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## CONTENTS

PREFACE.......................................................................................................................................................... v

_Chilton Davis Varner and Madison Kitchens_

Chapter 1  AUSTRALIA........................................................................................................................................ 1

_Colin Loveday and Sheena McKie_

Chapter 2  AUSTRIA.......................................................................................................................................... 14

_Eva Spiegel and Florian Horak_

Chapter 3  CHINA........................................................................................................................................... 25

_Ariel Ye, Yue Dai, Xinyu Li and Tianren Li_

Chapter 4  ENGLAND AND WALES........................................................................................................... 34

_Neil Beresford and Natasha Lioubimova_

Chapter 5  FRANCE......................................................................................................................................... 46

_Christophe Hénin and Julie Vasseur_

Chapter 6  INDIA............................................................................................................................................ 60

_Vivek Bajaj, Kaavya Raghavan and Sherien Kaul_

Chapter 7  ITALY.............................................................................................................................................. 72

_Daniele Vecchi and Michela Turra_

Chapter 8  JAPAN........................................................................................................................................... 83

_Akihiro Hironaka, Kazuyuki Ichiba and Hidenori Sato_

Chapter 9  PORTUGAL..................................................................................................................................... 94

_Joana Mota and Alexandre Pedral Sampaio_

Chapter 10  PUERTO RICO.............................................................................................................................. 104

_Albéniz Courret-Fuentes and Elaine M Maldonado-Matías_

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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 2019. Notably, several jurisdictions proposed or enacted landmark legislation to strengthen rules governing long-existing industries or, in some cases, emerging technologies (such as autonomous vehicles, artificial intelligence, robotics and the Internet of things). In 2019, for example, China amended its Pharmaceutical Administration Law and thereby established a product traceability system to ensure drug quality. The revised law also provides an array of enhanced criminal penalties and civil liabilities, including novel remedies such as punitive damages. Additionally, countries like Singapore, India and Switzerland implemented expansive new measures – whether by judicial decision or legislative decree – to improve regulatory oversight over food safety. Several jurisdictions also experienced a proliferation of product liability class actions, including countries that only recently began experimenting with class adjudication. In July, Russia ushered in class action suits at a time when product liability and consumer protection cases have surged in the wake of amendments to Russia’s Consumer Protection Law. This has led to the coinage of a new term in Russia – ‘consumer extremism’ – to describe frivolous suits designed to extract a quick settlement from sellers and manufacturers. Yet, other legal refinements impacting product manufacturers have not arrived as quickly as planned. In October, the European Commission delayed the widely anticipated launch of the European Database on Medical Devices (EUDAMED), an initiative designed to strengthen market surveillance and transparency for medical devices. While EUDAMED is not slated to take effect until May 2022, the deadline for medical device companies to recertify their products under the EU’s new Medical Device Regulation remains May 2020.

Other significant legal developments in 2019 were spawned in courtrooms rather than legislative bodies. For instance, the US Supreme Court decided a pivotal pre-emption
case that clarified what evidence a drug manufacturer must adduce to demonstrate that the Food and Drug Administration would not have approved the plaintiffs’ proposed warning. The Supreme Court also held that the determination of whether a manufacturer met this evidentiary burden constituted a question of law to be resolved by the judge, not a jury. Although the Court’s ruling provides valuable guidance to manufacturers seeking to limit their exposure to failure-to-warn claims arising under state law, it also left many questions unanswered (and, thus, open to lower court interpretation in the years to come). Moreover, courts in various jurisdictions grappled with issues concerning the types of entities within the supply chain that should be held liable for alleged product defects. For instance, the Supreme Court of Spain confronted the question of when a mere supplier can be considered the ‘producer’ of a product for purposes of strict liability. And courts in various jurisdictions are divided on whether online retailers that sell products supplied by third-party vendors can be deemed liable for product defects even though the online retailer never took possession or title of the vendor’s product. 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 to ensure compliance with increasingly complicated and evolving product liability regimes.

This edition covers 15 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 colleague Luke Bosso, who has been invaluable in assisting us in our editorial duties.

Chilton Davis Varner and Madison Kitchens
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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 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 ACL replaced a collection of federal and state consumer protection legislation with a single law that applies in all jurisdictions. The consumer protection regime, which was formerly found in the TPA was transferred to the ACL with substantial modification.

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.

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...
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 federal and state-based regulators with responsibility for administration of industry-specific regulation; for example, motor vehicles, 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 Common law

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), as well as a range of measures designed to protect consumers in particular transactions (e.g., unfair contract terms in standard form contracts, unsolicited consumer agreements and linked credit contracts).

iii Statutory warranties and guarantees

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

- goods that do not correspond with their description;
- goods that are not of acceptable quality;
- goods that do not conform to sample;
- goods that are not fit for a stated purpose; and
- non-compliance with express warranties.

Privity of contract is no barrier to relief

The operation of these statutory warranties and guarantees 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 may be 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 manufacture, 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.

There is some authority that supports the view that an increase in risk associated with using a particular good may, in certain circumstances, be sufficient to establish liability. It is necessary to consider the complete set of circumstances surrounding supply and use of a product. For example, the ACL provides that, in determining whether goods have a ‘safety defect’, regard is to be given to ‘all relevant circumstances’, including the manner in which
and the purposes for which goods have been marketed, their packaging, any instructions for use or warnings and what might reasonably be expected to be done with the goods. Similarly, whether goods are of ‘acceptable quality’ requires consideration of relevant matters, including the nature and price of the goods, statements made on the packaging or labelling, any representations made by the supplier or manufacturer and ‘any other relevant circumstances relating to the supply of the goods’.

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. If 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.

Many 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:

- making a false statement that is likely to cause a person to apply for or acquire financial services products;
- inducing another person to deal in financial products by making a misleading statement;
- engaging in dishonest conduct while carrying on a financial services business; and
- 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.

Further provisions of the Banking Act 1959 (Cth) or the National Consumer Credit Protection Act 2009 (Cth), together with oversight by the Australian Prudential Regulation Authority, may also be relevant, depending on the particular financial institution and the financial products it sells. Misconduct in the banking and financial services industries was a central focus for the Royal Commission held principally in 2018; the final report of which was published in 2019.

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 should be considered in deciding whether recall action is necessary include:

- the magnitude of the potential harm involved;
- the probability of such harm occurring;
- the availability and effectiveness of alternative remedial action; and
- 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 that:

a loss or damage has been suffered;

b 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 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 (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 (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.

If 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 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 this defence, 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.

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2 Part 5-4 of the ACL.
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 is 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:

- 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
- 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:

- the defect alleged did not exist when the goods were supplied by the manufacturer;
- the goods were defective only because there was compliance with a mandatory standard (discussed further below);
- 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
- 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 that 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 (the ACL also has its own applicable limitations periods), this is an area of complexity given the myriad 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.
Defective goods actions brought under Part 3-5 of the ACL must generally be commenced within three years of 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 must be commenced within three years of the time the person becomes aware, or ought reasonably to have become aware, that the guarantee had not been complied with.

For personal injury claims that relate to Parts 2-2, 3-3, 3-4, 3-5 or Division 2 of Part 5-4 of the ACL, the applicable limitation period is the later of the date of discoverability or the long-stop period as defined above.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, the 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

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3 Part 5-4 of the ACL.
4 Section 87F of the CCA and Part VIB of the CCA, more generally.
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.

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.

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.

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 in either 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, New South Wales and Queensland. There are also representative action procedures in other state jurisdictions.

A class action (also 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, 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.
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 for pain and suffering, loss of amenity and loss of expectation of life; and

b special damages, including for 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.
Australia

Recent legislation introduced increased penalties for certain breaches of the ACL (e.g., unconscionable conduct, making false or misleading representations and supplying goods that do not comply with applicable safety standards). For corporations, the maximum pecuniary penalty for these provisions is the greater of A$10 million, three times the value of the benefit obtained directly or indirectly, which is reasonably attributable to the act or omission, or, if the benefit cannot be determined, 10 per cent of the annual turnover of the body corporate in the previous 12-month period. The maximum pecuniary penalty for these provisions applicable to an individual is A$500,000.

V YEAR IN REVIEW

During 2019, the ACCC continued to be active in its supervision of consumer product recalls, as well as monitoring 'hot-topic' issues in product safety. According to the ACCC’s annual report for 2018–2019,5 A$49.2 million in penalties were obtained from litigated consumer protection matters, 1,930 mandatory injury reports assessed and 683 voluntary recall notifications published.

