jurisdiction

The DPL applies to all defective products distributed throughout Israel. When a claim under this law involves a product manufactured outside Israel, the term 'manufacturer' may also refer to the importer or, if the importer is unidentifiable, the Israeli distributor. The Israeli distributor may thus avoid liability if it supplies the injured party with details enabling the latter to identify and locate the manufacturer or importer, within a reasonable time frame following receipt of such request by the distributor; however, the DPL does not apply to injuries caused outside of Israel.

As for the applicability of the Israeli law to claims based on torts and involving an international element, the Supreme Court held[6] that the law governing such claims is the law of the place where the tort was committed (and in so ruling, replaced the previously held double-actionability test); however, deviations from this rule are possible where special justifications exist.

According to the Civil Procedure Regulations 5744-1984 (CPR), which apply to both regular tort actions and those brought under the DPL, an Israeli court is assumed to acquire jurisdiction to hear a claim filed with such court upon service of the pleadings on the defendant. If the defendant is located abroad, special leave from the court to serve the pleadings outside the Israeli court's jurisdiction is required.

According to the CPR, the court may permit service of pleadings outside the Israeli jurisdiction if, *inter alia*, the act or omission in question took place in Israel. In *Metallurgique de Gerzat SA v. Wilensky*,[7] the Supreme Court held that pleadings may not be served on the foreign manufacturer based on the said rule if the manufacturer did not intend to export the product to Israel. The court may also permit service of pleadings outside Israeli jurisdiction if, *inter alia*, the person abroad (e.g., a foreign manufacturer) is a necessary party, or the correct party in an action duly brought against another person on whom a summons was properly served within Israel.

A foreign party served with pleadings based on leave granted by the court as aforesaid may seek cancellation of such leave by arguing that the case does not fall within the list of matters allowing for service outside the jurisdiction, as prescribed by the CPR or that the Israeli court is not the proper forum to hear the case. In recent years, the tendency of the Israeli courts to accept *forum non conveniens* arguments has considerably declined, bearing in mind the effects of globalisation and technological developments.

6 CA 1432/03 *Yinon Food Products Producing and Marketing Ltd v. Magda Kar'an Tak*.

7 LCA 2752/03.

v Expert witnesses

Under the CPR, evidence relating to issues of expertise must be submitted by means of an expert opinion. An expert opinion pertaining to a medical issue should be attached to the pleadings. Each party has the right to cross-examine the other party's expert.

The court may itself appoint one or more experts on any matter in dispute between the parties. If the court appoints an expert with the parties' consent then, unless otherwise instructed by the court, the parties will not present expert opinions on their own behalf.

vi Discovery

Under Israeli law, discovery relates to documents and does not include depositions. A party to the litigation is obliged to disclose to its opponent, in a duly signed affidavit, the existence of all documents relevant to the dispute, which are or were in its possession or under its control.

The term 'documents' includes written records as well as materials such as videos, and the test for relevance is broad. A document is relevant if it assists a party to the litigation (the disclosing party or counterparty) to establish its case or damages its opponent's case. Objections to disclosure are usually limited to questions of relevance, and to the test of whether the discovery sought will facilitate a fair trial and save costs, or whether it would be burdensome and with little benefit to ascertaining the relevant facts in the actual trial.

A party is entitled to inspect any document referred to in the pleadings or affidavits of the other party, including the discovery affidavit. Thus, if a party objects to the other party inspecting a particular document mentioned in the discovery affidavit (on the ground that it is privileged), this objection must be clearly specified in the discovery affidavit. If a party is not satisfied with the extent of the other party's discovery or willingness to allow inspection, an application may be submitted to the court requesting further discovery or inspection, as applicable (or make similar orders relating to interrogatories).

Failure to comply with court orders on issues of discovery may lead to sanctions, including – albeit only in rare circumstances – striking out an action or defence. Documents and information received in the context of discovery should not be disclosed or used for any purpose other than the conduct of the trial in the framework of which discovery was made. The intentional destruction of documents that are, or may be, required as evidence in a judicial proceeding, or wilfully causing such documents to be unidentifiable or illegible, constitutes a criminal offence under the PL.

vii Apportionment

It is possible for multiple parties to share joint liability for the same wrongdoing. The DPL explicitly sets out that if damage is caused owing to a defective component, then both the component manufacturer and the product manufacturer may share joint liability (and, as mentioned above, the term 'manufacturer' can also refer to an importer or distributor). Joint liability is also available under both the CWO and the Contracts Law. The Supreme Court held, in the *Phoenicia* case, that if a defective product underwent several manufacturing stages and no information is available regarding the extent of the fault of each of the wrongdoers, liability should be equally divided among them. While the Supreme Court discussed the doctrine of market share liability, to date, such doctrine has not been adopted into the Israeli legal system.

In addition, a manufacturer served with a product liability action may attempt to obtain partial or full indemnification by means of a third-party notice served on another potentially liable party.

The acquisition of a manufacturer, distributor or seller through a purchase of shares in the ordinary course of business (i.e., not as part of recovery or insolvency proceedings) will usually not affect the liability of such manufacturer, distributor or seller in the case of defective products (i.e., the successor corporation will be liable therefor). In the case of the purchase of assets, successor liability will be determined according to the terms of the relevant asset-purchase agreement. Although not yet addressed by the courts in the context of product liability case law, based on general corporate law principles, a court may theoretically lift the corporate veil and impose liability on the acquiring company where the structure of the transaction is fraudulent and does not reflect the true commercial nature of the transaction.

viii Mass tort actions

According to the Class Actions Law 5766-2006, an application to approve a claim as a class action may be filed, *inter alia*, with regard to a claim against a dealer (see footnote 3, *supra*) that concerns a dispute between that dealer and a consumer, regardless of whether they are parties to a transaction.

The court may allow an application to hear a claim as a class action only if the following conditions are met:

a there is a reasonable likelihood that material common questions of fact or law will be decided in favour of the group;

b the class group mechanism is a fair and efficient way to resolve the dispute; and

c there is a reasonable likelihood that the interests of the entire group will be represented and administrated properly and in good faith.

The class-action mechanism is often pursued in cases involving mass product liability claims in Israel.

One of the most notable class action cases in Israel is *Tnuva Communal Marketing Centre v. Estate of Tufic*.[8] In this action, claims originated when it was discovered that, for almost two years, one of Israel's biggest milk distributors, Tnuva, mixed an organosilicon compound into milk as an anti-foaming agent, without disclosing the existence of such compound on the product's label. Despite there not being any real evidence of physical damage, the court held that compensatory damages in a class action may also include negative feelings, feelings of disgust or feelings of harming the consumer's autonomy. Nonetheless, within the framework of an appeal, the Supreme Court refused to adopt a purely objective approach for awarding compensation and held that actual damage is required, even if said damage amounts to merely negative feelings.

In addition to the class-action mechanism (albeit unrelated to it), the CPR provide that should a case involve several plaintiffs, one or several of them may be authorised by one or several of the others to appear, present arguments and act on their behalf at every stage of the legal proceedings.

ix Damages

As mentioned above, under the DPL, damages may be awarded for bodily (including psychological) injury only and the possible sums awarded for non-pecuniary damages, loss of

8 CA 10085/08.

earnings and loss of earning capacity are limited. Compensatory damages in product liability claims under the CWO include damages for bodily injury as well as damages to property or products.

Damages for bodily injury may be pecuniary (such as for the loss of capacity to earn money also during the 'lost years') as well as non-pecuniary (pain and suffering and reduction of life expectancy). According to the decision in the *Tnuva* case, compensatory damages may also include compensation for compromised consumer autonomy, which resulted in negative feelings. In addition, damages may also include consequential losses, such as loss of profits. The court is also authorised to issue an interim or permanent *mandamus* or injunction order in addition to damages or even as a sole remedy.

Case law has held that generally (in the absence of other specific provisions in statutory law), punitive damages may be awarded when the manufacturer is found to have acted with malice. In cases involving the tort of negligence, the court has ordered punitive damages only in specific and severe instances and, particularly, where 'some type of intention' was shown. The general view is that notwithstanding the courts' competence to do so, punitive damages will be awarded only in rare circumstances.

As for criminal penalties, general offences regulated by the PL, such as causing death or severe injury owing to negligence, may also apply in order to impose sanctions for the sale or distribution of defective products. Other legislation referring to specific products may similarly provide relief in the form of criminal sanctions where the case involves the sale or distribution of defective products.

In addition, the SL provides that it is a criminal offence to manufacture, sell, import or export a product that fails to comply with the requirements of an official standard (subject to the terms of said law). The Commissioner of Standardization is also empowered to impose financial sanctions or issue an administrative warning where it is found that a dealer breached the provisions of the SL.

Further, under the CPL, a dealer who misleads a consumer as to any matter material to a transaction or fails to disclose to a customer any defect, inferior quality or other feature known to it that materially diminishes the value of the product may be subject to criminal sanctions.

Criminal liability could also be imposed on certain key office holders in a corporation or on civil servants conferred with relevant responsibility (e.g., to oversee the safety of products). In one case,[9] charges were pressed against both a civil servant employed by the MOH and key office holders from Humana Corporation in a product liability case concerning the deficiency of a certain vitamin in baby formula, which resulted in the injury to, and – in two cases – death of, infants.

The CPL includes a chapter relating to administrative enforcement tools, which, *inter alia*, empower the Commissioner of Consumer Protection to impose an administrative fine on a dealer, if, *inter alia*, it fails to notify consumers of details the disclosure of which is mandatory under the CPL. Similar enforcement tools were adopted in the PO, the FL and the VL.

9 Criminal Case 2613/08 *State Attorney Branch Division (Petach Tikva) v. Frederik Black*.

V YEAR IN REVIEW

Over the past year we witnessed a wave of legislative developments that addressed, for the first time, in the framework of primary and secondary legislation, the recall of defective products, an issue previously mainly regulated in guidelines published by the relevant regulatory authorities. During the course of 2017, we expect that a series of new regulations will be enacted pursuant to the powers granted to the relevant ministers under such newly enacted legislation, which will provide clarity and regulate in greater detail, *inter alia*, the product recall process and related issues.

Chapter 13

ITALY

Francesca Petronio and Francesco Falco[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

Product liability in Italy was expressly regulated for the first time by Presidential Decree No. 224/1988, which implemented Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (the Product Liability Directive). Such Decree was then replaced by Legislative Decree No. 206 of 6 September 2005, (the Consumer Code), a whole comprehensive Act that covers, in addition to product liability, all the different phases in consumer dealings, from advertising to correct information, from consumer contracts in general to product safety, access to justice and consumer organisations.

The Consumer Code applies only to consumers, defined as 'any natural person who is acting for purposes that are outside his trade, business or profession'[2], claiming personal damages (death or physical injuries) or damages caused to goods that are normally destined for private use, both if caused by a defective product.

Article 127 of the Consumer Code provides that it does not affect any rights that an injured party may have under other statutory instruments; claims for damages can also be based on general tort or contract law. Such 'double protection' recognised to consumers has also been confirmed by the Court of Cassation, which in 2010 stated that provisions set forth by the Consumer Code accompany the alternative forms of protection already existing in the system, without replacing them.[3]

With regard to the protection afforded by instruments other than the Consumer Code, tort claims can be brought under Articles 2043 to 2050 of the Italian Civil Code (ICC); contractual claims are based on Articles 1490 et seq. ICC, which impose on the seller of a good the obligation to warrant that the good is free from defects.

Entrepreneurs and other subjects that do not fall within the consumer definition provided by the Consumer Code can only base their claims on general tort and contract law.

II REGULATORY OVERSIGHT

Ministries are responsible for oversight as set out under the Consumer Code. Their main task is to verify that all products placed on the market are safe. In particular, for any product they

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2 Article 3 Consumer Code.

3 Court of Cassation, 1 June 2010, No. 13,432.

may carry out inspections at production or packaging plants, warehouses, and sales depots; require all necessary information to be provided by the parties concerned; take samples of products and subject them to safety checks; and draw up reports.[4]

For any product that might be dangerous, they may ban its sale, marketing or display, for as long as necessary to carry out all safety appraisals, checks and controls and order, for a mandatory period, that the product or batch of products already marketed be adapted to specific safety requirements.

A manufacturer placing a dangerous product on the market is criminally liable and may be punished with imprisonment; in particular, if he or she places it on the market in violation of a restriction order issued by the competent authority he or she may be punished with imprisonment from six months up to one year and a fine from €10,000 to €50,000.

If the dangerous product is already on the market, the competent authority may ban its marketing and introduce measures required to ensure that the ban is enforced. It can also order that products already marketed be adapted to comply with safety requirements within a given deadline. Failure to comply with any of these requirements can bring financial penalties up to €25,000.

Moreover, for products that pose a serious risk to the health and safety of consumers, the Consumer Code implemented the Community Rapid Information System (RAPEX) set forth by Directive 2001/95/EC. In order to improve collaboration on market surveillance and other enforcement activities, any action concerning the recalling or banning of products taken by an EU national authority must be notified at EU level and is recorded in the RAPEX database.[5]

The Ministry for Productive Activities has also set up the National Council of Consumers and Users. The Council is composed of representatives of consumers' and users' associations and it is responsible for, *inter alia*:

a expressing opinions, where required, on the features of regulations concerning the rights and interests of consumers and users;

b formulating proposals in relation to the protection of consumers and users, also with reference to EU programmes and policies;

c promoting studies, research programmes and conferences on the rights of consumers and users and the control of the quality and safety of products and services;

d drawing up programmes for the distribution of information to consumers and users;

e establishing relations with similar public or private bodies from other countries and the European Union; and

f notifying the Department for Public Administration of any difficulties or obstacles in relation to implementing the provisions regarding simplification of the procedures or documentation in public authorities.[6]

4 Article 106 Consumer Code.

5 Annex II to the Consumer Code.

6 Article 136 Consumer Code.

III CAUSES OF ACTION

i Claims under the Consumer Code

The Consumer Code sets forth a 'special' liability regime that is completely independent of any contractual relationship between the injured party and the manufacturer and is, thus, usually regarded as a non-contractual liability.

Pursuant to Article 114 of the Consumer Code, producers are liable for any damage caused by product defects, where 'product' is defined as any moveable, even if part of another tangible or intangible item, including electricity.[7] Moreover, the manufacturer is held liable only if he or she has distributed the product, that is, if he or she has delivered it to the purchaser, user or a person connected with them.[8]

A good is considered 'defective' when it does not provide the safety one can reasonably expect, taking all circumstances into account, including: (1) the way in which the product was distributed, its packaging, evident features, instructions and warnings supplied; (2) the use to which the product can reasonably be put and the life cycle the product can be reasonably expected to undergo; and (3) the period during which the product was distributed.[9] Moreover, a good is considered defective if it does not offer the safety normally offered by other samples of the same series.[10]

Thus, the notion of 'defect' is strictly linked to that of safety, such that under the Consumer Code the defect necessarily implies some kind of danger to the consumer that uses it.[11]

Claims can be brought by both the consumer and the 'bystander' (i.e., any person exposed, even only occasionally, to the risk caused by the defective product).[12]

Under the liability regime set forth by the Consumer Code, both the manufacturer and the supplier can be held liable for damage caused by a defective product.

In particular, an action may be lodged against one of four different persons:

a the real producer, namely the subject manufacturing the product in the European Union;

b the apparent producer, namely any other person or persons presenting themselves as the manufacturer or manufacturers by placing a name, trademark or other distinguishing mark on the product, or the person who refurbishes the product;

c the importer, namely the manufacturer's representative, when the manufacturer is not established in the European Union, or the importer of the product, when there is no representative within the European Union; or

d the distributor, namely any other person in the supply chain insofar as their activities may affect the safety properties of a product.[13]

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7 Article 115 Consumer Code.

8 Article 119 Consumer Code.

9 Article 117, paragraph 1 Consumer Code.

10 Article 117, paragraph 3 Consumer Code.

11 Under Article 103 Consumer Code, 'safe product' is defined as any product 'which (under normal conditions of use or those which may be reasonably envisaged, including shelf life and, where applicable, usage, installation and maintenance requirements) does not present any hazard or only minimum risks arising out of use of a product and considered acceptable and consistent with a high level of personal health and safety'.

12 Court of Cassation, 29 May 2013, No. 13,458.

13 Article 103, paragraph 1, point d) Consumer Code.

With regard to the distributor, Article 116, paragraph 1 provides that 'where a producer cannot be identified, each supplier of a product shall be treated as its producer should he fail to inform the injured person, within three months of the date of application, of the name and domicile of the producer or person who supplied him with the product'. Thus, his or her liability follows that of the manufacturer in the sense that the supplier can be held liable only on the basis of the failure to identify the manufacturer.

If the supplier complies with such request, the third party named by the supplier (as the producer or previous supplier) may be brought for trial and the supplier ousted, if the person indicated appears and does not raise objections.[14]

ii Tort claims

An injured party, consumer or entrepreneur can bring claims for defective products on the basis of tort law, in particular pursuant to Articles 2043 to 2050 ICC.

Article 2043 ICC provides that any intentional or negligent act that causes an unjustified injury to another person obliges the person who has committed the act to compensate the damage suffered (*neminem laedere* principle). Liability under Article 2043 is not 'faultless'; thus, plaintiffs must prove both the damage allegedly suffered and causation between such damage and the defendants' negligence or wilful misconduct.

The ICC also sets forth a specific provision concerning liability for dangerous activities. Under Article 2050 ICC, whoever causes injury to another party in the performance of an activity that is *per se* dangerous is held liable unless he or she proves that he or she had taken all suitable measures to prevent injury. The ICC does not provide for a definition of 'dangerous activity', and Italian courts have applied the provision to a wide variety of claims, such as the marketing and distribution of toxic chemical products[15], cylinder gases[16] and smoking products.[17]

Article 2050 ICC sets forth a presumption of the defendant's liability; thus, the injured party only has to prove the dangerousness of the activity and causation between the activity and the damage suffered.

iii Contractual claims

When the injured party is in a direct contractual relationship with the manufacturer, claims can also be based on contractual law. In particular, Article 1494 ICC provides that the seller is responsible toward the buyer for compensation of damages, if he or she does not prove to have not known and that he or she should not have known the defects of the goods. Moreover, he or she must also indemnify the buyer for damages deriving from the defects of the product.

The relevant notion of 'defect' under Article 1494 ICC differs from that under the Consumer Code: while the protection afforded by the latter instrument is based on the 'safety' of the product, in contractual law goods can be considered 'defective' regardless of their safety.

Since the seller's liability under Article 1494 ICC is based on the contractual relationship between the parties, when goods go from the manufacturer to the final buyer through a series

14 Article 116, paragraph 5 Consumer Code.

15 Court of Cassation, 1 February 1995, No. 1,138.

16 Court of Cassation, 20 July 1979, No. 4,352.

17 Court of Cassation, 17 December 2009, No. 26,516.

of intermediate sellers, the buyer can bring two different actions: a contractual one under Article 1494 ICC against the seller and a non-contractual one pursuant to Article 2043 ICC or Article 2050 ICC (as long as he or she proves the danger of such an activity), against the manufacturer.

IV LITIGATION

i Forum

Product liability cases in Italy can be brought in civil courts. The Italian system is articulated in three levels: (1) first instance courts (justices of the peace and tribunals); (2) second instance courts (courts of appeal for tribunals' decisions and tribunals for justices of the peace's decisions); and (3) the Court of Cassation.

Courts of appeal, composed of panels of three judges, have second instance jurisdiction over decisions issued by tribunals. Eventually, parties have the right to challenge the decision issued by the court of appeal before the Court of Cassation, which is a court of last resort and whose review is limited to questions regarding the proper interpretation and application of the law.

Small claims (e.g., legal actions whose value is lower than €2,600) are under justices of the peace's jurisdiction. Decisions issued by such justices can be appealed before tribunals, which also have first instance jurisdiction over all cases not expressly assigned to other courts.

ii Burden of proof

When product liability proceedings are brought by consumers, pursuant to Article 120 of the Consumer Code, plaintiffs have the burden of proving:

- the defect of the product;
- the damage allegedly suffered; and
- the causation between the defect of the product and the damage claimed.

As recently confirmed by the Court of Cassation, the plaintiff is not required to prove negligence or wilful misconduct by the manufacturer (subjective element), but only the defect (objective element).[18] In particular, the Court of Cassation constantly affirmed that the consumer has to provide evidence of the causal relationship between the defect and the damage, and not of that between the damage suffered and the product.[19] In other words, he or she must prove that the damage was caused by the fact that the product did not provide the safety a person is entitled to expect. Thus, the burden of proof is met only when there is evidence that the damage occurred as a result of the normal use of the product for the purpose for which it was intended.[20]

As already mentioned above, as opposed to liability under the Consumer Code, liability under Article 2043 ICC requires the injured party to prove both the damage allegedly suffered and the causation between such damage and the defendants' negligence or wilful

18 Court of Cassation, 28 July 2015, No. 15,851.

19 Court of Cassation, 26 June 2015, No. 13,225.

20 See, *inter alia*, Court of Cassation, 13 August 2015, No. 16,808; Court of Cassation, 29 May 2013, No. 13,458.

misconduct. Instead, with regard to Article 2050 ICC, plaintiffs only have the burden of proving the dangerousness of the activity and the causation between the activity and the damages suffered.

Finally, in contractual claims plaintiffs are required to prove the existence of the contract and to solely allege that the product was defective; the burden to prove the contrary is up to the manufacturer.[21] Moreover, with regard to Article 1494 ICC, the Court of Cassation stated that the obligation on the seller also imposes regular checks; thus he or she is liable for damage caused by a defective product, if he or she does not prove that he or she had acted in such a way to check the goods' quality and the absence of any defect.[22]

iii Defences

Exclusion of liability

Under Article 118 Consumer Code, liability is excluded in the following cases:

a the manufacturer did not place the product on the market;

b the defect that caused the damage did not exist when the manufacturer placed the product on the market;

c the manufacturer did not manufacture the product for sale or distribution against payment of consideration, or did not manufacture or distribute it in the course of its business;

d the defect is owing to the product's compliance with a mandatory legal provision or with binding public measures;

e 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; or

f the manufacturer only manufactured one part of the product and the defect is entirely owing to the form of the product in which a component or raw material was incorporated or to the component supplier's compliance with the producer's instructions.

The burden to prove one of the above-mentioned exclusions lies with the manufacturer.

In order to further protect the consumer, the list set forth by such provision is exhaustive; thus, the manufacturer is not allowed to escape liability by proving the existence of different circumstances. Moreover, it is prohibited for the producer to contractually create additional grounds of defence; thus, any agreement aimed at excluding the manufacturer's liability in cases other than those under Article 118 is void or null.[23]

In claims based on general tort or contractual law, producers can defend themselves by proving that their fault was because of force majeure.

Contributory negligence

Liability is also excluded when the consumer who has suffered damage owing to a defective product, although having been aware of the defect and the related danger, has voluntarily exposed himself or herself to such risk.[24]

21 Court of Cassation, 2 December 2016, No. 24,731.

22 Court of Cassation, 10 July 2014, No. 15,824.

23 Article 124 Consumer Code.

24 Article 122, paragraph 2, Consumer Code.

Moreover, when the consumer has contributed to cause the damage, compensation is reduced proportionally, having regard to the seriousness of the negligence attributable to the same consumer and the extent of the consequences arising therefrom.[25]

In this respect, the Court of Cassation stated that the manufacturer cannot be held liable if the damage occurred as a result of the non-normal use of the product for the purpose for which it was intended.[26]

Statutes of limitations

The Consumer Code provides for a three-year statute of limitations from the day the injured person became aware, or should have become aware, of the damage, the defect and the identity of the producer, and in any event upon expiry of a 10-year period since the date the producer put the product into circulation.

Tort claims are time-barred five years after the event. As for contractual claims, the statute of limitations expires in 10 years. In the case of a contract of sale, claims can be brought only within one year of the sale and only as long as the injured party has reported the defect within eight days of discovery.

iv Personal jurisdiction

As for international jurisdiction (i.e., when proceedings involve an 'international element', such as one of the parties' domicile or the place of delivery), jurisdiction over product liability cases is regulated by EU Regulation 1215/2012 (Brussels I *bis* Regulation) as well as Law No. 218 of 1995. As a general rule, under Article 4 Brussels I *bis* Regulation, persons domiciled in a Member State must be sued in the courts of that Member State. However, the Regulation establishes some exceptions to such rule.

Firstly, it grants a specific protection to 'weaker parties' (i.e., insureds, consumers and employees). In particular, pursuant to Article 18(1) Brussels I *bis* Regulation, when the injured party is a consumer, regardless of the other party's domicile, proceedings can be brought in the courts of the Member State where the consumer is domiciled if the manufacturer pursues commercial or professional activities in that Member State.

Secondly, when the injured party is in a contractual relationship with the manufacturer, pursuant to Article 7(1)(b) Brussels I *bis* Regulation, proceedings must be brought in the courts of the Member State where, under the contract, the goods were delivered or should have been delivered.

Moreover, under Article 7(2) in matters relating to tort, delict or quasi-delict, persons domiciled in a Member State must be sued in the courts for the place where the harmful event occurred or may occur.[27]

25 Article 122, paragraph 1, Consumer Code.

26 Court of Cassation 13 August 2015, No. 16,808. In that case, the Court ruled that the manufacturer was not liable for the explosion of a tyre since the consumer had inflated it with a compressor that exercised a pressure four times higher than the suggested maximum.

27 In a case concerning product liability, the Court of Justice of the European Union found that, since the place of manufacture is the place where the event that damaged the product itself occurred, Article 5(3) Brussels I Regulation (now Article 7(2) Brussels I *bis* Regulation) must refer to the place where the manufacturer is established, and not to where the damage was later suffered (*Kainz v. Pantherwerke AG*, C-43/15).

For claims that fall outside the scope of the mentioned Regulation, international jurisdiction is governed by Law No. 218 of 1995. The general rule on jurisdiction is that Italian courts have jurisdiction if the defendant is domiciled or resides in Italy or has a representative in the country enabled to appear in court. Moreover, under Article 3(2), in matters regulated by the Brussels Convention under Sections 2, 3 and 4, Italian jurisdiction is established, applying the criteria contained therein, also to cases where the defendant is not domiciled in an EU Member State.[28]

With regard to 'national' proceedings, pursuant to Article 66 *bis* Consumer Code, exclusive jurisdiction to hear claims concerning product liability brought by consumers is attributed to the courts for the venue where the consumer is domiciled, if located within the Italian territory.

As for claims under Articles 2043 and 2050, jurisdiction is attributed to the courts of the place where the harmful event occurred; in contractual claims, proceedings must be brought in the courts of place where the counterparty is domiciled or the contract was signed.

v Expert witnesses

If the proceeding requires a high level of expertise or technical knowledge, courts can, voluntarily or upon a party's request, appoint one or more independent experts (*consulente tecnico di ufficio* (CTU)) selected from a lists filed with each court or, alternatively, upon authorisation by the President of the court. Parties are also allowed to appoint their own experts to provide technical evidence in support of their claims (*consulente tecnico di parte* (CTP)).

CTUs file a written report whereby they answer to all the questions raised by the judge, such as those concerning the defect of the product and causation; they can also take into consideration CTPs' remarks and comments. The experts' findings are evaluated by the judge, who can also disagree with them and disregard them as long as he or she gives adequate reasons for the decision.

vi Discovery

Italian law does not provide for the possibility of discovery as known in common law jurisdictions. Parties have to produce documents in support of their claims and are under no obligation to produce all the documents concerning the dispute. The court must rely only upon such evidence, refraining from personally investigating facts deemed relevant to the case. However, there are some exceptions to the aforementioned rule, such as that judges are allowed to appoint CTUs or to call witnesses referred to by other witnesses during their testimony.

In civil proceedings, significant importance is given to written documents. During evidence-gathering activities, at the request of one of the parties, the court can order the counterparty or any third party to exhibit documents considered necessary to the decision. In particular, such an order is issued if:

a it does not cause any damage to the counterparty or any third party;

b the requesting party indicates the specific documents to be exhibited;

28 The Italian Court of Cassation repeatedly ruled that, despite the adoption of Regulation 44/2001 then replaced by Regulation 1215/2012, since Law No. 218 of 1995 refers to the Brussels Convention, reference must be made exclusively to the provisions of such instrument.

c the requesting party proves that the other party has the requested documents;
d the document cannot be obtained in another way; or
e the evidence provided by the document is necessary to decide the case.

With regard to witness examinations, when submitting requests for evidence, parties must provide the court with a list of witnesses and questions in order for the judge to decide on their admissibility (i.e., if it is admissible under the rules governing civil proceedings, such as that testimonies on contracts are not allowed unless: (1) there is some kind of written evidence; (2) it is materially or morally impossible for the contractual party to provide written evidence; or (3) the contractual party has, without any fault, lost the document). During the hearing, the judge then questions the witnesses based on the questions presented by the parties. There is no formal cross-examination: only the judge interacts with the person called to testify, while the parties can solely suggest additional questions. Upon agreement between the parties, the judge can also order the testimony to be given by written statement.

vii Apportionment

Pursuant to Article 121 Consumer Code, if more than one person can be deemed liable for the same damage, they are all jointly liable toward the damaged party. In such cases, if only one of them indemnifies the injured person, the Consumer Code provides for a right of recourse against them. Liability is shared among all the persons on the basis of: (1) the risk attributable to each of them; (2) the degree of each person's fault; and (3) the consequences deriving from such fault. As a consequence of such provision, the consumer can sue any of them to obtain full compensation.

However, a distinction must be drawn between the manufacturer of the final product and the manufacturer of a single element of the product. The first is always liable even when the damage is caused by a defect of one of the elements composing the final product, as he or she has an obligation regarding product checks or verification. As for the second, he or she is liable only if the component he or she has provided effectively turned out to be the cause of the damage.[29]

In the case of tort claims, the same rule on joint liability is set forth under Article 2055 ICC, which provides that when the same damage is caused by several persons, they are all liable toward the injured party. Moreover, as stated above, when the buyer bought the goods from an intermediate seller and, thus, is not in a contractual relationship with the manufacturer, he or she is entitled to file a contractual claim against the seller, as well as a non-contractual one against the manufacturer.

viii Mass tort actions

In 2007, the Consumer Code was amended to introduce class actions as a tool to obtain compensation in certain kinds of multiple claims, including those for defective products.

Pursuant to Article 140 *bis* Consumer Code, class actions can be brought: (1) by each injured consumer; or (2) upon the consumers' mandate, by associations acting to protect

29 If that is not the case, the liability of the manufacturer of a single component is excluded under Article 118 Consumer Code.

the rights of a determined class of persons. The mechanism is based on an opt-in system; thus, other claimants can join the proceeding within the deadline set by the court at the first hearing.

Jurisdiction is attributed to the courts of the capital of the region where the defendant has its headquarters, and proceedings begin with a preliminary decision on the admissibility of the class action, which is declared inadmissible if:

a it is clearly unfounded;
b there is a conflict of interest;
c the rights enforced are not homogeneous; or
d the claimant is judged unsuitable to represent the interests of the entire class.

Such preliminary phase is followed by a merit phase concerning the assessment of liability and damage. The decision is delivered by a panel of judges, and it can provide for a direct conviction or, alternatively, set forth the criteria to calculate the amount due to the members of the group.

ix Damages

As a general rule, all damage, both monetary and non-monetary, suffered by the injured party is recoverable; punitive damages, however, cannot be awarded. More specifically, the Italian legal system recognises different categories of damage:

a economic damage, consisting of harm to economic assets;
b biological damage, which relates to physical and mental injury;
c moral damage, which consists of moral harm, pain and suffering; and
d existential damage, created by case law and consisting in damage that worsens a person's living condition.

With regard to non-monetary damages, the Court of Cassation stated that compensation is allowed both in cases of an express provision of law, (i.e. whenever it is acknowledged by a law provision) and in case the damage causes violation of a right that is constitutionally safeguarded[30] (e.g., health).

Pursuant to the Consumer Code, product liability claims can be brought to seek compensation for: (1) personal damage (death or physical injuries); or (2) destruction and deterioration of assets other than the defective product, as long as they are mainly and normally intended for private use by the damaged person.[31] Thus, with regard to personal injury, the injured party is entitled to compensation of both economic damage (e.g., for medical assistance) and biological damage.

V YEAR IN REVIEW

On 1 January 2017, the European Commission launched a public consultation on the evaluation of Directive 85/374/EEC on the liability for defective products. The aim of such consultation, whose deadline is set for 26 April 2017, is to collect stakeholders' comments and opinions on the use and performance of the Product Liability Directive, in particular

30 Court of Cassation, 31 May 2003, Nos. 8,827 and 8,828; Court of Cassation, 11 November 2008, No. 26,972.

31 Article 123 Consumer Code.

with regard to: (1) whether and to what extent it is in line with its objectives of guaranteeing at European Union-level the liability without fault of the producer; (2) whether it still meets the interested parties' needs; and (3) if it is fit for purpose with reference to new technological developments such as the internet.

Italian case law on product liability is developing in line with previous trends. An interesting decision has been issued by the Court of Cassation with regard to the notion of 'defective product'. In particular, the court recently held that under the Consumer Code the manufacturer's product liability is presumed and not objective, because it is independent from proof of the manufacturer's fault.[32] After confirming that, under the Consumer Code, it is up to the injured party to prove causation between defect and damage, since this is a prerequisite of product liability, it added that the product should be considered defective if it does not offer the safety a person can reasonably expect with regard to, *inter alia*: (1) the way it has been placed on the market; (2) its main features; (3) the instructions or warning provided; (4) the normal use of the product for the purpose for which it was intended; and (5) the period the product has been placed on the market.

In this case, the court rejected a claim for compensation for damages resulting from the explosion of a toxic house detergent, as it held that the product could not be considered defective since it had been manufactured and distributed in compliance with the safety standards required for that type of product.

32 Court of Cassation, 19 February 2016, No. 3,258.

Chapter 14

JAPAN

Akihiro Hironaka, Yutaro Kawabata and Yui Takahata[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

Japan is a civil law country, and it has a unified national legal and court system under a single Supreme Court. National statutes are the main source of law for civil liability, but court precedents also play an important role in filling gaps and clarifying the meaning of statutes.

The core source of civil liability for product defects had been tort liability under the Civil Code, Law No. 89 of 1896 (CC). However, in order to mitigate difficulties faced by victims of defective products in establishing tort claims against manufacturers and other entities responsible for the product defects, the Product Liability Act, Law No. 85 of 1994 (the PL Act) was enacted to create strict liability (i.e., no proof of negligence for the defect is necessary) in product liability claims. Tort liability can also be pursued even if the claims under the PL Act are available to the victim.[2]

Multiple administrative statutes also play an important role in the area of product liability. The purposes of these administrative statutes are as follows: (1) to prevent defective products from being distributed in the market (e.g., government approval and licensing systems); (2) to prevent defective products in the market from causing damage to consumers (e.g., recall and remedy systems); and (3) to provide prompt and effective relief to consumers that have actually suffered losses from defective products (e.g., special measures or relief for losses from defective products and a compulsory insurance system).

II REGULATORY OVERSIGHT

National courts decide the civil liability of the responsible entities by applying the relevant provisions of the CC and the PL Act described in Section I, *supra*. As for the administrative regulations, various administrative authorities oversee the safety of different categories of products as explained below.

i Food safety

The Food Sanitation Act, Law No. 233 of 1947, governs administrative matters to prevent the public health risks arising from human consumption of food. It is administered by the Ministry of Health, Labour and Welfare (MHLW) and the Consumer Affairs Agency

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2 PL Act, Article 6.

(CAA). This Act provides standards for methods of producing, processing, using, cooking or preserving food and additives, standards for the ingredients of food and additives, the mandatory labelling system for food and additives, and the procedures for investigating food poisoning causes and for reporting investigation results.

ii Drug safety

Drugs, quasi-drugs, cosmetics and medical-instruments are regulated by the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics, Law No. 84 of 2013 (the PMD Act). The MHLW administers the PMD Act. The PMD Act provides the regulations concerning the labelling, manufacturing methods, and false or exaggerated advertising of such products. It is necessary to obtain approval from the minister of the MHLW to manufacture and market drugs and quasi-drug ingredients covered under this Act.[3] The Pharmaceutical and Medical Devices Agency conducts safety tests of these products.

iii Industrial products safety

Regarding industrial products, an important statute providing applicable regulations is the Consumer Product Safety Act, Law No. 31 of 1973 (the CPS Act). The Ministry of Economy, Trade and Industry (METI) and the Consumer Affairs Agency (CAA) administer the CPS Act. The CPS Act provides a certification system called PSC marks, which mandates manufacturers of products that pose high risks to the lives and bodies of consumers to comply with technical standards determined by the government, and to put labels on such products that satisfy national standards.[4] If a product lacks such labelling, the government can order certain measures to be taken, including the collection of such products.[5] If a product has caused a serious accident, the manufacturer and importer of the product must report it to the CAA.[6] The CAA may then announce such incidents to the public, if it deems it necessary.[7] The CPS Act also provides certain measures to prevent accidents from prolonged use of products.[8] Incidents that are not serious must be reported to the National Institute of Technology and Evaluation (NITE).

Other relevant important statutes are as follows: (1) the Electrical Appliances and Materials Safety Act, Law No. 234 of 1961; (2) the Act on the Securing of Safety and the Optimisation of Transaction of Liquefied Petroleum Gas, Law No. 149 of 1967; and (3) the Gas Business Act, Law No. 51 of 1954. The METI also administers these Acts. These Acts provide certification systems similar to PSC marks under the CPS Act.

iv Vehicle safety

The Road Transport Vehicle Act, Law No. 185 of 1951 (the RTV Act), provides measures to secure the safety of vehicles. The Ministry of Land, Infrastructure, Transport and Tourism (MLIT) administers the RTV Act. The RTV Act mandates users of the vehicles to maintain

3 PMD Act, Article 14(1).
4 CPS Act, Article 4(1).
5 Id., Article 32.
6 Id., Article 35(1).
7 Id., Article 36(1).
8 Id., Article 32-2 et seq.

mandatory safety standards that are issued by the MLIT under the RTV Act[9] and also provides recall systems for manufacturers and importers of vehicles, tyres and child restraint seats that do not satisfy the mandatory safety standards.[10]

v The Consumer Safety Act and the Consumer Affairs Agency

The administrative regimes explained above, depending on the category of the products, had a shortfall by which defective products were not regulated because they inadvertently were not covered by the existing regimes. In response, in 2009 the government enacted the Consumer Safety Act, Law No. 50 of 2009, and created the CAA, to comprehensively administer matters for the protection of consumers, including protection from defective products. Under the Consumer Safety Act, when the national or local government, or another relevant government entity, is informed that a serious accident has occurred, the person in charge at these entities must immediately notify the CAA of the accident.[11] The CAA then collects information on the accident and responds with responsive measures.[12]

III CAUSES OF ACTION

The PL Act defines the term 'product' as a moveable item that is manufactured or processed.[13] Therefore, no processed agricultural products are subject to the PL Act.

The PL Act applies to manufacturers, processors and importers (collectively, 'manufacturers').[14] The PL Act also applies to any person who provides his or her name, trademark or other indication on a product as its manufacturer, and any person who provides his or her name, trademark or other indication on a product that misleads others into believing that he or she is its manufacturer.[15] The PL Act further applies to any person who provides his or her name, trademark, or other indication on a product and that holds him or herself out as a substantial manufacturer of a product in light of the manner and other circumstances under which the product is manufactured, processed, imported or sold.[16] The PL Act will not provide a cause of action against distributors or sellers of a product if such persons are not an entity specified above. Therefore, civil claims against distributors and sellers of a defective product (i.e., entities that may owe direct contractual liability to the consumers) must be brought on grounds of the warranty of defects, breach of contract or tort under the CC.

In order to prove liability under the PL Act, a plaintiff must establish: (1) a defect in the product; (2) damage to life, body or property; and (3) causation between the defect and the damage.[17] 'Defect' is defined under the PL Act to mean a lack of safety that the product ordinarily should possess, taking into account the nature of the product, the ordinarily foreseeable manner of use of the product, the time the product was delivered and other

9 RTV Act, Article 40 et seq.
10 Id., Articles 63-2 and 63-3.
11 Consumer Safety Act, Article 12(1).
12 Id., Article 13 et seq.
13 PL Act, Article 2(1).
14 Id., Article 2(3)(i).
15 Id., Article 2(3)(ii).
16 Id., Article 2(3)(iii).
17 Id., Article 3.

circumstances concerning the product.[18] 'Defect' above is interpreted to include the following three types: defect in manufacture, defect in design and defect in instructions or warnings. As mentioned above, it is said that the PL Act creates strict liability. However, it is noted that the Supreme Court of Japan denied the defective instructions or warnings in *re Iressa*, where a Japanese subsidiary of a UK pharmaceutical company was sued for the alleged defect in its drug, stating that it was unforeseeable that 'Iressa had the side effect of causing interstitial pneumonia which could rapidly become severe.'[19]

In Japan, there are no administrative or criminal procedures for the government to bring a claim seeking remedies for personal injury or property damage against the manufacturer, distributor or seller of a product.

Conflict-of-law issues often arise in cross-border product liability cases. Japanese courts determine the applicable law by applying the Japanese code concerning conflict-of-law rules, entitled the Act on General Rules for Applications of Laws, Law No. 78 of 2006 (AGRAL). AGRAL provides a general rule that where a claim against a manufacturer, processor, importer, exporter, distributor or seller of a product arises from a tort involving injury to life, body or property caused by a defect in the product that is delivered, the formation and effect of such claim shall be governed by the law of the place where the victim received delivery of the product.[20] However, the application of the general rule would be inappropriate especially where the manufacturer (or other entities mentioned above) could not have foreseen the distribution of a product in a particular market. Accordingly, in order to ensure foreseeability regarding the applicable law, AGRAL provides an exception to the general rule that if delivery of the product at a certain place is ordinarily unforeseeable, then the law of the principal place of business of the manufacturer (or other entities mentioned above) shall apply.[21]

IV LITIGATION[22]

i Forum

Product liability civil claims are determined by professional judges in national courts. No jury system exists for civil litigation.

Alternative dispute resolution (ADR) procedures also play an important role in resolving civil product liability claims in Japan. Some industries have established their own 'product liability centres' intended to resolve product liability civil claims through ADR. For example, the Electric Home Appliances PL Centre and Automotive Dispute Resolution Centre are two such institutions. Further, the National Consumer Affairs Centre of Japan also manages an ADR procedure that deals with product liability matters.

ii Burden of proof

During civil proceedings, plaintiffs must prove each required element of a product liability claim. With respect to the issue of how much proof is necessary for the judges to be persuaded

18 Id., Article 2(2).

19 *X v. AstraZeneca K.K.*, 67 Minshû 899 (Sup. Ct., 12 April 2013).

20 AGRAL, Article 18.

21 Id.

22 For general explanations on Japanese civil procedure, see Yasuhei Taniguchi, et al. eds., *Civil Procedure in Japan* (Rev. 2nd edn.) (Juris Publishing, 1999, Binder/Looseleaf), to which Akihiro Hironaka, one of the authors of this chapter, is a contributor.

(degree of proof), in *Miura v. Japan*, a medical malpractice case, the Supreme Court of Japan has defined the required degree of proof.[23] In that case, the Supreme Court found causation of a patient's injury owing to the negligence of a doctor based on the following standard: 'Proving causation in litigation, unlike proving causation in the natural sciences (which permits no doubt at any point), requires proof of a high degree of probability that certain facts have induced the occurrence of a specific result by taking into necessary and sufficient account that the judge has been persuaded of the truthfulness to a degree where an average person would have no doubt.' It is difficult to express the required degree of persuasion using a numerical formula under the standard 'proof of a high degree of probability', but the majority of judges appear to require a 70 to 80 per cent probability to uphold facts based on evidence submitted in civil lawsuits.[24]

iii Defences

If a claim is brought under the PL Act, the defendant may be exempt from liability if the defendant successfully proves that the defect in the product could not have been discovered given the state of scientific or technical knowledge at the time the product was delivered (this is called a 'development risk' or 'state of the art' defence).[25] Further, where the product is used as a component or raw material of another product, the manufacturer of the component or raw material that is named as the defendant may be exempt from liability if the defendant successfully proves that the defect has occurred primarily owing to compliance with the instructions concerning the design given by the manufacturer of the finished product, and the defendant is not negligent with respect to the occurrence of the defect.[26]

In addition, the PL Act provides for limitations of the period in which a claim under the PL Act will extinguish: (1) if the victim does not exercise his or her claim within three years from the time when he or she becomes aware of the damage and the party liable for damages; or (2) 10 years have elapsed from the time the product was delivered.[27] This 10-year period is calculated from the time of the occurrence of the damage if such damage is caused by substances that become harmful to human health when they accumulate in the body, or if the symptoms that represent such damage appear after a certain latent period.[28] As for tort claims under the CC, the prescription period is three years from the time the victim becomes aware of the damage and the identity of the perpetrator.[29] A tort claim also cannot be brought when 20 years have elapsed from the time of the tortious act.[30]

Comparative negligence is available with respect to the determination of the amount of damage to be compensated and can be asserted in defending a product liability claim either under the PL Act or as a tort under the CC.[31]

23 *Miura v. Japan*, 29 Minshû 1417 (Sup. Ct., 24 October 1975). See also *X v. Y*, 1724 Hanrei jihô 29 (Sup. Ct., 18 July 2000).

24 See Shigeo Itô, Jijitsu Nintei no Kiso 163 (Yûhikaku, supplemented ed., 2000).

25 PL Act, Article 4(i).

26 Id., Article 4(ii).

27 Id., Article 5(1).

28 Id. Article 5(2).

29 CC, Article 724.

30 Id.

31 Id., Article 722(2).

Compliance with applicable regulations is considered one of the important factors in determining whether there is a defect in a product; however, compliance or non-compliance with applicable regulations by itself will not automatically give rise to liability or preclude liability.[32]

In a majority of US states, the 'learned intermediary doctrine' has been recognised. The 'learned intermediary doctrine' means that a manufacturer of prescription medications and devices is released of its duty to warn users of the risks associated with its products, by warning the prescribing physician of the proper use and risks of the manufacturer's product. The Supreme Court, in *re Iressa*, in denying the defective instructions or warnings, stated that 'it was known at least among physicians engaged in anticancer therapy targeting lung cancer that when interstitial pneumonia occurred owing to the administration of these drugs including anticancer drugs, it could be fatal.'[33] This ruling of the Supreme Court is similar to the 'learned intermediary doctrine' above, in that the Court considered knowledge of the addressee of the information in determining the defective instructions or warnings in the product.

iv Personal jurisdiction

No provision for product liability claims

The Code of Civil Procedure, Law No. 109 of 1996 (CCP), provides a set of both domestic and international jurisdiction rules applicable to litigation in Japanese courts, but it does not include an express provision for product liability claims. Under the prevalent view, product liability claims are classified as tort claims for the purpose of determining their jurisdiction. With respect to international jurisdiction of tort claims, the CCP provides that the Japanese court has jurisdiction if the place where the tort took place is located in Japan, unless the result of a wrongful act committed in a foreign country occurred in Japan and the occurrence of such a result in Japan was ordinarily unforeseeable.[34] The jurisdiction of international product liability claims will be determined pursuant to this provision. The stream-of-commerce doctrine, discussed in the US courts, was not introduced when the CCP was revised in 2011 to include international jurisdiction provisions.[35]

The place where the tort took place

This phrase generally includes the place of the wrongful act and the place of the result. The place of the wrongful act includes the place where the product was manufactured. Unless advertisement on the internet constitutes part of the wrongful act, such act by itself does not constitute the basis for the jurisdiction of Japanese courts. On some occasions, allowing international jurisdiction at the place of the result will cause substantial difficulties for the defendants. In such circumstance, the prevalent view recognises exceptions where Japanese courts do not have international jurisdiction over the defendants.

32 See Economic Planning Agency, Consumer Policy 1st Division, Chikujyô Kaisetsu Seizôbutsu Sekininhô 72-73 (Shôjihômu Kenkyûkai, 1994).

33 *X v. AstraZeneca K.K.*, *supra*.

34 CCP Article 3-3(viii).

35 Law No. 36 of 2011.

The place of secondary loss or economic loss

Whether the place of secondary loss or economic loss is included in the 'place of the loss' has also been discussed in Japan. If it is included, courts within the consumers' place of residence will almost always have jurisdiction over the product liability claim, and the result will be too harsh for businesses. Therefore, lower court decisions rejected this theory.[36]

v Expert witnesses

The CCP has a set of provisions providing procedures for the examination of court appointed expert witnesses. Where the issues to be determined by judges are highly specialised and difficult to determine, the court can appoint expert witnesses to assist fact finding by the judges.[37] After an expert witness has provided his or her opinion to the court in writing or orally, both parties have an opportunity to examine the expert witness before the judges for the purpose of impeaching an unfavourable opinion, or to restore the credibility of a favourable opinion. A court may, when it finds it necessary, request a Japanese or foreign government agency or public office, or a juridical person that has adequate equipment, to give its expert opinion.[38]

In Japanese litigation practice, parties to a litigation frequently find their own private experts and have them author expert opinions addressed to the court. The parties may also request to examine experts before courts. Technically speaking, these private experts are classified as 'witnesses' rather than 'expert witnesses' under the CCP, because they are not appointed by judges. However, these private experts also perform an important role.

The court may require assistance from experts not only for fact finding, but also in the process of clarifying issues and conducting proceedings efficiently. In order to enable the court to obtain such assistance, the court may appoint an expert commissioner in the proceedings.[39]

vi Discovery

No extensive discovery system (as in the United States) exists in Japan, and only limited discovery is permitted. The Japanese discovery system is far from an effective tool for litigants to request useful evidence from the other party or third parties.

Request for document production order

The party may request a document production order (DPO) against the other party or third parties. The CCP provides that the possessors of the documents shall not refuse to produce the documents in the following circumstances:

a (1) as a party, the possessor has cited the document in his or her arguments in the action; (2) the party applying for the DPO was otherwise entitled under the law to

36 *Nihon Yûsen K.K. v. London Steamship Owners' Mut. Ins. Ass'n Ltd*, 31 October 2006, 1241 Hanrei taimuzu 338; *Greenlines Shipping Co Ltd v. California First Bank*, 525 Hanrei taimuzu 132 (Tokyo Dist. Ct., 15 February 1984).

37 See CCP Article 213.

38 Id., Article 218(1).

39 Id., Article 92-2(1).

possess or inspect the document; (3) the document was executed for the benefit of the petitioner; or (4) the document was executed with respect to a legal relationship between the petitioner and the possessor; and

b the document does not fall under any exemptions provided in the CCP.[40]

The exemptions provided for in (b) above are as follows:

a a document containing information with respect to which the possessor would have the right to refuse to testify, as self-incriminating or incriminating one's family;

b a document containing a secret in relation to a public officer's duties;

c a document containing professional secrets, including documents obtained by lawyers and doctors through performance of their duties;

d a document containing technical secrets or secrets useful for occupations;

e a document held by the possessor exclusively for his or her own use; and

f a document relating to criminal proceedings or juvenile delinquency proceedings.

Courts may decide not to examine documentary evidence if they deem it to be unnecessary,[41] and courts are strict when considering the necessity for issuing the DPO. If the court finds that the fact that the party seeks to establish a DPO is unnecessary for resolution of the dispute, the court will decline to issue the DPO.

Japanese evidence law does not have strict rules to exclude evidence (as in the United States) where the evidence is in danger of being unfairly prejudicial, confuses the issues, misleads the judges, etc. Therefore, whether a judge orders the DPO regarding 'other similar incidents' of a product defect, for example, depends on the judge's interpretation of the 'necessity' of such evidence to decide the issues in the case before him or her.

Interrogatory

A party, before the lawsuit is instituted, or while the lawsuit is pending, may inquire with the opponent to request information regarding the matters necessary for preparing allegations or proof.[42] This system is analogous to the US interrogatory, but this is not frequently used in Japan in practice.

Deposition

No deposition of parties, witnesses or experts exists in Japan.

Evidence preservation proceedings

If the party establishes that any circumstances exist where it will be difficult to examine evidence, including where the other party may spoil the evidence, it may request the court to issue an order to preserve the evidence.[43] The order is granted for an *ex parte* hearing of the petitioner, and the other party is notified of such an order only an hour or an hour-and-a-half before the judge executes the preservation order, which is issued to avoid another party spoiling the evidence.

40 Id., Articles 220(i)–(iv).

41 Id., Article 181(1).

42 Id., Articles 132-2, 163.

43 Id., Article 234.

vii Apportionment

When multiple entities are involved in a product liability case, such entities are jointly and severally liable for liability under the PL Act or tort. A named defendant that has compensated the victim exceeding the damages that it is required to bear may seek indemnification from other entities. The portion of the burden that should be borne by each entity is determined on a case-by-case basis, considering the fair burden of damages and taking into account various circumstances such as the situation in which the act occurred and the connection between the act and the damage.[44]

Under Japanese law, the successor of an entity, for example, by way of merger, will be liable for its predecessor's liability.

viii Mass tort actions

In Japan, there is no legislation creating a US-style class action for mass tort. In practice, plaintiffs bringing mass tort actions have been solicited through announcements on the internet and by other methods. However, a new law relating to mass tort actions was promulgated in 2013: the Act for Special Measures with respect to Civil Proceedings to Collectively Restore Damages to Assets of Consumers, Law No. 93 of 2013 (the Collective Claims Act). The Act was implemented on 1 October 2016, and organisations certified by the Prime Minister of Japan pursuant to the Consumer Contract Act, Law No. 61 of 2000 ('certified organisations') may now bring a claim in relation to consumer contracts against business operators for recovery of damages suffered by consumers with respect to: (1) performance of a contract; (2) unjust enrichment; (3) a claim for damages owing to breach of contract; (4) warranty against defects; and (5) a claim for damages arising out of tort.[45] However, damage to property other than the subject matter of the consumer contract, lost profits, personal injury, pain, and suffering are expressly excluded from the scope of a claim that can be brought under the Collective Claims Act.[46] The Collective Claims Act adopts an 'opt-in' method, adopted in European countries, as opposed to a US-style 'opt-out' method.

The proceedings provided in the Collective Claims Act are a two-stage process. During the first stage, the certified organisation files a lawsuit with the court against a business operator for a decision, with respect to property damage suffered by numerous consumers in relation to a consumer contract, on whether the business operator owes an obligation to pay monies to such consumers owing to common factual cause or common legal cause. Issues that would be decided during this first stage are: validity of contracts between consumers and the business operator; illegality of the acts conducted by the business operator; and the intent or negligence of the business operator. If the court finds that the business operator is liable or that the business operator has acted illegally and makes a decision upholding a claim during the first stage, the certified organisation then files a proceeding to commence the second stage, in which consumers may participate (i.e., opt-in). During the second stage, the specific amount of compensatory damages for each consumer will be determined. Thereafter, the certified organisation collects monies from the business operators, and the monies collected will be distributed to each consumer.

44 See Economic Planning Agency, Consumer Policy 1st Division, footnote 31, *supra*, at 128.

45 Collective Claims Act, Article 3(1).

46 Id., Article 3(2).

ix Damages

Recovery for economic damage, including lost profits and non-economic damage such as pain and suffering, are permitted in product liability cases under Japanese law, regardless of whether the claim is for breach of contract, tort or under the PL Act. In general, the remedy for damage is monetary compensation.[47] The amount of damages is determined by the judge because no jury system exists in Japan as explained in Section IV.i, *supra*. There is no law limiting the amount of damages that may be ordered. Japanese law does not allow punitive damages. Punitive damages awarded in a foreign litigation or arbitration will not be recognised in Japan because they infringe public policy of Japan.[48]

The PL Act limits its application to claims for damage arising from the infringement of life, body or property caused by the defect in the product. Damage that occurs only with respect to the defective product are excluded from the scope.[49] However, such damage can be pursued in claims under the PL Act together with other types of damage.

With respect to criminal liability, if death or injury is caused because of a failure to exercise due care in pursuit of social activities, a criminal penalty may be imposed under the Penal Code, Law No. 45 of 1907.[50]

V YEAR IN REVIEW

One of the significant developments in 2016 related to product liability is that the Collective Claims Act actually came into force on 1 October 2016. Prior to this development, government orders and an ordinance relating to the Collective Claims Act, and publication by the Consumer Affairs Agency (CAA) of the guidelines regulating certified organisations (the CAA Guidelines), were issued in 2015. As explained in Section IV.viii, *supra*, certified organisations have a significant role in the proceedings under the Collective Claims Act. Therefore, it is crucial that the certified organisations provide services properly and in accordance with the purposes of the Act. In this regard, the CAA Guidelines provide specific standards regarding examination, certification and supervision of the certified organisations.

For example, one concern regarding the Collective Claims Act before publication of the CAA Guidelines was that the certified organisations might only arbitrarily select cases in which they could expect to charge higher remuneration, despite it being important that the certified organisations proactively handle cases in which the amount of damage is relatively small to recover damages for consumers. In response to the above concern, the CAA Guidelines explain that the Prime Minister will supervise what types of cases the certified organisations handle.[51]

In addition, the main purpose of the Collective Claims Act is to protect consumers' interests: the CAA Guidelines explain that certified organisations are required to distribute

47 CC, Article 722(i), 417.

48 For punitive damages awarded in a foreign court, see *Northcon I, Oregon Partnership v. Mansei Kôgyô Co Ltd*, 51 Minshû 2573 (Sup. Ct. 11 July 1997).

49 PL Act, Article 3 proviso.

50 Penal Code, Article 211.

51 CAA Guideline, Section 5(4).

dividends to consumers in an amount that is at least 50 per cent or more than the amount recovered from the business operator. The certified organisations are also directed to increase dividend distribution by promoting the efficiency of their services.[52]

As of 1 February 2017, only one consumer group, which has handled consumer matters since 2004, is a certified organisation based on the Collective Claims Act.

The CAA is interested in making this system functional; therefore, it convened a study group of experts, including consumer group representatives, a scholar who is a retired judge and a certified public accountant to discuss the methods to support these organisations. The following methods of support by the government are being discussed, including: (1) information support regarding consumer damages; (2) financial support by letting the certified organisations utilise grants or crowd funding; and (3) support for security deposits by third parties on behalf of the certified organisations in the provisional attachment proceedings.

With the implementation of the Collective Claims Act, small claims that have not been pursued by consumers owing to the burden on the individual bringing the claim may be sought by the certified organisations, which may result in an increase in the number of lawsuits relating to product liability.

However, only a handful of organisations may be able to receive certification as a certified organisation under the Collective Claims Act, which may give rise to the issue of capacity. In addition, damage to property other than the subject matter of the consumer contract (i.e., lost profits, personal injury, pain, and suffering) are expressly excluded from the scope of claim that can be brought under the Collective Claims Act. Furthermore, punitive damages like in the US cannot be sought through Japanese litigation. All these factors suggest that the implementation of the Collective Claims Act may not have a significant impact on business operators.

Even if concern for litigation under the Collective Claims Act may turn out to be insignificant, this does not mean that product safety can be addressed easily. Japanese consumers are very sensitive about product safety. Therefore, if a business operator distributing products in Japan fails to take appropriate measures to address product safety issues, its reputation may be seriously harmed.

52 Collective Claims Act, Article 65(4)(iv), and the Guideline, Section 2(6).

Chapter 15

NIGERIA

Afe Babalola SAN[1, 2]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

Product liability is the liability of a manufacturer, supplier or retailer towards the customer for injury or loss resulting from a defect in that product. In a Nigerian context, product liability deals with the quality and safety of products between businesses (wholesalers, retailers, suppliers, manufacturers and distributors) and consumers. It is premised upon damage caused by a design, manufacturing, or instruction or warning defect in a product. When injuries occur as a result of use of a product acquired through a commercial transaction, the manufacturer may then be held liable for claims in tort, contract and criminal law if the product is defective.

The prevailing factor in determining the scope of product liability claims in Nigeria is consumer protection against the supply or production of defective products. This has been aptly stated by the nation's Supreme Court in the *Nigerian Bottling Co Ltd v. Ngonadi* case,[3] where the claimant or respondent sustained severe injuries from a brand of kerosene refrigerator that was sold to her by the defendant or appellant. Giving the concurrent judgment, Aniagolu JSC stated, *inter alia*:

> *… nothing appears to be elementary in this country where it is often the unhappy lot of consumers to be inflicted with shoddy and unmerchantable goods by some pretentious manufacturers, entrepreneurs, shady middlemen and unprincipled retailer whose avowed interest seems only, and always, to be to maximise their profits leaving honesty a discounted and shattered commodity.*[4]

The manufacturer's duty of care, long-established by the Appellate Committee of the UK House of Lords (now known as Supreme Court), in *Donoghue v. Stevenson*[5] is well-recognised by the Nigerian courts. In fact, *Donoghue v. Stevenson* appears to be the *locus classicus* on the issue of duty of care in the realm of law of negligence in the country.[6] However, for tortious liability to accrue in negligence, the evidence must demonstrate four basic components of the

1 Afe Babalola SAN is the principal of Afe Babalola SAN & Co (Emmanuel Chambers).

2 The information in this chapter is accurate as of April 2016.

3 [1985] 1 NWLR (Pt. 4) 739.

4 Ibid., at 753.

5 [1932] AC 562.

6 Cases where liabilities in tort were recognised include: *Ebelemu v. Guinness (Nig) Ltd* (Unreported) FCA/1/101/82 (1993); *Boardman v. Guinness (Nig) Ltd* [1980] NCLR 109; *Soremi v. Nigerian Bottling Co Ltd* [1977] 12 CCHCJ 2735; *Dumuje v. Nigerian Breweries plc* (Unreported) Suit No. ENC/ 236/94; 4 July 2001.

torts of negligence: (1) that there was a duty of care owed; (2) that the product was defective or there was a foreseeable misuse and thus the duty was breached; (3) that the defect caused the injury; and (4) that this was foreseeable and directly contributed to the plaintiff's loss.[7]

Negligence is a question of fact, not law, and each case is decided in the light of its own particular facts.[8] Until recently, claimants in Nigeria had found it difficult to succeed in their product liability claims largely because of the 'foolproof' production defence often employed by manufacturers to sway the judgments of the courts.[9] The decision of the Supreme Court in *Okwejiminor v. Gbekeji & Nigerian Bottling Co plc*,[10] which awarded liability for an ailment suffered by the appellant after drinking Fanta orange drink containing a dead cockroach, in spite of the foolproof production evidence advanced by the manufacturer, is, however, a welcome development for consumers. The manufacturer had argued that, although the presence of the cockroach in the Fanta orange drink might give rise to the inference of negligence, it took all reasonable care in its production process, and consequently, this care would have successfully rebutted negligence. The Court rejected this argument and affirmed that the manufacturer was liable in negligence to the appellant (Okwejiminor).

Product liability claims may also be brought for breach of contract, in particular of express terms relating to the products in question, under the United Kingdom Sale of Goods Act 1893, which has general application in the country as a pre-1900 English Statute of General Application.[11] Although local sale of goods laws are now applicable in different states of Nigeria, these laws are largely a reproduction of the Sale of Goods Act 1893.[12] Thus, a consumer who obtains a product by way of sale can sue the seller for any injury suffered in consequence under any of these sale of goods laws.

In addition, given the safety expectations of consumers in Nigeria, product liability claims may criminally lie against manufacturers in contravention of various statutes and regulations that prohibit various acts relating to defective product matters in terms of

7 See, e.g., *Nigerian Bottling Co (Nig) Ltd v. Ngonadi* [1985] 1 NWLR (Pt.4) 739; *Ebelemu v. Guinness (Nig) Ltd*; *Soremi v. Nigerian Bottling Co Ltd*; *Dumuje v. Nigeria Breweries plc* (Unreported) Suit No. ENC/236/94,4 July 2001.

8 See *Kalla v. Jarmakani Transport Ltd* (1961) All NLR 747.

9 To give a few pertinent examples: in *Onyejekwe v. Nigerian Breweries Ltd* (Unreported) Suit No. E/129/72, 1 June 1973 at 7, Anyah, J responding to the defence of the 'fool-proof' system of production put up by the manufacturer stated: 'I am convinced by the evidence of this witness, that is, DW 1, that the beer and the bottles undergo complete pasteurisation and sterilisation before the bottles leave the factory and that in these circumstances no living organisms can be found in the bottles unless afterwards tampered with.' In *Okonkwo v. Guinness (Nig) Ltd* [1980] 1 PLR 581 at 592, Obi-Okoye J, commenting on similar evidence demonstrated by the brewery manager of the defendants, said: 'In short, their precautionary measure was fool-proof and left no room for roots, leaves or bark of trees to be bottled with their stout. There was no rebutting evidence against which his evidence can be weighed. I am satisfied he knew what he was talking [about] and that he was not deceiving the court. I believe his evidence.' A similar statement was made by Iguh J in (*Boardman v. Guinness (Nig) Ltd*. His Lordship stated: 'If the system by which a manufacturer produced his commodity was as near perfection as human ingenuity could make it, the manufacturer in those circumstances would have proved that he had not been negligent' (at 126).

10 (2008) 5 NWLR (Part 1079) 172.

11 See Orojo, JO (1983) *Nigerian Commercial Law and Practice* (London, Sweet and Maxwell), p. 6. See also Mwalimu, C (2009) *The Nigerian Legal System*, Vol. 2 (New York, Peter Lang), p. 410.

12 For example, Sale of Goods Law 2003, Lagos State; Kaduna State Sale of Goods Law 1990; and Contract Law of Enugu State 2004.

whether: (1) the product is sold; (2) the product is designed or manufactured in a defective manner; (3) the harm caused by the product is foreseeable; and (4) the manufacturer fails to warn the user of a non-obvious danger.[13]

II REGULATORY OVERSIGHT

The Consumer Protection Council (CPC), established under Consumer Protection Council Act 2004 (previously the Consumer Protection Council Decree 1992, which came into force on 29 November 1992), is the principal regulatory agency charged with the protection of consumer rights and redress mechanisms aimed at protecting these rights.

The CPC, as a parastatal of the Nigerian federal government is supervised by the Federal Ministry of Trade and Investment. The Council is made up of a chairman, a representative from each state in Nigeria and persons representing the ministries of Health, Commerce, Industry, Science and Technology, and Petroleum Resources.

Under Section 2 of the Consumer Protection Council Act 2004 (the CPC Act), the functions of the CPC include:

a providing speedy redress to consumer complaints through negotiation, mediation and conciliation;

b seeking ways and means of eliminating hazardous products from the market and causing offenders to replace such products with more appropriate alternatives;

c causing an offending company or individual to protect, compensate, and provide relief and safeguards to consumers or communities injured by adverse effects of technologies that are inherently harmful;

d ensuring consumer interests receive due consideration at appropriate forums and provide redress for the exploitation of consumers; and

e encouraging the adoption of appropriate measures to ensure that products are safe for either intended or normally safe use.

Section 3 of the CPC Act gives additional powers to:

a apply to the court to prevent the circulation of any product that constitutes an imminent threat to public health or safety;

b compel manufacturers to certify that all safety standards are met in their products;

c require, as it deems necessary, quality tests to be conducted on consumer products;

d demand production of labels showing the date and place of manufacture of a commodity as well as certification of compliance;

e compel manufacturers, dealers and service companies, where appropriate, to give public notice of any health hazards inherent in their products;

f ban the sale, distribution, advertisement of products that do not comply with safety or health regulations.

13 These statutes include the following: the CPC Act (Cap. C25, Laws of the Federation of Nigeria (LFN) 2004); The Consumer Protection (Products and Services Monitoring and Registration) Regulations 2005; National Agency for Food and Drug Administration and Control Act 2004; Standard Organisation of Nigeria Act of 2015; Criminal Code Act (Cap. C38, LFN 2004); Penal Code (Northern States) Federal Provisions Act 2004; and Trade Malpractices (Miscellaneous Offences) Act (Cap. T12, LFN 2004).

Furthermore, Section 4 of the CPC Act provides for the establishment of a state committee to assist the CPC in each state in dealing with any alleged injury caused to the consumer who may seek redress in court. Section 6 of the 2004 Act also empowers consumers or communities to make a complaint in writing or to seek redress through the state committees for injury or loss suffered as a result of the use or impact of any products or services. The Court of Appeal in *Nigerian Breweries plc v. David Audu* underscored the broad consumer-focused provisions of the CPC Act and stated that it is unique in the sense that it seeks not only to preserve the consumers' civil rights of action for compensation, but also to give power to the Council created under its auspices to use the courts to prevent the circulation of any product that may constitute a potential hazard to consumers.

Apart from the CPC, the National Agency for Food and Drug Administration and Control (NAFDAC) was established by the National Agency for Food and Drug Administration and Control Act 2004. The functions of the Agency include regulating and controlling the import, export, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, detergents, bottled water and chemicals in Nigeria.[14]

Under the NAFDAC Act 2004, NAFDAC has regulatory oversight over the quality and safety of the aforementioned items and is empowered to, after appropriate analysis, make rulings or prescriptions on how any identified shortcomings may be addressed. NAFDAC can also issue regulations on products that, *inter alia*, impose liability for breach and require certification of regulated products before they can be sold to the general public.

Section 26 of the NAFDAC Act 2004, also empowers NAFDAC to conduct criminal proceedings, subject to the approval of the Attorney-General of the Federation, in respect of offences under Section 25 of the NAFDAC Act, or Regulations made pursuant to Section 30 of the NAFDAC Act.

In exercising the powers conferred on it by Section 30 of the Act, NAFDAC, since inception, has produced subsidiary legislation aimed at protecting consumers against defective products.[15]

Another regulatory agency is the Standards Organisation of Nigeria (SON), established by an enabling Act No. 56 of December 1971, which was re-enacted as the Standard Organisation of Nigeria Act, Cap. S9 (LFN) 2004, now repealed by the Standard Organisation of Nigeria Act 2015 (the Act). The functions of the SON under the Act are to standardise methods of production within Nigerian industries, and to provide for other connected matters. The SON's governing body is known as the Nigerian Standards Council, and exercises this function on behalf of the SON. In particular, the Standards Council is responsible for ensuring product safety by setting out Nigerian industrial standards and conducting tests to ensure compliance with product standards. In addition, the SON also regulates the quality of products manufactured in Nigeria.

III CAUSES OF ACTION

Black's Law Dictionary defines a cause of action as '[a] group of operative facts giving rise to one or more bases for suing; a factual situation that entitles one person to obtain a remedy

14 See Section 31 of the NAFDAC Act.

15 Subsidiary legislation includes: (1) National Agency for Food and Drug Administration and Control Tariff Charges Regulation; (2) Drug Products Advertisement Regulations; (3) Pre-Packaged Food (Labelling) Regulations 2005; and (4) Bottled Water (Advertisement) Regulations.

in court from another person'.[16] The approach to causation in tort is that the defendant act must have caused the damage, but the defendant's conduct may not be a cause of the damage if the damage would have occurred without it. In *Egbe v. Adefarasin*,[17] the Supreme Court of Nigeria drew a distinction between a cause of action and the right to enforce a course of action, stating that a cause of action is 'the factual situation that gives rise to judicial relief […] to be distinguished from a right of action [… which] is the right to enforce presently a cause of action'.[18] This suggests that while a cause of action cannot be assigned, the right to enforce a cause of action may be assigned or undertaken by a third party on behalf of the claimant.

Causation in contract liability claim, however, rests, on the key provision of the Sale of Goods Act 1893 mentioned in Section I, *supra*. This Act creates an implied term that goods sold 'in the course of the seller's business' are of 'merchantable quality'.[19] This appears to protect the weaker party (usually the buyers or consumers) from the stronger party (usually the manufacturer or carrier). In the main, taking into account any description of the goods and the cost/consideration provided for sale, if the goods bought are not fit for any purpose for which the goods are normally used, the vendor may be liable under the Nigerian law, because the goods are not of merchantable quality. Thus, the injured party is entitled to damages because breaches of conditions in this regard are treated as breaches of warranty. The injured party may also ask for repudiation barring the event stated by Section 11(1)(c) of the Sale of Goods Act 1893:

Where a contract of sale is not severable, and the buyer has accepted the goods, or part thereof, or where the contract is for specific goods, the property in which has passed to the buyer, the breach of any condition to be fulfilled by the seller can only be treated as a breach of warranty, and not as a ground for rejecting the goods and treating the contract as repudiated, unless there be a term of the contract, express or implied, to that effect.

Furthermore, liability in contract is usually (but not always) strict; in other words, there is no need to prove an element of negligence. For example, an innocent misrepresentation, if it induces the purchase of the product in question, can give rise to a claim for breach of the implied terms. Secondly, claims can be made in contract for pure financial losses.

With regard to criminal liability, Section 10(2)(b) of the the CPC Act 2004 empowers the Attorney-General of the Federation to institute action against a person who acts in breach of the provisions of the Act. Breach of these provisions can lead to one or possible offences under the following sections:

a Section 9(1): failure to notify immediately the general public of a risk or danger of defective product and cause to be withdrawn from the market such product;

b Section 11: issue or aid in issuing any wrong advertisement about a consumer item;

c Section 12(a)(b): sell or offer for sale any unsafe or hazardous goods (and provide any service or proffer any information or advertisement thereby causing injury or loss to a consumer);

d Section 18: negligence or refusal to appear and give evidence before the Council or the State Committee or to answer any lawful enquiry, or produce required document;

16 Garner, BA (ed.) (2009) *Black's Law Dictionary*, 9th edn. (St. Paul, Minnesota, West). p. 251.

17 (1987) NWLR (Pt. 47) 1.

18 Ibid, per Oputa JSC at 20. See also *Adimora v. Ajufo* (1988) 1 NSCC 1005, at 1018.

19 Section 14.

e Section 19: deliberately make false entry or statement in any report, account, record or memorandum; and

f Section 21: violation of any order of the Council or State Committee.

In particular, the penalty in relation to the above offences is fine or imprisonment, or both fine and imprisonment, but the Act provides no statutory defence for these offences. It might seem that whether the defence is made out will be a question of fact in each case.

Further, by virtue of paragraph 3(e) of the Fundamental Right (Enforcement Procedure) Rules 2009, anyone acting on behalf of another person may institute an action for the enforcement of a fundamental right of the person in whose behalf he or she acts. Also, the essential elements that constitute a cause of action are the wrongful act of the defendant that gives the claimant the cause of complaint and the consequential damage.[20]

Again, by virtue of the provisions of the CPC Act, charges can only be brought against producers of defective products by the CPC or a state committee alone.[21] This indicates that action will only take place after an investigation by the CPC or state committee of any alleged injury caused to the consumer seeking redress in court. Yet, such approach seems to run contrary to Section 36 of the Constitution of the Federal Republic of Nigeria 1999 (as amended), which entitles every Nigerian to unfettered rights to institute actions in the courts or other tribunals established by law.

IV LITIGATION

i Forum

The Constitution of the Federal Republic of Nigeria 1999 (as amended) vests the High Court of any state with the jurisdiction to hear and determine any civil (or criminal) proceedings in the country.[22] Nigeria has no less than eight different systems of courts generally classified as superior, subordinate and other courts.[23] The Federal High Court, consisting of a chief judge

20 See generally, *Gbadehan v. Kiladejo & Ors* (2012) 16 NWLR (1326) 392, at 413–414 (per Kekere-Ekun, JCA; *Ojukwu v. Yar'Adua* (2009) 12 NWLR (1154) 50, at 131–132 (per Niki Tobi, JSC).

21 Section 8 provides:

Whereupon an investigation by the Council or State Committee of a complaint by a consumer, it is proved that–

a the consumer's right has been violated; or

b that a wrong has been committed by way of trade, provision of services, supply of information or advertisement thereby causing injury or loss to the consumer.

22 Section 272(1). See also, *INEC v. RTCN (Anglican Communion Diocese) of Orlu* (2010) All FWLR (Pt. 511) 1015; *Lagga v. Sarhuna* (2008) 16 NWLR (Pt. 114) 427.

23 Superior Courts include the Supreme Court (the highest court), the Federal Court of Appeal (the second-highest court), the Customary Court of Appeal, the Shariah Court of Appeal in the Federal Capital Territory and also in each of the 36 states of Nigeria, the Federal High Court, the High Court in the Federal Capital Territory of Ahuja, state High Courts, and the Court of Resolution in northern parts of the country. Lower or subordinate courts include magistrates courts, district courts in the north (the equivalent of magistrates courts in the south), customary courts in the south and area or shariah courts in the north. Area or shariah courts include lower and upper area courts. Other courts are juvenile courts, coroners' inquests, the price control courts, the national industrial courts and military courts (Mwalimu, C (2005) *The Nigerian Legal System*, Vol. 1 (New York, Peter Lang), p. 305.

assisted by other judges, is conferred with exclusive jurisdiction to try offences committed in contravention of federal law, including product liability provisions under the federal laws as mentioned above.[24]

Unless specifically prescribed as exclusive, the state high court in each of the 36 federating units, consisting of a judge, who could form the required quorum,[25] has concurrent jurisdiction with the Federal High Court in every other matter, including product liability claims. In *Ompandec v. Ajoku*[26] the Court of Appeal stated that under Article 230(1)(q), (r), and (s) of the 1979 Constitution, which is Article 251(1) (q), (r) and (s) of the 1999 Constitution as amended, noted above, the Federal High Court enjoys exclusive jurisdiction in matters specified and no other court is competent to adjudicate. Interpretation of this provision must be ordinary as codified.[27]

Furthermore, pursuant to Article 251(1) of the Constitution, as amended, where a person seeks relief against the federal government or any of its agencies for damages, injunction or specific performance, both the high court of the state and the Federal High Court enjoy concurrent jurisdiction. For the issue of whether a court enjoys jurisdiction is determined by the claim as reflected in the writ of summons and the statement of claim.[28]

ii Burden of proof

The golden rule is that the onus of proof is on the claimant to discharge the burden of proving the assertion made.[29] In Nigeria, the claimant in an action for negligence must discharge both the legal and evidential burden of proof.[30] Since negligence is a question of fact, not law, it is the duty of the party who asserts it to prove it. Failure to prove the particulars of negligence pleaded renders the claimant's case unprovable.[31]

Lord Wright, in *Grant v. Australian Knitting Mills*,[32] stated that negligence is 'a specific tort in itself and not […] simply […] an element in some more complex relationship or in some specialised breach of duty'.[33] In this sense, as a tort in its own right, negligence is a crucial issue in product liability and has to be approached within the framework of

24 The CPC Act 2004, National Agency for Food and Drug Administration and Control Act, 2004; and Standards Organisation of Nigeria Act, 2004.

25 Section 273 of the Constitution of the Federal Republic of Nigeria 1999 (as amended).

26 (2001) 8 NWLR 379.

27 See *Alli v. Central Bank of Nigeria* (1997) 4 NWLR. 92; see also *University of Abuja v. Ologe* (1996) 4 NWLR 706.

28 *Akinfolarin v. Akintola* (1994) 3 NWLR 659.

29 *Chapman v. Oakleigh Animal Products Ltd* (1970) 8 KIR 1063 at 1072, CA, per Davies LJ ('I must not be taken, with respect, to be agreeing with the editor's observations about onus of proof. I think that it might be much safer to stick to the golden rule that the onus of proof is on the plaintiff'). See also Section 131 of the Evidence Act 2011.

30 *NBC v. Okwejiminor* (1998) 8 NWLR (Pt. 561) 295, at 208.

31 *Nigerian Breweries plc v. David Audu* (2009) LPELR-8863 (CA) at 33 (per Omoleye, JCA). See also *Nigerian Bottling Company plc v. Olarewaju* (2007) 5 NWLR (pt. 1027) at 255; *Nigerian Bottling Company plc v. Okwejiminor* (1998) 8 NWLR (Pt. 561) at 295 and 308.

32 [1936] AC 85.

33 Ibid, at 103.

the ordinary meaning of defect. Strict liability is not a general theory for tort liability in Nigeria.[34] As such, in bringing a product liability claim, the claimant has to show that the act of negligence caused of the injury suffered.

iii Defences

The manufacturers or producers of consumer products have a number of defences available if any claims are made against them. For example, it is a valid defence to show that:

a the production process followed a foolproof system of production and that there was a lack of nexus between the act complained of and the alleged injury or damage suffered;

b the product defect was not discoverable within the limitations of science and technology at the time of distribution; and

c the product complied with the standards or requirements with respect to the alleged defect.[35]

Contributory negligence is also a defence but the burden of proving it rests on the defendant, although this may also be inferred from the claimant's own evidence, or a balance of probability from the facts.[36]

As governing powers are divided between the federal government and those of each state of the country, different limitation periods are specified by the limitation laws of the respective states. The general rule is that the limitation period with regard to contract and torts claims is six years, and the time starts to run from the date when the cause of action accrued. Where a tort claim is in respect of a claim for damages for negligence, nuisance or breach of duty, the action must be brought within three years of the accrual of the cause of action.

iv Personal jurisdiction

In Nigeria, by virtue of the requirements of the courts to exercise concurrent jurisdiction with English courts,[37] suits may be maintained against any person who has no connection with Nigeria other than a transient presence. For this reason, product liability claims may be brought against foreign-based product manufacturers, distributors or sellers of defective products in the country.

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34 The concept of strict liability hinges on the idea that liability exists for no other reason than the mere existence of a defect. No breach of contract or act of negligence is required in order to incur responsibility and manufacturers will be liable for compensation if their products cause injury (Keeting, GC (2014) 'Strict Liability Wrongs'. In John Oberdiek (ed.) *Philosophical Foundations of the Law of Torts* (Oxford, Oxford University Press), p. 301).

35 See, generally, *Okwejuminor v. Gbekeji Nigerian Bottling Company* (2008) LPELR-2537(SC); (2008) LPELR-2537(SC); *Onyejekwe v. Nigerian Breweries Ltd*; *Boardman v. Guinness (Nig) Ltd*; *Okonkwo v. Guinness (Nig) Ltd*; *Ebelamu v. Guinness (Nig) Ltd* FCA/101/82; *Dumuje v. Nigerian Breweries plc & Ors*; *Soremi v. Nigerian Bottling Co Ltd*; *Nigerian Breweries plc v. David Audu*.

36 See, for example, *Baker v. Longhurst & Sons Ltd* (1933) 2 KB 461; *Gibby v. E Grinstead Gas and Water Co* (1944) 1 All ER 358).

37 Section 10 of the High Court of Law (Cap. 52) 1973: 'The High Court shall, in addition to any other jurisdiction conferred by the Constitution of the Federation or by this or any other enactment possess and exercise, within the limits mentioned in, and subject to the provisions of, the Constitution of the Federation and this enactment, all the jurisdiction, powers and authorities which are vested in or capable of being exercised by the High Court of Justice in England.'

But having regard to such matters as the convenience of parties and witnesses, and the interest of justice, Nigerian courts do apply *forum conveniens* in the context of an application for stay of an action that has commenced in Nigeria or other originating process outside Nigeria,[38] or an action that has commenced in breach of an exclusive jurisdiction clause selecting a different forum other than Nigeria.[39]

Further, having regard to the prospects of settling or winning a lawsuit, the probable amount of recovery, the likely costs of litigation, and the length of time required to resolve the dispute, the defendant has the responsibility to protest the absence of jurisdiction by a court to entertain a dispute.[40]

v Expert witnesses

An expert witness may be required to give evidence about a scientific, technical or professional issue – such as handwriting or foreign law;[41] however, the person giving the evidence must be called as a witness and must state his or her qualifications, training, experience and profession to satisfy the court that the person is an expert on the subject on which he or she gives an opinion, stating clearly the reasons for arriving at that opinion.[42]

vi Discovery

Claimants need access to a great deal of information to pursue their claims successfully. Accordingly, under the respective Civil Procedure Rules (CPR) of the various states in Nigeria, there are provisions for the parties to a litigious proceeding to give each other advance notice of any material documentation they intend to tender and rely upon at trial. Furthermore, any party may, in writing, request another party to produce documents that are, or have been, in its possession, custody, power or control, relating to any matter in question in the case.[43]

A court may also, at the insistence of either party to a legal proceeding, order (by the issuance of a subpoena) disclosure against a third party where the document of which disclosure is sought is in the custody or control of such third party and is likely to support the applicant's case or adversely affect the case of one of the other parties to the proceedings.[44]

vii Apportionment

The law permits apportionment of liability among entities other than the named defendant in ongoing proceedings as a defendant, in an action in which the right to any relief is alleged to

38 See *Barsoum v. Clemessy International* [1999] 12 NWLR (Pt. 632) 516; *Herb & 2 Ors v. Devimco* [2001] 52 WRN 19.

39 See *Sonnar Ltd & Anor v. Partenree Nordwind* 1987 NWLR (Pt. 66) 520; *Nika v. Lavinia* [2002] 8 WRN 95. CA; (2008) 10 CLRN 1SC; (2008) 16 NWLR (Pt. 1114) 509.

40 See *Elugbe v. Omokhafe* (2004) 18 NWLR (Pt. 905) 319; *Oloba v. Akereja* (1988) 3 NWLR (Pt. 84) 508.

41 Sections 67 to 71 of the Evidence Act 2011.

42 See *Shell Dev Co Ltd v. Otoko* (1990) 6 NWLR (Pt. 159) 693.

43 See, e.g., High Court of Lagos State (Civil Procedure) Rules 2012, Order 26, Rule 8; Federal High Court (Civil Procedure) Rules 2009, Order 43, Rule 8; High Court of the Federal Capital Territory, Abuja (Civil Procedure) Rules 2004, Order 32, Rule 9.

44 See, e.g., High Court of Lagos State (Civil Procedure) Rules 2012, Order 32, Rule 16; Federal High Court (Civil Procedure) Rules 2009, Order 20, Rule 15; High Court of the Federal Capital Territory, Abuja (Civil Procedure) Rules 2004, Order 41, Rule 27.

exist, whether jointly, severally or in the alternative.[45] In *Chief Otonyeseigha Ololo v. Nigerian Agip Oil Company Ltd & Anor*,[46] a case involving an accident resulting in total wreckage of the claimant's local passenger and goods boat *MV Ololo* near Degema along Nembe (Port Harcourt inland waterway), only the first defendant (the owner of a 40-metre long dumb barge named NOAC 502) was originally sued, but on application, the claimant was granted leave to join the second defendant who was a subcontractor of the first defendant at the time of the accident.

The court may, however, give judgment against one or more defendants as may be found liable according to their respective liabilities, without any amendment. The measure of damages is apportioned according to the level of blame attached to each party responsible for the damage, taking into account both causation and blameworthiness, and the amount recoverable will be allocated as the court thinks just and equitable according to the claimant's share in the responsibility for the damage.[47]

viii Mass tort actions

Mass tort actions are recognised in Nigerian legal jurisprudence under the various rules of courts in the 36 states of the federation. For example, the High Court of Lagos State (Civil Procedure) Rules 2012 permit claimants to join as parties to the same actions all or any of other persons severally – or jointly and severally – liable on any one contract, including parties to bills of exchange and promissory notes.[48] Similarly, the Federal High Court (Civil Procedure) Rules 2009, Order 9 Rule 4 permits class action in cases concerning trademarks, copyrights, patents and designs.

Also, in seeking redress for damages resulting from a defective product, Section 6 of the CPC Act provides that a consumer or community that has suffered a loss, injury or damage as a result of the use or impact of any goods, product or service may make a complaint in writing to or seek redress through a state committee. This indicates that the redress available to individuals also extends to 'communities'. Hence, in this sense the CPC Act can be said to contemplate class actions.

ix Damages

A distinction is drawn between general and special damages in Nigerian law. To succeed, a claim for special damages must be pleaded with distinct particularity and strictly proved;[49] however, general damages do not require proof, although the court is entitled to make its own assessment of the quantum of such general damages and, on appeal, such general damages will only be altered or varied if they were shown to be either so manifestly too high or so

45 See, e.g., High Court of Lagos State (Civil Procedure) Rules 2012, Order 13, Rule 4; Federal High Court (Civil Procedure) Rules 2009, Order 9, Rule 5.

46 (2001) LPELR-SC.82/1996.

47 Ibid. See also *Stapley v. Gypsum Mines Ltd* (1953) AC 663; *Davies v. Swan Motor Co (Swansea) Ltd* (1949) 2 KB 291.

48 Order 13, Rule 7.

49 *Universal Trust Bank Nig Ltd v. Adams Ajagbule & Anor* (2006) 8 CLRN 88. See also *Dumez (Nigeria) Limited v. Ogboli* (1972) 3 SC (Reprint) 188; (1972) 1 All NLR 241; *Osuji v. Isiocha* (1989) 6 SC (Part II) 158; (1989) 3 NWLR (Part 111) 623 and *Jaber v. Basma* (1952) 14 WACA 140; *Benin Rubber Products Limited v. Ojo* (1997) 9 NWLR (Part 521) 388.

extremely too low or that they were awarded on an entirely wrong principle of law as to make it, in the judgment of the appellate court, an entirely erroneous estimate of the damages to which the claimant is entitled.[50]

The court may also award the payment of interest at a rate of at least 10 per cent per annum to be paid upon the judgment.[51] In addition, the courts may also award costs to the successful party to cover the expenses incurred during the proceedings, as well as compensating the party for the time and effort expended in coming to court.[52]

Legal remedy is also available to claimant against manufacturer of a defective product in both the Criminal and the Penal Code Acts of Nigeria.[53] Again, the Food and Drugs Act[54] makes several provisions for the regulation of the manufacture, sale and advertisement, etc., of food, drugs and cosmetics.[55]

V YEAR IN REVIEW

The CPC recently signed a memorandum of understanding (MOU) with the Economic and Financial Crimes Commission (EFCC) on matters affecting consumers' economic and financial well-being. The objective of this MOU is to protect consumers and combat scams using a three-pronged approach: complaint data analysis to establish patterns, trends and hotspots; consumer education and sensitisation campaigns across the country; and case investigations, prosecution and redress.[56]

In the past year, the National Agency for Food Drug Control and Administration and the Standards Organisation of Nigeria, alongside the CPC, made giant strides in their efforts to protect consumers against the manufacturers for any product defects that cause them injury.[57]

In addition, the Consumer Protection Agency (CPA) Law, 2014, enacted by the Lagos State government, has also helped to improve consumer rights protection since its enactment. The CPA Law, which repealed the Lagos State Consumer Protection Committee Law,[58] is, however, not a federal law. This means that the law is only applicable in Lagos State.