The compulsory recall of Takata air bags (described as 'Australia’s largest ever recall') continued to be implemented across a range of motor vehicle brands. That compulsory recall followed extensive investigation and discussion with the ACCC and vehicle suppliers in Australia, in circumstances where a number of voluntary recalls had already been commenced. During the 2018–2019 financial year, 3.21 million Takata airbags were rectified in accordance with the compulsory recalls. Seven class actions are also now on foot in relation to the supply of motor vehicles with Takata airbags, which are also subject to voluntary or compulsory recall action.

Regulatory action by the ACCC in relation to the EA189 diesel emissions issues, which have been litigated globally, resulted in the Federal Court imposing a record penalty of AUS$125 million on Volkswagen AG for breach of the ACL: false representations about compliance with Australian diesel emissions standards. That penalty is currently subject to an appeal before the Full Federal Court. Class action proceedings against Volkswagen, Audi and Skoda arising from EA189 diesel emissions issues have been settled, subject to approval by the Court.

No further amendments to legislation arising from the ACL Review (initiated by Consumer Affairs Australia and New Zealand, and which concluded in 2017) were introduced during 2019. However, the ACCC’s Product Safety priorities for 2019 included progressing the development of a general safety provision that would require traders to ensure the safety of a product before it enters the market, with a corresponding penalty regime. As yet, no such provision has been proposed by way of exposure draft or legislation before Parliament.

Finally, the release of the final report of the Royal Commission into Misconduct in the Banking, Superannuation and Financial Services Industry in February 2019 has been followed by increased regulatory activity and the commencement of class action proceedings arising from matters the subject of that Royal Commission.

Chapter 2

AUSTRIA

Eva Spiegel and Florian Horak

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, which implemented 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 damage 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 damage to items of property is basically only to be compensated to the extent that the 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.

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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 that, taking all circumstances into account, could reasonably be expected, in particular with respect to:

a  the presentation of the product;

b  the use to which it can reasonably be expected that the product will be put; and

c  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 and instruction sheets.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, even to warn against 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

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³ Austrian Supreme Court, Case No. 1 Ob 62/11s of 28 April 2011 and Case No. 9 Ob 59/15i of 28 October 2015.

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

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

⁶ Austrian Supreme Court, Case No. 6 Ob 215/11b of 13 September 2012.
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 this 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 position are at fault. 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 those persons are habitually unable or unfit for the assigned work.

Under contract law the counterparty is responsible for damage caused by a 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, the concept of contract with protective effect for third parties has practical relevance mainly in cases where damage is not compensable under the Product Liability Act (such as, in particular, damage 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.

II REGULATORY OVERSIGHT

The European Directive 2001/95/EC on General Product Safety was implemented into Austrian law by enacting the Product Safety Act, 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
Austria

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

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 take appropriate measures, including the ordering of a product recall. Contravention of these 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 damage because of the 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 foreseeable 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 must 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 (or, respectively, the product defect) at issue. If this were the case, the conduct (or, respectively, the product defect) was not causal. However, doctrine and case law in addition apply the theory of adequate causation, meaning that damage that is the result of a totally atypical and extraordinary chain of circumstances of cause and effect are excluded from liability.

However, 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.

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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 or not in a state party to the Lugano Convention (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. 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 the 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:

a 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
b the law of the country in which the product was acquired, if the product was marketed in that country; or, failing that
c 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 (a), (b) or (c).

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

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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, Case No. 2 Ob 157/04h of 1 July 2004, Case No. 7 Ob 173/17t of 20 June 2018 and Case No. 3 Ob 152/19p of 11 September 2019.
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 (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 damage 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:

- the producer is established;
- the product was put into circulation; or
- 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 the 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.

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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 and Case No. 7 Ob 19/14s of 28 November 2012.
18 European Court of Justice, Case C-45/13 (Andreas Kainz).
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.

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.

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:

a. the opponent itself relied on the document in the course of the proceedings;
b. the opponent is obliged to hand the document over by a substantive law; or
c. 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 unenforceable. 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).

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, 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 the 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 who 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, however, 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 an 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. This 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 principle the same.

ix Damages

In cases of personal injury both under the Product Liability Act and fault-based liability under general civil law, compensation covers medical treatment costs, loss of income and appropriate damages for pain and suffering (which may also include mental damage and suffering owing
Austria

to the loss 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 pain and suffering are applied, and these are usually calculated by a court-appointed medical expert.

As regards damage to property, under the Product Liability Act, there is a deductible amount of €500, and damage 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.

V YEAR IN REVIEW

There have only been a few (published) decisions rendered by Austrian courts in the field of product liability over the past year.

One case concerned a claim against a producer of food packaging, which the plaintiff used to package his lasagne. The defendant supplied the plaintiff with cut-out cartons, which were only coated on one side with plastic (in accordance with the agreement between the parties). The coated side, which is supposed to protect the food as the ‘inside’ of the carton, was perceptible (visually) to the plaintiff. The plaintiff nevertheless packaged the lasagne on the uncoated ‘outside’. Subsequently, it turned out that the lasagne could not be removed from the cardboard without leaving residue. The plaintiff based his claim, inter alia, on product liability for damages suffered as a result of taking back goods from its customers. In its decision, the Supreme Court states that, according to the Product Liability Act, damage to property is only compensable if it was not suffered by an entrepreneur who used the item predominantly in its business. Further, the Supreme Court confirmed that goods intended for resale to third parties are considered as predominantly used in entrepreneurs’ businesses.19

19 Austrian Supreme Court, Case No. 3 Ob 21/19p of 20 February 2019.
Chapter 3

CHINA

Ariel Ye, Yue Dai, Xinyu Li and Tianren Li

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 Provisions of the Civil Law (the General Provisions);  
b the General Principles of the Civil Law;  
c the Tort Liability Law (TL);  
d the Product Quality Law (PQL); and  
e the Laws on the Protection of Consumer Rights and Interests (PCRI).

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, 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 Chinese 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 and the Pharmaceutical Administration Law.

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1 Ariel Ye is a senior partner, Yue Dai and Xinyu Li are partners and Tianren Li is a senior associate at King & Wood Mallesons.
2 Effective as of 1 October 2017.
3 Effective as of 1 July 2010.
4 Effective as of 1 September 1993, amended on 29 December 2018.
6 Effective as of 1 May 2004.
7 Effective as of 1 June 2009, amended on 29 December 2018.
In China, product liability may also give rise to criminal liabilities. Chapter 3 of the Chinese Criminal Law 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

Following the 2018 State Council’s institutional reform in China, the newly established State Administration for Market Regulation (SAMR) has become the regulatory authority responsible for regulating a wide range of products, including but not limited to automobiles, children’s toys and food. See Section V for further information.

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 measures to remedy the situation, such as issuing warnings or recalling the product. If they fail to take appropriate measures in a timely manner or provide insufficient remedies, thereby causing damage, the manufacturer and seller will be liable for tort. Since the formal implementation of the Measures for the Administration of the Recall of Defective Consumer Goods on 1 January 2016, the product recall system is more complete, with protection for consumers and supervision over manufacturers and sellers having been enhanced significantly. At present, SAMR and its attached agency, the Defective Product Administration Centre, oversee product safety and product recalls in China. In the first half of 2018, SAMR published 109 automotive product recall notices and recalled over 4.8 million defective automotive products. For other consumer goods, SAMR published 352 recall notices and recalled 36.25 million defective goods.

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 to conduct public supervision over products and protect consumer rights and interests. The consumer associations can perform many community duties such as:

- providing consumption information and advisory services to consumers;
- participating in formulation of laws, regulations, rules and mandatory standards relating to consumer rights and interests;
- participating in supervision and inspection of goods and services by the relevant administrative authorities;
- accepting consumer complaints and carrying out investigations and mediation regarding the complaint matters;

9 Effective as of 1 October 1997.
for acts that harm legitimate consumer rights and interests, supporting aggrieved consumers to file lawsuits or filing lawsuits by itself pursuant to the law; and

public advocacy regarding acts that may harm legitimate consumer rights and interests.

### III CAUSES OF ACTION

Under Chinese law, a manufacturer or seller, or both, will be liable for 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 the term 'product'. In general, product liability contains three elements:

- **a** the issue of whether the product is defective;
- **b** the damage or loss suffered; and
- **c** 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. Chinese 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 Chinese laws, a product must conform to the quality standards or specifications as presented by the manufacture and seller. If a product fails to conform to these 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 a car manufacturer breaches the Administrative Regulations on the Recall of Defective Automotive Products (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 1 per cent to

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10 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.
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.¹¹

Last, 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 Chinese civil system, there is a two-tier 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 be met to initiate a retrial are very strict, and a request for a retrial is granted at the court’s discretion. 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:

a the product is defective;
b damage or loss owing to the defective products; and
c 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

¹¹ See Article 24 of the Regulation on the Administration of Recall of Defective Auto Products (effective as of 1 January 2013).
will then have to prove that the product does not have any defects. It will thus have to prove that the product meets the national and industrial standards (if any), and will neither present any reasonably foreseeable danger to a person's health nor will it 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 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. 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. Last, 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 Chinese law, defences include procedural defences and substantive defences.