Nevertheless, Lagos State is considered the most populous city in Nigeria, and the commercial capital of the country. The CPA Law is imbued with all the powers of a body corporate and has representatives from the ministries of Health, Commerce and Industry,

50 See, e.g., *Zik Press Limited v. Ikoku* (1951) 13 WACA 188; *Idahosa v. Orosanye* (1959) 4 FSC 166; *Bola v. Bankole* (1986) 3 NWLR (Part 27) 141; *Ijebu-Ode Local Government v. Balogun and Company Limited* (1991) 1 SC (Part I) 1; (1991) 1 NWLR (Part 166) 136.

51 See High Court of Lagos State (Civil Procedure) Rules 2012, Order 35, Rule 4.

52 Ibid. Order 49, Rule 1.

53 Section 243 of Chapter XXIII of the Criminal Code (Cap. 77, LFN); and Section 184 of Penal Code (Cap 53, LFN 2004).

54 Cap. F32 LFN 2004.

55 Other consumer-focused statutes are: the Weight Act 1974 (Cap. W3, LFN 2004); Trade Practices (Miscellaneous Offences Provision) Act No. 67, 1992 (Cap. T12 LFN 2004) and Counterfeit Fake Drugs and Unwholesome Processed Food (Miscellaneous Provision) Act (Cap. C3, LFN 2004).

56 CPC press release, 'Consumer Protection Council Signs Memorandum of Understanding (MOU) with EFCC', 27 February 2015. Available online at http://cpc.gov.ng/?p=1391. Accessed 6 February 2016.

57 Okeke, J (2015) 'Have Consumers Fared Well This Year?' *The Nations*, 27 December. Available online at: http://thenationonlineng.net/have-consumers-fared-well-this-year/. Accessed 6 February 2016.

58 Cap. L15, Laws of Lagos State 2003.

Manufacturers Association of Nigeria and the SON, as well as two representatives from recognised private-sector organisations. The CPA Law complements the national CPC, in terms of promoting and protecting rights of consumers, and ensuring that their interests will always receive due attention.

In particular, Section 6 of the CPA Law provides for the use of negotiation, mediation and conciliation to allow for speedy redress of consumer complaints and to ensure replacement of hazardous products and their elimination from the market. Under this Section, the CPA is also empowered to list banned, withdrawn, restricted or unapproved products and require offending businesses to compensate their consumers or provide relief to them from the results of adverse effects of harmful products.

Section 11 of the CPA Law provides that if a complaint is filed by one or more consumer, the CPA or CPC may allow the complaint to be proceeded with or rejected within seven days, and whatever decision is reached 'may be taken to a court of Law if either of the parties is not satisfied with the decision of the Agency or Committee'.[59]

The draft Competition and Consumer Protection Bill, whose objective is to modernise the legal provisions for consumer protection in Nigeria, and at the same time build the required synergy between competition and consumer protection in the country, has been languishing at the National Assembly since 2009. The 8th National Assembly of the Federal Republic of Nigeria, inaugurated on 9 June 2015, is expected to give due consideration to this Bill in order to further protect the interest of consumers.

59 Section 11(3).

Chapter 16

PORTUGAL

Ana Lickfold de Novaes e Silva and Pedro Pires Fernandes[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

In Portugal there is a statutory-based product liability regime, which mainly derives from the European Directive 85/374/EEC (the Product Liability Directive) but that is also complemented by a complex set of rules deriving from both European and national legislation which overlap each other in some circumstances.

First and above all, Decree-Law 383/1989 transposed the Product Liability Directive into national law (the Product Liability Act), so governing the producer's liability coherently with the European Rules, substituting the former full application of the Civil Code regarding sale and purchase, non-fulfilment of contract and tort. It states that the producer is liable irrespectively of fault (i.e., subject to strict liability) and that a product has a defect if it does not grant the safety that is to be expected, taking all circumstances into account. The Product Liability Act was amended in 2001, by Decree-Law 131/2001, to bring it in line with European Directive 1999/34/EC. It should be noted that the Product Liability Act states that its application does not affect any rights that the injured person may have under other Acts. This results in the claimant having the opportunity to choose different pathways to pursue his or her indemnity demand, either against the producer, the distributor or both.

Complementary to this, Decree-Law 69/2005, which transposed European Directive 2001/95/EC, addresses general product safety (the Product Safety Act). It imposes a general safety obligation on both the producer and the distributor.

Additionally, Law 24/1996 (the Consumer Protection Act) introduced rules concerning consumer protection which regulate the rights and obligations resulting from the sale of goods between a professional seller and a non-professional buyer. This statute, in line with the Product Liability Act, states that the producer is liable irrespectively of fault. It further lists a set of rights that are granted to the consumer, such as the right to the quality of the products, to the protection of health and physical safety, to the protection of his or her economic interests, to information, to compensation for damages, to legal assistance and association with other consumers for the promotion of their mutual rights.

Decree-Law 67/2003 transposed European Directive 1999/44/EC concerning certain aspects of the sale of consumer goods and associated guarantees (the Sale of Consumer Goods and Guarantees Act), which – alongside the Consumer Protection Act – regulates the rights and obligations resulting from the sale of goods between a professional seller and a non-professional buyer. This statute also grants additional rights to the consumers, such as

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the right to substitution or repair of the goods, price reduction and the termination of the sales contract. Irrespectively of the seller's obligations, this statute allows the consumer to claim the substitution or repair of the goods directly from the producer.

In addition, the Civil Code holds a subsidiary importance, having its sale and purchase, non-fulfilment of contract and tort rules apply to situations where the above-mentioned statutes do not.

Finally, producers and distributors may also face misdemeanour and even criminal liability.

II REGULATORY OVERSIGHT

The main authority overseeing product regulation is the Ministry of Economy Consumer Directorate General (MECDG) and, within this, the Services and Goods Safety Commission (SGSC). The latter was created by the Product Safety Act, following the European Directive on this matter. The SGSC can broadly supervise the products and services placed and available on the market, having the competence to prohibit the manufacture or the import of products that it deems to be unsafe. It also has the power to order a recall. Further to this, the SGSC has the power to redirect its findings to the competent punitive authority, such as the Authority for Economic and Food Safety or the National Authority for Pharmaceuticals and Health Products.

The MECDG is also the Portuguese contact point within the EU Rapid Alert System for Dangerous Non-food Products.

III CAUSES OF ACTION

i Claims under the Product Liability Act

Normally, claimants will initiate proceedings under the Product Liability Act, which foresees that the producer is liable – with strict/no-fault liability – for damages caused by defective products it has introduced in the market.

Claims under this Act do not require the existence of a contractual relationship between the producer and the acquirer of the product, meaning that any injured person can initiate proceedings against the producer.

The notion of producer is quite broad and is construed in a way that protects the claimant against any possible uncertainty that may be involved with international trading and product circulation. Accordingly, the Act qualifies as producer:

a the real producer (i.e., the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part);

b the apparent producer (i.e., any person who, by putting his or her name, trademark or other distinguishing feature on the product presents him or herself as its producer);

c the importer (i.e., any person who imports into the EU a product for sale, hire, leasing or any form of distribution in the course of his or her business); and

d the supplier, if the producer cannot be identified and unless he or she informs the injured person, within three months, of the identity of the producer or of the person who supplied him or her with the product.

The notion of product is also very wide, comprising any moveable thing, even if incorporated in another moveable or immoveable thing.

A product shall be deemed defective if it does not provide the safety that a person is entitled to expect, taking all circumstances into account, including the presentation of the product, the use to which it could reasonably be expected that the product would be put and the time when the product was put into circulation. This means that the application of the Act does not rely on contractual statements and clauses but rather on the safety or dangerousness of the product. Nonetheless, a product shall not be deemed defective for the sole reason that a better product is subsequently put into circulation.

The application of the Product Liability Act will not imply the waiver of any rights that an injured person may have under contractual or non-contractual liability laws. It also will not set aside criminal or misdemeanour responsibility, if existent.

ii Claims under the Consumer Protection Act and the Sale of Consumer Goods and Guarantees Act

The Sale of Consumer Goods and Guarantees Act and the Consumer Protection Act are mostly driven by general consumer protection and contractual fulfilment rather than product safety, which is the central note of the Product Liability Act. It is important to keep in mind, however, that they provide for the possibility of a direct claim being lodged by the consumer against the producer, even if he or she had no contractual relationship.

For the application of the Sale of Consumer Goods and Guarantees Act and the Consumer Protection Act, a consumer will be the acquirer of goods or services from a professional seller for non-professional use.

If the consumer's rights are not met (quality of products, health protection, physical safety, information), he or she is entitled to ask for compensation resulting from the supply of a product or service that is not according to the contract entered into between the supplier and the consumer. He or she may also ask for the substitution of the goods, for the termination of the contract or for a price reduction. These rights will follow the goods even if they are sold to a third person.

The rights provided for in the Sale of Consumer Goods and Guarantees Act will expire after two (regarding moveables) or five years (regarding immoveables), starting from the date when the product or service was delivered. Notwithstanding these time limitations, the consumer will also need to notify the supplier or producer within two months (for moveables) or one year (for immoveables) of identifying the problem regarding the product or service.

iii Contractual claims

Contractual claims will rely on the rules of the Civil Code and will limit the claimant to launching proceedings merely against the contracting party, thus exempting the producer if there was no direct contractual relationship with the final customer.

A prerequisite for contractual liability in damages is that one of the parties has failed to fulfil his or her obligations under the agreement. This breach of agreement must, in turn, cause damage to the other party. Furthermore, there must be a causal link between the breach of agreement and the damage.

In simple terms contractual liability arises when there is an intentional or negligent failure to perform an enforceable obligation in a given contract. This notion underlies Article 798 of the Civil Code, where it is stated that: 'The debtor who guiltily fails to perform a given obligation is liable for the damage caused to the creditor.'

According to the rules set by the Civil Code on sale agreements, in particular under Article 913, the seller has the obligation to provide products that have no defects that may

lower their value or render their use impossible. In these situations, or if the products do not have the qualities assured by the seller or necessary to ensure the use they are meant for, the seller may be liable for breach of contract.

Recourse to claims under contractual liability may be justified, where possible, for time limitation reasons, given that, in general, contractual obligations benefit from a 20-year time bar.

iv Tort claims

An injured party may also base his or her claim on non-contractual liability, which is provided for in Article 483 of the Civil Code: 'Any person who wilfully or negligently violates in unlawful terms a third party's right, or any legal provision created for the protection of third parties' interests, shall be obliged to indemnify the injured party for the damages arising from such violation.'

Extra-contractual liability arises outside the scope of an agreement when someone violates an absolute right or fails to abide by general legal provisions.

v Criminal and misdemeanour charges

Civil liability does not exclude other sources of liability, such as criminal acts and administrative or misdemeanour offences.

Indeed, under Portuguese law, the same fact (action or omission) may give rise to civil and criminal liability, and, thus, the infringer may be responsible for paying compensation to the injured party and be simultaneously subject to criminal penalties. As such, the producer could be held criminally liable if the defect causes death or serious harm to a person, either for an act or for an omission, even if there was only negligence.

Criminal proceedings may be initiated by the injured person and then pursued by the public prosecutor. If the damage is serious, namely in cases of death or severe injury to someone, the public prosecutor will mandatorily have to initiate proceedings against the producer or the supplier, or both.

Compensation for damages arising out of non-contractual liability may be sought within the criminal proceedings. If not, the facts proved within the criminal proceedings will be binding within the civil proceedings as long as the parties that participated in the criminal proceedings are the same that subsequently litigate in the civil proceedings. Regarding third parties, facts proved within the criminal proceedings constitute a mere presumption and are subject to counterproof.

The producer and the supplier may also be subject to fines resulting from misdemeanour proceedings initiated before the various regulatory authorities. The determination of these fines can be subject to appeal to a court of law. In addition to fines, the producer or supplier may be subject – in the more serious situations – to (1) temporary closing of their business premises; (2) prohibition from continuing their activities; and (3) restitution of any benefit obtained from public authorities.

IV LITIGATION

i Forum

Product liability claims are generally determined in civil proceedings before state courts by professional judges. In Portugal there are no jury trials in civil proceedings and in criminal proceedings, where they are possible, they are very rarely used. Civil liability in product

liability cases may also be determined by an arbitral court, under the Portuguese Voluntary Arbitration Act (Law 63/2011), provided there is an arbitration agreement between the parties involved. There are also consumer arbitration centres which may determine claims below €5,000.

The Portuguese court system has three levels of ordinary courts: (1) the courts of first instance; (2) five courts of appeal; and (3) the Supreme Court of Justice. There are also justice of the peace courts which may try cases below €15,000.

The courts of first instance are divided into sections, such as civil, criminal, family and minors, commercial and labour. The civil section has general jurisdiction over all civil claims not exclusively attributed by law to other courts.

Decisions issued by the courts of first instance, where the value of the claim exceeds €5,000, can, in general, be appealed to the courts of appeal, which may, within the limits of the appeal lodged by the appellant, re-examine the facts and the applicable law. Appeals to the Supreme Court of Justice are exceptional and only for claims above €30,000. The scope of review by the Supreme Court of Justice is limited to the application of substantive law and procedural issues.

Regulatory liability will be initiated by the administrative authorities and subject to their decision. The producer will be heard in the proceedings and allowed to present its defence. The authorities' final decision can be challenged in a court of law.

Criminal proceedings will be pursued in criminal courts and will be promoted by the public prosecutor or the claimant, or both. The decision will be determined by a judge and may be appealed against.

ii Burden of proof

Product Liability Act

The general principle in Portuguese law is that the burden of proof of an allegation of facts falls upon the party who makes the allegation and wishes to rely on facts invoked.

Under the Product Liability Act, the claimant will have to prove the damage, the defect and the causal relationship between the two. The claimant will not have to prove the fault of the producer, given that under the Act the producer faces a strict liability regime.

The producer will bear the burden of proof regarding the facts that it may wish to rely on and that constitute the causes for exclusion of its responsibility that are referred to below, along with any other defences. Likewise, the producer will have the burden of proof regarding relevant dates that may result in the dismissal of the proceedings owing to the elapsing of the claimant's rights.

For causation, Portuguese law adopts the 'adequate causation' theory, generally in its negative formulation, which means that not only must the damage be a foreseeable and probable consequence of the defect, but that only damages that are a result of a totally atypical and extraordinary chain of events are excluded from liability.

Consumer Goods and Guarantees Act

Under the Sale of Consumer Goods and Guarantees Act, it is legally presumed – burdening the supplier or the producer, or both, with the need to prove otherwise – that products or services are not according to the contract if:

a they do not comply with the description given by the seller or do not possess the qualities of the goods which the seller has provided to the consumer as a sample or model;

b they are not fit for any particular purpose for which the consumer requires them and which he or she made known to the seller at the time of conclusion of the contract and which the seller has accepted;

c they are not fit for the purposes for which goods of the same type are normally used; or

d they do not show the quality and performance which are normal in goods of the same type and which the consumer can reasonably expect, given the nature of the goods and taking into account any public statements on the specific characteristics of the goods provided by the seller, the producer or his or her representative, particularly in advertising or on labelling.

The claimant has, however, to prove his or her damages and causality regarding the non-performance of the contract.

Contractual claims

Regarding contractual claims, the injured party bears the burden of proving the following requirements of contractual liability: (1) the unlawful non-fulfilment of the contract by the seller; (2) the damages; and (3) the causal link between the act or omission of the seller and the damages suffered.

Article 799 of the Civil Code provides a legal assumption of fault in contractual liability and therefore the seller bears the burden of proving that there was no wilful misconduct or negligence.

Tort claims

Non-contractual liability arises only when the general conditions of civil liability are present, which are: (1) voluntary fact; (2) unlawfulness; (3) some type of blameworthiness (fault); (4) damages; and (5) a causal link between the damages and the relevant illicit conduct (act or omission).

Contrary to contractual liability, there are, in general, no assumptions of fault in regard to non-contractual liability. This is one of the key differences between these two forms of civil liability. As provided for in Article 487 of the Civil Code: 'The injured party must evidence the fault of the author of the injury, except in the event that an assumption of fault is applicable.'

Regulatory or criminal proceedings

For any regulatory or criminal proceedings, it will be up to the prosecuting authority to prove the facts that hold its allegation.

iii Defences

Product Liability Act

Under the Product Liability Act, the producer may benefit from the exclusion of its responsibility if he or she proves – and regarding this the producer has the burden of proof – that:

a he or she did not put the product into circulation;

b having regard to the circumstances, it is probable that the defect that caused the damage did not exist at the time when the product was put into circulation by him or her;

c the product was neither manufactured by him or her for sale or any form of distribution for economic purpose nor manufactured or distributed by him or her in the course of his or her business;

d the defect is owing to compliance of the product with mandatory regulations issued by the public authorities;

e the state of scientific and technical knowledge at the time when he or she put the product into circulation was not such as to enable the existence of the defect to be discovered; or

f in the case of a manufacturer of a component, that 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 third party contributed to the damage, the court may reduce or exclude compensation, considering all circumstances.

The producer may also allege that the claim is time-barred, and this being owing to two different time limitation periods.

The first statute of limitation period is three years and regards relevant knowledge and beginning of proceedings against the producer. This limitation period shall begin to run from the day on which the claimant becomes aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer. If the claimant does not initiate proceedings within this three-year period, the claim will be time-barred. It should be noted that the acknowledgement of the existence of a defect by the producer interrupts the counting of this three-year period, according to Article 325 of the Civil Code. This is particularly relevant when the producer orders a recall that can lead the claimant to argue that it reflects a tacit acknowledgement of the claimant's right to compensation resulting from damages caused by a defective product. Article 325 of the Civil Code stipulates, however, that the tacit acknowledgement of the claimant's right to compensation is only relevant if it results from facts that unequivocally express it.

The second limitation period is 10 years and regards the date when the product entered into circulation. This limitation period shall begin from the date on which the producer put into circulation the actual product that caused the damage and will not be interrupted unless the injured person initiates proceedings against the producer.

None of these time-related defences, however, allow for the request of a US-like 'motion to dismiss' and so the defendant (producer) who wishes to invoke that the claim is time-barred must file its complete defence and, although this issue may be decided at the preliminary hearing that follows the written submissions, it is often the case that the proceedings go through a full trial and that the decision based on the statute of limitations is only made at the very end.

Clauses that exclude the producer's liability vis-à-vis the injured persons are not admissible and shall be treated by courts as non-existent.

Consumer Goods and Guarantees Act

Under the Sale of Consumer Goods and Guarantees Act, the producer may allege, in its defence, that:

a the defect results from the statements of the supplier and the use of the good;

b the product was not put into circulation;

c it can be assumed that, considering all circumstances, no defect existed when the product was put into circulation;
d it did not manufacture the product for sale or any other form of profitable distribution or it did not distribute it within its professional activity; or
e more than 10 years has passed since the product was put into circulation.

Contractual claims

Regarding contractual claims, the defendant can invoke any variety of defences that may serve to disprove the facts alleged by the claimant and fault (regarding which, as mentioned, there is a legal presumption).

Tort claims

In any tort claim, apart from invoking any facts that contradict and counterprove the facts alleged by the claimant, the defendant may allege that the claim is time-barred upon completion of three years after the injured person had the knowledge of his or her right, even if he or she does not know who is responsible for it and the full extension of damages. This limitation period is extended to five years if the injury resulted from an act or event that may constitute a crime.

Regulatory or criminal proceedings

Regarding regulatory or criminal proceedings, the defendant may invoke a variety of defences that do not especially relate to product liability.

iv Personal jurisdiction

The answer to this point has different approaches depending on whether the producer is a European Union national or not.

If the product manufacturer is a European Union national, European Parliament and Council Regulation No. 1215/2012 will apply. Therefore, if the claim has a contractual basis, the proceedings shall be initiated before the court where the obligation should have been fulfilled. In a situation regarding the sale of goods or the providing of services, it is considered that the place where the obligation should have been fulfilled is that where, according to the contract, the goods or services were or should have been delivered or provided. If the claim has a non-contractual basis, the proceedings shall be initiated before the court where the damage has occurred.

If the product manufacturer is not a European Union national and no other specific international regulation applies, the Portuguese Civil Procedure Code rules regarding international competence will be applicable. Under Article 62 of the Civil Procedure Code, the Portuguese courts will be internationally competent if: (1) the fact that gives rise to the claim occurred, even if only partially, in Portugal; (2) the claimed right can only become effective if proceedings are initiated before Portuguese courts; or (3) there is, regarding the claimant, a significant difficulty in filing the claim abroad. In any case, there must be some kind of relevant connection between the object of the proceedings and the Portuguese legal system.

v Expert witnesses

There is no obstacle regarding intervention of experts within proceedings being discussed in Portugal. Experts may, however, intervene in three different capacities.

First, the parties are entitled to present written expert opinions in order to better defend their allegations or to raise doubts regarding statements made during the proceedings, even by other experts. The parties may indicate these expert witnesses to testify as part of their defence who, alongside the factual witnesses, will be heard on specific and technical issues.

Additionally, an expert (single or panel of three) may be appointed by the court to perform an independent expert analysis, either at the parties' request or by court determination. These experts will draft a written report and may be heard during the trial to provide clarifications.

Lastly, both the parties and the judge may appoint experts who, although not witnesses, may assist them before and during the trial. These experts are not heard and merely assist the judge and the parties in understanding the specific matters being discussed.

vi Discovery

There is no common law-style 'discovery' system in Portugal. Parties have to lodge the documents they consider necessary to substantiate and support their claims themselves and are not obligated, unless ordered by the court, to disclose documents that would hinder their claims.

The parties may, however, request specific documents (which must be identified to the extent possible, since 'fishing expeditions' are prohibited) that are in the possession of the counterparty or even of a third party or official entity. If the facts the applicant wants to demonstrate through those documents are relevant to the case, the court will then notify the other party or the third party to present them.

Further to this, parties are entitled to appoint as witness any person they want, who shall be notified to appear before the court or otherwise be subject to the payment of a fine and ultimately to compulsory transport to the court.

Parties can also request the deposition of the counterparty regarding unfavourable facts for confession purposes. The party has, in principle, the prerogative of appointing whom it wants to represent it before the court.

The court – with or without previous party request – can determine that an expert's analysis or a judicial inspection be performed.

vii Apportionment

Under the Portuguese general product liability regime, if several persons are responsible for the damages, they will be jointly and severally liable. The injured party may claim damages from one or all liable parties. If the proceedings are filed against only one party, that party may either request the joinder of the other parties to those proceedings or it may later claim contribution in the payment to the other liable parties.

Regarding the internal relations between the liable parties, if the actual contribution of each cannot be precisely determined, they will answer equally.

Regarding successor liability, the Portuguese legal regime will hold liable whomever acquires the rights and obligations of the formerly liable corporation.

viii Mass tort actions

There are no 'class actions' in the US sense in Portugal.

However, it is possible for several claimants to consolidate their claims in a single proceeding, without any limitation of numbers. The claimants' requests may differ from each other but they must originate from the same fact or facts. For example, if a major car company recognises a defect, several claimants may begin proceedings jointly, although claiming their own damages that result from said defect. The advantages resulting from this kind of action are mainly legal costs. The disadvantages are the complexity of the proceeding involving several claimants, which would tend to lengthen the duration of the proceedings.

The Portuguese legal system also provides for an 'action to defend general interests' which allows for any citizen, association, local authorities or the Public Prosecutor's Office to initiate proceedings in view of the defence of public health, environment, quality of life, cultural heritage and public dominion issues, as well as the protection of the consumption of goods and services. These actions are, however, seldom used.

ix Damages

Portuguese law is based on the general principle that damages should place the injured party in the same position he or she would have been in had the event causing the damage not occurred. This includes both economic and non-economic (moral) damages. Punitive damages are not provided for and there is no cap on the amount of damages that can be awarded in the Portuguese legal system.

Under the Product Liability Act, damages are subject to the same general principles referred to above. However, damage to, or destruction of any item of property – other than the defective product itself – can only be awarded if the item of property is ordinarily intended for private use or consumption and was used by the injured party for his or her private use or consumption. If the damages to goods satisfy these two conditions, they may only be awarded if they exceed €500.

Criminal and misdemeanour sanctions can be imposed both on the producer company and on specific individuals within the corporation (if there is an individual responsibility).

V YEAR IN REVIEW

2016 was a quiet year for product liability, with no legislative changes. No major decisions were rendered by the Portuguese appellate courts, which, in essence, do not differ from previous case law.

In Portugal, injured parties mainly continue to claim directly from the supplier and the producer, having, in most cases, some difficulties in identifying them when they are foreign entities with no seat in Portugal. These difficulties tend to delay proceedings but ultimately the producer does end up being summoned to the proceedings.

Insurance companies are joined to the proceedings mostly at the request of the producer or the supplier and they tend to follow the defence strategy set out by the latter.

Portugal, like most EU Member States, has not implemented the principles set out in the European Commission's Recommendation on Collective Redress, 2013/396/EU.

Chapter 17

PUERTO RICO

Albéniz Couret-Fuentes and Elaine M Maldonado-Matías[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

Puerto Rico's legal system is unique among US jurisdictions. As a former colony of the Kingdom of Spain, it draws heavily from the civil law tradition. The Civil Code is the basic source of law in many areas of private law, including tort law.[2] Puerto Rican courts frequently rely on three sources of law: (1) written law; (2) judicial opinions; and (3) the work of *tratadistas*. The *tratadistas* ('treatise writers') are scholars who author detailed commentaries on the civil law, just like scholars who analyse the common law.[3]

However, owing to Puerto Rico's relationship with the US, which began with the 1898 Treaty of Paris,[4] common law has heavily influenced local legislation, judicial opinions and legal commentary.[5] Puerto Rico's system is thus a mixture of Spanish civil law, US common law and US-style constitutional and procedural law. As the federal district court in Puerto Rico once said, 'Puerto Rico is the beneficiary of two great legal systems. Out of the interaction and synthesis of these systems, but without eclipsing or banning one or the other, a new *Derecho Puertorriqueño* can and does emerge.'[6]

Product liability is an area heavily influenced by common law. The doctrine of strict product liability cannot be found in the Civil Code;[7] however, to 'fill a gap in our body of laws'[8] the Supreme Court of Puerto Rico incorporated the principle of strict product liability under the guise of Article 1802 of the Civil Code, Puerto Rico's general tort provision.[9]

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2 *In re Dupont Plaza Fire Litigation*, 687 F. Supp. 716, 726 (D.P.R. 1988).

3 Id.

4 Treaty of Peace between the United States of America and the Kingdom of Spain, Articles I-III, 10 December 1898, United States-Spain, 30 Stat. 1754, 1755 (1899) (Spain ceding the Philippines, various West Indies, Guam, and Puerto Rico to the US).

5 *In re Dupont Plaza Fire Litigation*, 687 F. Supp. at 727.

6 *Diaz Irizarry v. Ennia, N.V.*, 678 F. Supp. 957, 962 n.5 (D.P.R. 1988).

7 *Isla Nena Air Servs., Inc. v. Cessna Aircraft Co.*, 449 F.3d 85, 92 (1st Cir. 2006).

8 *Rivera Santana v. Superior Packaging, Inc.*, 132 D.P.R. 115, 125 n.4 (1992).

9 *Ramos Santiago v. Wellcraft Marine Corp.*, 93 F. Supp. 2d 112, 120 (D.P.R. 2000) ('The doctrine of strict product liability was created by the Supreme Court of Puerto Rico under the aegis of Article 1802 of the Civil Code (Puerto Rico's general tort statute).').

Even though, long ago, the Court urged legislation in the area of product liability,[10] the call fell on deaf ears. Hence, product liability law remains an area largely governed by case law.[11]

II REGULATORY OVERSIGHT

Like the federal government and the states of the Union, Puerto Rico has administrative bodies with regulatory, adjudicatory and enforcement authority over matters related to product safety. These include:

a the Department of Consumer Affairs, whose main purpose is to enforce regulation directed at protecting consumer rights, restrain inflation and oversee prices on consumer goods and services;[12]

b the Environmental Quality Board, charged with implementing Puerto Rico's constitutional and statutory public policy on environmental matters[13] and, as such, has regulatory and enforcement power regarding product and business regulations to control contamination and pollution; and

c the Occupational Safety and Health Administration of the Puerto Rico Department of Labor, which enacts and enforces workplace safety regulations.[14]

Puerto Rico can, and does, resort to the courts in the exercise of its *parens patriae* authority to seek damages, including in product liability cases.[15]

III CAUSES OF ACTION

Pursuant to Article 1802, '[a] person who by an act or omission causes damage to another through fault or negligence shall be obliged to repair the damage so done.'[16] A plaintiff ordinarily needs to establish three elements: (1) damage; (2) the causal relationship between the damage and the act or omission; and (3) that the act or omission was negligent or wrongful.[17] While the third prong requires showing negligent or wrongful conduct, according to the Supreme Court, this left a void when addressing many product liability claims.[18]

10 See *Rivera Santana*, 132 D.P.R. at 125 n.4.

11 See id. ('[the Puerto Rico Supreme Court] adopted, through case law, the US common law products liability principles […] to develop this field […] notwithstanding the fact that our legal system is rooted in the civil law that puts emphasis on positive or written law.').

12 3 L.P.R.A Section 341 et seq.

13 See P.R. Const Article VI, Section 19; 12 L.P.R.A. Section 8001 et seq.

14 29 L.P.R.A. Section 361 et seq.

15 See, e.g., *In re MTBE Prods. Liab. Litig. (Commonwealth of Puerto Rico v. Shell Oil Co. et al.)*, Civil Nos. 07-10470, 14-01014 (SAS) (S.D.N.Y.).

16 31 L.P.R.A. Section 5141.

17 *Santini Rivera v. Serv Air, Inc.*, 137 D.P.R. 1, 6 (1994); see also *Irvine v. Murad Skin Research Lab.*, 194 F.3d 313, 321 (1st Cir. 1999).

18 *Rivera Santana*, 132 D.P.R. at 125 ('In an effort to meet Puerto Rico's social needs, by judicial act, and as a question of public policy, we have laid down and adopted the manufacturer's strict liability rule for defective products.').

To fill the perceived gap, the Court relied heavily on the strict liability theory developed in California.[19] Puerto Rico law currently recognises the application of the strict liability doctrine for many claims involving: (1) design defects; (2) manufacturing defects; and (3) defects for failure to provide suitable instructions or warnings.[20] For these claims, the Court eliminated the requisite negligence factor of a general tort claim.[21] Under the strict liability rule governing cases of this kind in Puerto Rico's legal system, the injured party need not prove the negligence of the manufacturer or the seller, but must prove that the product was defective.[22]

i Design defects

To establish strict liability for a design defect under Puerto Rican law, the plaintiff must show that the defendants 'place[d] a product on the market, knowing that it is to be used without inspection for defects, and it has a defect that causes injuries'.[23] Puerto Rico has generally adopted the principles of strict liability set out in the Restatement (Second) of Torts Section 402A,[24] which provides that:

> *[O]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.*

However, Puerto Rican law rejects the Restatement's requirement that the product be 'unreasonably dangerous to the user or consumer'. Instead, the plaintiff only needs to establish that the product is unsafe.[25]

For design defect claims, the Supreme Court of Puerto Rico has embraced the 'two-alternatives test' set out in California in *Barker v. Lull Engineering*.[26] The first is known as the 'consumer expectations test' and imposes liability if 'the plaintiff establishes that the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner'.[27] The consumer expectations test applies when 'the everyday experience of the product's users permit a conclusion that the product's designs violated minimum safety assumptions.'[28] Under the 'risk-utility test', there is liability if the product's design proximately caused injury and the benefits of the product's design do not

19 See *Mendoza v. Cervecería Corona*, 97 D.P.R. 499 (1969); *Guevara v. Dorsey Labs., Div. of Sandoz, Inc.*, 845 F.2d 364 (1st Cir. 1988); see also *Collazo-Santiago v. Toyota Motor Corp.*, 937 F. Supp. 134, 136-39 (D.P.R. 1996) (collecting cases).

20 *Aponte Rivera v. Sears Roebuck de P.R., Inc.*, 144 D.P.R. 830, 839-40 (1998); *Rivera Santana*, 132 D.P.R. at 128; *Montero-Saldaña v. Am. Motors, Corp.*, 107 D.P.R. 452, 462 (1978).

21 *Rivera Santana*, 132 D.P.R. at 126 n.5.

22 Id. (emphasis added).

23 *Malavé-Félix v. Volvo Car Corp.*, 946 F.2d 967, 971 (1st Cir. 1991).

24 *Cruz Vargas v. R.J. Reynolds Tobacco Company*, 218 F. Supp. 2d 109, 119 (D.P.R. 2002).

25 Id. (citing *Montero Saldaña*, *supra*).

26 *Quintana-Ruiz v. Hyundai Motor Corp.*, 303 F.3d 62, 77 (1st Cir. 2002).

27 *Barker*, 573 P.2d at 446.

28 *Quintana-Ruiz*, 303 F.3d at 77.

outweigh the risk inherent in such design.[29] Where the defect in question involves complex and technical issues, 'particularly within the knowledge of the manufacturer', the risk-utility analysis applies.[30]

In a negligent design claim the plaintiff must establish that (1) the defendant owed a duty to prevent the harm by conforming to a reasonable standard of conduct; (2) the defendant breached that duty through a negligent act or omission; and (3) the negligent act or omission caused the plaintiff's harm.[31] The plaintiff bears the burden of establishing the applicable standard of care and proving that the defendant acted below the standard.[32]

ii Manufacturing defects

For manufacturing defects claims, the Supreme Court adopted the definition of 'defect' suggested by Chief Justice Traynor in *Greenman v. Yuba Powers, Inc*[33] to the effect that '[a] defective product may be defined as one that fails to match the average quality of like products, and the manufacturer is then liable for injuries resulting from deviations from the norm.'[34] 'A manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being and that liability is not one governed by the law of contract warranties but by the law of strict liability in tort.'[35]

iii Failure to warn

Strict liability failure to warn cases may exist 'if the manufacturer or seller fails to provide the user with adequate warnings or instructions on the dangers or risks inherent to its handling or use'.[36] These claims require showing that: (1) the manufacturer knew or should have known of the product's inherent risk; (2) warnings or instructions were not provided or those provided were inadequate; (3) the absence or inadequacy of the warnings made the product inherently dangerous; and (4) the absence of adequate warnings or instructions was the proximate cause of the injury.[37]

A negligent failure to warn claim requires a showing that the defendant 'failed to exercise due diligence to avoid foreseeable risks'.[38] Both strict liability and negligent failure to warn claims require that the plaintiff proves that 'it is more likely than not' that the defendant's failure to provide adequate warnings 'was a substantial factor' in causing the injury.[39]

29 Id.

30 Id. at 69; see also *Fremaint v. Ford Motor Co.*, 258 F. Supp. 2d 24, 30 (D.P.R. 2003) ('ordinary consumers are ill-equipped to decide what minimum safety to expect from seatbelts […]').

31 *Prado Álvarez v. R.J. Reynolds Tobacco Co.*, 313 F. Supp. 2d 61, 73 (D.P.R. 2004), aff'd, 405 F.3d 36 (1st Cir. 2005).

32 *Fremaint*, 258 F. Supp. 2d at 28.

33 327 P.2d 897, 901 (Cal. 1962).

34 *Rivera Santana*, 132 D.P.R. at 127.

35 Id. at 125-26 (quoting *Greenman*, 377 P.2d at 900) (internal quotation marks omitted).

36 Id. at 130.

37 *Carrelo v. Advanced Neuromodulation Sys.*, 777 F. Supp. 2d 303, 311–12 (D.P.R. 2011).

38 *Jiménez v. Pelegrina*, 112 D.P.R. 700 (1982).

39 *Prado Álvarez*, 313 F. Supp. 2d at 76.

iv Breach of warranty

Articles 1373-1375 of the Civil Code[40] require certain product quality warranties. A cause of action for violation of this duty requires showing that: (1) the defect was hidden or concealed; (2) was unknown to the purchaser at the time of the sale; (3) is harmful to the utility of the product; and (4) existed before sale.[41] The purchaser may choose to rescind the contract (redhibitory action) or demand a proportional reduction of the sale price (*quanti minoris* action).[42]

However, since the 1953 case *Castro v. Payco, Inc*,[43] Puerto Rico recognised a cause of action for breach of implied warranties based partly in the Puerto Rico Food, Drugs, and Cosmetics Act, and modelled on the doctrine developed in Louisiana.[44] These actions are, in essence, strict liability claims.[45] According to the Court, Puerto Rican law impliedly demands warranty that all products are wholesome and fit for human consumption. Citing the Louisiana decisions, the Supreme Court of Puerto Rico asserted that 'everyone knows the qualities, good or bad, of the things which he fabricates in the exercise of his art, craft or business and that lack of such knowledge is imputed to him as a fault which makes him liable to the purchasers of his manufactured products for the damages resulting from imperfections or defects which he did not make known to the purchasers and of which they are ignorant.'[46]

IV LITIGATION

i Forum

Product liability claims can be brought in the Puerto Rico Court of First Instance or in the US District Court for the District of Puerto Rico. Plaintiffs will frequently try to file the claim in federal court to demand a trial by jury, since Puerto Rican law does not provide for jury trials in civil cases.[47] Plaintiffs can file claim in federal court either when: (1) it is asserted

40 31 L.P.R.A. Sections 3841-43.

41 *Boyd v. Superior Court*, 101 D.P.R. 651 (1973); see also *Simonet v. SmithKline Beecham Corp.*, 506 F. Supp. 2d 77, 84 (D.P.R. 2007).

42 *Simonet*, 506 F. Supp. 2d at 84. The consumer may also seek *quanti minoris* remedy when a product does not comply with an express warranty. Id.

43 75 D.P.R. 63 (1953).

44 *In re Dupont Plaza Fire Litigation*, 687 F. Supp. at 787.

45 *Kunkel v. Motor Sports*, 349 F. Supp. 2d 198, 210 (D.P.R. 2004) (under Puerto Rico law 'breach of warranty claims are tantamount to strict liability claims under Puerto Rico law.') (citations and footnote omitted).

46 *Castro*, 75 D.P.R. at 73 (citing *Boyd v. J.C. Penney Co.*, 195 So. 87 (La. Ct. App. 1st Cir. 1940); *Ogden v. Rosedale Inn*, 189 So. 162 (La. Ct. App. Orl. 1939); *Kelly v. Ouachita Dairy Dealers Cooperative Associations*, 175 So. 499 (La. Ct. App. 2d Cir. 1937); *MacLehan v. Loft Candy Stores*, 172 So. 367 La. Ct. App. Orl. 1937).

47 See *González-Oyarzun v. Caribbean City Builders, Inc.*, 798 F.3d 26 (1st Cir. 2015) (holding that, like in the states of the Union, the Seventh Amendment to the US Constitution does not require Puerto Rico to provide jury trials in civil cases).

in a case that raises a federal question;[48] (2) under the court's diversity jurisdiction, when all the plaintiffs and the defendants reside in different 'states';[49] and (3) under the court's admiralty jurisdiction.[50]

Cases filed in Puerto Rican courts that are nonetheless removable to federal court[51] present important judgement calls for defendants. For instance, defendants need to decide whether their preference for a federal forum outweighs the risks of a trial by jury. US and foreign defendants may want to remove cases to federal court because the proceedings in Puerto Rican cases are mostly in Spanish.[52] English language proceedings in federal court facilitate these defendants' understanding of developments in their cases and their assistance in the litigation. Yet, since the federal court record must be in English, litigants will frequently need to spend money to translate relevant Spanish language decisions and commentary materials, documentary evidence and testimony.[53]

ii Burden of proof

Plaintiffs have the burden to establish the elements of the causes of action in Puerto Rican product liability cases.[54] The plaintiff must introduce evidence that affords a reasonable basis for the conclusion that it is 'more likely than not' that the conduct of the defendant was a substantial factor in bringing about the result.[55] Manufacturing defect claims where the

48 See 28 U.S.C. Section 1331 (governing federal question jurisdiction for cases 'arising under the Constitution, laws, or treaties of the United States'.); see also *Gaming Corporation of America v. Dorsey & Whitney*, 88 F.3d 536, 543 (8th Cir. 1996) ('The presence of even one federal claim gives the defendant the right to remove the entire case to federal court.') In addition to actions involving federal claims, in some, albeit limited circumstances, the 'federal ingredient doctrine' allows federal courts to exercise jurisdiction over a 'special and small category of cases' where a 'state-law claim necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.' *One & Ken Valley Housing Group v. Maine State Housing Authority*, 716 F.3d 218 (1st Cir. 2013) (quoting *Gunn v. Minton*, 133 S. Ct. 1059, 1065 (2013)).

49 28 U.S.C. Section 1332 (diversity jurisdiction); see also id. Section 1332(e) (providing that the term 'States' for purposes of the federal courts' diversity jurisdiction includes Puerto Rico).

50 Id. Section 1333 (admiralty jurisdiction).

51 Id. Section 1441 (removal of actions that could have been filed in federal court).

52 P.R. Rule of Civil Procedure 8.7 allows filings in English, but, as a matter of reality, the proceedings are largely conducted in Spanish.

53 See 48 U.S.C. Section 864 ('All pleadings and proceedings in the United States District Court for the District of Puerto Rico shall be conducted in the English language.'); *Puerto Ricans for P.R. Party v. Dalmau*, 544 F.3d 58, 67 (1st Cir. 2008) ('[F]ailure of defendants to provide a translated copy of a critical decision alone warranted denial of their motion.'); P.R. Dist. Local Rule 5(g) (requiring English translations for '[a]ll documents not in the English language which are presented or filed, whether as evidence or otherwise'); First Circuit Local Rule 30.0(e) ('Whenever an opinion of the Supreme Court of Puerto Rico (or other Commonwealth of Puerto Rico court) is cited in a brief or oral argument which does not appear in the bound volumes in English, an official, certified or stipulated translation thereof shall be filed.').

54 See, e.g., *Prado Álvarez*, 313 F. Supp. 2d at 75–76 ('In Puerto Rico, tort plaintiffs have the burden of establishing that the conduct of the defendant caused their injuries.'); *Muñiz-Núñez v. American Home Products Corp.*, 582 F. Supp. 459, 461 (D.P.R. 1984) ('The issue of causation, even in cases where liability is perfectly strict, requires the plaintiff to satisfy the burden of establishing that the particular defendant has sold a product which he should not have sold and that it caused his injury.')

55 *Prado Álvarez*, 313 F. Supp. 2d at 76.

risk-utility test analysis applies are characterised by burden-shifting. Plaintiffs must 'establish a *prima facie* case of causation'. If the plaintiff meets its burden, the defendants must show that the 'overall utility [of the product] exceeds the overall risk'.

Generally, the defendant bears the burden of establishing the facts that would eliminate or reduce liability. However, in actions filed after the initial time-limitations period has elapsed,[56] the plaintiff bears the burden of proving timeliness.[57]

iii Defences

Statutes of limitation

In Puerto Rico, the statute of limitations is substantive law, not a procedural matter.[58] A one-year limitations term applies to product liability claims under Article 1802.[59]

The limitations term begins when the injured person has actual or constructive notice of the injury and knowledge of the identity of the tortfeasor.[60] Article 1802 claims are subject to extrajudicial tolling by either an extrajudicial claim (usually a pre-complaint settlement demand) or an act of acknowledgment by the tortfeasor.[61]

Claims for breach of implied warranty owing to hidden defects under Articles 1373–1375 are subject to a six-month limitations term.[62] The term runs from the day on which the parties' efforts to solve the dispute are 'interrupted'.[63]

Intervening cause

'Intervening causes can break the chain of causation if they are not foreseeable.'[64] This refers to 'a cause of injury that 'comes into active operation in producing the result after the actor's negligent act or omission has occurred."[65]

Assumption of risk

Under Puerto Rican law, a defendant is allowed to argue that the plaintiff assumed the risks of a defective product. However, Puerto Rico has adopted the norm established in California in *Daly v. General Motors Corp*.[66] Accordingly, a plaintiff's assumption of risk will not eliminate the defendant's liability, but will only allow a reduction in the damages that can be recovered.[67]

56 See Section IV.iii, *infra*.

57 *Tokyo Marine & Fire Ins. Co. v. Pérez & Cia. Inc.*, 142 F.3d 1, 4 (1st Cir. 1998).

58 *Estate of Rosario v. Felken Tire Corp.*, 109 F. Supp. 3d 485, 490 (D.P.R. 12 2015).

59 31 L.P.R.A. Section 5298.

60 *González-Pérez v. Hosp. Interamericano de Medicina Avanzada*, 355 F.3d 1, 2 (1st Cir. 2004).

61 Article 1873 of the Civil Code, 31 L.P.R.A. Section 5303; see also *Sánchez et al. v. A.E.E.*, 142 D.P.R. 880 (1997).

62 Article 1379 of the Civil Code, 31 L.P.R.A. Section 3847.

63 *Ferrer Delgado v. General Motors Corp.*, 100 D.P.R. 246, 256 (1971).

64 *Malavé-Félix*, 946 F.2d at 972 (citing *Gines v. P.R. Aqueduct & Sewer Auth.*, 86 P.R.R. 518, 523 (1962)).

65 *Marshall v. Pérez Arzuaga*, 828 F.2d 845, 848 (1st Cir. 1987).

66 575 P.2d 1162 (Cal. 1978).

67 *McPhail v. Municipality of Culebra*, 598 F.2d 603, 606 (1st Cir. 1979) (citing *Montero Saldaña*, *supra*).

Comparative fault or negligence

Under Article 1802, a plaintiff's fault or negligence causes a corresponding reduction of its compensatory damages.[68] This doctrine applies to strict liability and negligence product liability claims.[69]

Absorption of fault

Under the absorption theory, if one tortfeasor is only slightly responsible, the overwhelming negligence of the other tortfeasor 'absorbs' the minimal negligence of the former and the latter bears all liability.[70]

iv Personal jurisdiction

Puerto Rico's long-arm statute extends personal jurisdiction to the full extent allowed under the US Constitution.[71] The exercise of personal jurisdiction is guided by 'whether the exercise of personal jurisdiction […] would abide by constitutional guidelines' of due process (i.e., the familiar test used in the US).[72]

While plaintiffs frequently sue parent companies together with their local subsidiaries, '[u]nder Puerto Rican law there is a presumption that a corporate entity is separate from its controlling entity.'[73] Courts only exercise jurisdiction over a foreign parent company when there is a 'plus factor' beyond the 'subsidiary's mere presence within the bosom of the corporate family'.[74] Plus factors include an agency relationship between the parent and the subsidiary or a finding that the subsidiary is a mere shell for the parent's operations.[75] Mere ownership of a subsidiary is insufficient to justify asserting personal jurisdiction over the parent wherever the subsidiary is present.[76]

v Expert witnesses

In federal litigation, courts apply the test set forth in the US Supreme Court decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[77] The First Circuit has said that *Daubert* requires 'that the proponent of the evidence show that the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion'.[78]

The committee in charge of drafting the current version of the Puerto Rico Rules of Evidence refused to endorse the *Daubert* approach in favour of a more flexible approach.[79]

68 *Cárdenas Maxán v. Rodríguez Rodríguez*, 125 D.P.R. 702 (1990).

69 *Montero Saldaña v. Am. Motors*, 107 D.P.R. 452, 463–65 (1978).

70 *Ruiz Troche v. Pepsi Cola of Puerto Rico*, 161 F.3d 77, 87 (1st Cir. 1998).

71 P.R. Rule of Civil Procedure 3.1(a)(2).

72 *González-Díaz v. Up Stage Inc.*, No. 11 Civ. 1689, 2012 WL 2579307, at *1 (D.P.R. 3 July 2012).

73 *Colón v. Blades*, 757 F. Supp. 2d 107, 109 (D.P.R. 2010) (internal quotations and citations omitted).

74 *In re MTBE Prods. Liab. Litig.*, 959 F. Supp. 2d 476, 489 (S.D.N.Y.2013) (quoting *Donatelli v. National Hockey League*, 893 F.2d 459, 465–66 (1st Cir. 1990)).

75 Id.; *Escude Cruz v. Ortho Pharm. Corp.*, 619 F.2d 902, 905 (1st Cir. 1980).

76 *Donatelli*, 893 F.2d at 465–66.

77 509 U.S. 579 (1993); see also *Cruz-Vázquez v. Mennonite Gen. Hosp., Inc.*, 717 F.3d 63 (1st Cir. 2013).

78 *Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998).

79 Comité Asesor Permanente de Reglas de Evidencia, Informe de las Reglas de Derecho Probatorio, 2007, at 424.

Instead, under Rules 702 and 703 the testimony of an expert is admissible if the witness has some scientific, technical or specialised knowledge that could help the court to understand the evidence or to adjudicate a fact in controversy.[80]

vi Discovery

Under the Puerto Rico Rules of Civil Procedure, discovery mainly includes the same practice used in federal litigation (i.e., meetings among attorneys to propose a discovery plan, initial disclosures, written discovery, production of documents, fact and expert witnesses depositions, subpoenas to third parties to compel testimony or the production of documents, and the duty to try to resolve discovery disputes without the need to request orders from the court). Puerto Rico also recognises most of the privileges applicable in federal litigation, such as the attorney-client privilege and the work product privilege, among others.

vii Apportionment

Under Puerto Rican law, 'all those who take part in the manufacturing and distribution chain of a product are solidarily liable, along with the manufacturer, to the injured party.'[81] Solidarity is very similar to joint and several liability. The essential feature of solidarity is that the solidary debtors are jointly responsible for the same obligation.[82] An aggrieved party may collect the entirety of the damages from one, some, or all of the joint tortfeasors.[83] Under Article 1098 of the Civil Code,[84] joint debtors can demand payment for the amount that exceeds their share of responsibility for the damages.[85]

viii Mass tort actions

Puerto Rico allows class actions in a manner very similar to federal law. The filing of a class action tolls the statute of limitations for all members of the putative class even if class certification is ultimately denied. The limitations term begins to run again once certification is denied.[86]

The judiciary has also adopted Complex Litigation Rules, allowing for the consolidation of cases, whether pending in one or more judicial regions, with the purpose of eliminating unnecessary burdens on the parties and the judiciary's resources.[87] The criteria to evaluate whether a complex litigation case should be created includes:

a the number of parties involved;

b the number of allegations and defences;

80 *S.L.G. Font Bardón v. Mini-Warehouse*, 179 D.P.R. 322, 344 (2010); see also Ernesto L Chiesa, Reglas de Evidencia de Puerto Rico 2009, at 223–224.

81 *Aponte Rivera*, 144 D.P.R. at 838 n.6; see also *Del Rosario-Ortega v. Star-Kist Caribe, Inc.*, 130 F. Supp. 2d 277, 284 (D.P.R. 2001) (citing *Ferrer Delgado v. Gen. Motors Corp.*, 100 D.P.R. 246, 257-258 (1971) ('[In] a cause of action in products liability, […] as a matter of public policy, each and every entity involved in the chain of distribution is strictly liable to the consumer'), *rev'd on other grounds sub nom. Exxon Mobil Corp. v. Allapattah Servs.*, 545 U.S. 546 (2005).

82 *Tokyo Marine and Fire Ins. Co.*, 142 F.3d at 5.

83 *Zurich American Ins. v. Lord Elec. Co. of Puerto Rico*, 828 F. Supp. 2d 462, 469 (D.P.R. 2011).

84 31 L.P.R.A. Section 3109.

85 See *García v. Gobierno de la Capital*, 72 D.P.R. 138 (1951).

86 *Rivera Castillo v. Mun. de San Juan*, 130 D.P.R. 683 (1992).

87 P.R. Complex Litigation Rule 3(d).

c the number of potential witnesses;
d the volume of potential evidence;
e the need for expert evidence;
f the complexity of the issues of fact and law and whether these need an unusual amount of evidence to be evaluated;
g the complexity of the remedy sought;
h whether a complex appellate process is anticipated;
i whether the cases have been certified as class actions; and
j the anticipated complexity of the pretrial proceedings.[88]

ix Damages

Courts applying Puerto Rican general tort law can only grant compensatory damages. Punitive damages are not available in Puerto Rico for strict product liability or negligence claims.[89] The trial courts have broad discretion in determining the amount of damages and the appellate courts will only reverse an award if it is extremely low or high.

V YEAR IN REVIEW

Recently, the Federal District Court in Puerto Rico faced an interesting situation as a result of a motion to dismiss a claim filed to recover damages for injuries suffered after a Florida resident allegedly consumed toxic shrimp in a Puerto Rican restaurant and suffered paralytic shellfish poisoning, eventually causing him incomplete quadriplegia.[90] The defendants argue against the imposition of strict liability because the relevant product was not manufactured or fabricated.[91]

Noting that the Supreme Court of Puerto Rico has, generally, applied the doctrine of strict liability to defects in manufactured food products, the Federal District Court found insufficient guidance to predict how Puerto Rico's highest court would rule with regard to products that are not manufactured or fabricated. Hence, invoking the process by which federal court asks a state's highest court to clarify a question of 'state law',[92] the District Court certified the following questions to the Supreme Court:

a Under the principles of product liability, is a supplier or seller strictly liable for the damage caused by human consumption of an extremely poisonous natural toxin found in a shrimp, even if said food product (and its 'defect') are not a result of manufacturing or fabrication process?
b If the previous question is answered in the affirmative, would it make a difference if the 'defect' of the food product is readily discoverable scientifically or otherwise?[93]

88 P.R. Complex Litigation Rule 5.
89 *Guardiola-Álvarez v. Departamento de la Familia*, 175 D.P.R. 668, 681 (2009); *Noble v. Corporación Insular de Seguros*, 738 F.2d 51, 54 (1st Cir. 1984).
90 *González Pagán v. JR Seafood*, 132 F. Supp. 3d 274, 275 (D.P.R. 2015).
91 Id. at 278.
92 See generally Jona Goldschmidt, *Certification of Questions of Law: Federalism in Practice* (1995).
93 *González Pagán*, 132 F. Supp. 3d at 284-85.

At the time of writing, the Puerto Rico Supreme Court has accepted the certified questions and the case has been fully briefed. The Court has not issued a decision on the certified questions.[94]

This year, the Puerto Rico Supreme Court opinion *Rodríguez Méndez v. Laser Eye*,[95] addressed whether a manufacturer can be strictly liability for damage caused owing to inadequate maintenance of a product after purchase. *Rodríguez* summarises and reiterates much of the prior case law on the subject but also includes important clarifications.

First, while the Court dismissed the case for lack of evidence, it held that manufacturers and sellers are strictly liable if they know or should have known of the inherent risks of the inadequate use of the product, such as not providing proper maintenance, and did not warn or provide adequate instructions about such risk and about proper maintenance.[96] In other words, insufficient instructions about adequate maintenance can lead to strict liability under a failure to warn claim.[97] Finally, citing New York case law, the Court endorsed the application of the substantial modification defence and stated that alterations or incorrect uses of a product constitute valid defences in claims related to products that are not defective when initially placed in the market.[98]

Maldonado Rivera v. Suárez,[99] is an interesting follow-up in the relatively recent developments in the law on statute of limitations. In its 2012 decision in *Fraguada Bonilla v. Hosp. Aux. Mutuo*,[100] the Court had held that commencing an action against a tortfeasor no longer tolls the statute of limitations for claims against absent joint and several tortfeasors.[101] Applying *Fraguada*, *Maldonado* held that a defendant cannot bring a third-party claim against a joint and several tortfeasor after the original plaintiff's claim against the third-party defendant is time-barred. The Court also clarified that in these situations the trial court must subtract the amount of damages attributable to the absent tortfeasors.[102]

94 *González Pagán v. JR Seafood*, CT2015-0012 (Puerto Rico Supreme Court).

95 195 D.P.R. 769 (2016).

96 Id. at 784.

97 Id. at 788.

98 Id. at 783 (citing *Hoover v. New Holland N. Am. Inc.*, 11 N.E. 3d 693, 702 (N.Y. 2014)).

99 195 D.P.R. 182 (2016).

100 186 D.P.R. 365 (2012).

101 *Arroyo v. Hospital La Concepción*, 130 D.P.R. 596 (1992) (abrogated in *Fraguada*).

102 *Maldonado*, 195 D.P.R. at 212.

Chapter 18

RUSSIA

Sergey Yuryev[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

Product liability in Russia is regulated by the Civil Code of the Russian Federation (the Civil Code) and the Law on Consumer Protection dated 7 February 1992 (the Consumer Protection Law). Certain specific issues are also governed by other normative acts such as decrees of the government of the Russian Federation.

In Russia, rather than having a single product liability statute, the relevant rules are scattered among a variety of different laws. The Civil Code and the Consumer Protection Law contain a number of provisions by which manufacturers (sellers, importers, service providers as well as their representatives) may incur liability for loss or damage suffered by the consumers (as defined below) of their products, regardless of whether a direct contractual relationship exists.

As Russia belongs to the continental system of law, court rulings (precedents) are not considered to be an official source of law. However, the legal interpretation provided by higher courts is of great importance to lower courts. Legal doctrine is also not recognised as a source of law.

The term 'consumer' is defined in the Consumer Protection Law – it is an individual who has the intention of ordering or acquiring goods (including works or services) or who orders, acquires or uses them exclusively for personal, family, household or other needs not relating to entrepreneurial activities.

If an individual does not meet the required definition (e.g., an individual entrepreneur, who buys goods in the course of his or her business), he or she is not subject to the Consumer Protection Law. In this case the product liability is regulated by the general provisions of the Civil Code concerning obligations and liability as well as Part II of the Civil Code governing particular types of obligations.

Article 1095 applies where goods, work or services obtained by a consumer or on behalf of a consumer have caused damage to health, life or property as a result of (1) a defective design or formula or other defect in such goods, works or services, or (2) unreliable or insufficient information concerning such goods, works or services. Strict liability is applied regardless of whether or not contractual relations exist.

If a product fails to comply with its description or the regulations regarding production or labelling, it is considered to be 'defective' for the purposes of this provision, thus subjecting the defendant to liability.

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The test for whether 'insufficient information' was supplied to a consumer is quite uncertain. Currently, a manufacturer or seller is not expressly exempt from providing information on a product even if the risks associated with its use are 'open, obvious or commonly known'. In such cases, however, the court may reduce a defendant's liability in accordance with Article 1083 of the Civil Code, which deals with contributory negligence. Article 1083, however, does not permit the court to completely absolve the defendant of all liability if a consumer's health is damaged using the product.

The Consumer Protection Law is regarded as being supplementary to the Civil Code. General provisions from the Civil Code may be relied upon where further definition is needed.

Like the Civil Code, the Consumer Protection Law also imposes strict liability for goods that have caused damage to the health, life or property of a consumer as a result of (1) a defective design or formula or other defect in such goods, or (2) failure to provide a consumer with complete and reliable information concerning such goods, works or services. Again, for this liability to arise, privity of contract is not required.

Similar definitions, concerns and defences to those discussed in the paragraph above concerning Article 1095 apply when considering this liability.

A claim for damage caused to health, life or property as a result of (1) a defective design or formula or other defect in such goods, or (2) failure to provide a consumer with complete and reliable information concerning such goods, works or services may be brought against a manufacturer (either seller or executor) at the consumer's discretion.

Pursuant to the Consumer Protection Law, a manufacturer or seller must, as soon as it becomes aware of any risks of its products to the life, health or property of a consumer or to the environment, suspend the production or sale of any such products already on the market until the risk is eliminated. If appropriate, the manufacturer (seller) must recall the product from the market and from consumers. In the latter case the manufacturer (but not the seller) must compensate the consumer against losses suffered as a result of the product's recall.

The recall of products can also be ordered by the relevant authority. If the product is not recalled, an injured person may claim compensation for any damage caused by the product.

The basic feature of the Russian legislation regulating product liability is its pro-consumer orientation, under which additional warranties and rights are given to the consumer. The current court practice suggests that the overall legislative goal is to provide additional protection of consumer rights.

II REGULATORY OVERSIGHT

Consumer protection legislation grants a number of state agencies the authority to ensure product safety and also to control the protection of consumer rights.

Under Russian law, the state control and supervision of consumer protection as well as sanitary and epidemiological safety of the population is conducted by the Russian Federal Consumer Rights Protection and Human Health Control Service (Rospotrebnadzor) either directly or via its territorial subdivisions, as well as by cooperating with other executive bodies of the Russian Federation.

State control and supervision of consumer protection by Rospotrebnadzor acting pursuant to its Regulations approved by Resolution of the Russian Government No. 322 dated 30 June 2004 includes:

a verification of the manufacturer's (distributor's, seller's, etc.) compliance with the obligatory requirements set by international treaties, the Russian Consumer Protection Law and other federal laws and legal acts on consumer protection, as well as decrees issued by Rospotrebnadzor's authorities; and

b inspection of products (works, services) as being in conformity with obligatory requirements ensuring safety towards consumers and environment as well as preventing harm and damages thereto.

In order to perform the above-mentioned functions, Rospotrebnadzor's officials are authorised to, *inter alia*:

a attend premises used by the manufacturer (distributor, seller) to conduct the necessary inspections and control;

b collect samples of products to conduct analysis;

c urge manufacturers (distributors, sellers) to end any violation of consumer rights and obligatory requirements established by law;

d initiate administrative proceedings and adjudicate administrative cases regarding consumer protection;

e apply to the court to protect consumers, the general public and to bring class actions; and

f claim for the liquidation of any manufacturer (distributor, seller, etc.), if such legal entity has repeated infringed the law (twice or more within one year) as well as having the power to notify relevant authorities accordingly to initiate criminal proceedings.

Rospotrebnadzor also has the right to give an expert opinion in consumer protection cases and provides guidance to consumers regarding applicable legislation and regulations.

Apart from Rospotrebnadzor, protection of consumer rights in Russia is also conducted by municipal authorities that review applications from consumers, give necessary consultations and apply to courts to protect consumers.

There are also voluntary associations of consumers (generally formed as non-commercial enterprises) (there are more than 300 registered in Russia) who also protect consumers by, *inter alia*:

a providing legal support and consultation to consumers regarding their rights and the measures to be undertaken in order to secure those rights;

b applying to the courts in support of consumers, the general public, and bringing class actions and conducting public control; and

c informing Rospotrebnadzor and other authorities (i.e., police and state prosecution) about revealed violations, etc.

III CAUSES OF ACTION

Under the Consumer Protection Law the following entities may be held liable:

a manufacturers (an entity or an individual entrepreneur (IE) producing goods for consumers);

b executors (an entity or an IE conducting works or rendering services to consumers);

c sellers (an entity or an IE selling goods to consumers);

d authorised entities or IE (an entity or an IE engaged in a certain type of business or established in the territory of the Russian Federation by the manufacturer (seller),

including a foreign manufacturer (foreign seller) on a contractual basis to exercise certain functions and authorised to accept and satisfy consumer claims in respect of goods of improper quality); and

e importers (an entity or an IE engaged in importing products for their subsequent sale on the territory of the Russian Federation).

As noted above, in Russia rather than having a single product liability statute, the relevant rules are scattered among various laws. The Civil Code and the Consumer Protection Law contain a number of similar provisions by which manufacturers (sellers, importers, executors as well as their representatives) may incur liability for loss or damage suffered by the consumers of their products.

Article 1095 of the Civil Code and the Consumer Protection Law apply where goods, work or services obtained by a consumer have caused damage to health, life or property as a result of (1) a defective design or formula or another defect in such goods, works or services, or (2) unreliable or insufficient information concerning such goods, works or services.

Strict liability is applied regardless of whether contractual relations exist.

The test for whether 'insufficient information' was supplied to a consumer is quite uncertain. Currently, a manufacturer or seller is not expressly exempt from providing information on a product even if the risks connected with its use are 'open, obvious or commonly known'. In such cases, however, the court may reduce the defendant's liability in accordance with Article 1083 of the Civil Code, which deals with contributory negligence. However, Article 1083 does not permit the court to discharge the defendant from liability completely if a consumer's health is damaged using the product.

The Code of Administrative Offences establishes liability for certain offences committed against a consumer, such as:

a selling goods and rendering works or services of improper quality or violating the requirements of technical regulations and sanitary rules; such administrative offence leads to a fine of up to 50,000 roubles and seizure of the improper goods;

b consumer deception – acting dishonestly in measuring, weighing or counting, misleading consumers in respect of properties and qualities of goods (works, services), or acting dishonestly towards consumers in any other way; such activities lead to a fine of up to 500,000 roubles; and

c violating other consumer rights, such as:

- failure to provide necessary and reliable information about the goods (works, services) or about the manufacturer, seller or executor thereof) as well as failure to provide a consumer with privileges and advantages established by law; punished by a fine of up to 10,000 roubles; and
- providing a contract with terms and conditions that infringe consumer rights established by law; punished by a fine of up to 20,000 roubles.

The Criminal Code of the Russian Federation establishes two types of criminal product liability:

a negligent and unlawful termination or limitation of electrical energy supply to consumers or disconnection of consumers from other life support sources (committed by an official or individuals conducting managerial functions in an entity), which caused major damage or grievous injury to health or death. Such is punished by up to five years' imprisonment; and

b production, storage, carriage or sale of goods (rendering services or works) that do not meet standards of safety for a consumer's life or health; as well as the wrongful issue or use of an official document certifying compliance of such goods, works or services with safety standards. Such activities are punished with up to 10 years' imprisonment.

IV LITIGATION

i Forum

The Russian civil court system consists of two branches: courts of common jurisdiction and state commercial courts that specialise in cases arising from economic and business activities of legal entities.

Consumer claims are tried exclusively by the courts of common jurisdiction. Initially, the case is resolved by the court of first instance (the district court). This initial ruling may be challenged by either the appeal instance (where the case is reviewed on the merits once again) or the cassation court (which reviews the 'procedural' aspect of the case). Afterwards, the case may be finally reviewed by the Supreme Court of the Russian Federation.

In cases of appeal or cassation the case is reviewed by the higher court. The Supreme Court of the Russian Federation conducts supervisory review of product liability claims.

Minor claims (involving an amount less than around €580) are tried by magistrate judges. All other consumer cases are reviewed by a district court as the first instance court.

ii Burden of proof

The defendant (manufacturer, seller, executor, etc.) always has the burden of proof in product liability cases.

The causation between the defect and the loss has to be proved (or at least be claimed) by the consumer. Thus, it is for the defendant to prove the absence of such causation.

iii Defences

The law provides for a set of defences available to manufacturers (sellers, importers, service providers and their representatives) in consumer protection cases.

Contributory negligence

Where a claimant is at fault for incurring damage, the compensation awarded may be reduced depending on the degree of fault of the claimant. This limitation of damages (as opposed to a complete defence) is available by virtue of Article 1083 of the Civil Code. Article 1083, however, does not permit the court to absolve the defendant of all liability if a consumer's health or life is injured by using the product in question. Article 1083 of the Civil Code also states that an injured party may not claim compensation for injury resulting from his or her intentional consent to incur the damage claimed.

Manufacturers (sellers, importers, service providers and their representatives) will be fully absolved from liability if the damage, including damage to health or life, is caused solely owing to the consumer's breach of the manufacturer's instructions for use, storage or transportation of the product. The burden of proof is on the defendant to establish that the claimant suffered damage as a result of improper use of the product.

Time limitation

Article 1097 of the Civil Code states that in product liability cases the damage shall only be compensated if such damage was caused within either (1) the established lifetime or shelf life of the product, or (2) if the lifetime or shelf life is not established, within 10 years of the date of manufacture of the product. However, the latter defence may only be used when the manufacturer or seller is not required to specify a lifetime or shelf life for the product. Where the manufacturer or seller is required, but simply fails to specify the lifetime or shelf life, a consumer incurring loss may make a claim for compensation regardless of the time the damage was caused. The 'established lifetime or shelf life' of a product is defined as the period during which the product should be able to be used by consumers without danger to health or property (this is different from the 'warranty period', which is the period of time during which a manufacturer warrants, for example, to restore, repair or replace a product if the buyer is not satisfied with its quality).

Compliance with regulatory requirements

Products and product ingredients are quite broadly regulated (e.g., 'GOSTs' or 'state standards' set out technical characteristics or requirements for products; methods for sampling and testing products; and methods of packing, transportation and storage). Consumer protection legislation grants a number of state agencies the authority to ensure product safety and also to control the protection of consumer rights. A manufacturer that has complied with all the regulations and state standards may argue that he or she acted in good faith. Such defence is likely to be taken into account by the court for the purposes of determining the amount of compensation to be awarded. However, in cases where damage is caused to a consumer's health or life, the court will not accept such defence.

Force majeure

The defence of force majeure is available under the Consumer Protection Law to negate a manufacturer's or seller's liability in consumer protection cases. The Civil Code defines force majeure as extraordinary circumstances unavoidable in a given situation, for example, natural disasters, war and other major events that are clearly outside a party's control and cannot be avoided by the exercise of due care by that party. The Civil Code expressly provides that the failure of third parties, such as suppliers and subcontractors, to perform their obligations to the contracting party does not constitute force majeure.

iv Personal jurisdiction

Any foreign company whose products are used in Russia may be sued by Russian courts even if the entity does not have a representative office in Russia. *De jure* the defendant's place of residence does not have any effect on the outcome of the case. However, in such circumstances certain problems relating to notification may occur.

Although Russia is a member of the Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters 1965, the process of notifying the defendant in such circumstances may be very time-consuming and involve bureaucratic acrimony.

A consumer may have a choice of jurisdiction depending on the particular case – the claim may be submitted to the first instance court located at the:

a defendant's registered office;

b place of consumer's residence (permanent or temporary); or
c place at which the consumer contract was entered into or performed.

v Expert witnesses

Pretrial examination

Subject to the Consumer Protection Law, a consumer has the right to pre-judicial expertise at the expense of the seller (manufacturer, etc.). Being conducted by the seller (manufacturer, etc.), such expertise is considered to be a way of protecting the consumer's rights and is conducted where there is a dispute as to the origin of a product's defects.

The consumer has the right to be present during such examination and may challenge the results in the court.

If the court rules in favour of consumer unions acting on behalf of the general public, the liable seller (manufacturer, etc.) will reimburse the costs for independent expertise evidencing the breach of obligatory product requirements.

Judicial examination

Subject to the procedural rules, the court will appoint experts if any questions requiring special knowledge in science, technology, etc., appear within the case. Such expertise may be delegated to a forensic expert institution, an individual expert or a group of experts.

Each party may raise questions to be reviewed by such experts. The final list of questions to be answered is determined by the court. If the court dismisses any question raised by a party, it shall give a substantiated response thereto.

If either party escapes participation in the expert evidence process or makes its conduct impossible by any means, the court may acknowledge the issue in favour of its counterparty.

The expert assessment may be conducted within a court hearing or outside if it is necessary owing to the nature of the examined issue. The parties have the right to be present during the examination.

An expert will conduct a complete, independent and justified examination by answering all the questions raised by the court and the parties. Afterwards, the expert shall come to trial and respond to the questions connected with the conducted examination.

Where the issues exceed the bounds of special knowledge or the materials and the documents are insufficient or improper, the expert will provide the court with a written and reasonable notification about the impossibility of conducting the examination.

The parties may demand the appointment of a particular expert, but it is the court that ultimately decides. The parties may also obtain private expert opinions, although such opinions have no significant value. Their main purpose is to influence the court-appointed experts in their conclusions (or to criticise it).

vi Discovery

The procedural legislation does not provide any special regulation similar to the discovery/disclosure procedure in the United Kingdom or the United States. Owing to fundamental differences in the procedure law, a Russian court has a much more significant role in the court hearing and the examination of evidence.

Subject to the procedural legislation, evidence is considered legally obtained information about the facts constituting the claims and objections of the parties, as well as other circumstances that are important for the correct examination and resolution of the case.

Such information may be obtained by the court from:

a explanations of the parties or third persons;
b testimony of witnesses;
c written or material evidence;
d audio and video materials; and
e expert examination.

No evidence may have its force established in advance. The court will assess the relevance, admissibility and authenticity of all evidence, as well as its sufficiency and interconnection.

Each party must prove the circumstances it refers to within the claim or objection. However, it is the court that determines which circumstances are relevant to the case and which party successfully proves it. The court may also propose the parties bring additional evidence.

Explanations of the parties or third persons

Explanations of the parties or third persons concerning the circumstances necessary to resolve the case are checked and evaluated like any other evidence. Thus, such explanations do not take precedence over other evidence, such as witness or material evidence. In addition, if the party acknowledges any facts constituting the claim of the counterparty, the latter does not have to prove it later on.

Witness evidence

Such evidence provides any facts that may assist the case adjudication. However, witness evidence may not be considered by the court if the witness cannot name the source of its information. Legal representatives, judges and members of the jury shall not be considered as witnesses.

Witnesses must come to trial and give true evidence. The Russian Criminal Code provides criminal liability for intentional misrepresentation by a witness.

Written and material evidence

Written evidence is any possible documents that provide information about the circumstances of the case and must be filed in original form or a duly verified copy.

Material evidence is any object that by its nature may lead to an adjudication of the case. Generally, such evidence is kept at the court. Where the material evidence cannot be delivered to the court, the judge shall examine the piece of material at the place where the evidence is kept.

vii Apportionment

The concept of 'apportionment' is not recognised by Russian law. As indicated, Russian legislation directly specifies the list of the 'liable' entities that bear joint and several liability under consumer claims.

viii Mass tort actions

The concept of class action is not recognised in Russian legislation. Under procedural law, if a judge establishes that there are several similar cases involving the same or similar parties,

or that various claims against the same defendant were filed in one court, the court may aggregate those cases into one proceeding in order to have a combined hearing, provided this ensures a more expedient and accurate consideration and resolution.

The Consumer Protection Law specifically allows certain state agencies, local authorities and consumer protection associations to file lawsuits on behalf of an indefinite number of consumers. In these cases, however, a court may only issue an injunction against the wrongdoing rather than award damages. Also, the court may declare the activity illegal; such a declaration would have a *res judicata* nature and may be subsequently used by an individual in a separate private claim for damages.

ix Damages

The general remedy against injury caused by defective products is compensation in the form of damages.

Russian law requires full compensation for all damage. The definition of damage includes expenses actually incurred or to be incurred in order to restore the right breached, property loss or damage and lost profits. In the case of bodily injury, the compensation may include regular payments based on the loss or earnings of the injured party and payments for medical treatment and medicine; in the case of wrongful death, payments shall be made to dependants. However, a court may take any contributory negligence or intent of the victim into account and lessen the amount of compensation if necessary.

In addition, the claimant may be awarded 'moral damages' (i.e., compensation for physical and emotional suffering) above the actual damages. Moral damages are available to the claimant only when the damage was caused at the fault of the defendant. The levels of moral damages awarded in reported case law have not been that high, however they do appear to be increasing.

Moreover, by virtue of the Consumer Protection Law if a claimant wins a case the court is required to impose a fine on the defendant equal to 50 per cent of the amount awarded to the claimant. The fine is normally payable to the state budget. In cases where the claim has been brought by a local authority or a consumer protection association, half of the penalty is payable to the local authority or the consumer protection association, respectively.

Apart from the right to claim for damages caused by a product of improper quality, the consumer has the right, at his or her own discretion, to choose to:

a demand its replacement with a product of the same brand (model, type);

b demand its replacement with a product of another brand (model, type) with the relevant recalculation of the purchase price;

c demand a proportional decrease of the price for the product;

d demand immediate and free-of-charge remediation of the defects of the product or reimbursement of the expenses of their remediation by the consumer or by a third person; or

e refuse to perform the sale-purchase agreement and demand the return of the price paid for the product – the consumer may return the defective product at the seller's request and at the seller's expense.

Additionally, the Consumer Protection Law provides that the seller (manufacturer, etc.) must pay a penalty to the consumer, of 1 per cent of the price of the goods for every day of delay,

for failure to abide by the time limits for satisfying the aforementioned remedies. Although the law does not cap the maximum amount of such penalty, the courts usually limit such compensation by awarding not more than 100 per cent of the price of the goods.

V YEAR IN REVIEW

Russia has now reached the stage where the consumer protection legislation has developed into a highly consumer-oriented set of rules and practices along with substantial supporting court practice and legislative guidance. There is an increasing number of product liability cases as a result of the developed awareness of consumers with regard to their rights. Moreover, legislators have introduced some guidance on the existing legislation, detailing the rights and obligations and increasing liabilities under consumer protection legislation.

In some instances, consumers demonstrate abusive attitudes towards the rights granted to them by the Consumer Protection Law and bring poorly reasoned claims with the sole purpose of harassing the seller or manufacturer (in Russia this is called consumer extremism). For example, in a recent case an individual asked the court to prohibit production and to withdraw from trade all tobacco products within the Russian Federation. To support the claim he referred to provisions of the Consumer Protection Law prohibiting production of goods that may cause harm to human health. Such cases arise quite frequently.

Chapter 19

SINGAPORE

Lim Ren Jun[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

In Singapore, there is no particular legislation solely dedicated to setting out liabilities that might arise owing to the manufacture, distribution or supply of a defective product. Rather, product liability laws span across a wide range of statutes as well as common law.

Product regulation and liability issues span a number of laws and regulations in Singapore, as specific laws cater to different types of products. For instance, the Sale of Food Act and the Food Regulations deal with food products. Medical devices and drugs (otherwise known as therapeutic products) are regulated under the Health Products Act. General consumer goods and controlled goods (mainly household electrical appliances) fall under one or both of the Consumer Protection (Fair Trading) Act and the Consumer Protection (Trade Descriptions and Safety Requirements) Act. The respective regulators and their ambits of enforcement for these categories of products will be examined in greater detail in the next section.

II REGULATORY OVERSIGHT

Thee various government bodies that oversee the regulation of products include:

a the Medical Device Branch of the Health Sciences Authority (HSA), which regulates medical devices in Singapore;

b the Therapeutic Products Branch of the HSA, which focuses on therapeutic products;

c the Land Transport Authority, which regulates vehicles by requiring their registration and that these vehicles be compliant with registration and technical requirements;

d the Standards, Productivity and Innovation Board of Singapore (SPRING Singapore), which regulates general consumer goods and ensures that the goods supplied are safe; and

e the Agri-Food and Veterinary Authority (AVA), which regulates the import and sale of food.[2]

Such powers of regulatory oversight are provided for by the relevant laws and regulations. For example, section 12G of the Consumer Protection (Fair Trading) Act (CPFTA)[3] provides SPRING Singapore with the power to conduct an investigation if it has reasonable grounds

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1 Lim Ren Jun is a principal at Baker McKenzie Wong & Leow. The author would like to acknowledge the assistance given by Carolyn Ang and Victor Looi Yi En in the preparation of this chapter.

2 Section 3(1) read with Section 2 of the Sale of Food Act (Cap. 283, 2002 Rev. Ed.).

3 Cap. 52A, 2009 Rev. Ed.

for suspecting, *inter alia*, that a supplier has engaged, is engaging or is likely to engage in an unfair practice. This power to conduct investigations is supplemented by ancillary powers, such as the power to apply for an injunction to restrain a person from knowingly abetting, aiding, permitting or procuring a supplier to engage in an unfair practice,[4] and the power to require documents, articles or information.[5] The Consumers Association of Singapore (CASE) also administers certain aspects of the CPFTA and handles consumer complaints generally.

The Consumer Protection (Safety Requirements) Regulations (CPSRR)[6] and Consumer Protection (Consumer Goods Safety Requirements) Regulations 2011 (CGSR),[7] issued pursuant to the Consumer Protection (Trade Descriptions and Safety Requirements) Act,[8] provide SPRING Singapore with the power to monitor the safety of certain goods known as controlled goods (e.g., household electrical, electronic and gas products), and general consumer goods respectively.

III CAUSES OF ACTION

There are six causes of action under which a manufacturer, distributor or seller (MDS) may be held liable for injury to persons or damage to chattels or property as a result of a defective product.

i Breach of contract

To rely on this cause of action, there must be a valid and legally binding contract between the claimant and the MDS of the product. Also, there must have been a breach by the MDS of either an express or an implied contractual term.

While express contractual terms and implied terms in fact are contract-specific, terms implied in law apply more uniformly across contracts of a similar kind. For instance, in a contract where a seller sells goods in the course of a business, there is an implied condition that the goods supplied under the contract are of satisfactory quality,[9] namely they should meet the standard that a reasonable person would regard as satisfactory, taking account of any description of the goods, the price (if relevant) and all the other relevant circumstances.[10] The same applies for a contract where the transferor transfers the property in goods in the course of a business.[11] Where these standards are not met, it is most likely possible to succeed in a claim for a contractual breach of an implied term.

One exception is where the unsatisfactory quality of the goods had been specifically drawn to the buyer's or transferee's attention before the contract was made. Another exception is where the buyer or transferee had examined the goods before the contract was made, and that examination ought to have revealed the unsatisfactory quality of the goods.[12]

4 CPFTA, Section 10.
5 CPFTA, Section 12H.
6 Cap. 53, Rg 1, 2004 Rev. Ed.
7 Cap. 53, No. S 113.
8 Cap. 53, 2013 Rev. Ed.
9 Section 14(2) of the Sale of Goods Act (Cap. 393, 1999 Rev. Ed.) (SOGA).
10 SOGA, Section 14(2A).
11 Section 4(2) of the Supply of Goods Act (Cap. 394, 1999 Rev. Ed.) (SPGA).
12 SOGA, Section 14(2C) and SPGA, Section 4(3).

ii Tort of negligence

An MDS may be held liable for injury to persons or property caused by the negligent manufacture, distribution or supply of a product.

To establish negligence, a claimant must prove that the MDS owes a duty of care to the claimant.[13] Most often, the court would find that a manufacturer owes end consumers a duty of care to ensure that the goods do not cause injury or harm to the latters.[14] Similarly, the court may find that a distributor owes a duty of care to the end consumers to check the safety of what it distributes.[15] Next, the claimant must show that the manufacturer has breached that duty of care by acting below the required standard of care.[16] In addition, the breach must have resulted in damage to the claimant. This damage can be physical, psychiatric or economic in nature.[17] Finally, any resulting losses cannot be too remote, and should be adequately proved and quantified.[18]

iii Misrepresentation

A claimant can sue a seller for fraudulent or innocent misrepresentation.

To establish fraudulent misrepresentation, the claimant must show that the seller knew or believed the representation about the goods to be false,[19] or did not believe in the truth of the representation, when it was made.[20] If the claimant is unable to do so, but is able to prove that the representation was made negligently, he or she may claim under the tort of negligence (see subsection ii, *supra*). Meanwhile, if the seller had neither acted fraudulently nor negligently, the claimant may only be able to sue for innocent misrepresentation. Under the Misrepresentation Act,[21] a person will be entitled to rescind a contract for innocent misrepresentation or claim damages in lieu of rescission.[22]

iv Claims under the CPFTA

A claim for product liability may also arise if a seller had entered into a transaction with an individual (who is not acting exclusively in the course of business), namely a consumer, and had engaged in unfair practices.[23] An unfair practice is relevant to product liability insofar as an MDS, for instance, makes a false or misleading claim in relation to the product being sold (e.g., advertising that a product is safe to use when it is actually not).

Even in the absence of an unfair practice, a seller would still owe obligations to the individual if the goods that have been ordered from the seller do not conform to the applicable contract at the time of delivery. Specifically, the seller is required to repair or replace the

13 *Spandeck Engineering (S) Pte Ltd v. Defence Science & Technology Agency* [2007] 4 SLR(R) 100; [2007] SGCA 37 (*Spandeck*) at [21].

14 *Donoghue v. Stevenson* [1932] AC 562.

15 *Watson v. Buckley, Osborne, Garrett & Co, Ltd* [1940] 1 All ER 174.

16 *Spandeck* at [21].

17 *Spandeck* at [115].

18 *Spandeck* at [21].

19 *DBS Bank Ltd v. Carrier Singapore (Pte) Ltd* [2008] 3 SLR 261.

20 *Taylor v. Ashton* (1843) 11 M & W 401 at 415.

21 Cap. 390, 1994 Rev. Ed. (Misrepresentation Act).

22 Misrepresentation Act, Section 2(2).

23 CPFTA, Section 6(1) read with Section 2(1).

goods, to allow the individual to pay less for the goods by an appropriate amount, or to allow the individual to rescind the contract with regard to the goods in question.[24] These provisions in the CPFTA are also known colloquially as 'lemon laws'.

An aggrieved individual may seek to sue the seller regarding the unfair practice,[25] though the amount claimed cannot exceed S$30,000.[26] Should the claim be above S$30,000, the individual has the option of abandoning the excess and recovering only an amount within the prescribed limit, which would be in full discharge of all demands in respect of that cause of action.[27]

v Filing a complaint with CASE

An affected consumer may also file a complaint with CASE to report a supplier that has engaged in an unfair practice. CASE is empowered to invite the supplier to enter into a voluntary compliance agreement, which may require the supplier to:

a compensate any consumer who has suffered loss or damage as a result of the unfair practice;
b reimburse CASE for any costs or expenses incurred by it; and
c publicise the voluntary compliance agreement.[28]

vi Failure to comply with regulations

Controlled goods

If an importer or manufacturer in Singapore intends, in the course of any trade or business to supply or advertise for supply any controlled goods[29] in Singapore, but fails to be registered or fails to register any of the said controlled goods, it will be guilty of an offence and shall be liable on conviction to a fine not exceeding S$2,000 or to imprisonment, or both, for a term not exceeding 12 months.[30] The same punishment applies if an MDS does not recall controlled goods as required by SPRING Singapore.[31]

Non-controlled goods

If an MDS supplies goods that have been publicly declared as unsafe for failing to conform to prescribed safety standards[32] in Singapore in the course of trade or business, it will be guilty of an offence and shall be liable to a fine not exceeding S$2,000 or to imprisonment for a term not exceeding 12 months, or both.[33] A second or subsequent offence will attract higher penalties.

24 CPFTA, Sections 12B(1)-(2).
25 CPFTA, Section 6(1).
26 CPFTA, Section 6(2) read with Section 6(6).
27 CPFTA, Section 6(5).
28 CPFTA, Section 8.
29 See First Schedule of the CPSRR.
30 CPSRR, Regulation 5.
31 CPSRR, Regulation 4(3).
32 CGSR, Regulations 3 and 4.
33 CGSR, Regulation 3(3).

Offences by corporations

Where an offence is proven to have been committed with the consent, connivance or neglect of an officer of the company, the officer as well as the company may also be held liable for the offence.[34]

IV LITIGATION

i Forum

Generally, product liability cases are heard in the same manner as most other civil cases, that is before a judge in the state courts or the Supreme Court of Singapore.

The court before which the claim will be brought at first instance is determined based on the quantum of the claim, as set out below:

a not exceeding S$60,000: magistrates' court;

b between S$60,000 and S$250,000: district court;[35] and

c above $250,000: High Court.

Any decisions made in these courts may subsequently be appealed to a higher court.[36]

An exception arises where the claim is below S$10,000 and can, therefore, be heard before the Small Claims Tribunal.[37] However, this limit of S$10,000 can be increased to S$20,000 if both the MDS and claimant consent to the increase in writing.[38]

ii Burden of proof

The burden of proof is generally on the party that initiates an action against a MDS. For instance, to claim that the implied contractual condition that the goods are of satisfactory quality has been breached, the claimant has to show how the goods in question are not of satisfactory quality.[39]

However, should a claimant seek to rely on section 12B(1) of the CPFTA as a cause of action, the lemon laws provide a presumption that goods that do not conform to the applicable contract at any time within the period of six months did not so conform as at the date of delivery, and it will be for the MDS to prove otherwise.[40]

iii Defences

General defence: expiry of limitation period

Generally, a claimant may not bring an action founded on a contract or on tort after the expiration of six years from the date on which the cause of action accrued.[41]

However, for a negligence action for damages, different rules apply:

34 CPSRA, Section 17.

35 Section 19(4) read with Section 2(1) of the State Courts Act (Cap. 321, 2007 Rev. Ed.).

36 Orders 55D and 57 of the Rules of Court (Cap. 322, R 5, 2014 Rev. Ed.) (ROC).

37 Section 5(3) read with Section 2(1) of the Small Claims Tribunal Act (Cap. 308, 1998 Rev. Ed.) (SCTA).

38 SCTA, Section 5(4).

39 *Compact Metal Industries Ltd v. PPG Industries (Singapore) Ltd* [2006] SGHC 242 at [102].