Relying on a statute of limitations is a procedural defence. There have been discussions on the limitation period to be applied in product liability cases. After the amendment of the PQL on 29 December 2018, the limitation period remains at two years, which still differs from the three-year limitation period provided in the General Provisions. We will have to wait to see what changes are effected in judicial practice to see which limitation period shall prevail.

In relation to substantive defences, there are three statutory defences under which a manufacturer may avoid liability. 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. Second, 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. Third, 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 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, if 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. Accordingly, the PQL regulates both manufacturers and sellers with businesses operating within China, including a seller who imports products manufactured outside China and sells the 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. 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. If the manufacturer and seller are domiciled in China, the Chinese courts will without doubt have jurisdiction over the proceedings. Even if the manufacturing and selling were committed outside China, if the damage occurs within China, the manufacturer and seller outside China may still fall under the jurisdiction of the Chinese courts.

v  Expert witnesses
The Chinese legal system recognises the role of expert witness in disputes. Any party can apply to a Chinese 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 Chinese 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.

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. However, if there is evidence that a party and its representative are unable to collect, the party may apply to the court for investigation.

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 collection. 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 cases, 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.

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.

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. 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. 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. The judgment or ruling will also apply to actions instituted during the statute of limitations by right holders that have not registered with the court.

ix Damages
Under Chinese law, where a defective product causes any harm to another person, the manufacturer or seller, or both, will assume tortious liability. 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 compensation in an amount equal to the remediation costs. Where the defect of a product endangers

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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, amended on 16 December 2008).
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.
25 See Article 16 of the TL; Article 44 of the PQL; Article 49 of the PCRI.
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 Chinese 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 health 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 product 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

China amended its Pharmaceutical Administration Law in 2019 and updated its pharmaceutical legal framework in overall aspects. As a key part of the update, a series of accountability mechanisms have been introduced, notably a pharmaceutical marketing authorisation holder system for pharmaceutical management, which covers pharmaceutical development, manufacturing, distribution and use activities.30 A pharmaceutical traceability system has also been established to ensure pharmaceutical quality and manage risks in the whole process.31

The 2019 amendment adjusted the definition and scope of fake pharmaceuticals and pharmaceuticals of inferior quality, and further made a clear distinction between them,32 which reflects a change in the legislation as to the standard to determine the category of a problematic pharmaceutical product and the nature of an illegal act. The focus of the standard goes beyond mere quality considerations.

The provisions on criminal, civil and administrative liabilities have experienced significant changes as well. Specifically, criminal liability was placed the first in the section of legal liability, which delivers a powerful message and indicates the position of the legislation

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 Chinese Food Safety Law.
30 See Articles 30–40 of the Chinese Pharmaceutical Administration Law.
31 ibid., Articles 7, 12, 36, 39.
32 ibid., Article 98.
on the violations and crimes endangering pharmaceutical safety.\textsuperscript{33} Administrative penalty rates for various violations have been raised drastically, in both the amount of the fines and in other forms.\textsuperscript{34} With respect to civil compensation, the idea of punitive damages has been introduced to the current legal framework.\textsuperscript{35} Moreover, an overseas enterprise as defined as a pharmaceutical marketing authorisation holder and its agent in China shall undertake joint liability for damages.\textsuperscript{36}

To address real issues and meet actual demand, the 2019 amendment of the Pharmaceutical Administration Law is problem-oriented, adopting a strict approach. It presents a high standard of regulation.

\textsuperscript{33} ibid., Article 114.
\textsuperscript{34} ibid., Articles 115, 116, 117, 118, 120, 122, 123, 129, 133, 138, 141, 142.
\textsuperscript{35} ibid., Article 144.
\textsuperscript{36} ibid., Article 38.
Chapter 4

ENGLAND AND WALES

Neil Beresford and Natasha Lioubimova

I \hspace{1cm} INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

Product liability law in England and Wales derives from three sources. The first is the law of contract. Where two or more parties have entered into a contract, their relationship is governed by the express terms of their agreement. In contracts for the sale of goods, the express terms are supplemented by terms implied by the Sale of Goods Act 1979 (in relation to business-to-business contracts) and the Consumer Rights Act 2015 (in relation to business-to-consumer contracts).

The second is the common law of tort. Those involved in the manufacturing, importation and sale of products are under a general duty to avoid causing harm to those who might reasonably be affected by their negligence. The duty extends, but is not limited to, consumers and users of products. Manufacturers are also under a duty not to make deceitful or misleading representations in connection with the sale of their products.

The third is legislation, deriving predominantly from the European Union and constructed around the two pillars of the Product Liability Directive of 1985 and the General Product Safety Directive of 2001. Those Directives were implemented into English law by the Consumer Protection Act 1987 (CPA) and the General Product Safety Regulations 2005 (GPSR) respectively. The CPA creates a strict liability compensation scheme in respect of defective products and the GPSR requires consumer products to be safe.

II \hspace{1cm} REGULATORY OVERSIGHT

Although there is a large volume of legislation that applies to specific products falling within specific sectors, the general requirements of product safety are set out in the GPSR.

The GPSR applies to all products that are intended for or are likely to be used by consumers,² and requires that those products are safe. GPSR defines a safe product as one that, under normal or reasonably foreseeable conditions of use, does not present a risk, or poses only the minimum risk that is compatible with the product’s use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons.³

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¹ Neil Beresford is a partner and Natasha Lioubimova is an associate at Clyde & Co LLP. The information in this chapter was accurate as at March 2019.
² Regulation 2 GPSR 2005.
³ ibid.

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GPSR also governs the recall of unsafe products. The discovery of an unsafe product must be notified to Trading Standards, the government body that enforces product safety legislation in England and Wales. Trading Standards decides which steps should be taken, including whether to trigger RAPEX, the EU alert system for unsafe consumer products.

Any person who places an unsafe product on the market is in breach of GPSR. This includes a manufacturer within an EU Member State, a company placing its name on the product, a company that reconditions the product, where the product is not manufactured in the EU, the importer of that product into a Member State and any professional in the supply chain whose activities may affect the safety of a product.

Breach of GPSR constitutes a strict liability criminal offence that is punishable with a maximum of 12 months’ imprisonment, a fine of £20,000 or both. The authorities have discretion as to whether to prosecute and will take into account any steps that the company has taken to remedy or mitigate the risk posed by the unsafe product.

GPSR imposes several other obligations on producers and distributors of products including the obligation on a distributor not to advertise or supply a product that it knows, or ought to know, is unsafe. The maximum penalty is 12 months’ imprisonment, a £20,000 fine, or both.

A person in breach of GPSR can escape liability by demonstrating that all reasonable steps were taken to avoid committing the offence. In practice, however, this is a high threshold.

III CAUSES OF ACTION

In this section, we consider four causes of action: breach of contract; negligence; deceitful and negligent misrepresentations; and action under the Consumer Protection Act 1987.

i Breach of contract

A buyer may claim against the seller for any injury, damage or loss caused by a product’s non-compliance with contractual terms. Such terms may be express or implied. The terms implied into business-to-business contracts are set out in the Sale of Goods Act 1979 (SOGA). The key implied terms are as follows:

a the product supplied will be of satisfactory quality. This is an objective standard, judged on the basis of what a reasonable person would consider to be satisfactory in the circumstances, taking into account all relevant factors such as, for example, the price of the product;

b the product supplied will be fit for purpose. If the buyer makes known to the seller (explicitly or implicitly) a particular purpose for which the product is being bought, the product must be reasonably fit for that purpose. This is the case even if the purpose is
not the normal use of the product. However, this term will not apply where the buyer does not rely, or it is unreasonable for him or her to rely, on the judgment of the seller in relation to the suitability of the product;

c a product sold by sample should be of the same quality as the sample that was supplied to the buyer.12 This requires goods to be free from any defects that would not have been apparent on a reasonable examination of the sample; and

d a product sold by description should correspond with that description.13

In a business-to-business contract, a party can exclude or restrict liability for any of the SOGA-implied terms, provided that it does so consistently with the Unfair Contract Terms Act 1977.14 The terms implied into business-to-consumer contracts are set out in the Consumer Rights Act 2015 (CRA). The key implied terms of the CRA mirror those set out in SOGA:

a the product supplied should be of satisfactory quality;15

b the product supplied should be fit for purpose;16

c a product sold by sample should correspond to that sample;17 and

d a product sold by description should correspond with that description.18

A business cannot exclude or restrict liability to any consumer for breach of those implied terms.19

ii Negligence

A person who has suffered injury or damage to their property as a result of the use of a defective product may have a right of action against the manufacturer, importer or seller of the product, even if there is no contract in place between them. A cause of action will arise if the claimant can show that:

a the defendant owed a duty of care;

b the defendant breached that duty of care;

c the breach caused the injury or damage complained of; and

d the injury or damage was a reasonably foreseeable consequence of the breach.

iii Deceitful and negligent misrepresentations

The law of tort imposes a general duty not to make misrepresentations in connection with the sale of products. Liability for misrepresentation can attach not only to the seller of a product but also, in appropriate circumstances, to the importer or manufacturer. For example, a motor company’s alleged misrepresentation of vehicle emissions characteristics, repeated through its dealership network, forms a central part of the civil claims arising from the Dieselgate scandal of 2015.