40 CPFTA, Section 12B(3).

41 Section 6(1)(a) of the Limitation Act (Cap. 163, 1996 Rev. Ed.) (LA).

a where the damages claimed consist of or include damages in respect of personal injuries to the plaintiff or any other person, an action may be brought within the later of:
- three years from the date on which the cause of action accrued; or
- three years from the earliest date on which the plaintiff has the knowledge required for bringing an action for damages in respect of the relevant injury;[42] and

b for damages other than personal injuries, an action may be brought within the later of:
- six years from the date on which the cause of action accrued; or
- three years from the earliest date on which the plaintiff or any person in whom the cause of action was vested first had both the knowledge required for bringing an action for damages in respect of the relevant damage and a right to bring such an action.[43]

Meanwhile, for an individual seeking to sue for unfair practices under section 6 of the CPFTA, the action should be within two years of:

a the date of the occurrence of the last material event on which the action is based; or

b the earliest date on which the consumer had knowledge that the supplier had engaged in the unfair practice to which the action relates.[44]

General defence: laches

If a claimant delays making a claim, the court may exercise its discretion in dismissing the claim, even though the claim was made within the limitation period. The key factors that the court may consider are the length of the delay and whether the acts done during that time would cause injustice to the defendant.[45]

Exemption or limitation of liability clauses

An MDS might seek to exclude liability for any contractual breaches or torts committed by including exclusion clauses in its contracts. However, an exclusion clause cannot exclude or restrict the MDS's liability for any death or personal injury resulting from its negligent actions.[46] As for other losses or damage that arise, the MDS would only be able to exclude or restrict its liability with a contractual clause, provided that the clause satisfies the requirement of reasonableness.[47] In addition, as against a person dealing as a consumer, a seller cannot rely on an exclusion clause to exclude or restrict the liability that arises from the breach of an undertaking as to the conformity of goods with their descriptions or samples, or as to their quality or fitness for a particular purpose.[48]

42 LA, Section 24A(2).

43 LA, Section 24A(3).

44 CPFTA, Section 12.

45 *Management Corporation Strata Title No. 473 v. De Beers Jewellery Pte Ltd* [2002] SGCA 13 at [33]–[34], applying *Lindsay Petroleum Co v. Hurd* (1874) L.R. 5 P.C. 221.

46 Section 2(1) of the Unfair Contract Terms Act (Cap. 396, 1994 Rev. Ed.) (UCTA).

47 UCTA, Section 2(1).

48 UCTA, Section 6(2)(a).

Claims under the CPFTA

A seller may argue that the consumer did not act reasonably in the circumstances, and therefore the actions of the seller cannot be considered as an unfair practice.[49] If a consumer unreasonably relies on a product advertising claim that is mere puff, for example, 'drink X gives you wings', the seller of the product cannot be considered as having engaged in an unfair practice.

Tort of negligence

A manufacturer may assert that the claimant had either expressly or implicitly accepted the risk of harm associated with the manufacturer's conduct. However, the manufacturer must prove that the consumer had full knowledge and understanding of the said risk,[50] that the consumer had voluntarily assumed that risk[51] and that the risk that he or she assumed was the one that occurred.

In addition, a manufacturer may assert the partial defence of contributory negligence in a situation where the losses or harm suffered by the claimant was partly owing to the claimant's own fault. In such a situation, the court may reduce damages accordingly as the court thinks just and equitable given his or her share of responsibility for the losses or harm suffered.[52]

iv Personal jurisdiction

In Singapore, personal jurisdiction can be categorised under 'general civil jurisdiction' and 'specific civil jurisdiction'.

General civil jurisdiction

An MDS is subject to the legal authority of the Singapore courts' jurisdiction if:

a the MDS has been served with a writ or other originating process in Singapore or outside Singapore in the manner prescribed by the Rules of Court[53]; or

b the MDS has submitted to the High Court's jurisdiction.[54]

Specific civil jurisdiction

An MDS that is a corporate entity may be subject to the legal authority of the Singapore courts' jurisdiction if the MDS was incorporated in Singapore,[55] and service was effected on the MDS at its registered address.[56]

Conversely, if the MDS was not incorporated in Singapore, it needs to first be present within Singapore, and then receive service of the claimant's originating process, for the MDS to be under the Singapore courts' jurisdiction.[57]

49 CPFTA, Section 5(3)(a).

50 *Thomas v. Quartermaine* (1887) 18 QBD 685.

51 *Williams v. Birmingham Battery and Metal Co* [1899] 2 QB 338.

52 Section 3(1) of the Contributory Negligence and Personal Injuries Act (Cap. 54, 2002 Rev. Ed.).

53 Cap. 322, R 5, 2014 Rev. Ed.

54 Section 16(1) of the Supreme Court of Judicature Act (Cap. 322, 2007 Rev. Ed.) (SCJA).

55 SCJA, Section 17(c), read with Section 4(1) of the Companies Act (Cap 50, 2006 Rev. Ed.).

56 Companies Act, Section 387.

57 SCJA, Section 16(1)(a).

Forum non conveniens

The Singapore courts generally uphold choice of law and jurisdiction clauses in contracts and will apply the principle of *forum non conveniens* to determine if Singapore is the appropriate forum to have the matter heard.

v Expert witnesses

Where there arises a need for an expert's opinion in a matter, the court may at any time, on its own volition or on the application of a party to a dispute, appoint an independent expert.[58] The expert should have scientific, technical or other specialised knowledge based on his or her training, study or experience.[59] Such knowledge should be in connection with the questions that he or she has been asked to address[60] and be something that the court is likely to derive assistance from.[61]

If more than one such question arises, two or more such experts may be appointed to inquire and report upon any question of fact or opinion that does not involve a question of law or of construction.[62] However, the court may limit the number of expert witnesses who may be called at the trial.[63]

vi Discovery

There are two key methods of discovery in civil actions initiated before the Singapore courts, namely discovery through requests for the production of documents and discovery through interrogatories.

Request for the production of documents

General discovery

The court may at any time order any party to a cause or matter to give discovery by making and serving on any other party a list of documents that are or have been in its possession, custody or power.[64]

This list of documents comprises those that:

a are or have been in the other party's possession, custody or power, and on which the party relies or will rely on; and

b could adversely affect the party's own case, adversely affect the other party's case or support another party's case.[65]

In either case, discovery must be necessary for disposing fairly of the cause or matter or for saving costs.[66]

58 ROC, Order 40, Rule 1(1).

59 Section 47(2) of the Evidence Act (Cap. 97, 1997 Rev. Ed.) (EA).

60 ROC, Order 40, Rule 1(4).

61 EA, Section 47(1).

62 ROC, Order 40, Rule 1(1).

63 ROC, Order 40A, Rule 1(1).

64 ROC, Order 24, Rule 1(1).

65 ROC, Order 24, Rules 1(2)(a) and 1(2)(b)(i)–(iii).

66 ROC, Order 24, Rule 7.

After granting such an order, the court retains the discretion on whether to release or modify the undertaking. Most often, it will only release or modify the undertaking in special circumstances and where the release or modification will not occasion injustice to the person giving discovery.[67]

Specific discovery

To supplement the process of general discovery, specific discovery is available in cases where there are documents that fall within the scope of general discovery but have not been disclosed to the other party. The court may at any time, on the application of either party to a cause or matter, make an order requiring any other party to make an affidavit stating whether any document or any class of document specified or described in the application is, or has at any time been, in its possession, custody or power, and if not then in its possession, custody or power, when it parted with it and what has become of it.

Besides general and specific discovery, a party may apply for discovery before action[68] or even discovery against a non-party.[69] These are, however, exceptional situations that require a party to show why it is just for the court to grant such an application.[70]

Interrogatories

A party to any cause or matter may apply to the court for an order giving it leave to serve on any other party interrogatories relating to any matter in question between that party and another party in the cause or matter.[71] The interrogatories should be necessary either for disposing fairly of the cause or matter, or for saving cost.[72]

The court may grant an order to administer interrogatories only if the party gives security for the costs of the person against whom the order is made, or on such other terms as the court thinks just.[73] If the court is not satisfied that interrogatories are necessary, or are necessary at that stage of the cause or matter, the court may dismiss or adjourn the application, and shall in any case refuse to make such an order.[74]

vii Apportionment

Regulatory obligations

If the products in question are medical devices and therapeutic products, the existing product registrant on the HSA's register will be held liable by the HSA for any defective products. Contractual arrangements may be made between the successor company and the previous registrant to apportion risk.

Tortious claims

The following considerations will apply to claims in tort.

67 *Crest Homes plc v. Marks* [1987] AC 829 at 860.
68 ROC, Order 24, Rule 6(1).
69 ROC, Order 24, Rule 6(2).
70 ROC, Order 24, Rule 6(5).
71 ROC, Order 26, Rule 1(2).
72 ROC, Order 26, Rule 1(1).
73 ROC, Order 26A, Rule 3.
74 ROC, Order 26A, Rule 2.

Joint liability

A party that authorises, procures or instigates the commission of a wrong may be held jointly liable with the party that actually committed the wrong. Accordingly, if a director of a manufacturing company, for instance, authorises, procures or instigates the company to be negligent in the preparation of a product or to be negligent or fraudulent in the making of representations to a consumer, the director can be held liable for his actions. In *TV Media Pte Ltd v. De Cruz Andrea Heidi and Another Appeal*,[75] one of the defendants was held to have directed, authorised and procured a company's negligence because of his involvement in all of the company's significant dealings with third parties, as well as his absolute control of the company.[76]

Meanwhile, a person who participates in a common design or joint enterprise in the commission of a tort may also be held liable for his or her actions. 'Common design' refers to a shared intention that is manifested either through an express[77] or an implied agreement.[78]

Several liability

There may be situations where, for instance, a manufacturer negligently produces a defective good, a seller then makes a fraudulent or negligent misrepresentation to the claimant regarding the same good and both actions lead to the same damage to the claimant. In such cases, both the manufacturer and the seller can be held severally liable for the losses and damage suffered by the claimant through a tortious action.

Vicarious liability

To impose vicarious liability on the MDS because of an individual's wrong:

a there must be an employer–employee relationship between the MDS and the individual;

b the individual must have committed a tort; and

c the individual's tort must have been so closely connected with his or her employment that it is fair and just that the MDS should be held vicariously liable for the individual's tort.[79]

First, to determine if there is a close connection, the court would take into account factors including, but not limited to, the opportunity that the MDS afforded the individual to abuse his or her power and the extent to which the wrongful act may have furthered the MDS's aims.[80]

Secondly, to decide if it is fair and just to impose vicarious liability, the court would take into account all relevant circumstances. This includes policy considerations such as the provision of compensation for innocent victims and the deterrence of future harm against employers to reduce the incidents of accidents and tortious behavior by their employees.

75 [2004] SGCA 29.

76 Ibid. at [136]–[140].

77 *Trek Technology (Singapore) Pte Ltd v. FE Global Electronics Pte Ltd and Others and Other Suits (No. 2)* [2005] 3 SLR 389, citing *Morton-Norwich Products Inc v. Intercen Limited* [1978] RPC 501 at 512.

78 Ibid., citing *Unilever Plc v. Gillette (UK) Limited* [1989] RPC 583 at 609.

79 *Skandinaviska Enskilda Banken AB (Publ), Singapore Branch v. Asia Pacific Breweries (Singapore) Pte Ltd* [2011] 3 SLR 540 at [75].

80 Ibid., at [87].

Once vicarious liability is established, the MDS can be held liable for the losses and damage arising from the individual's tort. One way in which the MDS may not have to bear such liability eventually is if the MDS had previously sought an indemnity from its employee.

viii Mass tort actions

Where numerous identifiable persons have the same interest in a proceeding, the proceeding may be begun, and, unless the court otherwise orders, continued by or against any one or more of them as representing all or as representing all except one or more of them.[81] Any judgment or order subsequently given would then be binding on all the persons as representing those whom the claimants sue.[82] Such actions help to ensure that all interested parties are represented without being joined as parties, so that the dispute in the suit may be finally determined. [83]

ix Damages

Breach of contract

Where an MDS breaches a contract with the claimant, the court will compensate the claimant with damages for the losses that he or she has suffered as a result. In particular, the consumer may, in many situations, elect between expectation damages and reliance damages, though these damages are subject to proof. Expectation damages are damages to put the consumer in the position that he or she would have been in had the contract been performed.[84] Where a good is defective, a consumer may claim for the diminution in market value of the good owing to the defect, or the cost of repairing the good. Conversely, reliance damages are based on the expenses that the claimant incurred in reliance on the MDS's promise to perform its obligations.[85]

An exception to the freedom to elect what kind of damages to receive is where expectation damages are hard to quantify or are too speculative. In such a situation, the consumer may receive reliance damages instead.[86]

Claims under the CPFTA

The damages claimable under the CPFTA in respect of an unfair trade practice are subject to a limit of S$30,000.[87] Similarly, where the claim is not for money, but for a remedy or relief in respect of the subject matter, the value of the claim should not exceed S$30,000.

Tort of negligence

If a claimant is physically injured by a negligent act of the MDS, he or she may claim damages for both pecuniary and non-pecuniary losses. With regard to pecuniary losses, the court will award damages that would put the claimant in the position as if the injury had not been

81 ROC, Order 15, Rule 12(1).

82 ROC, Order 15, Rule 12(3).

83 *Abdul Rahman v. Ling How Doong and others* [1994] 1 SLR(R) 1054; [1994] SGHC 92.

84 *Gunac Enterprises (Pte) Ltd v. Utraco Pte Ltd* [1995] 1 SLR 11 at 14.

85 *Van Der Horst Engineering Pte Ltd v. Rotol Singapore Ltd* [2006] 2 SLR 586 at [54].

86 *McRae v. Commonwealth Disposals Commission* (1950) 84 CLR 377.

87 CPFTA, Section 6(6).

sustained.[88] This may include (present and future) medical expense, loss of future income, future transport costs and future nursing care and nursing home expenses.[89] With regard to non-pecuniary losses, the court may award damages for the claimant's loss of amenities, and for pain and suffering.[90]

Misrepresentation

If the court finds the MDS liable for fraudulent misrepresentation, the court may award all losses flowing directly from the claimant's reliance upon the fraudulent misrepresentation, regardless of whether or not such loss was foreseeable (and including all consequential losses as well).[91] Similarly, the MDS would be liable for the same type of damages if it had made a negligent misrepresentation to a claimant which led to the claimant suffering losses. This is unless the claimant had reasonable ground to believe and did believe up to the time the contract was made that the facts represented were true.[92] If the MDS is found liable for innocent misrepresentation, the court may also order damages in lieu of rescission.[93]

V YEAR IN REVIEW

i Statutory developments

Most recently, on 13 September 2016, the CPFTA was amended to strengthen the protection of consumers from unfair trade practices, which include the making of false claims in product advertising. In addition, SPRING Singapore, which is now appointed as the administering agency for the CPFTA, has been given wide investigative and enforcement powers against errant retailers that engage in unfair trade practices.

SPRING Singapore may also apply to court to obtain a declaration that a supplier is engaging in an unfair trade practice, or an injunction restraining the supplier from engaging in the unfair trade practice, along with ancillary orders to facilitate compliance. For instance, the court may order errant retailers to publicise the fact that injunctions have been ordered against them.[94]

The amendments came into effect on 9 December 2016.[95]

ii Case law developments

The High Court held in *Honey Secret Pte Ltd v. Atlas Finefood Pte Ltd and others*[96] that because the good in question (viz, honey) was not properly labelled, it did not comply with

88 *Chartered Electronics Industries Pte Ltd v. Comtech IT Pte Ltd* [1998] 3 SLR 502 at [16].

89 *Poh Huat Heng Corp Pte Ltd and others v. Hafizul Islam Kofil Uddin* [2012] SGCA 31 at [7].

90 *Tan Kok Lam (next friend to Teng Eng) v. Hong Choon Peng* [2001] SGCA 27.

91 *Wishing Star Ltd v. Jurong Town Corp* [2008] 2 SLR 909 at [21], affirming *Doyle v. Olby (Ironmongers) Ltd* [1969] 2 QB 158.

92 Misrepresentation Act, Section 2(1).

93 Ibid., Section 2(2).

94 CPFTA, Section 9.

95 Consumer Protection (Fair Trading) (Amendment) Act 2016 (Commencement) Notification 2016 (Act 25 of 2016).

96 [2016] SGHC 164.

Regulation 5 of the Sale of Food Act. Therefore, the honey could not be considered as being of 'satisfactory quality' under either Section 14(2) of the SOGA or Sections 4(2) or 4(2A) of the SPGA.

iii Other developments

CASE received a total of 19,102 consumer complaints in 2016. Out of these 19,102 complaints, CASE took action for 1,763 cases. The largest proportion of these complaints related to motorcars (24 per cent).[97]

There were several product recalls in Singapore in 2016, some of which include the following.

Between March and April 2016, the AVA, the Ministry of Health (MOH) and the National Environment Agency (NEA) collaborated in investigating more than 70 cases of food poisoning that resulted from a durian puff bakery's kitchen. The AVA looked into the suppliers of the ingredients used in making the pastries and found no lapses in food safety at the suppliers' establishments. Meanwhile, the NEA suspended the bakery's licence on 22 April 2016, resulting in the bakery having to halt the production, sale and distribution of its pastries.

On 23 August 2016, the AVA announced that a Taiwanese milk tea beverage was to be recalled because the tea contained an unapproved food additive. This was notwithstanding that there was no risk of food safety that was linked to the additive.

97 Consumers Association of Singapore, *CASE - Consumer Guides | Statistics*, retrieved from https://www.case.org.sg/consumer_guides_statistics.aspx (last accessed 21 February 2017).

Chapter 20

SPAIN

Alex Ferreres Comella and Cristina Ayo Ferrándiz[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

In the Spanish legal system, product liability regulations were to be found, until 2007, in Article 1902 of the Civil Code (CC), which used to set out the rules concerning liability in tort, in the General Law for the Protection of Consumers and Users and in the Defective Products Liability Act, which transposed the EEC Directive of 25 July 1985 concerning Liability for Defective Products (the 85/374 Directive).

The moment at which the product had been put into circulation determined which particular set of rules applied. For these purposes 'putting into circulation' meant the voluntary delivery of the product by the manufacturer, which, for practical purposes, meant distributing the product or making it available to the relevant persons.

Under the Defective Products Liability Act's final provision, this Act applied to those instances of product liability in which the relevant product had been put into circulation after 8 July 1994 (i.e., on the day following the coming into force of the Defective Products Liability Act). The General Law for the Protection of Consumers and Users applied to any products put into circulation between 13 August 1984 and 8 July 1994 and, finally, Article 1902 of the CC applied to any products put into circulation before the coming into force of the General Law for the Protection of Consumers and Users, that is, before 13 August 1984.

Note that where one particular set of rules applied the rest did not and, as has just been stated, the moment at which a product had been put into circulation determined which set of rules applied.

The rules differed in such matters as the identification of the person responsible, the circle of possible injured persons and the damages covered. However the underlying purpose of all those sets of rules and the definition of a defective product were the same. The latter was explicitly addressed in the 85/374 Directive and the Defective Products Liability Act (which, as indicated, transposed the 85/374 Directive).

The diversity of product liability regimes came to an end by virtue of the coming into force of Royal Legislative Decree 1/2007, which enacted the Consumers and Users Protection (Consolidation) Act and other complementary regulations.

Both the General Law for the Protection of Consumers and Users and the Defective Products Liability Act (among other consumer protection regulations) were repealed following their consolidation into Royal Legislative Decree 1/2007. This means that Royal

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Legislative Decree 1/2007, which does not substantially differ from the Defective Products Liability Act (and therefore follows the guidelines laid down by the 85/374 Directive), is currently the only set of rules applicable to liability for defective products.

The Third Transitory Provision of Royal Legislative Decree 1/2007 provides for specific rules applicable to any product put into circulation before 8 July 1994 (i.e., before the coming into force of the Defective Products Liability Act). However, a scenario calling for the application of such transitory rules is highly unlikely to arise. This is because under Section 144 of Royal Legislative Decree 1/2007, the liability of manufacturers expires after 10 years as of the date on which the product was put into circulation, as was the case under Section 14 of the Defective Products Liability Act.

II REGULATORY OVERSIGHT

Although Royal Legislative Decree 1/2007 contains some provisions regarding general safety of products, it is Royal Decree 1801/2003 concerning general product safety that transposed into Spanish law the EU General Product Safety Directive (2001/95/CE), the main and general regulation in safety issues.

Like the Directive, Royal Decree 1801/2003 is a general and horizontal, non-contractual regulation on general product safety, applicable to all product types put into circulation in Spain. Pursuant to this regulation, only safe products can be put into circulation on the Spanish market.

The National Agency on Consumption and Food and Nutrition Safety (AECOSAN)[2] is the regulator, with nationwide competence, and the regional authorities are competent[3] within their own territories.

However, it must be noted that this regulation will only apply to all product types in the absence of any specific existing regulation. Indeed, there are some specific products (food, cosmetics or medicines, for instance) that have specific safety regulation and sometimes need prior administrative approval to be put on the market.

Likewise, the AECOSAN will be competent provided that there is no specific body in charge of the safety of specific products (such as the Spanish Agency of Medicines and Medical Devices (AEMPS)).

2 The National Consumption Institute was the competent regulator. Owing to recent restructuring, the National Consumption Institute was merged with the Spanish National Agency on Food and Nutrition Safety to create the AECOSAN.

3 Dirección General de Consumo, in Andalucia; Dirección General de Consumo, in Aragón; Agencia de Sanidad Ambiental y Consumo in Asturias; Dirección General de Consumo in the Balearic Islands; Dirección General de Comercio y Consumo, in the Canary Islands; Dirección General de Comercio y Consumo, in Cantabria; Agencia de Protección Civil y Consumo, in Castilla y León; Instituto de Consumo de Castilla-La Mancha, in Castilla La Mancha; Agencia Catalana de Consumo, in Catalonia; Consejería de Sanidad y Consumo, in Ceuta; Instituto de Consumo de Extremadura, in Extremadura; Instituto Gallego de Consumo, in Galicia; Dirección General de Salud Pública y Consumo, in La Rioja; Dirección General de Consumo, in Madrid; Dirección General de Sanidad y Consumo, in Melilla; Dirección General de Atención al Ciudadano, Drogodependencias y Consumo, in Murcia; Dirección General de Familia, Infancia y Consumo, in Navarra; Dirección de Consumo, in the Basque Country; Dirección General de Comercio y Consumo, in Valencia.

III CAUSES OF ACTION

Taking into consideration the regulations noted above, the following are the causes of action when putting a product into circulation.

i Civil law

Royal Legislative Decree 1/2007

A product is deemed to be defective where it does not sufficiently guarantee the safety that is expected of it.

In order to establish whether a given product is or is not defective, it must satisfy the non-safety test. Other tests, including that of substandard quality or unfitness for purpose, do not apply.

Royal Legislative Decree 1/2007 does not draw a distinction among the three types of defects traditionally identified by legal scholars:

a manufacturing defects that arise from flaws in the manufacturing process and often affect individual products within the same series;

b project or design defects that arise from flawed technical designs prior to manufacture (that is, at the technical ideation stage of the product) and often affect all of the units manufactured; and

c information defects that arise from flawed, incomplete or insufficient information that misleads consumers as to the manner in which a given product should be used or its degree of safety.

As for information defects it may be argued that, by using the degree of safety test in order to establish whether a product is or is not defective, the law actually calls for an assessment of the extent to which the potential risks associated with a particular product are known. In this way, a product will be regarded as defective when it falls short of providing the safety expected of it or, to put it differently, when it does not provide the safety that consumers expect.

Conversely, no liability will arise where the risks associated with a given product are known by the injured person as, in these circumstances, the fact that a product is not safe is part and parcel of what is to be expected from the relevant product (theory of assumed risks). This may occur because (1) such risks are obvious (e.g., a knife or a pair of scissors are cutting instruments), because (2) such risks are socially and culturally known by the public (e.g., risks associated with tobacco or alcohol consumption), or because (3) the manufacturer, in compliance with its duty to provide the necessary information about its product, had provided to the injured persons adequate instructions for its use and information about the risks associated with such use.

Clearly, safety expectations are to be assessed from an objective standpoint and by having regard to the average individual's knowledge and to the manufacturer's lawful expectations about use. The subjective perspective of the particular injured person must be disregarded for these purposes.

Both the 85/374 Directive and Royal Legislative Decree 1/2007 provide that the product presentation, the reasonable use of the product, and the moment of its putting into circulation are criteria that must be taken into account to establish the expectations that injured persons could properly have of the relevant product.

The scope is limited to the liability of producers and suppliers exclusively for bodily harm sustained as a result of the use or consumption of a defective product and for damage caused to things other than the product itself, provided that the defective product itself was meant for private consumption (i.e., not intended for professional use).

Any other type of damage (moral or over the product itself) must be sought under general civil regulation.

Royal Decree 1801/2003

Under Royal Decree 1801/2003, only safe products can be put into circulation on the Spanish market. This means that each party in the distribution chain must take appropriate measures to ensure that all products are safe; and where any party knows that a product already put into circulation is not safe, it must take appropriate corrective measures.

A product will be considered safe provided that, under normal and reasonable conditions of use, it does not present any risk or presents only such risks that are acceptable and compatible with the intended use of the product, taking into consideration circumstances such as the characteristics of the product, any information provided with it, or the consumer it is directed towards.

Royal Decree 1801/2003 also sets out a presumption that a product is safe when it has been produced in accordance with Spanish or European compulsory regulations on health and safety or, where no specific regulation exists, in accordance with Spanish standards (UNE standards), European Commission recommendations, or the current state of the art, for instance that the state of scientific and technical knowledge at the time of putting into circulation was not such as to enable the existence of the defect to be discovered.

Conversely, Royal Decree 1801/2003 presumes that a product is not safe when it has been produced without CE or EC marks, or whenever a product has been produced without passing any compulsory authorisations or controls.

This regulation applies basically over producers and distributors, although it is also applicable over any party in the production and distribution chain.

ii Criminal law

Criminal law provides for certain crimes in the field of product liability. Causing risk to persons (without it being necessary for such risk to have materialised in harm to specific persons) by placing medicines and products intended for human consumption on the market, whether by violating safety or health regulations or by unauthorised adulteration or handling, is defined as a crime against public health. In cases other than those involving the manufacture and marketing of medicines and products intended for human consumption, the damage caused by a defective product can be characterised as a crime of homicide or of injury, in both cases owing either to gross or to ordinary negligence, provided that the violation may be qualified as criminal depending on the importance of the safety rules that have been violated.

IV LITIGATION

i Forum

Civil procedure is regulated by the Spanish Civil Procedural Act enacted on 7 January 2000.

The Spanish legal system is unitary and uniform throughout the territory. This means that its courts are organised in territorial terms into provincial districts, each of which groups together several geographical areas, which, in turn, comprise several municipalities.

The lowest level of the civil jurisdiction is made up of the courts of first instance, which are formed each by one single judge. In general, these courts hear in the first instance all proceedings to which the parties are private individuals and companies, and they are almost exclusively in charge of hearing and examining evidence and pleadings submitted by the parties and, subsequently, of rendering their judgments.

The provincial court of appeal hears appeals against decisions rendered by the courts of first instance. There is a provincial court of appeal in each of the 50 provinces that make up the Spanish territory, and in populous provinces such court is divided into several sections, each sitting with three magistrates.

Apart from the Superior Court of Justice, which is the highest court of each of the autonomous communities into which the Spanish territory is divided and, basically, are in charge of hearing motions for dismissal in connection with specific matters of law of their own and respective autonomous community, the Supreme Court is the highest court in product liability cases, although some issues might be brought before the Constitutional Tribunal.

In product liability cases, the jurisdictional function, both in terms of fact-finding and of the legal declaration of liability, corresponds exclusively to the judges and the courts. Jury courts before which some crimes are tried do not have jurisdiction over product liability cases.

Furthermore, in Spain, there are two basic declarative procedures for seeking payment of compensation: the verbal proceeding or the ordinary proceedings. Which stream a case falls under will depend on the amount claimed: (1) seeking payment of compensation of up to €6,000 is handled in verbal proceedings, and (2) for cases where the amount claimed is more than €6,000, the claim is handled in ordinary proceedings.

In both cases, the civil procedure starts with the filing of the claim. The claim must include all factual allegations on which it is based, in as much detail as possible, as well as the legal grounds on which it is based. However, under the principle of *jura novit curia*, (1) the plaintiff is not required to set out the legal grounds in thorough detail, and (2) the legal grounds claimed are not binding upon the judge, who may uphold the action based on alternative legal grounds.

If verbal proceedings are initiated, once the claim has been filed and given leave to proceed, the defendant is notified so that he or she may present a defence (or a counterclaim brief) within a term of 10 working days (which includes all days of the year except Saturday, Sundays, national holidays, non-working days in the autonomous region and/or city where the proceedings take place, and the month of August).[4]

Subsequently, the court will call the parties to a hearing in which they propose the evidence they are going to submit, the evidence is produced and, if the court deems it necessary, final conclusions are presented.

4 Until very recently, the main difference between verbal and ordinary proceedings was that in verbal proceedings the plaintiff used to file a written lawsuit, while the defendant did not file a written response to the lawsuit. In this type of proceedings, the court summoned the parties to a hearing where the defendant presented its response orally and the evidence was submitted. However, this has been recently modified in the Spanish Procedural Act and in verbal proceedings the brief of response is also submitted in writing.

If ordinary proceedings are initiated, once notified of the lawsuit, the defendant will have a 20-working day time period to file the brief of response. Subsequently, the court will call the parties to a preliminary hearing in which they propose the evidence they are going to submit, and, finally, the court calls the parties to the trial where the evidence and final conclusions are presented. In this case, therefore, there are two different hearings.

ii Burden of proof

The general principle that the burden of proof of a factual allegation lies on the person who makes the allegation is one that presides over the Spanish legal system.

In accordance with the general civil liability regime under Royal Legislative Decree 1/2007, the party claiming product liability must provide evidence of the existence of a defect in the product, of the damage or injury, and of the causal relationship between the two.

In Spain, the standard of proof of that causal link is in theory high. The Supreme Court formally requires that evidence of the existence of a causal link must be clear and precise, and not based on mere deduction, conjecture or probability. Therefore, in principle, it requires absolute evidential certainty.

Consequently, in Spain, tests applied elsewhere like the 'more probable than not' rule are, in theory, not applicable. And statistics or epidemiology do not appear to be sufficient by themselves to prove a causal link.

In practice, however, judges and courts often reach decisions in a manner that comes close to applying the 'more probable than not' rule, in particular, through recourse to the judicial presumption, whereby the judge or court applies human logic rules to deduce a fact and deems it proven (deduced fact) on the basis of the evidence of one or more basic facts.

On other occasions, the courts have determined the causal relationship by reference to statistics and epidemiology – which are deemed to be insufficient by themselves to establish the causal link – in combination with other basic facts.

The ruling on the rapeseed oil case is an illustrative example of the use of epidemiological studies by the Spanish Supreme Court. Although the events took place in 1981, the Supreme Court did not issue a final judgment on this case until 26 September 1997.

In that case, the Supreme Court found that (1) a link between the consumption of rapeseed oil and the disease suffered by more than 20,000 injured parties had been epidemiologically determined; (2) the pathology found in the injured parties was new (it had never before been diagnosed) and consequently no risk factors inherent to the disease had been identified by the scientific community; (3) none of the parties to the proceedings proposed any alternative causal hypothesis other than the consumption of rapeseed oil; and (4) once the denatured rapeseed oil was removed from the market and its consumption had been suspended, no new cases of intoxication were diagnosed.

Importantly, epidemiology was not considered in itself to be sufficient proof of a causal relationship. Epidemiology was just one more link in the Supreme Court's logical reasoning chain that led to the evidential conclusion of the existence of a causal relationship.

iii Defences

Royal Legislative Decree 1/2007 specifically provides for the statutory limitation of actions brought by virtue of this law within a term of three years of the time the victim sustained the injury or damages.

It also provides that the rights of the victim will lapse 10 years after the date the product was put into circulation (provided that no legal action has been instigated in that period).

In relation to the start of the computation of the limitation period, Article 1969 of the Civil Code provides that 'the time limit for all sort of legal actions, when not otherwise provided for under a special provision, will start on the day that such actions may be brought.' As for the time when the case is deemed to be actionable, it has been chiefly understood to be identified with the time when the injured party learned of the damage or injury sustained ('from the time the aggrieved party learned of it', as noted under Article 1968.2 of the Civil Code).

This criterion regarding the start of the time limit is also applied within the product liability context: 'from the date the injured party sustained the injury or damage'.

In any consideration of limitation periods, the Spanish courts tend to lean generously in favour of the interests of the plaintiffs.

Apart from the statute of limitations defence, Royal Legislative Decree 1/2007 provides that manufacturers or importers are not liable, as long as evidence of any of the following circumstances is provided:

a the product was not put into circulation by the relevant manufacturer or importer;

b having regard to the circumstances, it was to be expected that no defect existed at the time at which the product was put into circulation;

c the product was not manufactured for sale or for any other method of distribution for an economic purpose, or was neither manufactured nor imported, supplied or distributed in the course of a professional or business activity;

d the defect was the result of manufacturing the product in accordance with mandatory rules in force; or

e the state of scientific and technical knowledge at the time of putting into circulation was not such as to enable the existence of the defect to be discovered (i.e., the 'state-of-the-art' defence).

Under this exemption-of-liability clause, damages caused by a defective product are not amenable to compensation where the state of scientific or technical knowledge at the time the damage was caused was not such so as to avoid such damage.

Therefore, manufacturers whose production activity adheres to the scientific and technical knowledge available at the time of putting their products into circulation will be relieved of liability provided that the state of scientific and technical knowledge was not such so as to allow the discovery of the defect.

Some scholars suggest that reliance on generally known empirical knowledge is not enough for manufacturers to successfully prove this exemption of liability cause. Manufacturers need also to ensure that they rely on state of the art scientific knowledge and research. This is tantamount to an implicit duty on the part of manufacturers to conduct research into the safety of their products whatever the manufacturer's turnover, market position or financial resources.

There are two product types where manufacturers will be liable despite having conducted their activity in accordance with the state of scientific and technical knowledge available at the time of putting their products into circulation: drugs and foodstuffs meant for human consumption. This means that the law imposes a more stringent and direct duty to conduct research into the safety of these products.

In addition to the grounds for exoneration listed above, Royal Legislative Decree 1/2007 also contemplates the possibility that a manufacturer's liability may be reduced owing to the intervention of third parties or of the injured party, and in the latter case the manufacturer's liability may not arise at all.

Indeed, if a third party has intervened in the manufacturing of the product, the manufacturer who would have paid any applicable indemnity sum would be entitled, by means of a 'recovery or repetition action', to recover from such third party that party's share of the cost of the damage.

With regard to intervention by the injured party (fault of the victim), the manufacturer must prove that the damage would not have occurred without the injured party's intervention, or that the injury or damage caused would, at least, not have been so serious.

iv Personal jurisdiction

As a member of the EU, Spain is subject to the provisions set out in Article 7.2 of the Council Regulation 1215/2012,[5] on jurisdiction, recognition and enforcement of judgments in civil and commercial matter. Under that article, any person who has suffered damages as a consequence of a defective product can sue any EU manufacturer before the courts of the country where the harmful event has occurred or may occur. That will normally coincide with the courts of the claimant's own domicile.

The same rule is set out in Spanish law in connection with cases involving non-EU manufacturers. Therefore, foreign manufacturers are subject to Spanish jurisdiction provided that the damages caused by the defective product have been caused within the Spanish territory.

However, where the product has not been manufactured in Spain, and has not been sold or advertised in Spain, but the injury occurs within the Spanish territory, it may be argued that the harmful event has not properly occurred in Spain (i.e., while damage as such will have occurred in Spain, the harmful effect – the putting into circulation of a defective product – may not be understood to have occurred therein).

v Expert witnesses

The Spanish Civil Procedural Act provides for the expert witness who is a person having the technical, scientific, artistic or practical knowledge of the relevant issue, as well as the direct knowledge or news of the facts or events as a witness.

As a general rule, experts' reports should be filed together with the initial writs of claim and of defence; however, a number of exceptions are set for cases where special circumstances exist.

Thus, if a plaintiff shows that the proper defence of his or her rights prevented him or her from delaying the filing of his or her claim, he or she may submit an expert report subsequently, provided that he or she announces it in the writ of claim and the report is filed prior to the pretrial hearing. Logically, this possibility is absolutely limited, in principle, to cases of statutory limitations taking into consideration that the defendant has only 20 working

5 Entered into force on 10 January 2015 (formerly ruled in Article 5.3 of the Council Regulation No. 44/2001).

days to file the brief of response, it can file it five days prior to the preliminary hearing, provided that it justifies that it could not be obtained before the expiration of the term provided by law to file the defence brief and it announces its filing in the brief of response.

If the need for expert witness evidence becomes manifest in view of the pleadings contained in the defendant's writ of defence, or in view of the complementary pleadings made by any of the parties prior to or at the preliminary hearing, the parties may provide any such expert witness report until five days before the start of the trial.

Moreover, any of the parties may prefer to request from the court the appointment of an expert but it should do so, expressly, in its initial writ.

In principle, expert reports, as any other mean of evidence, must be proposed by the parties; however, the law provides that the appointment of an expert by the court can also be requested when the need for expert testimony becomes evident either in view of the pleadings contained in the writ of defence (in which case only the plaintiff may request it) or in view of any complementary pleadings by any of the parties before or at the preliminary hearing.

vi Discovery

The Spanish legal system does not provide for a general disclosure procedure.

However, the law does provide for coercive measures in relation to document disclosure only in two specific situations.

In the event that preliminary proceedings[6] have commenced, the law provides for the possibility for the court to enter and to search premises in order to obtain certain documents requested by the plaintiff, in cases where the person or entity to which they refer or who are in possession of such documents, refuses to disclose them.

During the ordinary proceedings, the law provides for the possibility to request from the other parties disclosure of documents referring to the object of the proceedings.[7] Should the party or parties unjustifiably refuse to disclose the requested private documents, the court may either (1) attribute to such document the evidential value alleged by the requesting party, or (2) issue an express injunction for the documents to be furnished, when it is deemed advisable given the nature of the documents, of the other evidence brought to the proceedings and of the contents of the allegations and claims made.

However, unlike for the preliminary proceedings, here the law does not provide for the entry and search of premises in the event of a refusal of document disclosure. However, the party who refuses to disclose documents required by the court may be in contempt of court, which is characterised as a criminal offence.

vii Apportionment

Spanish courts may apportion liability in those cases in which several agents have contributed to the damaging event, it being possible to determine the specific level contribution of each of those; however, market share liability has not yet been applied by the Spanish courts.

6 This is an exceptional procedure, simply aimed at preparing the proceedings (and therefore, prior to filing the lawsuit) whose purpose is for the potential plaintiff to verify the suitability of the defendant and the object of the claim.

7 The requesting party must in such cases provide a simple copy of the requested document or, in the absence thereof, indicate the contents of the requested document in the most accurate terms possible.

On the contrary, in those cases in which it is not possible to determine the specific level of contribution of each agent to the damaging event (while it is certain that all of them have to some – unknown – extent contributed to it), courts may find all the agents liable jointly and severally.

In the case of merger or acquisition of the manufacturing company, the beneficiary of the merger or acquirer undertakes any potential product liability incurred by the acquired company as a result of its manufacturing and putting into circulation of unsafe products. The mentioned succession on liability does not occur, however, where a company purchases a brand or a production line of producer, but the producer continues to exist as such.

viii Mass tort actions

The Spanish Civil Procedure Act instituted a system of collective actions whereby certain consumer associations can exercise a legal action on behalf of (1) either a determined (or easily determinable) or (2) undetermined number of consumers who have sustained injuries or suffered a loss as a consequence of consuming a product or using a service.

The Civil Procedure Act states that if the number, identity and specific circumstances of the aggrieved consumers are determined or are easily determinable at the declaratory stage of the proceedings, both the consumer associations and the groups of aggrieved consumers by themselves (i.e., they do not need to be represented by a consumer association) hold capacity to sue on behalf of all the aggrieved consumers. In this regard, the group is considered to be legally constituted as the representative plaintiff (i.e., as the plaintiff in the proceedings) when at least 50 per cent of its members have joined it.

In turn, only the consumer associations that are members of the Spanish National Consumer Committee have legal standing to file legal actions on behalf of an undetermined number of consumers.

Although the specific requirements that a collective claim must fulfil in order to be accepted (as it happens with the class actions) are not regulated, the Civil Procedure Act requires that the damaging event be the same.

In the case of joinder of actions, which also exist in the Spanish regulations, a plaintiff can aggregate different legal actions against different defendants provided that the issues of fact that underlie each of the actions are sufficiently common. Pursuant to this regulation, the damaging event does not need to be the same, but there must be a connection between actions. Taking into consideration that each case can be somehow different, although must be connected, the limit of this type of action is the procedural economy principle.

ix Damages

The Spanish civil liability system is based on compensatory grounds. Consequently, indemnifiable damages should match the impairment or loss suffered by a person as a result of a given event or fact, whether such impairment or loss affects the person's natural vital attributes or his or her property or assets.

Indemnifiable damages include both the strictly economic damages and also 'non-material damages' (including, for instance, suffering or pain).[8]

8 'Non-material damages' are not economically assessable, although compensation for such damage is imposed by law. In practice, each court determines the economic value of such non-material damage according to each specific case, and this is generally proportional to the strictly economic damages that are granted.

Punitive damages are not contemplated in the Spanish legal system.

Royal Legislative Decree 1/2007 establishes an accrued liability limit of €63,106,270.96 (this is a global civil liability for producers for death and personal damages caused by identical products affected by the same defect).

Damages in respect of the cost of medical monitoring can be recovered.

Additionally, according to the Spanish laws on torts, nothing prevents a claimant from seeking compensation in kind (*in natura* as opposed to monetary compensation). In this regard, to the extent that it could be understood as a means of compensation in kind in connection with mental damage (suffering or anxiety), medical monitoring might be accepted as a form of compensation.

V YEAR IN REVIEW

Some consumers' and users' associations in Spain announced the initiation of a collective action against some vehicle manufacturers in order to claim economic compensation for those affected by the emissions scandal. For the moment no collective action seems to have yet been filed, although some individual cases have already been lodged and in fact decided differently depending on the specific circumstances of the case, which can be used as a test case for any collective action.

In any case, the pharmaceutical industry continues to be a target of many of the most significant product liability claims in Spain. Recently, the Spanish Supreme Court issued a decision on a product liability case in the aviation sector. The relatives of more than 100 passengers and crew who were killed when two aircraft in which they were travelling collided over Germany in 2002 filed a product liability claim against two companies that had supplied the anti-crash technology installed on the aircraft. The plaintiffs alleged that the technology had design and manufacturing defects and that they were decisive factors in causing the accident. The Supreme Court upheld the decision of the lower court, finding the defendant companies liable and ordering them to pay the victims over €600 million in compensation.

Most recently, the Court of Appeal of Madrid upheld an appeal filed by the manufacturer of the banned pregnancy drug thalidomide against a decision of a court of first instance in Madrid that ordered the appellant to pay a significant amount in compensation to several people who were born with birth defects in the 1960s. In its decision, the Court of Appeal of Madrid accepted the statute of limitation defences that the manufacturer had argued to refute its liability, which was recently confirmed by the Supreme Court.

In general, the increase of product safety standards and the severity of legal consequences (the putting into circulation of unsafe products for consumption might be a criminal offence under certain circumstances) have caused an increase in awareness among producers and distributors on the need to monitor product safety. As a result, product recalls have grown significantly in Spain during the past decade.

Chapter 21

SWITZERLAND

Frank Scherrer, Caroline Müller Tremonte and Caspar Humm[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

In Switzerland product liability is governed mainly by the Product Liability Act (PLA), contract law, general tort law and criminal law.

Although Switzerland is not a Member State of the European Union, its product liability and product safety legislation to a large extent implements EU legislation. The PLA is based on Directive 85/374/EEC on liability for defective products.

Until the PLA came into effect in 1993, product liability was mainly governed by the rules on contract law and tort law. The PLA does not affect other legal rights.[2] Therefore, in addition to the rules of the PLA, the rules of the Swiss Code of Obligations (CO) on contract and tort law can still apply if a product is defective. A claim may be based on different legal grounds. Furthermore, a person responsible for a defective product can be subject to criminal liability.

According to the PLA, a producer is liable if a defective product leads to the death or injury of a person, or damage to, or destruction of, property for private use.[3]

The following persons are deemed to be producers:

a the manufacturer (in whole or in part) of the defective product;
b any person who applied its name or trademark to the product;
c any person who imported the product for commercial distribution; and
d the person who supplied the product, if the producer (*a* to *c*) cannot be identified.[4]

According to the PLA, a product is deemed to be defective if, at the time it is marketed, it is not as safe as it can justifiably be expected to be, taking into account all circumstances. Special consideration must be given to:

a the ratio between benefit and risk;
b the method and manner used to present the product (particularly the product information);
c the use of the product that can be reasonably expected; and
d the point in time the product was placed on the market.

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2 Article 11 PLA.
3 Ibid., Article 1.
4 Ibid., Article 2.

The subsequent launch of an improved product on the market does not in itself make an older product defective.[5] In a decision of 2013, the Federal Supreme Court clarified that a dysfunction of products that serve to protect against dangers, such as a fire extinguisher, is also to be qualified as a defect although strictly speaking the dysfunction does not concern the safety of the extinguisher as such.[6]

The Product Safety Act (PSA) of 2009 as well as many other administrative laws and corresponding ordinances contain rules on conformity assessments and on standards and proceedings that specific products have to fulfil in order to be considered safe. To a large extent such rules refer to or implement EU or international harmonised standards and proceedings. The PSA provides in its Article 6 that the applicable technical standards are published in the Swiss Federal Gazette.

II REGULATORY OVERSIGHT

In Switzerland, administrative laws grant different regulatory agencies the authority to enforce legal rules on product safety. The regulatory authorities' competences depend mainly on the nature of the product. Based on the federal structure of Switzerland there is often also a cantonal authority competent for enforcement of the legal rules. Prominent authorities are the Federal Food Safety and Veterinary Office, competent in the fields of food safety, nutrition, cosmetics and animal health and the Federal Inspectorate for Heavy Current Installations, competent in the fields of electrical products, domestic installations and heavy-current installations.

The PSA is applicable if no other federal legal rules on the safety of products apply.[7] The State Secretariat of Economic Affairs (SECO) is responsible for coordinating the enforcement of the PSA.[8]

According to the PSA the manufacturer or other distributors (importer, retailer or service provider) of consumer products have to notify the competent authorities if they have reason to assume that their product is a danger to the safety or health of the user or third parties.[9] Notification can be made with the form provided under https://www.seco.admin.ch/seco/de/home/Arbeit/Arbeitsbedingungen/Produktsicherheit.html. Product recalls can be published on the website of the SECO free of charge.

It is also possible for consumers, assessment bodies and authorities to notify the SECO if they suspect a product to be defective.

The competent authority can take the necessary measures to ensure the safety of products, such as inspecting products, banning the distribution of or confiscating certain products, and issuing warnings regarding certain products (see Article 10 PSA).

Similar rules apply based on other federal laws. For example, the Swiss Agency for Therapeutic Products (Swissmedic) is the competent authority in the field of the safety of medicinal products and medical devices. The Act on Therapeutic Products vests Swissmedic with broad competences for ensuring the safety of these products.

5 Article 4 PLA.

6 BGE 139 II 534.

7 Article 1 Section 3 PSA.

8 Article 3 of the Ordinance on Product Safety.

9 Article 8 Section 5 PSA.

As many different authorities have competences in the field of product safety, it is often not entirely clear for the distributor or manufacturer which agency has to be notified in case of product defects and which agency is authorised to enforce legal rules on product safety.

III CAUSES OF ACTION

Actions for product liability may be based on the PLA, general tort law and contract law. Furthermore, criminal provisions may apply. Federal and cantonal laws governing certain products or activities such as railways or explosives may also serve as a basis for product liability claims.

Under the PLA, the manufacturer is liable for damages in case of death or personal injury or damage to things which are intended for private use or consumption and have been used mainly for private purposes. Under the PLA, the manufacturer is not liable for damages to the defective product. To prevail in a claim based on the PLA, the plaintiff must generally show the following elements: (1) the damage; (2) the defect; and (3) adequate causation of the damage by the defective product.

Under contract law and tort law, damage caused by a breach of contract or an illegal act must be compensated. To prevail in a claim based on breach of contract or general tort law, the plaintiff must generally show the following elements: (1) the damage; (2) the breach of contract or breach of a protective legal provision; (3) adequate causation of the damage by the breach of contract or breach of a protective legal provision; and (4) a fault of the liable person (intent or negligence). In case of breach of contract, the fault is presumed and the contract partner must prove that no fault is imputable to it. Unless the state is damaged itself, the government may not start civil actions for product liability.

In case of intentional or negligent distribution of a defective product, the provisions of the Swiss Criminal Code may apply, such as common assault, endangering of health, serious assault or homicide through negligence. Penalties for such crimes range up to 10 years of a custodial sentence (in case of intentional serious assault).

The PSA provides for penalties (a fine of up to 40,000 Swiss francs) in case of putting into circulation a product that does not fulfil the requirements of the PSA, if the safety or health of the user or third parties is thereby endangered. Various sector-specific laws also contain criminal provisions.

Companies can, generally, be held criminally liable if a criminal act is committed in the exercise of commercial activities in accordance with the purpose of the corporation and if it is not possible to attribute this act to any specific individual owing to inadequate organisation of the company.[10] In such cases, a fine of up to 5 million Swiss francs can be imposed on the company.

IV LITIGATION

i Forum

Product liability claims are tried before the general civil court system. The system is partly regulated by cantonal law, thus there are some local variations. There are four distinct levels of ordinary civil courts:

10 Article 102 of the Swiss Criminal Code.

a the local conciliation authority;
b the local court of first instance;
c the cantonal high court; and
d the Federal Supreme Court.

With certain exceptions, the claimant must start by initiating a mandatory conciliation proceeding. The conciliation authority will try to reconcile the parties in a conciliation hearing (Articles 201 and 203 of the Swiss Civil Procedure Code (CPC)). The parties must appear in person at the conciliation hearing, but may be accompanied by a legal representative. Parties domiciled outside of the canton or in a foreign country are exempt from the obligation to appear in person and may send a representative on their behalf.[11] The conciliation authority can, on petition, issue decisions on monetary claims if the value of the claim does not exceed 2,000 Swiss francs.[12] For claims of a higher value, the conciliation authority has no competence to decide on the merits of the case.

The local courts of first instance are competent to hear civil cases for which no reconciliation was achieved before the conciliation authority. Court decisions are rendered by one or several judges, depending on cantonal law and value of the claim.

There are no jury trials in Switzerland for civil lawsuits. A civil trial is commenced by filing a written statement of claim to the local court of first instance, within three months of authorisation to proceed being granted by the conciliation authority.[13] Usually, there will be an exchange of one or two written statements and, thereafter, one or several days in court (hearing witnesses, final statements by the parties). Swiss litigation is, in practice, highly focused on the written statements and on the other documents submitted by the parties, although, formally, the oral part of the proceeding and other means of proof are not less meaningful. After the first written statements have been filed, the instructing judge will usually hold a hearing and propose a settlement to the parties.

Judgments by the conciliation authority and the courts of first instance can be appealed (the details vary depending on the value of the claim) and brought before the cantonal high court.

If the value of the claim is over 100,000 Swiss francs, the parties can agree to commence proceedings directly before the cantonal high court.[14]

Some cantons have installed commercial courts that are competent to hear certain claims that would otherwise be handled by the regular civil courts. For product liability claims, the following preconditions of the competence of commercial courts are relevant: registration of at least the defendant in the commercial registry in Switzerland or in a comparable registry in his or her country of domicile and value of the claim of at least 30,000 Swiss francs. If the claimant is not registered in the commercial registry, but the defendant is, the claimant may choose whether to proceed before the commercial court or the ordinary courts.

Judgments by the cantonal high court and the commercial court can be appealed before the Federal Supreme Court, the highest court in Switzerland, if the value of the claim amounts to at least 30,000 Swiss francs (subject to further preconditions).[15]

11 Article 204 CPC.
12 Ibid., Article 212.
13 Ibid., Article 209.
14 Ibid., Article 8.
15 Article 77 et seq. of the Federal Law on the Federal Supreme Court (FCL).

For any stage of a civil proceeding, the claimant or the party appealing respectively will be required to pay an advance on the court fees.

Proceedings by the administrative authorities regarding product safety are separate from civil proceedings. Federal administrative authorities can issue orders and obligate a manufacturer or distributor to take certain measures regarding product safety (e.g., a product recall).[16] Orders by federal administrative authorities can be appealed before the Federal Administrative Court.[17] Judgments of the Federal Administrative Court are subject to appeal before the Federal Supreme Court.[18]

Criminal proceedings are handled by cantonal criminal authorities (i.e., public prosecutors and criminal courts; usually the local court of first instance and, on appeal, the cantonal high court and the Federal Supreme Court). Criminal courts may also decide civil claims connected to criminal allegations.[19] Administrative authorities are often also vested with certain competences to impose fines. They issue penal orders that are subject to appeal.

ii Burden of proof

In civil litigation, the burden of proof for an alleged fact rests on the person who derives rights from that fact; therefore, in a product liability case, the burden of proof for the preconditions of product liability rests on the plaintiff. The plaintiff needs to prove the defectiveness of the product, the damage and adequate causation. Adequate causation means, according to the Federal Supreme Court, that a cause must be appropriate to cause a result of the kind occurred or to considerably facilitate the occurrence of such a result based on general experience of life and the usual course of things. The standard of proof is overwhelming likelihood.[20] The defectiveness does not necessarily need to be proven by an expert opinion.

iii Defences

The producer is not liable for a defective product under the PLA if it proves any of the following:

a it did not market the product;
b the product was not defective when it was put into circulation;
c it did not manufacture the product for a business purpose or within the framework of its professional activity;
d the defect is attributable to compliance with compulsory, official regulations;
e the error was not identifiable on the basis of scientific and technological knowledge at the time the product was put into circulation (development risk); or
f it had produced only base material or part of the product and the defect was caused by the construction of the product, in which the base material or part was incorporated, or by the instruction given by the producer of that product.[21]

Apart from defects owing to compliance with compulsory, official regulations, there is no 'regulatory compliance defence' in civil litigation, that is, liability cannot be excluded only

16 Article 10 PSA.
17 Article 31 of the Federal Act on the Federal Administrative Court.
18 Article 75 FCL.
19 Article 122 of the Swiss Criminal Procedure Code.
20 BGE 133 III 81, E.4.2.2.
21 Article 5 PLA.

because all regulatory requirements have been complied with. As defectiveness is assessed based on all circumstances, compliance with regulatory requirements and the assessments of the experts of the regulatory authorities, however, need to be taken into account.

In administrative proceedings, compliance with (harmonised) technical standards constitutes a (disputable) presumption that the product complies with the essential health and safety requirements.[22]

The statute of limitation period for product liability claims under the PLA is three years from the day when the injured person gained or could have gained knowledge of the damage, the defectiveness and the person of the manufacturer. Claims under the PLA are in any case time-barred if no lawsuit is filed within 10 years from the day when the product in question was put on the market.

The statute of limitation period for product liability claims under general tort law is one year from the day the injured person gained knowledge of the damage and the person liable or 10 years from the day of the damaging act or omission. In case of a longer limitation period for a criminal act, this longer period would apply.

The general statute of limitation period for contractual claims is five (foodstuffs, everyday retail goods) or 10 years (other goods). Claims based on defects of a purchased product must, however, generally be brought within two years after the delivery of the product. The buyer is obliged to notify the seller immediately when he or she discovers a defect.

Apart from the statute of limitations there are additional defences against contractual claims or claims under general tort law.

iv Personal jurisdiction

International jurisdiction is determined by the Convention on Jurisdiction and the Enforcement of Judgments in Civil and Commercial Matters of 30 October 2007 (the Lugano Convention (LC)) for parties domiciled in a contracting state of the Lugano Convention.

According to the Lugano Convention, claims must generally be brought before the courts of the state in which the defendant is domiciled. However, the Lugano Convention defines a number of exceptions to this general rule. There are several situations in which a person domiciled in a contracting state may be sued in another contracting state. The relevant additional forums for product liability cases are:

a for claims based on the PLA or general tort law, the courts at the place where the harmful event occurred;[23]

b in matters relating to a contract, the place of performance of the obligation in question (i.e., in the state where the defective product was delivered);[24]

c for civil claims for damages or restitution that are based on an act giving rise to criminal proceedings, the court handling those criminal proceedings, to the extent that such court has jurisdiction, under its own law, to entertain civil proceedings;[25]

d if a number of defendants are sued together, in the courts of the place where at least one of them is domiciled;[26] and

22 Article 5 PSA.

23 Article 5.3 LC.

24 Ibid., Article 5.1.

25 Ibid., Article 5.4.

26 Ibid., Article 6.1.

e in an action on a warranty or guarantee, or in any third-party proceedings, in the court of the primary proceedings.[27]

In cases where the defendant is not domiciled in a contracting state of the Lugano Convention, international jurisdiction of Swiss courts is determined by the Federal Act on International Private Law (PILA).

The PILA provides for the following additional places of jurisdiction besides the domicile of the defendant which are relevant for product liability trials:

a for claims based on the PLA and general tort law, the courts at the place where the harmful act was committed or where its effect took place or, for claims based on the activities of a Swiss branch office, at the branch office's domicile;[28]

b for claims based on a contract, the place of performance of the characteristic contractual obligation;[29] and

c for claims based on contracts with consumers, the domicile of the consumer.[30]

v Expert witnesses

In civil litigation, the parties have to present the facts of the case to the court in substantiated form and are obligated to offer evidence supporting their factual statements. The court must review or administer the evidence offered by the parties for facts that are disputed among the parties and that are legally relevant to the case. The following evidence is admissible: testimony, physical records, inspection, expert opinion, written statements and questioning as well as statements of the parties.[31] The court forms its opinion based on its free assessment of the evidence.[32]

According to the Federal Supreme Court, expert opinions commissioned by the parties themselves are not to be regarded to be expert opinions in the meaning of the CPC. Such a 'private expert opinion' may not be treated as evidence by the courts but rather as a mere statement by the respective party.[33]

Parties can, however, request the court to appoint an independent court expert. Parties have the right to be heard regarding the identity of the expert and the questions he or she shall be asked. They may also request that the court asks additional questions after reviewing the expert opinion. Usually, as far as technical or scientific matters are concerned, a court will rely strongly on a court expert's opinion.

vi Discovery

Swiss law does not provide for the possibility of discovery or depositions as they are known in common law jurisdictions. The parties generally have to gather the evidence they consider necessary to substantiate their claim or defence themselves or request the court to collect such

27 Ibid., Article 6.2.
28 Article 129 PILA.
29 Ibid., Article 113.
30 Ibid., Article 114.
31 Article 168 CPC.
32 Ibid., Article 157.
33 BGE 141 III 433.

specified evidence in the evidentiary proceeding. In the evidentiary proceeding in a pending lawsuit, the court may order a party to produce certain pieces of evidence. If the party refuses to comply with such an order, the court may weigh this behaviour against this party.[34]

The CPC does provide the possibility of precautionary taking of evidence by the court if the applicant shows credibly that evidence is at risk or that he or she has a legitimate interest.[35] If an expert opinion will supposedly be a central piece of evidence in a future court proceeding, a party can request that the court commissions such expert opinion before an actual trial is commenced based on Article 158 CPC.[36]

Witnesses may be summoned to appear in court if a party requests that they are questioned. The questioning of witnesses is conducted by the court. The parties or their representatives respectively may ask additional questions.

vii Apportionment

In principle, a court decision may only hold that the named defendant is liable towards the claimant. If the defendant named in a lawsuit would, in case it loses the trial, turn towards a third party like a manufacturer, it is possible to either invite the third party to join the process or file a formal claim against this third party. In the first situation, the third party is not obliged to join the process, whereas in the second the process is extended to it.

Where several persons are liable for the same damage based on similar or different causes (e.g., several persons being considered as manufacturer or a doctor is liable based on contract and a manufacturer based on product liability), the law states that the judge may determine to what extent they have recourse claims against the others.[37] If two or more persons are liable based on different legal grounds, law provides that the person having caused the damage through tort shall bear the damage primarily and the person being liable without fault and without contractual obligation shall bear the damage lastly.[38]

viii Mass tort actions

Class actions are not known in Switzerland. Several claimants can ask that their respective claims be joined and the proceedings are conducted together, but the claims remain separate from each other and are judged separately.

ix Damages

There are no maximum limits of damages available for one claimant or available from one manufacturer. According to Swiss law, damage is generally defined as the difference between the injured person's actual assets compared with this person's hypothetical assets if the damaging event had not taken place.

Under the PLA, the injured person may claim for compensation of personal damage and material damage to things for private usage. The PLA provides for a retention of 900 Swiss francs. These limitations do not apply for liability under general tort law or contract law. Damages can also be allocated if the amount of the damage cannot yet be exactly defined;

34 Article 164 CPC.

35 Ibid., Article 158.

36 BGE 140 II 16, E. 2.5.

37 Article 50 CO.

38 Ibid., Article 51.

however the damaging event must have occurred. Punitive damages are not available in Switzerland. Amends for non-economic damages such as pain and suffering are available to the injured person or their next of kin. The amounts are usually moderate, but range up to about 100,000 to 200,000 Swiss francs in cases of severe violations of physical integrity.

V YEAR IN REVIEW

While in 2015 the Swiss Federal Supreme Court decided the rather prominent case regarding the contraceptive Yasmin, which is an important decision for product liability law (confirming that the degree of safety that can justifiably be expected from a product has to be based on the expectations of professional experts if the product in question is intended only for use by professional experts), in 2016 the Federal Supreme Court did not issue any decision regarding product liability, nor was there any pending case prominently discussed in public. Cases on product liability that are decided by the Federal Supreme Court are rather rare.

With regard to product safety, in 2016 the Swiss Federal Administrative Court ruled in four cases concerning different product categories. One case concerned the rules applicable to the import of a certain product. In three cases the competent authority had conducted a safety assessment and prohibited or stopped the marketing of the products if certain conditions could not be met. Assessment was conducted in one case because in another European country the marketing of the product had been prohibited and in one case because a third party had notified the competent authority.

Product recalls are quite often a precautionary measure taken by the manufacturer/importer and are not necessarily based on orders by the competent authorities. Recalls concern many different categories of products. Some of the recalled products can be found on lists published by the competent authorities, for example, the Federal Food Safety and Veterinary Office,[39] the Federal Office of Communications[40] as well as Swissmedic[41] regarding medical devices and pharmaceutical products.

Product recalls in the focus of public attention are, in particular, recalls concerning foodstuffs and toys and other products used for or by children and babies as well as other products used by consumers, such as pharmaceuticals and medical devices.

39 https://www.blv.admin.ch/blv/de/home/gebrauchsgegenstaende/rueckrufe-und-oeffentliche-warnungen.html.

40 https://www.bakom.admin.ch/bakom/en/homepage/equipments-and-installations/non-compliant-equipment.html.

41 www.swissmedic.ch.

Chapter 22

UNITED STATES

Chilton Davis Varner and Bradley W Pratt[1]

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

Product liability in the United States is complex and constantly evolving, governed by distinct legal systems in each of the 50 states and the federal government. Each state has developed its own constitutional and statutory framework, and its own common law through decisions by the courts. Owing to the peculiarities of the US federalist system, product liability lawsuits sometimes end up in federal courts, which must nonetheless apply the applicable state's law of product liability. Many industries are heavily regulated by the federal government and federal regulations. All of this leads to a complex, interesting, and sometimes confusing, interaction between state and federal law. Fortunately, many of the most important principles of product liability are similar throughout these jurisdictions. This chapter contains an overview of these principles, without purporting to describe every statute, regulation or common-law rule that may apply in a given product liability lawsuit.

As a general matter, US product liability law, in its current state, favours the right of an injured consumer to sue. The litigation environment in the United States for product manufacturers may present greater potential exposure and liability concerns than elsewhere.

II REGULATORY OVERSIGHT

The federal government has created a number of administrative agencies to regulate product safety. Among the most prominent is the Consumer Product Safety Commission (CPSC), which, as the name suggests, oversees the safety of consumer products;[2] the Food and Drug Administration (FDA), which, *inter alia*, regulates the marketing and labelling of food and prescription drugs;[3] the National Highway Traffic Safety Administration (NHTSA), which regulates motor vehicle safety;[4] the Federal Aviation Administration (FAA), which governs all aspects of air transportation;[5] the Federal Railroad Administration (FRA), which oversees trains and railways;[6] and the Occupational Safety and Health Administration (OSHA), which

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2 See www.cpsc.gov; see also Consumer Product Safety Act, 15 USC. §§2051 et seq.

3 See www.fda.gov; see also Food, Drug & Cosmetic Act, 21 USC. §§301 et seq.

4 See www.nhtsa.gov; see also National Highway Traffic Safety Administration Authorization Act, 49 USC. §§30101 et seq.

5 See www.faa.gov; see also Federal Aviation Act, 49 USC. §§40101 et seq.

6 See www.fra.dot.gov; see also 49 USC. §§20101 et seq.

was created to prevent injuries in the workplace.[7] Under certain circumstances, the rules and regulations promulgated by these federal agencies may pre-empt conflicting state law, barring an otherwise viable product liability claim.[8] Each state may also have its own laws, agencies, and regulations governing some aspects of product safety.

III CAUSES OF ACTION

i Strict liability

Strict liability is one of the most common and plaintiff-friendly causes of action. It is recognised in the vast majority of states either through common law or by statute. A plaintiff asserting strict liability need not prove fault by the manufacturer; that is, a manufacturer can be liable even if it acted reasonably in designing and constructing the product and followed all applicable procedures and protocols, but nonetheless ended up producing a product later adjudged 'defective'.[9]

To prevail on a claim of strict liability, a plaintiff must generally show the following elements: (1) the product contained a defect; (2) the defect existed at the time the product left the manufacturer's control; (3) the defect rendered the product unreasonably dangerous; and (4) the defect actually and proximately caused the plaintiff's injuries.[10]

Generally, there are three types of defects for which a manufacturer may be strictly liable: a defect in manufacture, a defect in design, and a defect in labelling.[11] To prove a manufacturing defect, a plaintiff must show that a product became unreasonably dangerous because it (1) did not meet manufacturing specifications or (2) deviated from the great majority of otherwise identical products with the same design.[12] In determining whether a design defect exists, most courts apply a risk-utility analysis, weighing the benefits and utility of a product's design against its resultant risks.[13] Some courts also apply a 'consumer

7 See www.osha.gov; see also Occupational Safety & Health Act, 29 USC. §651 et seq.

8 See discussion on pre-emption, Section IV.iii, *infra*.

9 See, e.g., *Myrlak v. Port Auth. of N.Y. & N.J.*, 723 A.2d 45, 52 (N.J. 1999); *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 900 (Cal. 1963). All participants in the product's chain of distribution may be strictly liable. See Restatement (Second) of Torts §402A, cmt.f. (stating that the strict liability rule applies 'to any manufacturer […], to any wholesale or retail dealer or distributor, and to the operator of a restaurant'); *Simon v. Nortrax N.E., LLC*, 941 N.Y.S.2d 706, 708 (N.Y. App. Div. 2012).

10 See, e.g., *Sheehan v. N. Am. Marketing Corp.*, 610 F.3d 144, 149 (1st Cir. 2010) (discussing Rhode Island law); *Barton v. Adams Rental, Inc.*, 938 P.2d 532, 536–37 (Colo. 1997); Restatement (Second) of Torts §402A.

11 Labelling defects are discussed in Sections III.iii and III.iv, *infra*.

12 See *Am. Tobacco Co. v. Grinnell*, 951 S.W.2d 420, 434 (Tex. 1997) ('[A] plaintiff has a manufacturing defect claim when a finished product deviates, in terms of its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous'); *In re Coordinated Latex Glove Litig.*, 121 Cal. Rptr. 2d 301, 313 (Cal. Ct. App. 2002) ('A defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line'. (internal quotation marks omitted)); see also *Rix v. Gen. Motors Corp.*, 723 P.2d 195, 200 (Mont. 1986) (defining a manufacturing defect as an imperfection that occurs 'in a typically small percentage of products of a given design as a result of the fallibility of the manufacturing process' [internal quotation marks omitted]).

13 See, e.g., *Evans v. Lorillard Tobacco Co.*, 990 N.E.2d 997, 1012 (Mass. 2013); *Warner Fruehauf Trailer Co. v. Boston*, 654 A.2d 1272, 1278 (D.C. 1995). States use a variety of factors to determine whether utility outweighs risk, such as (1) the utility of the product to the public as a whole and to the individual

expectations' test, according to which a product's design is defective if the product fails 'to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner'.[14]

Causation is a necessary element of any strict product liability claim. In toxic tort cases, a plaintiff must prove both (1) 'general causation' – that a particular substance is capable of causing the injury at issue; and (2) 'specific causation' – that the substance did in fact cause the particular injury of this particular plaintiff.[15] In all product liability cases, the plaintiff must also prove 'proximate' or 'legal' causation (i.e., that the injury was a reasonably foreseeable consequence of a product defect or wrongful act).[16] Notably, a product defect or wrongful act need not be the sole cause of the injury, as long as it is a significant proximate cause. There may well be other contributing causes of the injury.[17]

Sometimes, a plaintiff will allege that a product defect enhanced, rather than caused, the injury.[18] Such claims are commonly referred to as 'enhanced injury', 'second-collision', or 'crashworthiness' claims,[19] and are premised on the theory that accidents (e.g., car crashes) are foreseeable with certain products and manufacturers must take reasonable steps to design and produce products that will 'minimize the unavoidable danger'.[20] A crashworthiness plaintiff need show only that 'the defective product was the proximate cause of the enhanced injuries – not the proximate cause of the accident itself'.[21]

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user; (2) the nature of the product and the likelihood that it will cause injury; (3) the availability of a safer design; (4) 'the potential for designing and manufacturing the product so that it is safer but remains functional and reasonably priced'; (5) 'the ability of the plaintiff to have avoided injury by careful use of the product;' (6) the degree to which the plaintiff was aware of the product's potential danger; and (7) 'the manufacturer's ability to spread any cost related to improving the safety of the design'. *Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204, 208-09 (N.Y. 1983).

14 *Perez v. VAS S.p.A.*, 115 Cal. Rptr. 3d 590, 603–04 (Cal. Ct. App. 2010); *Delaney v. Deere & Co.*, 999 P.2d 930, 944–45 (Kan. 2000) (adhering to the consumer-expectations test and discussing the merits of that test as opposed to the risk-utility approach); see also *Evans*, 990 N.E.2d at 1012 ('The vast majority of States have adopted the risk-utility balancing test […] rather than the consumer expectations test […]').

15 See *Ranes v. Adams Labs., Inc.*, 778 N.W.2d 677, 687–88 (Iowa 2010); *Richardson v. Union Pac. R.R. Co.*, 386 S.W.3d 77, 80 (Ark. Ct. App. 2011).

16 *Jones v. Detroit Med. Ctr.*, 806 N.W.2d 304, 305 (Mich. 2011) (defining proximate cause as 'a foreseeable, natural, and probable cause' (internal quotation marks omitted)); *Krause v. U.S. Truck Co.*, 787 S.W.2d 708, 710 (Mo. 1990) ('[F]rom the essential meaning of proximate cause arises the principle that in order for an act to constitute the proximate cause of an injury, *some* injury, if not the precise one in question, must have been reasonably foreseeable'. (internal quotation marks omitted)).

17 See *Stull v. Fuqua Indus., Inc.*, 906 F.2d 1271, 1277 (8th Cir. 1990) (holding that, under Missouri law, a lawnmower manufacturer could be held liable for the plaintiff's injury when the plaintiff 'encountered a swarm of bees just prior to the accident, moved to avoid the bees and then got his foot caught underneath the mower'); *Jurado v. W. Gear Works*, 619 A.2d 1312, 1318 (N.J. 1993) ('Even if a defect is a contributing or concurring cause, but not the sole cause, of an accident, the manufacturer will be liable').

18 See, e.g., *Mazda Motor Corp. v. Lindahl*, 706 A.2d 526, 529 (Del. 1998); *Larsen v. Gen. Motors Corp.*, 391 F.2d 495, 501 (8th Cir. 1968); *Kupetz v. Deere & Co.*, 644 A.2d 1213, 1218–19 (Pa. Super. Ct. 1994).

19 *Mazda Motor Corp.*, 706 A.2d at 530.

20 *Huddell v. Levin*, 537 F.2d 726, 735 (3d Cir. 1976); *Larsen v. Gen. Motors Corp.*, 391 F.2d 495, 501-02 (8th Cir. 1968); *Farmer v. Int'l Harvester Co.*, 553 P.2d 1306, 1315 (Idaho 1976) ('[I]t is […] the manufacturer's duty to design and manufacture its products so as to eliminate unreasonable risks of foreseeable injury in the event of collision or other impact').

21 *Mazda Motor Corp.*, 706 A.2d at 531.

ii Negligence

To prove negligence, a plaintiff must show that (1) the defendant owed a duty to the plaintiff; (2) the defendant breached that duty; and (3) the breach actually and proximately caused the plaintiff's injury.[22] The primary difference between strict liability and negligence is that the latter requires a showing of fault, while the former does not. It is frequently stated that strict liability focuses on the condition of the product, while negligence focuses on the conduct of the manufacturer.[23]

As a general principle of tort law, every person has a duty to act 'reasonably' under a given set of circumstances. In keeping with this principle, a manufacturer has a duty to design and construct products that are reasonably safe for their foreseeable uses.[24] In addition, a non-manufacturing dealer or supplier of a product may have a duty to inspect a product if it knows or has reason to know that the product may be defective.[25]

Because a reasonable person will obey the law in most circumstances, a violation of a statute or regulation may constitute negligence in itself, or 'negligence *per se*'.[26] The negligence *per se* doctrine does not impose strict liability, but merely reduces a plaintiff's burden of proof on the elements of duty and breach. A plaintiff who proves negligence *per se* must still establish that the defendant's statutory violation actually and proximately caused the injury.[27]

iii Failure to warn

An increasingly popular cause of action in product liability is the failure-to-warn claim, alleging that the manufacturer failed to provide an adequate warning of the dangers associated with its product. These claims may be premised on either strict liability or negligence.[28]

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22 See, e.g., *Weigle v. SPX Corp.*, 729 F.3d 724, 731 (7th Cir. 2013) (discussing Indiana law); *Glorvigen v. Cirrus Design Corp.*, 816 N.W.2d 572, 581–82 (Minn. 2012).

23 See, e.g., *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 833 (Neb. 2000).

24 *Robinson v. Brandtjen & Kluge, Inc.*, 500 F.3d 691, 696 (8th Cir. 2007) (discussing South Dakota law); *Sexton v. Bell Helmets, Inc.*, 926 F.2d 331, 335 (4th Cir. 1991) (discussing Kentucky law).

25 *Dutchmen Mfg., Inc. v. Reynolds*, 891 N.E.2d 1074, 1086 (Ind. Ct. App. 2008); *Lind v. Beaman Dodge, Inc.*, 356 S.W.3d 889, 901 (Tenn. 2011) (stating that a failure-to-inspect action can be maintained only in negligence, not in strict liability); see also *Duncan v. Ford Motor Co.*, 682 S.E.2d 877, 884 (S.C. Ct. App. 2009) ('A manufacturer who incorporates into his product a component made by another has a responsibility to test and inspect such component, and his negligent failure to properly perform such duty renders him liable for injuries proximately caused as a consequence').

26 Restatement (Second) of Torts §288B ('The unexcused violation of a legislative enactment or an administrative regulation which is adopted by the court as defining the standard of conduct of a reasonable man, is negligence in itself'); see also, e.g., *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455, 460 (4th Cir. 1960) (stating that the Federal Food, Drug, and Cosmetic Act 'imposes an absolute duty on manufacturers not to misbrand their products, and the breach of this duty may give rise to civil liability').

27 See *Heath v. La Mariana Apartments*, 180 P.3d 664, 670 n.3 (N.M. 2008); *Sikora v. Wenzel*, 727 N.E.2d 1277, 1281 (Ohio 2000); *Atl. Mut. Ins. Co. v. Kenney*, 591 A.2d 507, 512 (Md. 1991).

28 As one court explained, a failure-to-warn claim based on negligence requires proof 'that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care', but the 'rules of strict liability require a plaintiff to prove only that the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution', *Carlin v. Superior Court*, 920 P.2d 1347, 1351 (Cal. 1996). Many courts, however, do not recognise a distinction between negligence and strict liability in failure-to-warn cases. See, e.g., *Ford Motor Co. v. Rushford*, 868 N.E.2d 806, 810 (Ind. 2007) ('Under either [strict liability or negligence] a product may be defective […] where

The exact elements needed to prove a failure-to-warn claim vary between states.[29] Generally speaking, however, a plaintiff must show that the manufacturer had a duty to warn and breached that duty, proximately causing the plaintiff's injuries.[30]

A manufacturer has a duty to warn consumers of dangers associated with the use of its products when the manufacturer knows or should know of such dangers.[31] Sometimes, a product will contain a latent defect that does not manifest itself until months or years after the product is first sold. For this reason, a number of states impose a continuing duty on a manufacturer to warn of hazards that become known to the manufacturer after the sale.[32] Importantly, manufacturers have no duty to warn of 'open or obvious' dangers in their products.[33]

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the manufacturer fails in its duty to warn of a danger or instruct on the proper use of the product as to which the average consumer would not be aware'); *Adeyinka v. Yankee Fiber Control, Inc.*, 564 F. Supp. 2d 265, 279 n.17 (S.D.N.Y. 2008) ('[W]here liability is predicated on a failure to warn, New York views negligence and strict liability claims as equivalent'. (internal quotation marks omitted)); *Madsen v. Am. Home Prods. Corp.*, 477 F. Supp. 2d 1025, 1033 n.12 (E.D. Mo. 2007) ('The Iowa Supreme Court has abandoned any distinction between strict liability and negligence in products liability failure-to-warn cases'); *Crislip v. TCH Liquidating Co.*, 556 N.E.2d 1177, 1183 (Ohio 1990) ('[T]he standard imposed upon the defendant in a strict liability claim grounded upon an inadequate warning is the same as that imposed in a negligence claim based upon inadequate warning').

29 In Florida, for example, a plaintiff must show that '(1) the warnings accompanying an item were inadequate, (2) the inadequacy of the warnings caused the plaintiff's injury, and (3) the plaintiff suffered an injury from using the product'. *In re Fosamax Prods. Liab. Litig.*, 707 F.3d 189, 193 (2d Cir. 2013) (discussing Florida law); see also *Fontenot v. Taser Int'l, Inc.*, 736 F.3d 318, 332 (4th Cir. 2013) (stating that, under North Carolina law, 'a claimant bringing a product liability action under a failure to warn theory must establish that the defendant's failure to provide an adequate warning or instruction was a proximate cause of the harm' (internal quotation marks omitted)). In Georgia, the plaintiff must show that 'the defendant had a duty to warn, that the defendant breached that duty, and that the breach proximately caused the plaintiff's injury'. *Dietz v. SmithKline Beecham Corp*, 598 F.3d 812, 815 (11th Cir. 2010) (discussing Georgia law). Sometimes, a failure-to-warn claim will be incorporated into a design-defect claim, as some states consider an inadequate warning to be a design defect. See *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2474–75 (2013) (discussing New Hampshire law).

30 See, e.g., *Dietz v. Smithkline Beecham Corp*, 598 F.3d 812, 815 (11th Cir. 2010) (discussing Georgia law); *Huggins v. Stryker Corp.*, 932 F. Supp. 2d 972, 986 (D. Minn. 2013).

31 See, e.g., *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994); *Bristol-Myers Co. v. Gonzales*, 561 S.W.2d 801, 804 (Tex. 1978); *Swift v. Serv. Chem., Inc.*, 310 P.3d 1127, 1131 (Okla. Civ. App. 2013).

32 See *Robinson v. Brandtjen & Kluge, Inc.*, 500 F.3d 691, 697–98 (8th Cir. 2007) (discussing South Dakota law); *Hunter v. Werner Co.*, 574 S.E.2d 426, 431 (Ga. Ct. App. 2002) ('A negligent failure to warn claim may arise from a manufacturer's post-sale knowledge acquired months, years, or even decades after the date of the first sale of the product' (internal quotation marks omitted)); see also Restatement (Third) of Torts: Prod. Liab. §10 & cmt. a (discussing post-sale duty to warn, and recognising such a duty 'whether or not the product is defective at the time of original sale'). But see *Jablonski v. Ford Motor Co.*, 955 N.E.2d 1138, 1160-61 (Ill. 2011) (noting that a manufacturer has a continuing duty to warn if it 'knew or should have known of the hazard' at the time of manufacture, but declining to adopt the broader rule in the Restatement (Third) of Torts: Prod. Liab. §10). The post-sale duty to warn may not last indefinitely, however. For example, one court held that a manufacturer of a printing press did not have a post-sale duty to warn of the risk of operating the machine, where the press was manufactured over 60 years before the injury. See *Robinson*, 500 F.3d at 697–98 ('Whatever the scope of the post-sale duty to warn, it does not extend to warning each individual employee of a company that owns a press some sixty-one years after the sale').

33 See, e.g., *Zavala v. Burlington N. Santa Fe Corp.*, 355 S.W.3d 359, 374 (Tex. App.--El Paso 2011, no pet.); *Martino v. Sullivan's of Liberty*, 722 N.Y.S.2d 884, 885 (N.Y. App. Div. 2001).

iv Fraud or misrepresentation

A product liability plaintiff may allege that a manufacturer committed fraud or misrepresentation, either through affirmative acts, such as false advertising, or through non-disclosure, such as a failure to disclose a known defect. To prove intentional fraud, a plaintiff must typically establish (1) a false representation (or, in some jurisdictions, omission) of a material fact; (2) 'scienter,' i.e., knowledge that the representation is false; (3) intent to mislead; (4) justifiable reliance on the misrepresentation or omission; and (5) damages.[34]

Although many fraud-based product liability claims are grounded in common law, most states have also promulgated 'consumer protection' statutes that specifically prohibit misrepresentations in advertising, marketing or labelling, and grant private individuals a cause of action for such misrepresentations.[35]

v Breach of warranty

Actions for a breach of warranty are somewhat unique in the products liability context because they are governed largely by the law of contracts rather than torts. Most states have adopted some version of the Uniform Commercial Code (UCC), Article 2, which applies to contracts for the sale of goods and provides for both express and implied warranties. Implied warranties generate the most product liability litigation. The most important of implied warranties is that of 'merchantability', or fitness for 'ordinary use'.[36] The implied warranty of merchantability has been stated to exist in every contract for the sale of goods if the seller is 'a merchant with respect to goods of that kind'.[37] Of course, a seller may disclaim any implied warranties, for example, by conspicuously labelling the product 'as is'.[38]

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34 *ReMax N. Atlanta v. Clark*, 537 S.E.2d 138, 141 (Ga. Ct. App. 2000); *Prospect Dev. Co. v. Bershader*, 515 S.E.2d 291, 297 (Va. 1999). Notably, expressions of opinion, 'puffing' (exaggerated praise of a product), or predictions of future performance usually will not amount to fraud. In one recent Georgia case, for example, a manufacturer's representation that the allegedly defective trailers would 'never rust' in their lifetime and 'should have no problem remaining operable for 10 to 14 or 15 years' were 'mere opinions, expectations, and predictions of the future and thus could not serve as the basis for either a fraud or a negligent misrepresentation claim'. *Home Depot USA., Inc. v. Wabash Nat'l Corp.*, 724 S.E.2d 53, 60 n.4 (Ga. Ct. App. 2012).

35 See, e.g., California Consumers Legal Remedies Act, Cal. Civ. Code §1750 et seq.; Florida Deceptive & Unfair Trade Practices Act, Fla. Stat. §501.201 et seq.; New York Deceptive Acts & Practices Act, N.Y. Gen. Bus. Law §349 et seq. Federal law also prohibits food, drug, and cosmetic manufacturers from misbranding their products by using 'false or misleading' labels, 21 USC. §§343(a), 352(a), 362(a), but does not grant a private cause of action for such violations, see *Adventure Outdoors, Inc. v. Bloomberg*, 552 F.3d 1290, 1295 (11th Cir. 2008).

36 UCC §2-314(1); 18 *Williston on Contracts* §52:78 (4th edn).

37 UCC §2-314(1). A contract for sale may also contain an implied warranty of 'fitness for a particular purpose' if the seller 'has reason to know any particular purpose for which the goods are required,' and the buyer relies 'on the seller's skill or judgment to select or furnish suitable goods'. Id. §315.

38 See UCC §2-316 ('[T]o exclude or modify the implied warranty of merchantability or any part of it the language must mention merchantability and in case of a writing must be conspicuous, and to exclude or modify any implied warranty of fitness the exclusion must be by a writing and conspicuous'); see also, e.g., Wis. Stat. Ann. §402.316 ('Unless the circumstances indicate otherwise, all implied warranties are excluded by expressions like 'as is', 'with all faults' or other language which in common understanding calls the buyer's attention to the exclusion of warranties and makes plain that there is no implied warranty').

IV LITIGATION

i Forum

A plaintiff may bring a product liability claim in either state or federal court, although, for various reasons, plaintiffs generally prefer state courts.[39] When a plaintiff files suit in state court, the defendant will sometimes 'remove' the case to federal court, provided the requirements for federal jurisdiction are met.[40] Federal courts have limited jurisdiction, and, broadly speaking, will only hear (1) cases that arise under federal law, such as the US Constitution or federal statutes; (2) cases where the parties are 'diverse,' that is, where the plaintiffs and defendants reside in different states, or where a plaintiff is suing a foreign country or foreign citizen; and (3) admiralty cases, which include claims for injuries sustained on vessels on navigable waters.[41] Importantly, when a federal court exercises diversity jurisdiction, the court applies federal procedural rules but state substantive law.[42] In both state and federal courts, the plaintiff usually will be entitled to a trial by jury, though he or she may elect to try the case before a judge (also called a 'bench trial').[43]

The structure of court systems in the United States is as follows. In the federal system, each state contains one or more federal trial courts called 'district courts'. The losing party in the district court may appeal as of right to one of 13 federal appellate courts called 'circuit' courts of appeal.[44] A party who loses in the circuit court of appeals may seek review in the US Supreme Court via a petition for a writ of certiorari, although the chances of obtaining review in the Supreme Court are quite low.[45] State court systems vary widely as to their

39 One reason for preferring state courts is that state courts have a reputation for favouring their own citizen-plaintiffs over large, out-of-state corporations. See Paul Rosenthal, 'Improper Joinder: Confronting Plaintiffs' Attempts to Destroy Federal Subject Matter Jurisdiction', 59 *Am. U. L. Rev.* 49, 57–58 (2009).

40 Federal 'removal' proceedings are governed by 28 USC. §§1441 and 1446.

41 See 28 USC. §1331 (governing federal question jurisdiction); 28 USC. §1332 (governing diversity jurisdiction); 28 USC. §1333 (governing admiralty jurisdiction); see also Admiralty Jurisdiction Extension Act, 46 USC. §30101 and the Death on the High Seas Act, 46 USC. §30302–30308.

42 *Gasperini v. Ctr. for Humanities, Inc.*, 518 U.S. 415, 426–28 (1996). Classifying a given rule as substantive or procedural 'is sometimes a challenging endeavor'. Id. at 427. Generally, however, 'procedural' rules are those governing the filing of pleadings, motions, and discovery (i.e., the Federal Rules of Civil Procedure), while 'substantive' law includes the particular state law on strict liability, negligence, causation and various tort defences.

43 The Seventh Amendment to the US Constitution guarantees the right to a trial by jury in civil cases. US Const. amend VII. Although this constitutional right applies only in federal courts, see *Minneapolis & St. Louis R. Co. v. Bombolis*, 241 U.S. 211, 217 (1916), a vast majority of states also guarantee the right to a trial by jury in civil cases, see *Aftercare of Clark Cnty. v. Justice of Las Vegas Tp.*, 82 P.3d 931, 933 (Nev. 2004) (discussing the right to a jury trial in Nevada); Eric J Hamilton, 'Federalism and the State Civil Jury Rights', 65 *Stan. L. Rev.* 851, 855–56 (2013).

44 For example, a party appealing from a decision of a district court in Florida, Georgia or Alabama will appeal to the US Court of Appeals for the Eleventh Circuit, and a party appealing from a district court in New York will appeal to the US Court of Appeals for the Second Circuit.