12 Section 15 SOGA 1979.
13 Section 13 SOGA 1979.
14 Section 6(1A) Unfair Contract Terms Act 1977.
15 Section 9 CRA 2015.
16 Section 10 CRA 2015.
17 Section 13 CRA 2015.
18 Section 11 CRA 2015.
19 Section 31(1) CRA 2015.
A defendant may be held liable for making a deceitful misrepresentation if the claimant can show that:

a the defendant made a false representation to the claimant;
b the defendant knew that the representation was false, or was reckless as to whether it was true;
c the defendant intended that the claimant should rely on that representation; and
d the claimant relied on that representation to its detriment.  

If there is no evidence of deliberate wrongdoing, the claimant might instead choose to bring a claim under the Misrepresentation Act 1967, the common law of negligence, or both. The ordinary remedies for misrepresentation are damages or the rescission of the contract. If the claimant succeeds in making allegations of deceitful conduct, the ordinary rules of remoteness of damage do not apply and the defendant may become liable for punitive or exemplary damages.

iv Consumer Protection Act 1987

The CPA imposes strict liability on manufacturers, importers and retailers for injury or damage caused by a defective product. The claimant is not required to prove fault on the part of the defendant as long as he or she can prove that the product was defective and that the defect caused him or her to suffer injury or damage.

What is a product?
The term ‘product’ includes any goods or electricity, and includes a product that is contained in another product as a component or a raw material.

What is a defect?
A product is defective if the safety of the product is not such as persons generally are entitled to expect, taking into account all the circumstances, including the following factors:

a the way in which, and purposes for which, the product has been marketed or packaged, the use of any mark in relation to the product and any instructions for, or warnings with respect to, doing or refraining from doing anything with or in relation to the product; 
b what might reasonably be expected to be done with or in relation to the product; and 
c the time when the product was supplied by its producer to another.

In practice, the identification of a product defect has given rise to considerable difficulty. In the case of A v. National Blood Authority, it was held that the generic risk of blood contamination with Hepatitis C was sufficient to make the producer liable for injury to users, despite the fact that scientific knowledge was unable to identify the blood products in which the contamination might arise. The court dismissed an argument raised on behalf of the defendant that the risks arising from the use of the product should be set against the product’s advantages for society as a whole.

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20 Eco 3 Capital Ltd and others v. Ludsin Overseas Ltd [2013] EWCA Civ 413.
21 Section 1(2)(c) CPA 1987.
22 Section 3 CPA 1987.
The approach in *A v. National Blood Authority* was questioned in the later case of *Wilkes*. In that case, the court preferred to frame the issue as one of safety, not fitness for purpose. The first step was to identify the defect, and the second step was to consider all the circumstances, including the balance of the product’s benefits as against its risks. 

*Wilkes* was followed by the case of *Gee*, which concerned metal-on-metal hip implants that shed metal debris through normal use, which caused some patients to suffer an adverse reaction. The court considered various factors, including the functional advantage of the product, the risk posed and the information available in respect of the same. It concluded that the shedding of debris was a characteristic that was part of the normal behaviour of the product, whereas a defect is the abnormal potential for harm, in other words, something about the condition or character of the product that elevates the underlying risk beyond the level of safety that the public is entitled to expect from a product of that type.

**Who is liable?**

Liability under the act can rest with any of the following parties:

- **a** the producer or manufacturer of the product;
- **b** any person that puts its name on the product and holds itself out to be the producer or manufacturer; and
- **c** any person who imports the product into the EU.

The CPA confirms that liability between these parties is joint and several. This means that a claimant is able to claim against any one of the responsible parties for the entirety of his or her loss, and then that responsible party is free to seek a contribution for some or all of that loss from the other responsible parties.

Although the supplier of the product does not have primary liability, they may nevertheless be held liable under the CPA if the claimant requests the identity of one of the parties listed above, but the supplier is unable to identify that party.

**IV LITIGATION**

**i Forum and jurisdiction**

Under the European regime, a manufacturer, supplier or importer can be sued in England and Wales in any of the following circumstances:

- **a** if the contract for the supply of the product in question contains a choice of jurisdiction clause conferring jurisdiction upon the courts of England and Wales;
- **b** if the defendant is domiciled in England and Wales;
- **c** if the place of performance of a contractual obligation is England and Wales.

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26 ibid., Mrs Justice Andrews at 112.
27 Sections 1(2) and 2(2) Consumer Protection Act 1987.
28 Sections 2(1) and 2(5) Consumer Protection Act 1987.
30 Article 25 Brussels Regulation (Recast) (EU) 1215/2012.
31 Article 4 Brussels Regulation (Recast) (EU) 1215/2012.
32 Article 7(1) Brussels Regulation (Recast) (EU) 1215/2012.
if a tortious act causes loss or damage in England and Wales;\(^{33}\) and

if there are multiple defendants and the claims are closely connected, the claimant can bring proceedings in the place where any one of the defendants is domiciled.\(^ {34}\)

The common law applies to cases that fall outside the European regime. Where the defendant is physically present in England and Wales, proceedings may be served on him or her regardless of whether the claim has any connection with the jurisdiction. If a claimant wishes to serve proceedings on a defendant outside the jurisdiction it is necessary to seek the permission of the court.

**ii Burden of proof**

The burden of proof rests with the claimant. In most cases, the civil standard is applied. This means that the claimant must prove its case on the balance of probabilities. Where a party makes allegations of deliberate wrongdoing, a raised civil standard may be applied. This is based upon the notion that a party is:

> entitled to be protected against . . . a serious allegation by evidence of greater weight or by a higher standard of proof than would otherwise be required in an ordinary civil case.\(^ {35}\)

**iii Defences**

**Limitation**

Limitation varies depending on the type of claim:

- **in contract**, limitation expires six years after the breach of the contract.\(^ {36}\) In the context of product liability, this is commonly the date of supply;

- **in tort claims in general**, limitation expires six years after the date of damage;\(^ {37}\)

- **in tort claims specifically relating to personal injury or death**, limitation expires three years after the date of damage or the date of the victim's knowledge of the damage.\(^ {38}\) This is subject to a 15-year longstop;\(^ {39}\)

- **under the CPA**, limitation expires three years after the date on which the claimant became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer.\(^ {40}\) This is subject to a 10-year longstop.\(^ {41}\) There is scope for divergence between the CPA and Product Liability Directive on this front; the former calculates the longstop from the time when the producer or importer 'supplied the product to another',\(^ {42}\) whereas the latter calculates the longstop from 'the date on which the producer put into circulation the actual product which caused the damage'; and

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\(^{33}\) Article 7(2) Brussels Regulation (Recast) (EU) 1215/2012.

\(^{34}\) Article 8(1) Brussels Regulation (Recast) (EU) 1215/2012.


\(^{36}\) Section 5 Limitation Act 1980.

\(^{37}\) Section 2 Limitation Act 1980.

\(^{38}\) Section 11 Limitation Act 1980.

\(^{39}\) Section 14B Limitation Act 1980.

\(^{40}\) Section 11A Limitation Act 1980.

\(^{41}\) Section 11A Limitation Act 1980.

\(^{42}\) Section 4(2) CPA 1987.
in claims for contribution, limitation expires two years from the date that the claimant is held liable for that damage by way of a court judgment, an arbitral award or a settlement.43

**Contributory negligence and misuse**

A user’s own negligent conduct or misuse of the product may provide a defence to liability in tort, in contract (where there is a parallel liability in tort) and under the CPA.44 The user’s negligence may be so serious as to break the chain of causation between the wrongdoing and the damage, in which case the manufacturer will face no liability.45 In less serious cases the user’s claim will be reduced in proportion to his or her own negligent contribution to the injury or damage.46

**State of the art**

No negligence attaches to a product that is designed, manufactured and sold in accordance with current scientific knowledge.