45 The Supreme Court typically has full discretion over which cases to hear and grants only a tiny fraction of certiorari petitions filed, usually in cases of exceptional importance or in cases of conflict between lower federal courts. For example, during the October 2011 term, the Court had a total of 8,949 cases on the docket, but heard oral argument in only 79 cases, and reviewed and decided an additional 137 cases without oral argument. See Statistical Table, 'Supreme Court of the United States – Cases on Docket, Disposed of, and Remaining on Docket at Conclusion of October Terms, 2007 Through 2011', available at www.uscourts.gov/Statistics/JudicialBusiness/2012/statistical-tables-us-supreme-court.aspx.

organisation, but most have a structure similar to the federal court system, with trial courts of general jurisdiction, intermediate appellate courts, and, at the top of the pyramid, a state supreme court that reviews only a small number of cases.[46]

ii Burden of proof

In most civil cases, including product liability cases, a plaintiff must prove each element of a claim by a preponderance of the evidence.[47] This standard 'directs the fact finder to decide whether the existence of a contested fact is more probable than its nonexistence,' and 'where evidence weighs evenly on both sides in a controversy, the fact finder must resolve the question against the party who has the burden of proof'.[48] In contrast, the defendant usually bears the burden to prove an 'affirmative' defence, such as a statute of limitations.[49]

iii Defences

Statutes of limitation and repose

A statute of limitations is a law that establishes a time limit for bringing a lawsuit.[50] The length of time within which a plaintiff must bring suit (if at all) varies from state to state. Usually, it ranges from two to four years and begins to run upon the date the injury occurred or, in a number of states, the date the injury was, or should have been, discovered (the latter is known as the 'discovery rule').[51] Some states also have statutes of 'repose,' which are laws that

46 There are exceptions. For example, the State of West Virginia does not have an intermediate appellate court and, until recently, there was no 'right' of appeal from the trial court, only a petition of certiorari to the West Virginia Supreme Court of Appeals, which that Court had the discretion to grant or deny. See Victor E Schwartz, 'Sherman Joyce and Cary Silverman, West Virginia as a Judicial Hellhole: Why Businesses Fear Litigating in State Courts', 111 *W. Va. L. Rev.* 757, 760–61 (2009). In 2010, the Supreme Court of Appeals adopted new rules that allow the Court to decide all appeals on the merits. See W. Va. R. App. P. 21 (effective 1 December 2010) (allowing the Court to decide appeals via a short 'memorandum decision'); id., clerk's cmt. (stating that, under Rule 21, 'every appeal, unless dismissed, will result in a decision on the merits'); see also West Virginia Judiciary, www.courtswv.gov/supreme-court/index.html ('In 2010, the Supreme Court [of West Virginia] revised the rules of Appellate Procedure. The revised rules are an effective method of providing a full review and a decision on the merits in all properly prepared and filed appeals').

47 See, e.g., *Gann v. Anheuser-Busch, Inc.*, 394 S.W.3d 83, 86 (Tex. App.--El Paso 2012, no pet.); *Lawson v. Honeywell Int'l, Inc.*, 75 So. 3d 1024, 1027 (Miss. 2011).

48 *People v. Taylor*, 618 P.2d 1127, 1135 (Colo. 1980); see also *In re B.D.-Y.*, 187 P.3d 594, 598 (Kan. 2008) (defining 'preponderance of the evidence' as 'evidence which is of greater weight or more convincing than the evidence which is offered in opposition to it' (internal quotation marks omitted)).

49 See *Pension Trust Fund for Operating Eng'rs v. Mortg. Asset Securitization Transactions, Inc.*, 730 F.3d 263, 271 (3d Cir. 2013).

50 *Black's Law Dictionary* (9th ed. 2009).

51 For example, Florida provides a four-year limitations period for claims of negligence, fraud or injury to personal property, and a two-year limitations period for wrongful death. Fla. Stat. §95.11(3)–(4). Florida's four-year statute of limitations in product liability cases 'begins to run 'from the date that the facts giving rise to the cause of action were discovered, or should have been discovered with the exercise of due diligence'.' *R.J. Reynolds Tobacco Co. v. Ciccone*, 123 So. 3d 604, 610 (Fla. Ct. App. 2013) (quoting Fla. Stat. §95.031(2)(b)), overruled in part on other grounds by *Soffer v. R.J. Reynolds Tobacco Co.*, 187 So. 3d 1219 (Fla. 2016). California and Oklahoma have a two-year statute of limitations for personal injuries caused by negligence. Cal. Civ. Proc. Code. §335.1; 12 Okla. Stat. Ann. §95.A. And New York and Wisconsin each have a three-year statute of limitations for personal injury. N.Y. C.P.L.R. §214.5; Wis. Stat. Ann. §893.54.

bar a claim after a specified time period even if the plaintiff has not yet suffered an injury.[52] Statutes of repose are generally longer, more final, and less subject to exceptions than statutes of limitation. They usually begin to run from some date unrelated to the injury, such as the date of a product's manufacture.[53] Some states do not apply statutes of limitations and repose to claims against the state or government agencies.[54]

Contributory negligence, assumption of risk and comparative fault

The doctrine of contributory negligence has historically barred a plaintiff from any recovery if the plaintiff's own negligence contributed in any way to the injury.[55] Closely related to this principle is the 'assumption of risk' doctrine, according to which persons who engage in certain dangerous activities, such as sports, are found to have consented – either directly or by implication – to the risks naturally arising from such activities. They therefore cannot recover for consequent injuries.[56] More recently, however, most states have adopted some version of a 'comparative fault' system, either 'pure' or 'modified,' in preference to the harsh consequences of the rules of contributory negligence and assumption of risk.[57] Under comparative fault, a plaintiff whose negligence contributed to the injury can still obtain a partial recovery in proportion to his or her own fault.[58] In a 'pure' comparative fault state, a plaintiff can recover

52 See *Black's Law Dictionary* (9th ed. 2009).

53 As one court explained, '[s]tatutes of limitations promote judicial economy and fairness, but do not create any substantive rights in a defendant to be free from liability'. *Anderson v. United States*, 46 A.3d 426, 437 (Md. 2012). Statutes of repose, on the other hand, are meant 'to provide an absolute bar to an action or to provide a grant of immunity to a class of potential defendants after a designated time period'. Id. at 437–38; see also *Combs v. Int'l Ins. Co.*, 354 F.3d 568, 589 n.11 (6th Cir. 2004) ('[A] statute of limitations might bar an injured plaintiff from bringing a product liability action more than three years after he discovered his injury, whereas a statute of repose would bar the action three years after the manufacturer produced the product'). Like statutes of limitations, statutes of repose differ from state to state. For example, Texas has a 15-year statute of repose for product liability cases. Tex. Civ. Prac. & Rem. Code §16.012(b) ('[A] claimant must commence a products liability action against a manufacturer or seller of a product before the end of 15 years after the date of the sale of the product by the defendant'). In Washington, the statute of repose is 12 years for product liability cases, but may be overcome with evidence that the product's useful safe life is longer than 12 years. Wash. Rev. Code §7.72.060; *Lisby v. PACCAR, Inc.*, 316 P.3d 1097, 1100 (Wash. Ct. App. 2013).

54 See *State v. Lombardo Bros. Mason Contractors, Inc.*, 54 A.3d 1005, 1023–24 (Conn. 2012); *Ohio Dep't of Transp. v. Sullivan*, 527 N.E.2d 798, 799, 801 (Ohio 1988); *Okla. City Mun. Imp. Auth. v. HTB, Inc.*, 769 P.2d 131, 134 (Okla. 1988).

55 *Li v. Yellow Cab Co.*, 532 P.2d 1226, 1230 (Cal. 1975); Restatement (Second) of Torts §467 ('Except where the defendant has the last clear chance [to avoid injury], the plaintiff's contributory negligence bars recovery against a defendant whose negligent conduct would otherwise make him liable to the plaintiff for the harm sustained by him').

56 *Ross v. Clouser*, 637 S.W.2d 11, 14 (Mo. 1982); *Baccari v. KCOR, Inc.*, 971 N.Y.S.2d 458, 458 (N.Y. App. Div. 2013); see also *Anderson v. Ceccardi*, 451 N.E.2d 780, 783 (Ohio 1983); *Simmons v. Porter*, 312 P.3d 345, 353 (Kan. 2013) (stating that a 'majority of comparative fault jurisdictions' have modified or abolished the assumption-of-risk doctrine).

57 See *McIntyre v. Balentine*, 833 S.W.2d 52, 57 (Tenn. 1992).

58 *McIntyre*, 833 S.W.2d at 57; see also *Tegman v. Accident & Medical Investigations, Inc.*, 75 P.3d 497, 499 n.4 (Wash. 2003) ('Under proportionate liability a negligent party is liable for his or her own proportionate share of fault and no more' (internal quotation marks and alteration omitted)). The plaintiff may even recover a full amount, regardless of fault, if the defendant partly caused the injury through intentional or grossly negligent conduct. See *Hampton Tree Farms, Inc. v. Jewett*, 974 P.2d 738, 748 (Or. Ct. App. 1999).

damages even if the plaintiff's percentage of fault exceeds that of the defendant. In a 'modified' comparative fault jurisdiction, a plaintiff cannot recover any damages if the plaintiff's fault exceeds that of the defendant.[59]

Federal pre-emption and primary jurisdiction

Under the 'Supremacy Clause' of the US Constitution, federal law on the same subject takes precedence over state law.[60] This rule of federal 'pre-emption' typically applies in three circumstances: (1) when a federal statute specifically provides for pre-emption ('express pre-emption'); (2) when federal law directly conflicts with state law and it is impossible to comply with both ('conflict pre-emption'); and (3) when 'the scope of a federal statute indicates that Congress intended federal law to occupy a field exclusively' ('field pre-emption').[61] Pre-emption may play a vital role in product liability cases when the defendant's industry is heavily regulated by the federal government, as in the case of the aviation industry or the food and drug industries. For example, an airline may defend against a failure-to-warn claim by arguing that federal law occupies the entire field of aviation safety, thereby pre-empting any state-imposed liability.[62] Or a drug manufacturer may defeat a design defect claim by arguing that federal regulations, which take precedence over conflicting state law, prohibited it from changing the design of its drugs.[63]

59 For example, in Tennessee, a plaintiff may recover 'so long as a plaintiff's negligence remains less than the defendant's negligence […]; in such a case, plaintiff's damages are to be reduced in proportion to the percentage of the total negligence attributable to the plaintiff'. *McIntyre*, 833 S.W.2d at 57; see also *Brodsky v. Grinnell Haulers, Inc.*, 853 A.2d 940, 944 (N.J. 2004) ('A plaintiff's contributory negligence does not bar a recovery so long as that negligence 'was not greater than the negligence of the person against whom recovery is sought or was not greater than the combined negligence of the persons against whom recovery is sought'); *Wilson v. Image Flooring, LLC*, 400 S.W.3d 386, 396 & n.10 (Mo. Ct. App. 2013); *Davis v. LeCuyer*, 849 N.E.2d 750, 755-56 & n.5 (Ind. Ct. App. 2006).

60 U.S. Const. art. VI, cl. 2; *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981).

61 *Kurns v. Railroad Friction Prods. Corp.*, 132 S. Ct. 1261, 1265–66 (2012); see also *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 108 (1992); *Patriotic Veterans, Inc. v. Indiana*, 736 F.3d 1041, 1049 (7th Cir. 2013). For an example of express pre-emption, see the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, 21 USC. §360k(a) ('[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement […] which is different from, or in addition to, any requirement applicable under this chapter to the device […]').

62 See *Montalvo v. Spirit Airlines*, 508 F.3d 464, 468 (9th Cir. 2007) (holding that the Federal Aviation Act and the applicable federal regulations pre-empted plaintiff's failure-to-warn claims against various airlines); see also *Kurns v. Railroad Friction Prods. Corp.*, 132 S. Ct. 1261, 1264–68 (2012) (holding that the federal Locomotive Inspection Act was intended to 'occupy the entire field of regulating locomotive equipment', thereby pre-empting the plaintiff's state-law claims against a locomotive parts manufacturer alleging asbestos-related injuries).

63 See *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2476–77 (2013). A state law tort suit brought by a private individual – not just a state statute or regulation – can trigger conflict pre-emption. See id.; *Geier v. Am. Honda Motor Co.*, 529 US 861, 881 (2000).

Other defences

Product alteration or misuse

A manufacturer generally will not be liable for injuries caused by a defective product if the plaintiff used the product 'in a manner which the manufacturer did not intend or reasonably anticipate'.[64]

State of the art

A manufacturer may rely on the state-of-the-art defence by presenting evidence that the product, even if defective in hindsight, conformed to the technological standards of the time in which it was made.[65]

Sophisticated user

Under the sophisticated user doctrine, a manufacturer has no duty to warn consumers of dangers associated with a product if the manufacturer reasonably believes that the consumer (an experienced professional, for example) knows, or should know, of such dangers.[66]

64 *Black v. M & W Gear Co.*, 269 F.3d 1220, 1234 (10th Cir. 2001) (discussing Oklahoma law). As one judge put it, if 'a plaintiff undertakes to use his power saw as a nail clipper and thereby snips his digits, he will not be heard to complain'. *Suter v. San Angelo Foundry & Mach. Co.*, 406 A.2d 140, 162 (N.J. 1979) (Clifford, J., concurring); see also *Jurado v. W. Gear Works*, 619 A.2d 1312, 1318 (N.J. 1993); *Montgomery Ward & Co. v. Gregg*, 554 N.E.2d 1145, 1156 (Ind. Ct. App. 1990); *Higgins v. Paul Hardeman, Inc.*, 457 S.W.2d 943, 948 (Mo. Ct. App. 1970); *Brown v. U.S. Stove Co.*, 484 A.2d 1234, 1241 (N.J. 1984) (holding that a heater manufacturer could be held liable for injuries resulting from the plaintiff's alteration of the heater, as the plaintiff's expert testified that 'it was commonplace to alter these heaters so they could generate more heat than that for which they were originally designed').

65 For example, the Kentucky Products Liability Act provides that, in a product liability action, 'it shall be presumed […] that the product was not defective if the design, methods of manufacture, and testing conformed to the generally recognized and prevailing standards or the state of the art in existence at the time the design was prepared, and the product was manufactured'. Ky. Rev. Stat. Ann. §411.310(2); see also Iowa Code §668.12 (providing a state-of-the art defence). But see *Kelley v. Hedwin Corp.*, 707 S.E.2d 895, 899 (Ga. Ct. App. 2011) ('A manufacturer's proof of compliance with industry-wide practices, state of the art, or federal regulations does not eliminate conclusively its liability for its design of allegedly defective products' (internal quotation marks omitted)); *Murphy v. Chestnut Mountain Lodge, Inc.*, 464 N.E.2d 818, 823 (Ill. App. Ct. 1984) ('While it is true that the state of the art is not a defense to strict liability, evidence of the existence of feasible alternative designs is relevant and admissible in actions predicated on strict liability as well as those sounding in negligence' (citations omitted)); *In re Hawaii Fed. Asbestos Cases*, 665 F. Supp. 1454, 1457 (D. Haw. 1986) (discussing Hawaii law and stating that the state-of-the-art defence was inadmissible in strict liability cases because 'the product's design is considered at the time of trial not at the time of manufacture').

66 *Johnson v. Am. Standard, Inc.*, 179 P.3d 905, 910–11 (Cal. 2008); *Humble Sand & Gravel, Inc. v. Gomez*, 146 S.W.3d 170, 183 (Tex. 2004) ('When the foreseeable users of a product have special training, a supplier has no duty to warn of risks that should be obvious to them, even if persons without such training would not appreciate the risks'); *Hines v. Remington Arms Co.*, 648 So. 2d 331, 337 (La. 1994); Restatement (Second) of Torts §388 cmt. k. For example, a chemical manufacturer may have no duty to warn a professional exterminator of dangers related to a commonly used pesticide. Cf., e.g., *Johnson*, 179 P.3d at 916 (holding that manufacturers of air conditioning equipment had no duty to warn a heat, ventilation, and air conditioning technician of dangers associated with brazing refrigerant lines and exposure to phosgene gas).

Learned intermediary doctrine

According to the learned intermediary doctrine, a manufacturer does not have a duty to warn end consumers of product dangers if the manufacturer can reasonably rely on an intermediary, such as a prescribing physician in a pharmaceutical case, to provide such warnings.[67] The manufacturer's duty runs solely to the learned intermediary (e.g., the prescribing doctor), not to the end patient/consumer.

Economic loss rule

Most states follow some version of the economic loss rule, pursuant to which manufacturers are not liable in strict liability or negligence if a defect causes only 'economic loss'; that is, damage to the product itself, without any other property loss or personal injury.[68] In these states, damage to the product itself, such as diminished resale value, may be compensable under principles of contract, but not under tort law.[69]

Government contractor defence

A contractor hired by the government generally cannot be held liable for performing the contract 'in conformity with specifications established by the government'.[70] This may be a form of pre-emption in federal contractor cases.[71]

Regulatory compliance

Evidence that a product complied with all applicable safety regulations may be helpful to show that the manufacturer acted reasonably in designing and manufacturing the product and that the product was not defective. Importantly, though, this defence, standing alone, will probably not absolve the defendant of liability absolutely.[72]

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67 See, e.g., *Seifried v. Hygenic Corp.*, 410 S.W.3d 427, 432 (Tex. App.--Houston [1st Dist.] 2013, no pet.) ('[W]hen a drug manufacturer properly warns a prescribing doctor of the dangers of its product, the manufacturer is excused from warning each patient who receives the drug'); see also *Bodie v. Purdue Pharma Co.*, 236 F. App'x 511, 521 (11th Cir. 2007) (holding that, under Alabama's learned intermediary doctrine, an allegedly inadequate drug label was not the proximate cause of the plaintiff's injury because the doctor prescribed the drug based not on the label, but on his own independent knowledge of the drug's risks and benefits). Sometimes the 'learned intermediary' doctrine is also referred to as a 'sophisticated user' intermediary doctrine. See *Pfeifer v. John Crane, Inc.*, 164 Cal. Rptr. 3d 112, 130 (Cal. Ct. App. 2013).

68 *Home Depot*, 724 S.E.2d at 59; *Corporex Dev. & Constr. Mgmt., Inc. v. Shook, Inc.*, 835 N.E.2d 701, 704 (Ohio 2005); *Filak v. George*, 594 S.E.2d 610, 618 (Va. 2004). As one court explained, economic loss 'means damages for the loss of the value or use of the defective product itself, costs of repair or replacement of the defective product, or the consequent loss of profits, unaccompanied by any claim of personal injury or damage to other property'. *Home Depot*, 724 S.E.2d at 59. The economic loss rule is usually not a defence to claims of intentional fraud or misrepresentation. Id. at 59; *Peterson Grp., Inc. v. PLTQ Lotus Grp., L.P.*, 417 S.W.3d 46, 62 (Tex. App.--Houston [1st Dist.] 2013, no pet.); see also *Va. Transformer Corp. v. P.D. George Co.*, 932 F. Supp. 156, 163 (W.D. Va. 1996) (stating that 'the fraud exception to the economic loss rule' applies only to actual fraud, not constructive fraud).

69 See, e.g., *Giddings & Lewis, Inc. v. Indus. Risk Insurers*, 348 S.W.3d 729, 738 (Ky. 2011).

70 *Banks v. Parish of Jefferson*, 108 So. 3d 1208, 1222 (La. Ct. App. 2013).

71 See *Boyle v. United Techs. Corp.*, 487 U.S. 500, 508-11 (1988).

72 *Blueflame Gas, Inc. v. Van Hoose*, 679 P.2d 579, 591–92 (Colo. 1984); *Hernandez v. Badger Constr. Equip. Co.*, 34 Cal. Rptr. 2d 732, 756–57 (Cal. Ct. App. 1994) ('Compliance with regulations, directives or trade custom does not necessarily eliminate negligence but instead simply constitutes evidence for jury consideration with other facts and circumstances'). As one court explained, 'the focus in a strict liability

Employer immunity

Every state has enacted worker's compensation laws that provide the exclusive means of compensation for job-related injuries and shield employers from any resulting tort liability.[73] However, employers can still be held liable for injuries caused by intentional torts or wilful misconduct.[74]

Lack of privity

Lack of privity, or a direct contractual relationship between the defendant and plaintiff, is usually not a defence to tort claims premised on strict liability, negligence or fraud.[75] A showing of privity may be required in some states, however, for a claim premised on a breach of contractual duty, such as breach of warranty.[76]

iv Personal jurisdiction

No court may exercise power over a defendant absent personal jurisdiction. A defendant wishing to challenge personal jurisdiction must do so promptly at the beginning of the lawsuit, or else risk waiving this defence. The reach of personal jurisdiction is governed by (1) the forum state's deliberately far-reaching 'long-arm' statute[77] versus (2) the federal constitutional requirements of due process (i.e., whether it is 'fair' to subject someone outside the forum to the forum's legal power). At the most basic level, due process requires that the defendant have at least 'minimum contacts' with the forum state before being subject to personal jurisdiction in that state.[78] Although the law of 'minimum contacts' is constantly

claim is on the product itself, and not on the degree of care employed by the seller or distributor of the product'. *Blueflame Gas, Inc.*, 679 P.2d at 591. Therefore, 'a product may be in a defective condition unreasonably dangerous to the user or consumer notwithstanding the supplier's compliance with a safety regulation related to that product'. Id. at 591–92.

73 1 Modern Workers Comp. §100:1; see, e.g., Mich. Comp. Laws §418.131 (providing that Michigan's worker's compensation act 'shall be the employee's exclusive remedy against the employer for a personal injury or occupational disease'); Fla. Stat. §440.11 (stating that an employer's liability under Florida's worker's compensation scheme 'shall be exclusive and in place of all other liability'); see also *Boston ex rel. Estate of Jackson v. Publix Super Markets, Inc.*, 112 So. 3d 654, 656 (Fla. Ct. App. 2013) ('The worker's compensation statutes provide a strict liability system of compensation for injured workers in which the worker receives the guarantee of rapid compensation for work related injuries but in return is precluded from bringing a common-law negligence action').

74 See, e.g., *Lentz v. Young*, 536 N.W.2d 451, 457 (Wis. Ct. App. 1995); Mich. Comp. Laws §418.131 (stating that the 'only exception' to the exclusive worker's compensation remedy 'is an intentional tort').

75 See, e.g., Ga. Code Ann. §51-1-11(a) ('[N]o privity is necessary to support a tort action'); *Standard Chartered PLC v. Price Waterhouse*, 945 P.2d 317, 339 (Ariz. Ct. App. 1996); *Jim's Excavating Serv., Inc. v. HKM Associates*, 878 P.2d 248, 253 (Mont. 1994); see also *Butler v. Turner*, 555 S.E.2d 427, 431 (Ga. 2001) ('When a material fact is wilfully misrepresented to induce another to act and upon which the other acts, a cause of action is created in the injured party, and privity is not necessary to give rise to such a cause of action'); *Velazquez v. Decaudin*, 854 N.Y.S.2d 163, 167 (N.Y. App. Div. 2008).

76 See, e.g., *Ragone v. Spring Scaffolding, Inc.*, 848 N.Y.S.2d 230, 233 (N.Y. App. Div. 2007); *Blake v. John Doe* 1, 623 N.E.2d 1229, 1231-32 (Ohio Ct. App. 1993).

77 See, e.g., N.Y. C.P.L.R. §302 (New York's long-arm statute); Fla. Stat. §48.193 (Florida's long-arm statute); Cal. Civ. Proc. Code §410.10 (California's long-arm statute; allowing the exercise of jurisdiction 'on any basis not inconsistent' with the California Constitution or the US Constitution).

78 *International Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945); *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 474 (1985). For other important Supreme Court cases exploring personal jurisdiction, see *Daimler*

evolving, this standard currently presents a low bar. Personal jurisdiction will likely exist if a defendant transacts any business in the forum state, perhaps if only through a website, and the lawsuit is related to such a transaction.[79] Importantly, a company may always be subject to personal jurisdiction in a state, regardless of what any particular lawsuit alleges, if the company is incorporated in that state or conducts a majority of its business there (also known as 'general' personal jurisdiction).[80]

v Expert witnesses

All jurisdictions in the United States allow expert witnesses – including those with no personal knowledge of the facts – to testify at trial. The use of experts is prevalent in product liability cases. Because the US legal system is adversarial in nature, each party is responsible for hiring its own experts to prove its case, and judges only rarely retain independent experts for assistance.[81] As a result, product liability trials will often involve a 'battle of the experts', the outcome of which may dictate the jury's verdict.[82]

In federal courts, the admission of expert testimony is governed by Federal Rule of Evidence 702 (mirrored in many states' statutes or rules of procedure). Rule 702 allows a qualified expert to testify if the expert's testimony (1) assists the trier of fact; (2) is 'based on sufficient facts or data'; (3) is 'the product of reliable principles and methods'; and (4) involves a reliable application of those 'principles and methods to the facts of the case'.[83] Before

AG v. Bauman, 134 S. Ct. 746 (2014); *Asahi Metal Indus. Co. v. Superior Court*, 480 U.S. 102 (1987); *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286 (1980); *McGee v. International Life Ins. Co.*, 355 U.S. 220 (1957).

79 See *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 475-76 (1985) (stating that personal jurisdiction exists where the out-of-state defendant 'deliberately has engaged in significant activities within a State, or has created continuing obligations between himself and residents of the forum' (citations and internal quotation marks omitted)). For example, the Eleventh Circuit recently held that a New York resident was subject to personal jurisdiction in Florida in a lawsuit alleging a trademark violation where the defendant operated an interactive website selling counterfeit goods, and some Florida residents used the website to purchase those goods. *Louis Vuitton Malletier, S.A. v. Mosseri*, 736 F.3d 1339, 1355–1358 (11th Cir. 2013). One popular test for determining personal jurisdiction in internet cases has been formulated in *Zippo Mfg. Co. v. Zippo Dot Com, Inc.*, 952 F. Supp. 1119, 1123–24 (W.D. Pa. 1997). According to *Zippo*, 'the likelihood that personal jurisdiction can be constitutionally exercised is directly proportionate to the nature and quality of commercial activity that an entity conducts over the Internet'. Id. at 1124. Thus personal jurisdiction will exist where 'the defendant enters into contracts with residents of a foreign jurisdiction that involve the knowing and repeated transmission of computer files over the Internet', but not 'where a defendant has simply posted information on an Internet Web site which is accessible to users in foreign jurisdictions'. Id. It is important to note, however, that the above 'minimum contacts' standard is relevant only to 'specific' jurisdiction; that is, jurisdiction over a particular lawsuit that arises out of the company's contacts with the state. See *Daimler AG*, 134 S. Ct. at 754. If a company is incorporated in the forum state or conducts the majority of its business there, it may be subject to 'general' personal jurisdiction, meaning that it will be always subject to suit there, regardless of what any particular lawsuit alleges. See id. at 761.

80 See *Daimler AG*, 134 S. Ct. at 761.

81 But see *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1392-93 (D. Or. 1996) (appointing independent experts to advise the court on admissibility of expert testimony in litigation alleging injuries caused by silicone breast implants); see also Fed. R. Evid. 706 (governing court-appointed expert witnesses).

82 See *Croskey v. BMW of N. Am., Inc.*, 532 F.3d 511, 516 (6th Cir. 2008).

83 Fed. R. Evid. 702; see, e.g., Del. Rule Evid. 702; N.C. Rule Evid. 702(a); Ariz. Rule Evid. 702; Ga. Code Ann. §24-7-702(b); see also *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589–90 (1993); *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999).

admitting expert testimony into evidence, the trial judge must ensure that the testimony 'both rests on a reliable foundation and is relevant to the task at hand'.[84] Sometimes, a party will seek to bar the other's expert testimony on the grounds that the expert's methodology was scientifically unreliable.

vi Discovery

Parties in civil litigation in the United States are usually entitled to considerably broader discovery than elsewhere. Such discovery can often become time-consuming, expensive and sometimes case-dispositive as a result. In federal courts, discovery is governed by the Federal Rules of Civil Procedure,[85] and may be obtained through a number of methods, including depositions, interrogatories (usually limited to 25), requests for production of documents, requests for inspection of evidence or premises, and requests for admissions.[86] A party may also move the court to obtain a physical or mental examination of the other party.[87]

The scope of discovery is extensive. Parties may seek information 'regarding any non-privileged matter that is relevant to any party's claim or defense'.[88] Such information need not be admissible in evidence as long as it 'appears reasonably calculated to lead to the discovery of admissible evidence'.[89] Most states have modelled their procedural rules on the

84 *Daubert*, 509 U.S. at 597. Litigants should be aware that proposed expert testimony must also be disclosed before trial. Fed. R. Civ. P. 26(a)(2). The framework for analysing the admissibility of expert witnesses stems from the so-called '*Daubert* trilogy', which consists of *Daubert, General Electric Co. v. Joiner*, 522 U.S. 136 (1997), and *Kumho Tire Co.*, 526 U.S. 137. See *Truck Ins. Exch. v. MagneTek, Inc.*, 360 F.3d 1206, 1209 (10th Cir. 2004). Daubert instructed the courts to consider four factors in determining the admissibility of expert testimony: (1) whether the expert's theory or technique can be tested; (2) whether the theory has been subjected to peer review and publication; (3) the rate of error in the scientific technique; and (4) whether the technique has been generally accepted in the scientific community. *Daubert*, 509 U.S. at 593–94. In *Joiner*, the Supreme Court held that a district court's admission or exclusion of expert testimony under *Daubert* can be overturned on appeal only if the district court had abused its discretion. *Joiner*, 522 U.S. at 141–43. In *Kumho Tire Co.*, the Supreme Court held that *Daubert* applies not only to 'scientific' testimony, but to any expert testimony based on technical or other specialised knowledge. *Kumho Tire Co.*, 526 U.S. at 141. Notably, not all states have adopted the *Daubert* approach to expert evidence, and some continue to apply the earlier, more narrow framework enunciated in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). Under the *Frye* approach, 'scientific evidence is admissible if the methodology that underlies the evidence has general acceptance in the relevant scientific community'. *Grady v. Frito-Lay, Inc.*, 839 A.2d 1038, 1043–44 (Pa. 2003).

85 See Fed. R. Civ. P. 26-37.

86 Fed. R. Civ. P. 26, 30, 33, 34, 36. Importantly, under the federal rules, a party must make certain initial disclosures without awaiting a discovery request by the opposing party. Fed. R. Civ. P. 26(a).

87 Fed. R. Civ. P. 35.

88 Fed. R. Civ. P. 26(b)(1).

89 Fed. R. Civ. P. 26(b)(1); see also, e.g., Ill. S. Ct. Rule 201. Certain amendments to the Federal Rules of Civil Procedure have been proposed recently, including a change to Rule 26(b), which governs the scope of discovery. See Committee on Rules of Practice and Procedure of the Judicial Conference of the United States, Preliminary Draft of Proposed Amendments to the Federal Rules of Bankruptcy and Civil Procedure (August 2013). The amended Rule 26 would require discovery to not only be 'non-privileged' and 'relevant,' but also 'proportional to the needs of the case, considering the amount in controversy, the importance of the issues at stake in the action, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit'. Id. at 289–90.

federal system and allow for similar methods and scope of discovery.[90] Thus, in a product liability suit against a manufacturer, plaintiffs may ask for information on the product's design, prior recalls, and other accidents, complaints, or lawsuits involving the same type of product.[91] Discovery is not limitless, however, and a party may (and usually will) object to requests for information or documents on a number of grounds, including that the requests are overly broad, unduly burdensome, seek irrelevant materials or seek information protected by the attorney-client privilege, work product privilege or trade secret privilege.[92]

Judges in federal and state courts encourage parties to conduct discovery with minimal court supervision and to resolve discovery disputes among themselves. In the federal system, the district court will usually appoint a magistrate judge[93] to preside over discovery matters, and a state court may appoint a 'special master' to address unique or voluminous discovery issues.[94]

vii Apportionment

Joint and several liability

According to the principle of joint and several liability that governs product liability cases in many jurisdictions, if multiple defendants are found to be responsible for the plaintiff's injuries, each defendant is liable for the entire amount of damages but has a legal right to seek contribution from other defendants.[95] Thus, a plaintiff may join all tortfeasors in one action and choose which one to pursue for recovery.[96] It is then up to the defendant to seek

90 See, e.g., Ill. St. S. Ct. Rule 201 (allowing discovery through 'depositions upon oral examination or written questions, written interrogatories to parties, discovery of documents, objects or tangible things, inspection of real estate, requests to admit and physical and mental examination of persons'); Cal. Civ. Proc. Code §§2017.010, 2019.010.

91 See *Smith v. BIC Corp.*, 869 F.2d 194, 200–201 (3d Cir. 1989); *Uitts v. Gen. Motors Corp.*, 58 F.R.D. 450, 452–53 (E.D. Pa. 1972).

92 See *Lamoureux v. Genesis Pharmacy Servs., Inc.*, 226 F.R.D. 154, 158–59 (D. Conn. 2004); 6 James Wm. Moore et al., *Moore's Federal Practice* §§26.41, 26.47, 26.60 (3d ed.); see also Martin H. Redish & Colleen McNamara, 'Back to the Future: Discovery Cost Allocation and Modern Procedural Theory', 79 *Geo. Wash. L. Rev.* 773, 779–80 (2011).

93 Unlike district court judges, circuit court judges, and Supreme Court justices, federal magistrate judges (appointed by the subject district court) are not appointed under Article III of the Constitution. They have limited power to try cases, dependent on the consent of both parties. See *Roell v. Withrow*, 538 US 580, 582 (2003) (stating that federal magistrate judges are authorised 'to conduct 'any or all proceedings in a jury or non-jury civil matter and order the entry of judgment in the case', as long as they are 'specially designated […] by the district court' and are acting '[u]pon the consent of the parties'.' (quoting 28 USC §636(c)(1)). Nonetheless, discovery matters and disputes in federal courts are frequently referred to magistrate judges.

94 A special master is a person 'specially appointed to help a court with its proceedings'. *Black's Law Dictionary* (9th ed. 2009). A special master 'may take testimony, hear and rule on discovery disputes, enter temporary orders, and handle other pretrial matters'. Id.

95 See, e.g., *Sehl v. Neff*, 26 A.3d 1130, 1133–34 (Pa. Super. Ct. 2011); *State v. Therrien*, 830 A.2d 28, 36–37 (Vt. 2003).

96 See *State v. Therrien*, 830 A.2d 28, 37 (Vt. 2003).

(by agreement or legal process) contribution by other defendants. A number of states have abolished the doctrine of joint and several liability in favour of apportioning damages based on each party's percentage of fault.[97]

Successor liability

Traditionally, a purchaser of a company's assets (rather than stock) is not liable for the seller's liabilities unless (1) the successor company assumed the seller's liabilities via an express or implied agreement; (2) the purchasing company effectively merged with the selling company; (3) the transaction was fraudulent; or (4) the buying company was a mere continuation of the seller.[98] Some states have developed an additional exception in product liability cases – the 'product line' theory – according to which successor corporations inherit their predecessors' liability for product defects if they 'undertake the manufacture of the same products as the predecessor'.[99] A parent company usually cannot be held liable for the torts of its subsidiary, or *vice versa*, unless the parent exerts such control over the subsidiary as to make it 'a mere adjunct, instrumentality, or alter ego' of the parent, or some other basis exists to pierce the corporate veil.[100]

Market share liability/enterprise liability

The 'market share' principle of liability, adopted in a minority of states, can be applied if multiple companies produced identical products (e.g., generic drugs) and a plaintiff cannot identify the manufacturer of the particular product that caused the injury. In such cases, the plaintiff may join in the lawsuit all manufacturers of the product at issue. Then, each defendant 'will be held liable for the proportion of the judgment represented by its share of [the] market unless it demonstrates that it could not have made the product which caused plaintiff's injuries'.[101] This theory has been sparingly applied by the courts. In the majority of states and product liability cases, there remains a burden on the plaintiff to prove that he or she was injured by the defendant's specific product.[102]

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97 See *Jamerson v. Quintero*, 313 P.3d 532, 534 (Ariz. Ct. App. 2013) (noting that the Arizona legislature generally abolished joint and several liability and that, 'in the usual case, each defendant "is liable only for the amount of damages allocated to that defendant in direct proportion to that defendant's percentage of fault"' (quoting Ariz. Rev. Stat. §12-2506)).

98 See *Aguas Lenders Recovery Grp. v. Suez, S.A.*, 585 F.3d 696, 702 (2d Cir. 2009) (discussing New York law); *Ray v. Alad Corp.*, 560 P.2d 3, 7 (Cal. 1977). Some courts apply a fifth exception: lack of adequate consideration in the transfer. See *Fizzano Bros. Concrete Prods., Inc. v. XLN, Inc.*, 42 A.3d 951, 954 & n.2 (Pa. 2012).

99 *Huff v. Shopsmith, Inc.*, 786 So. 2d 383, 387 (Miss. 2001); see also *Ray v. Alad Corp.*, 560 P.2d 3, 11 (Cal. 1977); *Dawejko v. Jorgensen Steel Co.*, 434 A.2d 106, 110 (Pa. Super. Ct. 1981). Companies usually handle this issue through a contractual provision.

100 *Duff v. Southern Ry. Co.*, 496 So. 2d 760, 762 (Ala. 1986); see also *Robinson v. Terex Corp.*, 439 F.3d 465, 468 (8th Cir. 2006) ('A parent corporation is generally not liable for the debts of its subsidiaries, and the doctrine of piercing the fiction of corporate identity should be applied with great caution'); *IDS Life Ins. Co. v. SunAmerica Life Ins. Co.*, 136 F.3d 537, 540 (7th Cir. 1998); John S. Allee et al., *Product Liability* §2.02[18] (2008).

101 *Sindell v. Abbott Labs.*, 607 P.2d 924, 936-37 (Cal. 1980).

102 See, e.g., *Holcomb v. Ga. Pac., LLC*, 289 P.3d 188, 197 (Nev. 2012); *Sutowski v. Eli Lilly & Co.*, 696 N.E.2d 187, 192 (Ohio 1998); *Namm v. Charles E. Frosst & Co.*, 427 A.2d 1121, 1125 (N.J. Super. Ct. App. Div. 1981); see also *Wood v. Eli Lilly & Co.*, 38 F.3d 510, 513-14 (10th Cir. 1994) (applying Oklahoma law); *Mulcahy v. Eli Lilly & Co.*, 386 N.W.2d 67, 75–76 (Iowa 1986).

Contribution/indemnity

A buyer of goods that are slated for resale may enter into an indemnity agreement with the seller, whereby the seller agrees to indemnify the buyer for third-party product liability claims. Such agreements are generally enforceable and subject to the general contract laws of each state.[103]

viii Mass tort actions

Class actions

In product liability cases where the amount of damages suffered by each plaintiff is relatively small, a class action is often attractive as the only economically viable option for bringing a lawsuit. In federal courts, a class action may proceed only if (1) the class is 'so numerous that joinder of all members is impracticable'; (2) there are 'questions of law or fact common to the class'; (3) the claims or defences of class representatives are 'typical of the claims or defenses of the class'; and (4) the class representatives can 'fairly and adequately protect the interests of the class'.[104] Most states have similar requirements for class actions.[105]

One of the most important developments in the law of class actions in the last decade was the enactment of the Class Action Fairness Act of 2005 (CAFA).[106] This statute expanded the scope of federal jurisdiction over class actions, making it easier for defendants to remove such actions from state to federal courts.[107]

Aggregated mass actions

Under federal law, when multiple civil actions, either class or individual, are filed in different federal districts but involve the same subject matter, these lawsuits may be consolidated in one district court for pretrial proceedings.[108] This consolidation is referred to as multi-district litigation (MDL), and is intended 'to provide centralized management of pretrial proceedings and to ensure their "just and efficient" conduct'.[109] Actions may be transferred to an MDL either by a specially created judicial panel or by motion of a party.[110] At the conclusion of pretrial proceedings, MDL cases are transferred back to their home districts for trial or other

103 See *Bradley v. Earl B. Feiden, Inc.*, 8 N.Y.3d 265, 274-75 (N.Y. 2007) ('When the intent is clear, an indemnification agreement will be enforced even if it provides indemnity for one's own or a third party's negligence'); *Deminsky v. Arlington Plastics Machinery*, 657 N.W.2d 411, 420-21 (Wis. 2003) ('[A]greements to indemnify a party against its own negligence must be strictly construed, but so long as that standard is met, such agreements are valid').

104 Fed. R. Civ. P. 23(a).

105 See, e.g., Ala. R. Civ. P. 23; 735 Ill. Comp. Stat. §5/2-801.

106 28 USC. §1332(d).

107 See *Standard Fire Ins. Co. v. Knowles*, 133 S. Ct. 1345, 1348 (2013) ('CAFA provides the federal district courts with 'original jurisdiction' to hear a 'class action' if the class has more than 100 members, the parties are minimally diverse, and the 'matter in controversy exceeds the sum or value of $5,000,000' (quoting 28 USC. §1332(d)(2), (d)(5)(B))); see also *Progressive West Ins. Co. v. Preciado*, 479 F.3d 1014, 1015 (9th Cir. 2007).

108 See 28 USC. §1407.

109 *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc.*, 238 F. Supp. 2d 270, 273 (D.D.C. 2002).

110 28 USC. §1407(c); *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 460 F.3d 1217, 1230 (9th Cir. 2006).

resolution.[111] Many states also provide similar mechanisms for aggregating certain actions before a single judge for pretrial proceedings.[112] One popular venue for aggregated mass tort actions is the Philadelphia Court of Common Pleas.[113]

Government actions

Sometimes, a state government (e.g., a state attorney general) will bring a product liability lawsuit against a manufacturer on behalf of the state's citizens.[114] As recently explained by the Supreme Court, such lawsuits do not qualify as 'mass actions' under CAFA, and thus are not removable to federal court, because they only have a single plaintiff – the state – not the 100 or more required under CAFA.[115]

ix Damages

Compensatory damages

As a primary method of recovery, most product liability plaintiffs will seek compensatory damages, which include both an economic and non-economic component. Economic or 'special' damages are those that are particular to each plaintiff, including 'out-of-pocket medical expenses, future medical expenses, lost wages and lost earning potential'.[116] Non-economic or 'general' damages are those that plaintiffs are generally expected to incur in personal injury cases, such as mental suffering, inconvenience, loss of enjoyment, or other losses of lifestyle.[117] Some states impose caps on the amount of non-economic damages available to plaintiffs.[118]

Injunctive relief

In most states, to obtain an injunction, a plaintiff must show that there is no adequate remedy at law and that he or she will suffer irreparable harm absent an injunction.[119] Many product liability plaintiffs will not be able to show a need for an injunction because, by virtue of their lawsuits, they are already aware of dangers associated with a particular product defect

111 See 28 USC. §1407(a).

112 See Cal. Rule of Court 3.541 et seq.; Or. R. Civ. P. 32.K.

113 See www.courts.phila.gov/common-pleas/trial/civil/clc.asp.

114 See Fla. Stat. §501.207(1)(c) (authorising state authorities to bring an actual-damages lawsuit on behalf of one or more consumers for a violation of Florida's Deceptive & Unfair Trade Practices Act); see, also, e.g., *Mississippi ex rel. Hood, Att'y Gen. v. AU Optronics Corp.*, 134 S. Ct. 736, 740–41 (2014) (discussing a product liability action brought by the state on behalf of its citizens under Mississippi law).

115 *AU Optronics Corp.*, 134 S. Ct. at 741–46.

116 See, e.g., *Meals ex rel. Meals v. Ford Motor Co.* 417 S.W.3d 414, 419 (Tenn. 2013); *Kaiser v. Hardin*, 953 So. 2d 802, 810 (La. 2007). Special damages may be determined with relative certainty, and may only be awarded on the basis of proof. See *Kaiser*, 953 So. 2d at 810.

117 See, e.g., *Jenkins v. State ex rel. Dep't of Transp. & Dev.*, 993 So. 2d 749, 767 (La. Ct. App. 2008); *Meals*, 417 S.W.3d at 420; *Meerscheidt v. State*, 931 P.2d 220, 224 (Wyo. 1997); Restatement (Second) of Torts §904. Non-economic damages are difficult to quantify, and plaintiffs are not required to prove their exact value. See, e.g., *Meals*, 417 S.W.3d at 420.

118 See, e.g., Mich. Comp. Laws §600.2946a (imposing a $280,000 or $500,000 cap on non-economic damages in product liability actions); Md. Code Ann. §11-108(b)(2) (imposing a $500,000 cap on non-economic damages in actions for personal injury or wrongful death).

119 See *Buetow v. A.L.S. Enters., Inc.*, 650 F.3d 1178, 1183 (8th Cir. 2011) (discussing Minnesota law); *Levisa Coal Co. v. Consolidation Coal Co.*, 662 S.E.2d 44, 53 (Va. 2008); *Sadat v. Am. Motors Corp.*, 470 N.E.2d 997, 1002-03 (Ill. 1984).

or inadequate label, and will be able to avoid those dangers in the future.[120] Some states may allow injunctive relief in the form of medical monitoring when a plaintiff alleges exposure to dangerous substances but cannot prove a physical injury (such as cancer) because the disease has not yet manifested itself.[121]

Punitive damages

Punitive damages may greatly enhance a plaintiff's monetary recovery in a product liability case. Although states use a variety of different standards to determine the propriety of awarding punitive damages, most will allow such damages only upon a heightened showing of fault, such as intentional wrongdoing or conscious disregard for the safety of others.[122] Most states will also require a plaintiff to establish the availability of punitive damages by 'clear and convincing evidence' – a higher standard of proof than the usual 'preponderance of the evidence' standard.[123]

Criminal prosecutions

Criminal prosecutions against individuals or companies, though possible, are relatively rare in the product liability context. When such prosecutions do occur, they usually target company executives or other high-level individuals for conspiracy, lying to government authorities, or committing other types of fraud or intentional misrepresentation, not for merely introducing

120 See Daniel S. Wittenberg, Impacts of the FDASIA and Recent Food and Drug Law Litigation, 2013 WL 5293063 at 9 (Aspatore 2013).