A specific state-of-the-art defence is available under the CPA.47 Its application has been considered in various cases including Gee,48 where the court focused on the reasonable beliefs of the producers and orthopaedic surgeons involved at the time rather than facts that became known in hindsight.

A state of the art defence will not assist in defending a claim for breach of the requirement that a product is fit for purpose, but it is likely to be helpful in defending allegations of unsatisfactory quality.

**Sophisticated user or learned intermediary**

To decide whether a product is defective, courts take into consideration all the relevant circumstances including the way in which the product has been marketed, and any instructions or warnings that come with the product.

The learned intermediary defence applies where the manufacturer supplies the necessary information about its product to an expert intermediary, such as an architect or doctor, who then deals directly with the end consumer. The rationale is that, where the learned intermediary fails to pass on any instructions or warnings regarding the product, it is the intermediary (and not the manufacturer) that should face liability for loss.

The ‘learned intermediary’ is a defence in tort. It is not strictly a defence under the CPA, but it is one of the factors to be taken into account in deciding whether a product is defective.49

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43 Section 10 Limitation Act 1980.
44 Section 6(4) of the CPA 1987 applies the Law Reform (Contributory Negligence) Act 1945.
45 Lambert v. Lewis [1981] 2 WLR 713.
46 Law Reform (Contributory Negligence) Act 1945.
47 Section 4(1)(e) CPA 1987.
49 Section 3 CPA 1987.
Regulatory compliance

No negligence is likely to attach to a product if the design, manufacture and sale comply with all applicable regulations. Regulatory compliance is not an automatic defence under the CPA, although it will be taken into account as an indication that the level of safety of the product was as persons generally were entitled to expect. Upon proof of regulatory compliance, it is generally for the claimant to persuade a court that the product was unsafe.\(^{50}\)

Miscellaneous defences under the CPA

There are a number of additional defences available under the CPA:\(^{51}\)

\(a\) the defect in the product is attributable to compliance with a requirement imposed by or under UK and EU law;

\(b\) the defendant did not supply the product to another person;

\(c\) the defendant supplied the product outside the course of its business and without a view to profit;

\(d\) the defect did not exist at the time of the supply of the product. For example, if the product developed the defect as a result of being handled, transported or stored incorrectly;

\(e\) the product was part of another defective product, and the defect arose in that other product. This defence does not apply if the manufacturer of the component was involved in the design of the final product, or if the component was partly responsible for the defect in the final product; and

\(f\) the claimant was engaged in illegal activity when the loss was suffered.

iv Expert witnesses

The Civil Procedure Rules permit parties to a dispute to appoint either a single joint expert or their own individual experts. In most cases, parties opt to have their own experts unless the court orders otherwise. The participation of expert witnesses is governed by Part 35 of the Civil Procedure Rules (CPR). The key points are as follows:

\(a\) the parties must obtain the court’s permission to rely on an expert from a particular discipline.\(^{52}\) That expert’s evidence must be ‘reasonably required to resolve the proceedings’\(^{53}\) and the instructing party must provide an estimated cost of obtaining the evidence;\(^{54}\)

\(b\) each expert’s duty is to the court, not to the instructing party;

\(c\) each expert must provide its evidence by way of written report addressed to the court, unless otherwise specified. That report must be compliant with the form and content requirements set out in CPR Part 35 and the accompanying Practice Direction;

\(d\) each party then has the right to put questions to the expert to clarify any conclusions; and

\(e\) the court can direct the parties’ experts to meet to discuss the issues in the proceedings and prepare a statement of points on which they agree and disagree.

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\(^{50}\) Wilkes v. Depuy, Hickinbottom J at 100.

\(^{51}\) Section 4.1 CPA.

\(^{52}\) CPR 35.4(1).

\(^{53}\) CPR 35.1.

\(^{54}\) CPR 35.4(2).
Although expert evidence provides helpful guidance for the court, it should be approached with care. In *Gee*, 55 for example, the court was required to consider expert evidence in the fields of biostatistics and epidemiology. It did so carefully, noting that ‘some aspects’ of the evidence were ‘less satisfactory than others’. 56

v Discovery or disclosure

There are two stages to the discovery of documents, which in England and Wales is called ‘disclosure’. The first is pre-action disclosure in accordance with the Pre-Action Protocols of the CPR; the second is following the commencement of proceedings. The purpose of pre-action disclosure is to encourage the parties to disclose the documents that support their case, support the efficient management of proceedings and allow the parties to:

a understand each other’s positions;
b make decisions about how to proceed;
c try to settle issues without proceedings;
d consider engaging in alternative dispute resolution to assist with settlement; and
e reduce the costs of resolving the dispute.57

Once proceedings have commenced, the discovery obligations become more onerous. Each party is required to disclose to the other the existence of:

a the documents on which he or she relies;
b the documents that adversely affect his or her own case; and
c the documents that support another party’s case.58

Product liability cases often involve very extensive design documents and production records, which can run to thousands of documents. This can become strategically relevant – for example, when deciding on the best timing for settlement offers.

vi Apportionment and contribution

Under the Contribution (Civil Liability) Act 1978, a party can seek contribution from another party where that other party is responsible for the same harm.59 In the product liability context, a right of contribution frequently arises in the context of multiparty supply chains, or where a learned intermediary is involved in the chain of supply. In those cases, in deciding the appropriate apportionment of liability, the court will consider the relative blameworthiness and causative potency of each defendant’s conduct.

56 ibid., Mrs Justice Andrews BDE at 259.
57 *Practice Direction on Pre-Action Conduct, Rule 3.*
58 *CPR 31.6.*
59 Section 1(1).
vii  Mass tort actions
There is no class action procedure. The closest concept is that of the Group Litigation Order (GLO). A GLO is an order that allows a number of different claims, which give rise to related issues, to be managed collectively. A GLO is not a separate cause of action. It is a procedural tool to help courts manage multiple cases efficiently. GLOs are rarely used: since they were introduced in 2000 only 105 have been issued.

viii  Damages
There are four types of damages that can be awarded in England and Wales:

a  general damages;
b  special damages;
c  punitive damages; and
d  exemplary damages.

Punitive and exemplary damages are rarely awarded because the general approach is that damages are compensatory. The courts draw a distinction between losses arising from property damage or personal injury (consequential losses) and those that do not (pure economic losses, such as loss of profit). The recoverability of these types of loss is dependent on the cause of action.

Contract
Damages in contract are awarded on the basis of expectation – to put the claimant in the position it would have been if the contract had been performed as expected. This is subject to the rules on the remoteness of damage, which limit the scope of recovery to losses:

a  that arise naturally from the breach; or
b  whose existence in the event of breach should have been within the reasonable contemplation of the parties when the contract was made.

If they meet the test for remoteness, damages for the following losses are recoverable: personal injury, property damage, pure economic loss and loss of enjoyment (in limited cases). However, the recoverability of damages can be excluded or limited by the express terms of the agreement between the parties.

Negligence
Damages in negligence are awarded with a view to restoring the victim of negligence to their former position had the negligence not occurred. Damages for property damage and personal injury are most routinely awarded in negligence. Damages for pure economic losses are generally not recoverable unless a special relationship has arisen between the parties. This is rare, but occurs where the defendant has used its expertise to give advice and:

a  the advice was required for a specific purpose of which the defendant was aware;
b  the defendant knew that the claimant was likely to act on the defendant's advice for that purpose; and
c  the claimant reasonably did so to his or her detriment.

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60  Part III of CPR 19.
61  Hadley v. Baxendale 156 ER 145.
The recoverability of losses also depends on the losses being reasonably foreseeable.62

**Deceit and misrepresentation**

Damages in deceit are recoverable for property damage, personal injury and pure economic loss. The rules of remoteness, however, differ from those in negligence. In relation to deceit, the defendant will be liable for all losses that flow directly from the deceit – whether they are foreseeable or not. This means that, where losses have been exacerbated by an unforeseen event, they will still be recoverable from the defendant. This is, however, subject to the claimant’s duty to mitigate its potential losses.63

**Consumer Protection Act**

Damages under the CPA, as in tort, are intended to restore the injured party to the position had the product not been defective. There is no provision for the award of punitive damages. Damages for personal injury and property damage are recoverable only where the loss exceeds £275.64 The following are not recoverable:

a. pure economic losses (this includes damage to the defective product itself);
b. where the product is a component of a bigger product, damage to the greater product; and

c. damage to business property.65

It is thought that the test of reasonable foreseeability would apply to the remoteness of loss under the CPA.

**V  YEAR IN REVIEW**

There are two key developments to highlight.

i  **The meaning of ‘defect’**

The case of *Gee*66 was an important development, in that it approved the more holistic approach to the identification of a defect taken in *Wilkes*,67 and once again questioned the approach taken in *A v. National Blood Authority*.68 The case has broadened the scope of considerations to be taken into account in future cases.

ii  **Automated vehicle statute**

In anticipation of fully automated vehicles being on the roads in the near future, Parliament has passed the Automated and Electric Vehicles Act 2018, which makes inroads into establishing who will be liable for accidents involving automated and semi-automated cars. For example, the Act creates a direct right of action against the motor insurer of an automated vehicle that

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64  Section 5(4) CPA.
65  Section 5(2) and (3) CPA.
causes an accident, while also preserving the motor insurer’s right to claim contribution from any other person who was responsible for the accident. This would include the manufacturer, if the issue arose from a product defect. We expect, however, that it will be some time before any of these provisions are put into practice.
Chapter 5

FRANCE

Christophe Hénin and Julie Vasseur

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 or contractual. The Directive was adopted in the European Union on 25 July 1985 to protect consumers against damage 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 against France, following the 13 January 1993 ruling by the European Court of Justice (ECJ).

Notwithstanding this 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, the French Supreme Court applied the Directive provisions and dismissed the provisions of the French Civil Code. Finally, on 19 May 1998, France transposed the Directive and the FCC included an exhaustive set of regulations in this respect: the new Title IV bis, ‘Liability for defective

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1 Christophe Hénin is a partner and Julie Vasseur is an associate at Intuity.
2 Based on Article 1240 of the French Civil Code 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 Based on Article 1231-1 of the French Civil Code 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.
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.
products, just after the chapter relating to general civil liability rules. In 2002, however, the ECJ ordered France to amend its existing law, which incorrectly transposed the Directive. The ECJ ruled that the French legislation, which exposed suppliers and distributors to legal claims on the same basis as producers, was illegal. Again, in 2006, 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.

On 26 January 2016, Law No. 2016-41 for the modernisation of our healthcare system was enacted 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.

A reform related to contract law, general social insurance schemes and proof of obligations was implemented the same year and ratified in 2018.

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 and Safety (ANSES) 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, ANSES, 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, in accordance with the EU directives, the conditions for granting a marketing authorisation for medicinal products for human use (i.e., original products and generics), either nationally or through the European centralised or decentralised procedure, are contained and detailed within the French Public Health Code (PHC). 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 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 ANSM (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 the 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 provided by EU directives, and by the PHC under Article L.5121-9-2 et seq. The manufacturer of medicinal products for human use must also comply with the good manufacturing practices laid down with the intention of providing minimum requirements that a manufacturer must meet while manufacturing these products, to ensure they are in compliance with requirements of safety, quality and efficacy included in the medicinal product master file. Downstream, good distribution practices should also be observed. The safety of medicinal products is thus ensured by the ANSM, which has general competence, under certain circumstances, to suspend or withdraw a marketing authorisation or to order the recall of any lot or batch of a medicinal product, as well as to carry out an inspection on the manufacturing site.

III CAUSES OF ACTION

As defined by general French civil liability rules, the producer is liable for any loss or damage caused by a defective product put into circulation, whether or not the producer has a contract with the injured person. In this respect, the injured person must prove actual damage, a defect of the product and a causal link between the defect and the damage.


17 Article L.5121-9-2 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’.


19 ibid., Commission Guideline 2013/C 343/01.

20 Article L.5121-9 of the PHC.

21 Article L.5312-3 of the PHC, concerning the cases mentioned in articles L.5312-1, L.5312-2 and L.5311-1 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. For instance, it is recognised that certain active ingredients for therapeutic use that are considered dangerous do not characterise de jure the defectiveness of the product. Similarly, the defectiveness of a medicinal product cannot be inferred from the simple fact that the medicine triggered the damage alleged by the patient, or from the fact that the marketing authorisation listed the possible defect as an adverse reaction. On the contrary, such a listing provides to the consumer or patient ‘the safety that can be legitimately expected from the product’. Recent French case law recognised that when the adverse reactions are too significant in comparison with the benefits expected, the product should be considered as ‘defective’, regardless of any reference to these side effects on the leaflet.

Concerning the causal link between the defect and the damage, at first, 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; however, patients were facing some major difficulties in providing the necessary scientific evidence. Therefore, the case law has admitted ‘proof by presumption’, when these presumptions are ‘serious, specific and consistent’. The judges’ assessment is based on several elements, such as the acquired scientific data on the potential causal link between the product and the damage alleged, and the time between the occurrence of the damage and when the medicine was taken, as well as the absence of other causes that could explain the occurrence of the injury to the patient.

25 Supreme Court, civ I, 19 June 2019, No. 18-19.239. The liability of a manufacturer for the defect of his product cannot be sought where, at the date of marketing authorisation, the causal link between the side effects and the product was not scientifically proven.


27 Court of Appeal, Bordeaux, 18 March 2015, No. 13/03029.

28 Supreme Court, civ I, 24 January 2006, No. 03-19.534; Court of First Instance, Nîmes, 1 February 2016, No. 14/03320. See also Supreme Court, civ I, 4 July 2019, No. 18-16.809 which considers that the defectiveness of the product cannot be established on the fact that adverse effects were added ex post to the leaflet while such adverse effects were highly unlikely to be linked to the product in such a case.

29 Supreme Court, civ I, 24 January 2006, No. 02-16.648 – 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; in addition, see the decision of the Supreme Court, 27 November 2019, No. 18-16.537.

30 Supreme Court, civ I, 26 September 2018, No. 17-21.271.

31 Supreme Court, civ I, 23 September 2003, No. 01-13.063.

32 Court of Appeal, Versailles, 25 November 2005 No. 04/03953. 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.
In the Mediator case, judges found these three criteria had been met – even though, in one case, the medical history of the patient led the court to partly exclude the liability of the manufacturer.

Nevertheless, the Supreme Court remains particularly demanding when it comes to admitting the existence of these presumptions.

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, specific and consistent presumptions as proving the defect in the vaccine and the causal link between the defect and the damage suffered, notwithstanding the absence of scientific proof.

On 21 June 2017, the ECJ approved the option to rely on these evidentiary rules as long as the burden of proof or the effectiveness of the system of liability introduced by the Directive is not disregarded, and the existence of a causal link is not always considered to be established when certain predetermined causation-related factual evidence is presented.

Since then, the Supreme Court has upheld the rejection by the trial judges of compensation claims from patients attributing their multiple sclerosis to the hepatitis B vaccine.

The victim is also likely to 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 aim of the public action is to have the criminal offence publicly determined and punished. However, a victim who has been ‘personally’ harmed by the criminal offence and who seeks compensation may start a civil action, which may be brought before the same criminal court. For example, if the patient dies because of the medicine, the manufacturer may be sued for manslaughter or for an actively or passively deceptive product.

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33 See Section V. Court of First Instance, Nanterre, 22 October 2015, No. 12/07/07723 and No. 13/06176, confirmed by Court of Appeal, Versailles, 14 April 2016, No. 15/08232; upheld by the Supreme Court on 20 September 2017, No. 16-19643.


35 Supreme Court, 12 November 2015, No. 14-18.118 – see also Supreme Court, 22 September 2016, No. 15-20.791, which ruled that since the decision of the ECJ will influence the judgment of the appeal before the Supreme Court, it is appropriate to stay the proceedings until that decision is rendered.

36 Supreme Court, 20 December 2017, No.15-12.882 and 16-11.267; Supreme Court, 18 October 2017, No.14-18.118. See also the decision of the Supreme Court that rejects causal link between the hepatitis B vaccine and the Catch Syndrome: Supreme Court, 14 November 2018, No. 17-27.980 and 17-28.529.

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

38 Article 3 of the CCP.

39 Article 221-6 of the CCP.

40 Article 213-2 of the Consumer Code. A product may be considered actively deceptive whenever the indications, for example, affixed to the leaflet or to the immediate or outer packaging do not exactly correspond to the technical or marketing authorisation file. The same product may also be considered passively deceptive if relevant information for the protection of public health is missing.
France

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\(^{41}\) establishes an autonomous alternative compensation scheme in relation to medical liability. The aim is to resolve the difficulties encountered by victims of serious medical accidents such as iatrogenic disorders,\(^{42}\) by allowing them to obtain quick and easy access to compensation.