121 See, e.g., *Stead v. F.E. Meyers Co., Div. of McNeil Corp.*, 785 F. Supp. 56, 57 (D. Vt. 1990); *Bocook v. Ashland Oil, Inc.*, 819 F. Supp. 530, 537 (S.D.W. Va. 1993) (stating that Kentucky would allow recovery for medical monitoring if the plaintiff shows '*some* present physical harm, however slight'); Johns S. Allee et al., *Product Liability* §11.02[2A] (2008); Am. L. Prod. Liab. 3d §60:15.

122 For example, in Missouri, punitive damages may be awarded in a product liability suit 'if the jury finds that the defendant knew of the defect and danger of the product at the time it sold the product, and that the defendant thereby showed complete indifference to or conscious disregard for the safety of others'. See *Sch. Dist. of Independence, Mo., No. 30 v. US Gypsum Co.*, 750 S.W.2d 442, 446 (Mo. Ct. App. 1988); see also *Ehrhardt v. Brunswick, Inc.*, 231 Cal. Rptr. 60, 64 (Cal. Ct. App. 1986) ('Punitive damages may be awarded in a product liability action if it is shown that the defendant placed a product on the market in conscious disregard of the safety of consumers and others'). In Maryland, punitive damages may be awarded only if 'the plaintiff has established that the defendant's conduct was characterized by evil motive, intent to injure, ill will, or fraud, i.e., 'actual malice'.' *Owens-Illinois, Inc. v. Zenobia*, 601 A.2d 633, 652 (Md. 1992); see also *Masaki v. Gen. Motors Corp.*, 780 P.2d 566, 571 (Haw. 1989) ('[T]o justify an award of punitive damages, a positive element of conscious wrongdoing is always required. Thus, punitive damages are not awarded for mere inadvertence, mistake, or errors of judgment'. (citations and internal quotation marks omitted)). And, in New York, a plaintiff may obtain punitive damages by proving 'willful or wanton conduct which demonstrates a conscious disregard of the rights of others or conduct so reckless as to amount to such disregard'. *Dubecky v. S2 Yachts, Inc.*, 651 N.Y.S.2d 602, 604 (N.Y. App. Div. 1996 (internal quotation marks omitted)).

123 See Ala. Code §6-11-20; *Smith v. Brown & Williamson Tobacco Corp.*, 410 S.W.3d 623, 630 (Mo. 2013); *Johnson v. Johnson*, 747 S.E.2d 518, 523 n.4 (Ga. Ct. App. 2013).

a defective product to market.[124] Notably, however, the Food, Drug, and Cosmetic Act (FDCA) criminalises even the unintentional production or distribution of 'adulterated or misbranded' food, drugs and cosmetics.[125]

V YEAR IN REVIEW

i Notable court decisions

In August 2016, the California Supreme Court held that California had specific personal jurisdiction over Bristol-Myers Squibb Co (BMS) concerning claims of roughly 600 non-resident consumers. The decision has significant potential implications for where product manufacturers and other corporations can be sued.[126] The case involved 86 California residents and 592 non-residents alleging injury from the drug Plavix, a medication used to inhibit blood clotting.[127] BMS moved to quash service of summons for the non-resident plaintiffs, claiming that the San Francisco Superior Court lacked general jurisdiction to hear the case because BMS is neither incorporated nor headquartered in California. Additionally, BMS argued that the court lacked specific jurisdiction over BMS because: (1) the complaint did not allege that the non-residents' injuries had occurred or been treated in California; and (2) Plavix was never manufactured in California, nor was any work involving its research and development, labelling, packaging, regulatory approval, or marketing strategy performed by its California employees.[128]

In a 4-3 decision, California's highest court upheld the Court of Appeal's decision that, although there was a lack of general jurisdiction,[129] BMS had purposefully availed itself of the California forum such that the exercise of specific jurisdiction would not be unreasonable. Specifically, the court held that 'BMS's nationwide marketing, promotion, and distribution of Plavix created a substantial nexus between the nonresident plaintiffs' claims and the company's contacts in California concerning Plavix.'[130] The court explained that its holding would not open the door to forum shopping in California because specific jurisdiction will be considered only on a 'case-by-case basis, focusing on the nature and quality of the defendant's activities in the state'.[131] However, this decision will nevertheless be of great moment to product manufacturers because it threatens to create an all-purpose forum in plaintiff-friendly

124 See, e.g., 18 USC. §1001 (criminalising the making of false statements in government matters); 49 USC. §30170 (imposing enhanced criminal penalties for making false statements related to automobile defects).

125 See 21 USC. §331(a)–(c), (k); *United States v. Park*, 421 U.S. 658, 672–73 (1975) (stating that the FDCA does not 'make criminal liability turn on awareness of some wrongdoing or conscious fraud' (internal quotation marks omitted)).

126 *Bristol-Myers Squibb Co. v. Superior Court*, 1 Cal. 5th 783 (Cal. 2016).

127 Id. at 789.

128 Id. at 790.

129 The superior court denied BMS's motion to quash on general jurisdiction grounds, concluding that its activities in California were sufficiently extensive to subject it to the jurisdiction of California courts. California's Court of Appeal then summarily denied BMS's petition for a writ of mandamus on the same day as the US Supreme Court's watershed decision in *Daimler AG v. Bauman*, 134 S. Ct. 746 (2014), discussed above. After the California Supreme Court transferred the matter back to the appellate court to reexamine the issue in light of *Daimler AG*, the Court of Appeal again denied the writ – this time on specific jurisdiction grounds.

130 Id. at 804.

131 Id. at 807.

California. It also arguably subverts the landmark decision from *International Shoe* and that case's progeny.[132] That said, the California Supreme Court's decision will now be reviewed once again: on 19 January 2017, the US Supreme Court granted BMS's petition for a writ of certiorari, meaning that BMS's appeal of the California Supreme Court's decision will be heard later this year.[133]

In September 2016, the US Court of Appeals for the Fifth Circuit delivered a somewhat surprising procedural ruling in the metal-on-metal hip implant MDL, when it denied Johnson & Johnson's petition for a writ of mandamus seeking to overturn a district court order that allowed plaintiffs to subpoena remote company witnesses to testify via live satellite link.[134] This marked a significant departure from the presumptive rule that a trial subpoena may only command attendance within 100 miles of a person's residence or place of employment. The defendants argued that the district court's blanket order allowing video testimony was a violation of the court's subpoena power under Rule 45 of the Federal Rules of Civil Procedure because it did not require the plaintiffs to show 'good cause in compelling circumstances and with appropriate safeguards', as is required by Rule 43(a).[135] This ruling, along with decisions from a handful of other courts allowing for technology to reach witnesses outside of the 100-mile trial radius, may mean that defendants can expect to see more motions to put up witnesses live via video at trial, given that such trial testimony is argued to be a better way for juries to assess the credibility of a witness, compared to pre-recorded deposition testimony. It is yet unclear whether this practice will become more prevalent, and, if so, whether executives of product manufacturers residing outside the United States could be ordered to testify via contemporaneous video transmission at trials taking place thousands of miles away.

ii Federal laws and regulation

Last year witnessed the passage of benchmark legislation and regulation affecting product manufacturers in both traditional and emerging industries. In May 2016, the FDA issued a final rule that brought all tobacco products within the ambit of its regulatory authority, including products previously unregulated at the federal level such as e-cigarettes, cigars, hookahs and pipe tobacco.[136] Among other things, the rule will impose new health warnings and pre-market approval requirements. The new rule also prohibits sales to minors and proscribes vending machine sales (except in adult-only facilities). Meanwhile, in July 2016, President Obama signed into law a bipartisan bill that establishes comprehensive federal labelling requirements for food products containing genetically modified organisms (GMOs) and prohibits states from enacting their own GMO labelling laws.[137] These laws may augur similar legislation in other jurisdictions around the world.

132 *Int'l Shoe Co. v. Wash.*, 326 U.S. 310 (1945) (holding that a party may be subject to the jurisdiction of a state court if that party has 'minimum contacts' with the forum in question).

133 *Bristol-Myers Squibb Co. v. Superior Court*, 2017 U.S. LEXIS 787 (U.S. Jan. 19, 2017) (No. 16-466).

134 *In re DePuy Orthopaedics Inc.*, No. 16-11419, Order Denying Petition for a Writ of Mandamus (5th Cir. 27 September 2016).

135 Fed. R. Civ. P. 43(a).

136 FDA, Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,974 (10 May 2016) (codified at 21 C.F.R. pts. 1100, 1140 & 1143).

137 National Bioengineered Food Disclosure Standard, Pub. L. No. 114-216, 130 Stat. 834 (29 July 2016).

On 14 December 2016, the FDA announced a final eight-page guidance on when it will choose to notify the public of an emerging signal, or a potential defect, with a medical device.[138] The guidance includes a timeline that the FDA will use, along with a list of the factors it intends to consider in making its decision. The medical device industry, however, has voiced serious concerns that the guidance will negatively impact providers and patients by creating confusion and unnecessary fears that could lead to potentially harmful health outcomes.[139] Although those in the industry confirm that safety is a top priority, they are concerned that certain public notifications may be 'incorrect, incomplete or misleading and may deter use of a safe and effective medical device'.[140]

iii State laws and preemption

In August 2016, the New Jersey Supreme Court held that state-law failure-to-warn claims brought against generic drug makers are not pre-empted by federal law when the claim is premised on a failure to update labelling in a timely manner to match that of the FDA-approved brand-name drug.[141] The case involved nearly 1,000 consolidated lawsuits brought against over 50 brand-name and generic manufacturers of Reglan (metoclopramide), a prescription drug used to treat gastroesophageal reflux. The plaintiffs alleged that certain generic manufacturers waited as long as four-and-a-half years to update the labelling to conform to that of the brand-name drug, which warned that therapy should not exceed 12 weeks in duration.[142] Defendants contended the claims were barred by the US Supreme Court's landmark ruling in *PLIVA, Inc. v. Mensing*,[143] which held that state law failure-to-warn claims against generic drug makers were generally pre-empted because the FDCA requires generic drugs to maintain the same safety and efficacy labelling as the brand-name drug. The New Jersey Supreme Court disagreed, however, holding that 'if a generic drug manufacturer is seeking safe-harbour protection under the sameness doctrine, then it must exercise reasonable diligence to learn of updates to the brand-name labelling.'[144] The decision leaves several questions unanswered, such as what the court meant by 'reasonable diligence' to find updates and how much 'lag-time' for updates is appropriate. Because the New Jersey Supreme Court's opinion deepens a growing divide among the courts,[145] the issue may soon find its way to the US Supreme Court for resolution.

138 FDA, Public Notification of Emerging Postmarket Medical Device Signals ('Emerging Signals'): Guidance for Industry and Food and Drug Administration Staff, 81 Fed. Reg. 90,365 (14 December 2016), available at www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm479248.pdf.

139 See Mixter, 'FDA Guidance Could Trigger Misleading Device Reports: Industry,' *Bloomberg BNA: Product Safety & Liability Reporter*, 2 January 2017, available at http://news.bna.com/psln/PSLNWB/split_display.adp?fedfid=102354593&vname=pslrnotallissues&wsn=500374000&searchid=29210280&doctypeid=1&type=date&mode=doc&split=0&scm=PSLNWB&pg=0.

140 Id.

141 *In re Reglan Litig.*, 142 A.3d 725 (N.J. 2016).

142 Id. at 738.

143 564 U.S. 1058 (2011).

144 Id. at 741.

145 Compare *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013) (state-law claims concerning generic drug warnings that do not comply with federal duty of 'sameness' are not preempted by FDCA), with *Morris v. PLIVA, Inc.*, 713 F.3d 774 (5th Cir. 2013) (state-law claim against generic manufacturer preempted because FDCA-mandated labelling obligation sounds exclusively in federal, not state, law).

iv Automotive industry

In October 2016, the Northern District of California granted final approval to a settlement in the Volkswagen 'Clean Diesel' MDL.[146] The litigation began only a year earlier, after the US Environmental Protection Agency (EPA) issued a notice that the company had violated the Clean Air Act by installing 'defeat devices' in its vehicles, which allegedly were designed to pass US emissions tests while emitting up to 40 times the legal level of nitrogen oxide. The $14.7 billion settlement – the largest in US automotive history – included over $10 billion to buy back cars and provide compensation to car owners, $2.7 billion for environmental remediation and $2 billion to build zero-emission vehicle infrastructure.[147] Various other automakers, including Fiat Chrysler and Mercedes, now face their own emissions-related litigation.

In July 2016, the US Court of Appeals for the Second Circuit reversed portions of a 2015 ruling by a US bankruptcy court that had shielded American car maker General Motors from liability over certain economic loss claims in its ongoing ignition switch litigation.[148] The litigation stems from GM's disclosure in 2014 that over 2 million of its vehicles contained ignition switches that could inadvertently move out of the 'run' position under certain conditions. The Second Circuit's ruling held that, because GM did not disclose the ignition switch issue prior to its 2009 bankruptcy, enforcing the sale order would violate plaintiffs' procedural due process. In December, General Motors petitioned the US Supreme Court for a writ of certiorari to review the Second Circuit's ruling. That petition is pending at the time of writing.

146 *In re Volkswagen 'Clean Diesel' Mktg., Sales Practices, & Prods. Liab. Litig.*, 2016 U.S. Dist. LEXIS 148374 (N.D. Cal. 25 October 2016).

147 Salvatore, 'Where 5 Top MDLs Stand At The End of 2016,' *Law360*, 21 December 2016, available at https://www.law360.com/articles/873829/where-5-top-mdls-stand-at-the-end-of-2016.

148 *Elliott v. GM LLC (In re Motors Liquidation Co.)*, 829 F.3d 135 (2d Cir. 2016).

Appendix 1

ABOUT THE AUTHORS

CRISTINA AYO FERRÁNDIZ

Uría Menéndez

Cristina Ayo Ferrándiz is a member of the litigation practice area of Uría Menéndez's Barcelona office. She joined the firm in September 2000, and became a counsel in January 2013.

She focuses her practice on advising on contentious and pre-contentious civil and commercial issues. Ms Ayo specialises in judicial proceedings before the Spanish courts and tribunals and national and international arbitration proceedings relating to contractual liability, non-contractual liability and product liability, as well as contractual, corporate, lease agreements, banking, financial and private party disputes.

AFE BABALOLA SAN

Afe Babalola SAN & Co (Emmanuel Chambers)

Afe Babalola SAN was called to the Bar in England in 1963. He is a member of the Lincoln's Inn, London, a registered member of the Bar of England and Wales and a distinguished member of the Nigerian Bar.

Aare Babalola started his legal practice in the Chambers of Olu Ayoola and remained there until 1965, when he established the firm of Afe Babalola SAN & Co (Emmanuel Chambers).

He was admitted into the Nigerian Inner Bar as a Senior Advocate of Nigeria (SAN) in 1987. Aare Babalola has been in practice for over 50 years and is an active uninterrupted member of the Nigeria Bar Association and International Bar Association (IBA). He is a fellow and president of the Nigerian Institute of Advanced Legal Studies, a fellow of the Chartered Institute of Arbitrators Nigeria, fellow of the Leadership Institute of Nigeria, and a member of the Body of Benchers, the highest legal body in Nigeria. He was the Pro-Chancellor of the University of Lagos from 2001 to 2007, and is a traditional chief (the Aare of Yorubaland), a holder of the award of the Officer of the Order of the Federal Republic (OFR) and Commander of the Order of the Niger (CON).

Aare Babalola is actively involved in both domestic and international educational activities. In 2010, he established the Afe Babalola University Ado-Ekiti, a not-for-profit federal government-licensed private university.

VIVEK BAJAJ

AZB & Partners

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

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

MURILO CASTINEIRA BRUNNER

Mattos Filho, Veiga Filho, Marrey Jr e Quiroga Advogados

Murilo Castineira Brunner represents domestic and foreign clients in civil and commercial litigation. He has been involved in environmental and consumer matters, providing counsel for leading manufacturers and service providers in both individual and class actions.

He has experience in litigation involving heavy industry and the automotive sector. He has represented major internet and telecom companies.

His litigation experience includes preparing defences, briefs and appeals in trial and appellate courts, as well as in Brazil's Superior Court of Justice and Supreme Federal Court. He makes court appearances on behalf of clients at trial and appellate levels. He is a member of the São Paulo Lawyers Association.

ALBÉNIZ COURET-FUENTES

Sepulvado & Maldonado, PSC

Albéniz Couret-Fuentes is an income partner of Sepulvado & Maldonado, PSC, in San Juan, Puerto Rico. His practice extends to virtually all litigation affairs of the firm, including matters of antitrust and trade regulation, trademarks and copyrights, securities, commercial litigation, distribution and franchising, environmental and land use law, constitutional law, employment law, class actions, injunctive relief practice, and counselling in the oil and gas industry. He is also actively involved in the firm's appellate practice.

YUE DAI

King & Wood Mallesons

Ms Dai is a partner in the dispute resolution and litigation group specialising in the cross-border litigation and arbitration practice.

Ms Dai has extensive practical experience in handling international commercial litigation and arbitration cases, including shareholding, trade, construction and derivatives disputes for well-known state-owned enterprises, multinational companies and financial institutions before CIETAC, the Beijing Arbitration Commission, ICC, HKIAC and the PRC courts at all levels.

During the years of 2005 to 2009, Ms Dai also provided regular legal support for the Beijing Organizing Committee for the Olympic Games. She was awarded with the Distinguished Contribution to Judicial and Administrative Security for the Olympic Games by Chaoyang District's Bureau of Justice.

Ms Dai joined KWM in 2005.

Ms. Dai attained her LLB and LLM from China Foreign Affairs University and LLM in Global Business Law from the University of Washington School of Law. She is a licensed attorney in both the People's Republic of China and Washington, United States.

In addition, Ms Dai also serves as committee member of the Youth Federation and Young Lawyer Working Committee of Chaoyang District Bar Association.

Ms Dai is fluent in both Chinese and English.

FIONA EAST

Weightmans LLP

Fiona East is head of the product liability team at Weightmans LLP with over 25 years' experience of claims arising out of the Sale of Goods and Consumer Protection Acts and prosecutions under the General Product Safety Regulations. She is experienced in a range of legal, commercial and reputational issues in connection with product recalls and is sensitive to issues around supplier relationships and customer relations. She defends personal injury and property claims resulting from alleged failed components, unsafe products in the workplace and a diverse range of other consumer products. She has a particular specialism relating to the automotive industry. She is ranked in *The Legal 500* and is described as a 'tenacious litigator' with 'a vast amount of knowledge' and 'excellent commercial judgement'. Notable cases she has acted in include *Howmet Ltd v. Economy Devices Ltd* [2016] EWCA Civ 847.

FRANCESCO FALCO

Paul Hastings (Europe) LLP

Francesco Falco is a senior associate in Paul Hastings' Milan office. He focuses his practice in civil and commercial litigation, developed in 10 years of representing and advising leading companies.

Mr Falco's litigation experience enabled him to assist other clients with several corporate and commercial transactions. These matters primarily involved restructuring transactions, mergers and acquisitions, project financing and other related matters.

With the opening of the Italian gas market, Mr Falco assists leading clients in cases related to breaches of gas supply agreements.

Mr Falco was seconded for one year to the Paul Hastings New York office to advance his skills on white collar crime (anti-corruption; global compliance). In Italy, Mr Falco focuses on anti-money laundering legislation.

ALEX FERRERES COMELLA

Uría Menéndez

Alejandro Ferreres Comella is a partner of Uría Menéndez and the head of the litigation and arbitration practice areas of the Barcelona offices of the firm.

He is a practising litigator in the jurisdictions of Madrid and Barcelona, among others, and concentrates his practice in the areas of contractual liability and tort. In particular, he

has taken part in the defence of car manufacturers, pharmaceutical companies, tobacco companies and the chemical industry in some of the most important product liability cases in Spain, including several collective claims.

He is considered a leading lawyer in the main international legal directories by *Chambers and Partners* and *Who's Who Legal*, among others.

IGNACIO FLORES

Estudio Beccar Varela

Ignacio Flores is a junior partner of Estudio Beccar Varela, where he works in the Civil and Commercial Litigation Department. Through and extensive and intensive professional practice in the litigation area of the firm, Ignacio has worked in all sort of judicial civil and commercial proceedings in all instances (mediation, court, ordinary and extraordinary appeals, national federal and local), representing both plaintiffs and defendants. He has a wide experience in mediations, judicial and arbitral proceedings involving the termination of long term contractual relations (such as distribution, agency and others collaboration agreement between companies), civil and commercial liabilities in general, manufacturer's liability, credit card systems, banking liabilities, habeas data, consumer law, issues concerning the devaluation of the argentine currency, having been involved in collective and individual proceedings, environmental liabilities proceedings, preliminary and injunction proceedings and in general any proceeding in civil and commercial matters.

Ignacio received his law degree from the Universidad Nacional de Buenos Aires (1993) and obtained his LLM in Company Law from the Universidad Austral. He teaches in the Lawyers Practice Program (PEA in Spanish) of the FORES (Foro de Estudios sobre la Administración de Justicia) where he coordinates the Procedural Practice area. He is a member of the Colegio Público de Abogados de la Capital Federal (Buenos Aires Bar Association), Colegio de Abogados de Buenos Aires and Colegio de Abogados de San Isidro.

He speaks Spanish, French and English.

GONZALO GARCÍA DELATOUR

Estudio Beccar Varela

Gonzalo García Delatour is a partner of Estudio Beccar Varela. His practice areas include civil and commercial litigation, insolvencies, bankruptcies and restructuring and domestic and international arbitration. He has represented local and foreign clients in complex litigation cases and international arbitration proceedings under the rules of the ICC, UNCITRAL, LCIA, AAA, CIADI, CAM, as well as in domestic arbitration before the Arbitral Tribunal of the Buenos Aires Stock Exchange, MAE and CEMA. He has acted as counsel in several cases involving banking and contractual disputes, product liability, torts, oil and gas, mining, agency and distribution matters and real estate and construction, among others. He is also very active in daily legal assistance in general corporate and commercial matters to several local and foreign companies established in Argentina.

Gonzalo received his law degree from the Universidad de Buenos Aires (2000), with a specialisation in business law. He participated as visiting scholar in a Research Program in Comparative Law, at Denver University School of Law (Denver, USA, 2005) and worked as a foreign associate at Hughes Hubbard & Reed (New York, USA, 2006).

He has participated in numerous meetings and seminars in connection with domestic and international arbitration. He is author of several articles on his area of expertise. He

is a member of the Colegio Público de Abogados de la Capital Federal (Buenos Aires Bar Association); the Colegio de Abogados de San Isidro (Buenos Aires); the Spanish Club of Arbitration; the Rioplantense Chapter of the CEA; the Young International Arbitration Group of the LCIA; the Business Center of Mediation and Arbitration; and the International Bar Association.

He speaks Spanish and English.

ANTHONY B HADJIOANNOU

Kyriakides Georgopoulos Law Firm

Anthony B Hadjioannou, was born in Corinth on 18 December 1947. He studied Law at the University of Athens and has been a member of the Athens Bar Association since 1976. Currently he is the head of the litigation department of Kyriakides Georgopoulos Law Firm. His litigation experience spans 41 years during which he has handled numerous complex cases before all levels of the Greek courts. He has particular experience concerning distribution and agency agreements.

As an attorney for major local and international producers, he has been involved in product liability matters and has defended claims for alleged defective products. Anthony has handled numerous trademark and patent cases and has defended the interests of our clients against infringement. Finally, he has considerable drafting experience in civil and commercial matters and is an expert in real estate transactions and auctions, particularly in negotiating and drafting complex lease agreements. He also served as a permanent representative of our firm to an association of European lawyers, namely 'The Club'.

GERT-JAN HENDRIX

Linklaters LLP

Gert-Jan Hendrix has been an associate in the litigation department of Linklaters in Brussels since 2013. He joined Linklaters after receiving his LLM from the University of Chicago. Mr Hendrix also holds a bachelor's degree in law and a master's degree in international and European law from the Catholic University of Leuven. His main focus is commercial litigation and arbitration.

CHRISTOPHE HÉNIN

Intuity

Having received a PhD in European and pharmaceutical law, Christophe Hénin, partner and founder of Intuity in 2005, was previously a partner of the US law firm Proskauer Rose. He has a comprehensive expertise and regularly assists eight of the 10 most important innovative pharmaceutical companies in every area of pharmaceutical law, in European and French law, and intervenes in product liability, regulatory, competition or distribution law cases, in civil, criminal, competition and arbitration litigations. Mr Hénin has built close relationships with government institutions, public and administrative authorities, as well as with the pharmaceutical and health associations.

In 2013, he was particularly active within product liability cases and issues, in particular within the health sector in France and at the European level. Mr Hénin notably managed many cases within the 'contraceptive pill scandal' for several pharmaceutical companies, as

well as the furosemide case, and was entrusted with advising the pharmaceutical manufacturer on the criminal complaints issued against the oral anticoagulant medicinal product.

GABRIELE HINTSTEINER

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Gabriele Hintsteiner is a senior associate at Wolf Theiss and a member of the firm's dispute resolution practice group. She has a PhD from the University of Salzburg and holds an LLM degree in public international law from the University of Helsinki. Her main practice area is litigation in civil and commercial law matters. She is particularly experienced in handling complex cross-border product liability cases in a broad spectrum of industries, including clients in the chemical, electronic and hydraulic industries.

AKIHIRO HIRONAKA

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Akihiro Hironaka has been a partner of the dispute resolution group of Nishimura & Asahi since 2007. He has extensive experience dealing with large-scale and complex disputes, including successful representations of foreign and Japanese vehicle manufacturers in defending important product liability lawsuits. Mr Hironaka also successfully represented a foreign corporation in an international arbitration involving an alleged defect in the design of a foreign factory. Further, he successfully represented a foreign corporation in a cross-border M&A dispute involving a breach of representations concerning numerous product defects. Mr Hironaka is a graduate of the University of Tokyo (LLB, 1993) and Harvard Law School (LLM, 2003), and is admitted to the Bars of Japan and New York. He served as a Japanese district court judge from 1998 until 2000, and worked at Arnold & Porter (Washington, DC) from 2003 to 2004. Mr Hironaka has authored numerous publications concerning dispute resolution, including Yasuhei Taniguchi et al. (eds.), *Civil Procedure in Japan* (contributor, Juris Publishing) and *International Arbitration and Corporate Strategy* (co-editor, Yûhikaku). He is an individually ranked lawyer in the category of dispute resolution with *Chambers Global/Asia-Pacific 2016* and *Who's Who Legal 2016*.

CASPAR HUMM

Wenger & Vieli AG

Caspar Humm's professional qualifications include the Lic.iur., University of Zurich, Switzerland, 2009 and being admitted to the Bar in Switzerland in 2014.

Mr Humm's areas of practice include pharmaceutical and health law; life sciences; product liability law; corporate and commercial law; information technology and data protection law; intellectual property law; unfair competition law; and litigation.

Recent mandates include advising and representing pharmaceutical and other companies in legal proceedings concerning product liability; advising pharmaceutical companies and manufacturers of medical devices regarding contracts, cooperation with other stakeholders in the health-sector, clinical trials and data protection on a regular basis; and advising and representing pharmaceutical companies in administrative and appeal proceedings regarding price decreases and revisions of marketing authorisations.

Mr Humm speaks German and English.

YUTARO KAWABATA

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Yutaro Kawabata is a partner at Nishimura & Asahi and is a member of the firm's international dispute resolution practice group. He has advised and represented clients in district courts, high courts and at the Supreme Court of Japan on a variety of matters related to product liability, tort liability and contract claims. Mr Kawabata graduated from Keio University (LLB, 2002), and was admitted to practise law in Japan in 2004.

MARIA S KANELLOPOULOU

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Maria was born in Athens on 11 December 1987. She studied at the University of Thrace, and obtained her postgraduate degree in Business Law (LLM) at Panteion University (Athens) in 2014. Maria joined the Kyriakides Georgopoulos Law Firm in January 2013 and has been a member of the Athens Bar Association since 2010. She works for the litigation department of the firm and has gained significant experience in commercial and civil litigation. Her experience involves also the handling of cases on breach of law of obligations, torts, distribution and agency agreements and debt collection.

MORAN KATZ

S Horowitz & Co

Moran Katz is a partner at S Horowitz & Co, where she specialises in dispute resolution, with an emphasis on intellectual property, information technology, product liability, professional negligence and contractual disputes.

In the particular field of product liability, Ms Katz advises and represents leading international manufacturers across a broad spectrum of industries, including pharmaceutical, aviation and transportation, industrial products, consumer products and other high and low-tech industry sectors. She also defends clients in court served with product liability claims (including class actions). In addition, she advises manufacturers and distributors throughout the stringent regulatory product recall processes and represents them before the relevant local authorities, where required. Ms Katz has also been involved in the drafting of various contracts, the subject matter of which concerned, *inter alia*, product liability-related contractual issues.

Her expertise in product liability has been recognised by *The Legal 500*, where she has been ranked as 'particularly recommended'.

XINYU LI

King & Wood Mallesons

Mr Xinyu Li is an associate in King & Wood Mallesons' dispute resolution practice. Mr. Li specialises in corporate litigation, joint venture dispute resolution, international litigation and arbitration, PE dispute resolution and product liability.

Mr Li has participated in dozens of the domestic and international litigation and arbitration-related proceedings in the areas of corporate, contract, securities, product liability and foreign investment. He has represented clients before the courts at various levels in China, as well as at the China International Economic and Trade Arbitration Commission,

Beijing Arbitration Commission and Singapore International Arbitration Centre. He also has experience of assisting clients to respond in proceedings before foreign courts.

Mr Li joined King & Wood Mallesons in 2010. Prior to joining King & Wood Mallesons, Mr Li did his internship in the New York office of a Wall Street firm, with its securities department.

Mr Li received his LLB and LLM degree from Southwest University of Political Science and Law and his second LLM degree from Temple Law School. He was admitted to practice in China in 2008.

Mr Li's working languages are Chinese and English.

LIM REN JUN

Baker McKenzie Wong & Leow

Ren Jun is a Principal with Baker McKenzie Wong & Leow. He represents local and international clients in both contentious and non-contentious intellectual property matters. He also advises on a full range of healthcare, as well as consumer goods-related legal and regulatory issues.

Ren Jun keenly advises on a full range of issues relating to the healthcare industry. These include regulatory compliance in respect of drugs, medical devices, health supplements, food products and cosmetics; clinical trials; product liability/recall issues; data exclusivity; patent linkage; competition; and anti-corruption issues.

Ren Jun also represents local and international intellectual property-intensive clients in matters such as civil and criminal litigation for all forms of intellectual property infringement; border enforcement; local and international filing and prosecution strategies; domain name disputes; opposition and revocation actions; general litigation; and anti-corruption issues. In addition, he plans and executes anti-counterfeiting operations for various clients in Singapore and around the Asia-Pacific region.

Ren Jun advises on various intellectual property-related and non-intellectual property-related commercial issues arising from mergers and acquisitions; licensing; franchising; data protection; due diligence; audits; and valuation.

Ren Jun also assists clients on a wide spectrum of regulatory issues affecting the consumer goods industry such as licensing; advertising; trade libel; harassment; and product liability/recall.

COLIN LOVEDAY

Clayton Utz

Colin Loveday has over 20 years' experience defending complex multi-plaintiff claims involving representative actions and is internationally recognised for his expertise and industry-leading experience in product liability law and class actions. He has led the defence team in some of Australia's largest and most complex class actions and in doing so, has worked extensively with in-house counsel and lawyers in the US and Europe, developing international defence strategies and working with international expert witnesses.

Mr Loveday has a commanding track record in defending class actions and has been actively involved in the running of trials in the past decade. He has extensive experience in defending and resolving class actions, whether by having them struck out at an early stage, running representative trials to resolve critical issues or implementing resolution schemes. He understands the tactical and procedural nuances of class action litigation and works with

clients to develop strategies to address them. He is also engaged in providing strategic advice to boards and senior executives in relation to high-level issues and tactics.

Mr Loveday 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.

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

ELAINE M MALDONADO-MATÍAS

Sepulvado & Maldonado, PSC

Elaine M Maldonado-Matías is the managing partner at Sepulvado & Maldonado, PSC, in San Juan, Puerto Rico. Before joining Sepulvado & Maldonado, she was a capital member at Puerto Rico's largest law firm, McConnell Valdés. While at McConnell she chaired the Welfare and ERISA Litigation Practice Area and was a partner of the labour and employment law practice group. Since joining Sepulvado & Maldonado in 2008, she has continued her employment law practice, and has also successfully performed in high-stakes multi-district litigation involving environmental law, tort and product liability issues.

SHEENA McKIE

Clayton Utz

Sheena McKie is a senior associate in the Sydney office of Clayton Utz, with experience in complex product liability and class action litigation. She has been involved in a broad range of product liability and general commercial matters, including advisory and contentious work, including specifically for clients in the pharmaceutical and medical device industries, as well as suppliers and manufacturers of consumer goods.

Ms McKie is experienced in advising clients on a variety of regulatory issues, including registration and listing, advertising and marketing requirements, as well as product safety issues, including product recalls. She has experience in the running of both small and large-scale commercial litigation matters, including class actions, in the Supreme Court of NSW and the Federal Court of Australia.

Ms McKie has worked closely with counsel in the US, EU and New Zealand in advisory matters including product recalls as well as the coordinated defence of similar claims internationally.

CAROLINE MÜLLER TREMONTE

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Caroline Müller Tremonte's professional qualifications include obtaining the Lic.iur. from the University of Zurich, Switzerland, 2004; being admitted to the Bar in Switzerland in 2008; and gaining an LLM in international business law, National University of Singapore, 2012.

Her areas of practice include pharmaceutical and health law; product liability law; life sciences; data protection law; unfair competition and cartel law; and employment law.

Recent mandates include advising and representing pharmaceutical companies in legal proceedings concerning product liability and regarding marketing authorisations. Ms Müller

has advised and represented pharmaceutical companies in appeal proceedings regarding price decreases and revisions of marketing authorisations. She also advises pharmaceutical companies on a regular basis regarding contracts, advertising, sponsoring and gifts, and data protection.

Ms Müller is also performing the legal review for the advertising and PR material of a multinational pharmaceutical company concerning Switzerland.

She speaks German and English.

ANA LICKFOLD DE NOVAES E SILVA

Vieira de Almeida & Associados – Sociedade de Advogados, RL

Ana Lickfold de Novaes e Silva has a law degree from the Catholic University Faculty of Law and has completed postgraduate degrees in banking, securities and insurance law at the Coimbra University Faculty of Law and in management and corporate law at the Nova University of Lisbon Faculty of Economics. Ana joined Vieira de Almeida & Associados in 2004 and is managing associate in the litigation and arbitration practice group, mainly focused on civil and commercial litigation, representing national and foreign companies in significant disputes before the courts of Portugal and Portuguese and international arbitration centres, namely the International Chamber of Commerce. Among those claims, she has represented and advised various multinational corporations within product liability litigations, including the automotive and pharmaceutical sectors. Ana was co-author of *Commentary to the Voluntary Arbitration Law*, 2014.

AVI ORDO

S Horowitz & Co

Avi Ordo is a key partner at S Horowitz & Co, where he specialises in dispute resolution. In his more than 20 years as a practitioner, he has acquired significant experience in handling, *inter alia*, complex product liability, professional negligence and tortious disputes, and conflicts and cases related to insurance and product recalls.

Mr Ordo's product liability experience stretches across a broad range of industries, including pharmaceutical, aviation and transportation, medical devices and consumer products. In addition, he has been involved in cases encompassing all types of damage, including bodily injury and property damage, as well as a wide array of causes of damage, such as fire or failure in design, planning, assembly, installation or maintenance.

He is also highly experienced in collaborating with and guiding professional experts (including in complicated technical and scientific fields), as well as in dealing with complex and multi-jurisdictional cases.

Mr Ordo was chosen by *Corporate INTL* magazine as Israel's 'Product Liability Lawyer of the Year for 2011'. *The Legal 500* describes him as a 'significant figure' in the insurance legal market. *Chambers Global* has quoted Mr Ordo's clients as saying that he 'considers arguments in depth and makes prudent judgements under pressure'. In 2013 he was awarded the lucrative *International Law Office's* Client Choice award for litigation in Israel, quoting his clients, who describe him as 'a true standalone lawyer in the Israeli market and an absolute pleasure to work with', as well as an attorney who 'uniquely combines intelligence, thoroughness, a strong work ethic and the ability to translate the heavy local legal lingo into commercial sense, and his work product is consistently outstanding'.

FABIO TEIXEIRA OZI

Mattos Filho, Veiga Filho, Marrey Jr e Quiroga Advogados

Fabio Teixeira Ozi advises clients in complex civil and commercial litigation including antitrust, securities claims, and environment-related claims, in administrative, judicial and arbitration proceedings. He also has significant experience in pre-claim settlement negotiations. He has been distinguished for his understanding of the legal issues common to the automotive industry and agribusiness, and his work on product liability matters including class action lawsuits and actions brought by government agencies in charge of consumer rights. He is a member of the São Paulo Lawyers Association.

FRANCESCA PETRONIO

Paul Hastings (Europe) LLP

Francesca Petronio is a partner in the litigation practice of Paul Hastings and is based in the firm's Milan office. Ms Petronio has extensive experience in litigation, domestic and international arbitration, bankruptcy, corporate and commercial litigation matters, as well as the management of pre-litigation situations and data privacy. In addition, she deals with compliance programme-related issues, white collar crimes and data privacy issues providing assistance to domestic and international clients in internal investigations.

ANNIE PHILIP

AZB & Partners

Annie Philip is a senior associate with AZB & Partners' Bangalore office. Her primary practice areas include private equity, mergers and acquisitions, general corporate law and labour and employment law. She has advised on structuring of private equity and foreign investment transactions and has drafted and negotiated key transaction documentation in this regard. She has also contributed to several articles on product liability developments in India, and has a keen interest in the emerging issues relating to this field.

Ms Philip received BA LLB (Hons) from the West Bengal National University of Juridical Sciences in 2009 and began her career at Khaitan & Co in the same year. She has been with AZB & Partners since 2011.

PEDRO PIRES FERNANDES

Vieira de Almeida & Associados – Sociedade de Advogados, RL

Pedro Pires Fernandes holds an LLB and a master's degree from the Coimbra University, focused on contractual and tort law. Further to this, he has attended a European private law course lectured at Salzburg University. Additionally, he has completed an extension course on arbitration at Nova University of Lisbon. Pedro joined Vieira de Almeida & Associados in 2011 and is currently a senior associate in the litigation and arbitration practice group. In such capacity he has been involved in several disputes, mainly focused on commercial and civil matters, both in arbitration and litigation. Among those claims, he has represented and advised a number of multinational corporations regarding product liability litigations, including in the automotive and pharmaceutical sectors.

BRADLEY W PRATT

The Pratt Law Firm

Bradley Pratt is a partner at The Pratt Law Firm, where his practice focuses on high exposure trucking accident litigation, catastrophic personal injury cases, product liability/mass torts, pharmaceutical and medical device cases, consumer fraud litigation, whistleblower actions, business disputes, and class actions. Prior to founding The Pratt Law Firm in 2016, he was a Partner at King & Spalding. In 2012, he was awarded the 'Rising Star Award' in product liability litigation by *Law360*, honouring five attorneys under the age of 40 in this specialism nationwide whose 'accomplishments in major litigation and transactions belie their age'.

FRANK SCHERRER

Wenger & Vieli AG

Frank Scherrer has obtained his Licence en droit from the University of Neuchâtel, Switzerland, 1991; LLM in European Legal Studies, University of Exeter, UK, 1993; Dr.iur., University of Zurich, Switzerland, 1996; and was admitted to the Bar in Switzerland in 1999. His areas of practice include pharmaceutical and health law; product liability law; contract law; unfair competition and cartel law; and advertising law.

Recent mandates include advising and representing pharmaceutical and other companies in product liability matters, as well as advising and representing pharmaceutical companies on a regular basis regarding marketing authorisation and reimbursement, contracts, advertising, sponsoring and gifts, clinical trials and data protection. He has also represented pharmaceutical companies in appeal proceedings regarding price decreases and revisions of marketing authorisations.

Mr Scherrer speaks German, English and French.

EVA SPIEGEL

Wolf Theiss Rechtsanwälte GmbH & Co KG

Eva Spiegel became a partner at Wolf Theiss in 1998 and has 20 years of experience in international dispute resolution and insolvency matters. She is a member of the firm's dispute resolution practice group and insolvency and restructuring team. Eva regularly advises and represents clients in liability disputes, banking and insurance litigation and contentious insolvency matters.

She has broad experience in handling complex product liability matters for international and national suppliers and producers in a wide variety of industries, including a significant number of cases with a cross-border focus. Clients are industry leaders in the automotive, electronics, hydronic, pharmaceutical and chemical industries.

YUI TAKAHATA

Nishimura & Asahi

Yui Takahata is an attorney-at-law at Nishimura & Asahi. She has worked in various areas of practice, such as dispute resolution including international arbitration on distribution agreements, M&A, general corporate, and corporate crisis management. She is a graduate of Waseda Law School (JD, 2012), and was admitted to practise law in Japan in 2010.

CHILTON DAVIS VARNER

King & Spalding LLP

Chilton Varner joined King & Spalding in 1976. She became the first female partner in the firm's litigation department, and the first female to serve on the firm's management committee. She is the senior partner on King & Spalding's product liability team, which *The American Lawyer* has twice recognised as one of the top three such practices in the country. She has been named on the shortlist of best female litigators by the *National Law Journal*, *Chambers and Partners*, *Law360* and *Benchmark*. Recently, *Best Lawyers* named her 'Litigator of the Year' in her region.

JOOST VERLINDEN

Linklaters LLP

Joost Verlinden specialises in domestic and cross-border litigation and national and international arbitration. He has significant experience in all forms of commercial litigation: accountants' liability, banking litigation, construction cases, contractual disputes, corporate litigation (including post-acquisition claims and shareholder disputes), insolvency disputes, product liability, sovereign debt issues and white-collar crime. He represents clients before all Belgian courts and acts as counsel and arbitrator in CEPANI, Belgian Federation of Diamond Bourses, ICC, SCC, UNCITRAL and *ad hoc* arbitrations.

Joost is the author of numerous articles on arbitration, class actions, civil procedure, corporate litigation, insolvency law and product liability. He is constantly recommended as a leading attorney for dispute resolution in Belgium by *Chambers and Partners* and by *The Legal 500*. He has been a litigation partner since 1998.

CHRISTOPH WAGNER

Heuking Kühn Lüer Wojtek

Christoph Wagner attended the University of Heidelberg Law School from 1984 to 1989. He completed the First State Examination in Heidelberg in 1989, the Second State Examination in Munich in 1992, was admitted to the Bar in 1993 and was admitted as a notary in 2000.

ARIEL YE

King & Wood Mallesons

Ariel Ye has more than 25 years of experiences in cross border commercial dispute resolution. As a senior partner, Ms Ye focuses on international arbitration, China-related compliance work and cross-border dispute resolution. She has represented domestic and foreign clients before various arbitration institutions (CIETAC, SCC, HKIAC, AAA, ICC, etc.).

Ms Ye is one of the most respected Chinese lawyers in the field of international arbitration. She is a member of many arbitration institutions (SIAC, ICCA and LCIA, etc.) as well as a listed arbitrator of AAA, CIETAC, HKIAC and SIAC.

Ms Ye is also an expert on commercial bribery and other regulatory and compliance related matters.

Ms Ye joined King & Wood Mallesons as a partner in 2004. Prior to this, she had practised law in other firms for 15 years.

Ms Ye received her LLB from the Law School of Peking University and a master's degree from the Law School of China Academy of Social Sciences as well as a LLM degree from Harvard Law School. She was admitted in the PRC and New York State respectively.

Ms Ye's working languages are Chinese and English.

SERGEY YURYEV

CMS Russia

Sergey Yuryev is a partner of CMS Russia, and heads the dispute resolution practice. He has worked at the firm since 2000. Before joining CMS, he worked at an American law firm in its Moscow and Baku offices, as well as in the United States.

Mr Yuryev has over 20 years of experience advising clients in the following practice areas: dispute resolution, general commercial and employment law. Leading CMS Russia's dispute resolution practice, he handles commercial, corporate and energy disputes.

Mr Yuryev holds a master of laws degree from the Moscow State Institute of International Relations (1995), as well as an LLM from the Southern Methodist University School of Law of Dallas, Texas (1997). He is fluent in English.

Appendix 2

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