In this regard, the National Office for Compensation of Medical Accidents (ONIAM) was established to compensate victims of therapeutic hazards, medical accidents, iatrogenic diseases and nosocomial infections.\(^{43}\) This has been further extended, specifically to victims of medical accidents resulting from health emergency measures\(^{44}\) or compulsory vaccinations, contaminated blood products, benfluorex\(^{45}\) (active principle of the medicinal product Mediator) and, more recently, sodium valproate and derivatives.\(^{46}\)

This being said, pursuant to Article L.1142-4 et seq. of the PHC, the victim of a medical accident, iatrogenic disease or nosocomial infection may refer his or her case to the competent commission for conciliation and compensation (CCI).\(^{47}\) Depending on the seriousness of the injury,\(^{48}\) this procedure aims at reaching conciliation or 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 application and requests any missing documents. When the file is complete, the CCI theoretically has a period of six months to issue its opinion.\(^{49}\)

If the application is deemed admissible, the president of the CCI appoints an expert, or a body of experts, and sets a deadline for submission of the expert report. A copy of this report is then sent to each party; in turn, the parties are summoned before the CCI and

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\(^{41}\) Law of 4 March 2002 No. 2002-303 concerning the patients' rights and the quality of the national health system.

\(^{42}\) Disorders or adverse effects resulting from medical treatment, owing to the use of a medicinal product or to the intervention of a healthcare professional.

\(^{43}\) See the Annual Public Report of the Court of Accounts, February 2017: ‘Fifteen years after the enactment of the Law of 4 March 2002, the exercise of such compensation is far removed from the initial objectives and proves to be particularly disappointing, as evidenced by the limited number of beneficiaries.’

\(^{44}\) Victims vaccinated against influenza A virus as part of the vaccination campaign decided by the Orders of the Minister of Health of 4 November 2009 and 13 January 2010.

\(^{45}\) The Amended Finance Act for 2011 of 29 July 2011.

\(^{46}\) Law of 29 December 2016.

\(^{47}\) There are 25 CCI, organised into seven inter-regional divisions.

\(^{48}\) Article D1142-1 of the PHC: ‘the threshold of seriousness is determined according to the following criteria:

- the damage must have caused permanent damage of more than 24 per cent to physical and mental integrity;
- or have resulted in a work disability or temporary functional deficit of at least six consecutive months, or six months of a non-consecutive 12-month period’.

\(^{49}\) The actual average processing time was eight and a half months in 2016.
may be assisted or represented by a person of their choice. Following the meeting, the CCI issues a notice signed by the president and sent to the parties, and which is accompanied by documents required for any eventual offer of compensation.

If the parties concerned disagree on the compensation proposed, the case is then 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, 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 is given for doing so. The assessment of whether a reason is legitimate requires examination in particular of the utility of the measure sought with regard to the further litigation, 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 settlement of the dispute.

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 the measures sought on the basis of Article 145 of the CPC. In practice, Article 145 of the CPC is frequently used to seek an expert report 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 FCC, a product is defective ‘when it does not provide all the safety that can be legitimately expected from it’.

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. As mentioned above, the French jurisdictions previously required a direct and certain causal link, but judges now admit ‘proof by presumption’ when these presumptions are ‘serious, specific and consistent’. French courts definitively acknowledge that inconsistent presumptions alone cannot establish the

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51 Court of First Instance, Rouen, (interim relief) 6 December 2001; Court of First Instance, Toulouse, (interim relief) 11 December 2003.
52 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.
53 Court of Appeal, Paris, 26 September 2012 No. 11/23165; Court of Appeal, Paris, 11 October 2012, No. 11/23194.
54 See Section III.
55 See Section III.
existence of a causal link any more than the mere possibility of a causal link.\textsuperscript{56} One judgment even recognised that while the plaintiffs in the Distilbene case were relieved of the normal burden of proof relating to the intake of the medicine by their mother (owing to the age of the facts), they were nevertheless required to prove the causal link between the active principle\textsuperscript{57} and the alleged damage.

\section*{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, as regards medicinal products, pharmaceutical companies have a strong incentive to provide exhaustive information in the summary of the product characteristics 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.\textsuperscript{58}

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 results from compliance of the product with mandatory regulations issued by the public authorities.

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 that time 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.\textsuperscript{59}

\section*{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 himself or herself as the producer.

\textsuperscript{56} Supreme Court, civ I, 23 September 2003; Supreme Court, civ II, 31 March 1983, bull, civ, 1983 II, 89.
\textsuperscript{57} Supreme Court, 22 June 2017, No. 16-19047 and 16-23033.
\textsuperscript{58} See, for example, Court of First Instance, Nanterre, 13 February 2014.
\textsuperscript{59} ECJ, 29 May 1997, Commission of the European Communities v. United Kingdom of Great Britain and Northern Ireland, Case C-300/95.
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.60

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.61

Pursuant to Article 1245-7 of the FCC, where two or more persons are liable for the same damage, they must be jointly and severally liable,62 without prejudice to the provisions of national law as regards 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 shall be extinguished upon the expiry of a 10-year period from the date on which the product was put into circulation, unless the injured person has, in the meantime, instituted proceedings 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 the day the plaintiff becomes aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer.63 With regard to the coordination of these two time lines, the three-year limitation period is included within the 10-year period during which the liability of the manufacturer can be sought.64

However, it follows from the principle of non-retroactivity that this rule does not apply to defective products that 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 implementation of Law of 19 May 1998.65 In such cases, actions for damages are subject to a different rule, which is a time limit of 10 years from the establishment of the damage as provided under French law.66

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In addition, Law No. 2016-41 for the modernisation of our healthcare system stated that claims brought before the ONIAM are now barred after 10 years from the establishment of the damage.67 The 10-year rule also applies to claims resulting from a contamination with the hepatitis B or C virus or human T-lymphotropic virus,68 and human immunodeficiency virus69 caused by transfusion of blood products or injection of blood derivatives, to actions.

60 The ‘producer’ might thus have several meanings. This terminology obviously refers to the manufacturer, but it can also include within its scope other actors, such as a parallel importer, Supreme Court, civ I, 4 June 2014, No. 13-13558.
61 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.
63 Court of Appeal, Paris, 4 September 2012, No. 11/23170; Court of Appeal, Paris, 26 September 2012, No. 11/23165; Court of Appeal, Reims, 12 November 2013, No. 12/00410.
64 Court of Appeal, Versailles, 22 January 2015, No. 13/08038; Court of Appeal, Versailles, (interim relief) 28 May 2014, No. 13/07340; Court of First Instance, Nanterre, 1 June 2017, No. 14/11657.
65 See Section I; Supreme Court, civ I, 15 May 2015, No 14-13.151.
67 Article L.1142-28 of the PHC.
68 Article L.1221-14 of the PHC.
69 Article L.3122-1 of the PHC.
for compensation for damage directly related to mandatory vaccination\textsuperscript{70} 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.\textsuperscript{71}

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 in 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 obligations contracted, either in France or in foreign countries, with a French citizen. In addition, and more substantially, Article 7 of EU Regulation 1215/2012 of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters\textsuperscript{72} allows and recognises the French jurisdiction within the EU, 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 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.\textsuperscript{73}

\textbf{v \quad Expert witnesses}

In proceedings before the civil courts, as mentioned in Section IV.ii, Article 145 of the CPC is frequently used by French judges in practice, to obtain an expert report to 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 could use an expert report compiled by their own experts as part of their defence.

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

\textbf{vi \quad Discovery}

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

\textsuperscript{70} Article L.3111-9 of the PHC.
\textsuperscript{71} Article L.3131-4 of the PHC.
\textsuperscript{73} Articles 113-2 and 113-7 of the FCC.
vii Apportionment

In situations where several persons are liable for the same damage, the principle of the protection of the consumer requires the possibility of obtaining full compensation for the damage from any one of those persons.

A fair apportionment of risk between the injured person and the producer or the distributor implies that the producer should be able to free himself or herself from liability if he or she furnishes proof of 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 causing the damage. The contributory negligence of the injured person may also be taken into account to reduce or disallow the producer’s liability.

viii Mass tort actions

As mentioned in Section I, Law No. 2016-41 was enacted on 26 January 2016 and embraces class actions. The law entered into force on 26 September 2016.74

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 ANSM75 and liability insurers. Such an action is brought before a civil or administrative court (depending on the defendant) in the name of several plaintiffs 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 cases, the court will directly determine within the judgment the criteria to be met 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 the case of a 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.

This 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, even if the new legislation does not simplify the judicial process for patients, it will clearly facilitate the expansion of French business litigation with a specialisation by certain French law firms in mass torts, as in the United States.76

74 Official Journal of the French Republic, 27 September 2016, No. 0225, Text No. 5. Decree No. 2017-888, 6 May 2017 defined the procedural rules applicable before both judicial and administrative judges.

75 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).

76 Taking into due account that Decree No. 2014-1251, 28 October 2014 regarding lawyers’ means of communication allowed lawyers to advertise through flyers, posters, movies, radio or television; Council of State, 9 November 2015, Nos. 386296 and 384728 stated that this provision complies with Directive 2006/123/EC.
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 extend to medical or pharmaceutical expenses, expenses related to requiring assistance from a third person, moral prejudice (pain and suffering,\textsuperscript{77} compensation for disfigurement and loss of amenity), direct material prejudice (work disability) and indirect material prejudice (revenue loss of subsidies). They also include damage to goods and property (damage resulting from the destruction or deterioration of goods, economic damage, operating losses, loss of use, loss of profit, expenses caused by damage to goods, etc.).\textsuperscript{78}

Recently, questions have been raised about possible compensation for patients afraid of developing a certain disease after having taken a medicine. It is well known that administrative judges (unlike judicial judges)\textsuperscript{79} have always been reluctant to establish a principle of compensation for the prejudice of anxiety.\textsuperscript{80}

This dissension between judicial and administrative judges has been reflected in the Mediator case, in which the Administrative Court of Appeal of Paris, in a series of judgments dated 2 July 2015,\textsuperscript{81} confirmed by the Council of State on 9 November 2016,\textsuperscript{82} chose not to indemnify ‘concerns that could not be legitimately proven’, while the interim relief judge took the opportunity to rule differently.\textsuperscript{83} Within the context of diethylstilboestrol, the Supreme Judicial Court ruled that the anxiety injury is an autonomous injury that is different from the physical injury and independent from the proof of causal link.\textsuperscript{84}

In French civil law, damages are strictly limited to compensation. For this reason, punitive damages are not used since they are deemed to be contrary to 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.

\textsuperscript{77} In this regard, the French Supreme Court recently confirmed that a victim can obtain compensation for post-traumatic stress; Supreme Court, Crim, 21 October 2014, No. 13-87669.
\textsuperscript{78} Damages resulting from injury to the product itself are excluded from product liability, but may be covered by the guarantee against hidden defects (Article 1641 et seq. of the FCC). Damages resulting from non-compliance of the goods with the intended use are subject to the obligation of conformity (Article L.217-4 et seq. of the French Consumer Code).
\textsuperscript{79} The Supreme Court first admitted compensation for the prejudice of anxiety caused by exposure to asbestos dust; Supreme Court, 11 May 2010, No. 09-42.241; 3 March 2015, No. 13-20.486.
\textsuperscript{80} Action relating to asbestos; Council of State, ass., 3 March 2004, No. 241150.
\textsuperscript{81} Administrative Court of Appeal, Paris, 2 July 2015, Nos. 14PA04137, 14PA04138, 14PA04139, 14PA04140, 14PA04141, 14PA04142, 14PA04143 and 14PA04156. More recently, Administrative Courts of Appeal have again issued decisions along these lines: Administrative Court of Appeal, Paris, 19 November 2019, No. 18PA00180 and 18PA00163.
\textsuperscript{82} Council of State, 9 November 2016, No. 393108; see also the recent decision of the Administrative Court, Paris, 19 October 2017, No.1312485/6-2.
\textsuperscript{83} Court of First Instance, 28 January 2016, Nos. 15/01586 and 15/01743, but annulled by the Versailles Court of Appeal, on 27 October 2016, Nos. 16/03382 and 16/03018, because of the existence of a serious challenge raised by Servier regarding the development-risk exemption.
\textsuperscript{84} Supreme Court, 14 November 2019, No. 18-10794; Supreme Court, 19 June 2019, No. 18-10612.
As an example, the maximum penalty for manslaughter, pursuant to Article 221-6 of the French Criminal Code 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 Criminal Code, 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 \hspace{1em} YEAR IN REVIEW

In France, and in particular within the healthcare sector, litigation has increased considerably in the past five years, and this trend is reinforced by the adoption of the class-action mechanism.

Indeed, since the Mediator case in 2013, 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 have launched several actions.

Victims have been able to seek a remedy either from the manufacturer or from the state. However, in 2016 and 2017, it was recognised that the state shall be partly exempted from liability in the event of any fault on the part of the pharmaceutical company Servier, which was under state control at that time; it would, in that case, be up to the victims to seek a remedy from the company that is found liable. Recent decisions have considered that victims who have received compensation in non-contentious proceedings have the possibility of seeking state liability before the administrative courts.

In December 2016, a French class action was initiated against Sanofi before the Paris court of first instance in relation to medicinal products based on valproate and derivatives (Dépakine, Micropakine, Dépakote, Dépamide and generics) that may have produced birth defects and developmental disorders.

The consequences of this matter have become a political issue and French public authorities have responded by creating another compensation fund. In a case of 2019, Sanofi relied on the compliance of its leaflet with the mandatory rules issued by the competent

85 Out of a total of 8,942 claims addressed to the ONIAM, 1,942 have so far succeeded for the plaintiffs.
86 See Section III. The Court of First Instance of Nanterre compensated the Mediator victims on the basis of liability for defective products – the Court of First Instance, Nanterre, 22 October 2015, Nos. 12/07723 and 13/06176. Although the compensation was judged derisory, Servier filed an appeal against the decision. The Court of Appeal of Versailles, on 14 April 2016, Nos. 15/08232 confirmed the first instance decision. The Supreme Court on 20 September 2017, No. 16-19643 upheld the appeal decision.
87 Administrative Court, Paris, 3 July 2014, No. 1312345/6 and 12 September 2014, No. 1312391/6; upheld by the Administrative Court of Appeal, Paris, 31 July 2015, Nos. 14PA04082, 14PA04083 and 14PA04146; also upheld by the Council of State, 9 November 2016, No. 393904.
88 Council of State, 9 November 2016, No. 393902; Administrative Court, Paris, 4 August 2017, Nos. 16PA00157 and 16PA03634: the faults committed by Servier were likely to exonerate the state of 70 per cent of its liability.
89 Council of State, 31 December 2019, No. 420232.
90 Court of Appeal Paris, 14 March 2017, No. 16/17958: declared the action launched by APESAC (the patients’ support association) inadmissible for lack of standing.
91 See Section IV.i. Article 150 (V) of the French Finance Law for 2017.
authority at the time the medicine was taken. The Supreme Court referred the case to the trial courts and we are now awaiting the decision that will determine the defectiveness of the product in the light of the company's duty to inform the patients.\textsuperscript{92}

At the beginning of 2017, the Levothyrox case was also placed in the spotlight. Commercialised at the end of March 2017 at the request of the ANSM, the new formula (i.e., change of excipients) of the medicinal product Levothyrox prescribed in the treatment of hypothyroidism and manufactured by Merck was accused of causing many adverse effects, such as cramps, headaches, intense tiredness, dizziness and hair loss.

Beyond the criminal investigation launched by the health division of the Marseille public prosecution service, a class action was filed early 2018 before the District Court of Lyon. On 5 December 2018, the latter dismissed the Levothyrox victims considering there was no fault in respect of the company's duty to inform regarding the leaflet content. The appeal decision should be issued on 9 April 2020.

Decisions of several first instance Courts regarding the unreliability of the serodiagnostic tests used in the detection of Lyme disease are expected later this year too.

Finally, an extensive investigation made in November 2018 is now seriously questioning the certification processes and the control of medical implants in Europe, and more particularly in France. According to data gathered from the inventory of material vigilance reports of the ANSM, the number of incidents notified in France, related to these implants, would have doubled in 10 years, with more than 18,000 cases in 2017 and about 158,000 incidents in 10 years. From March 2020, the new EUDAMED database will help to conduct market surveillance on medical devices throughout Europe and include:

\begin{itemize}
  \item[a] data related to registry of manufacturers, authorised representatives and devices;
  \item[b] data related to certificates issued, modified, supplemented, suspended, withdrawn or refused according to established procedures; and
  \item[c] data obtained in accordance with the vigilance procedure on incidents or near-incidents that occur during the use of the medical device.
\end{itemize}

Aside from the general trend for an increase in civil and criminal litigation, which must now be considered a key and central legal fact (particularly since the Mediator case, and particularly within the health sector), the availability of the class-action mechanism in France is undoubtedly increasing the risk of litigation across all the industrial sectors. This should lead companies to adopt protective behaviours, or to renew and reinforce existing practices (e.g., in terms of internal compliance and audit) and, in doing so, to duly consider the whole spectrum of regulation in their respective sectors, including in relation to regulatory obligations, transparency rules and conflicts of interest.

\textsuperscript{92} Supreme Court, 27 November 2019, No. 18-16-537.
Chapter 6

INDIA

Vivek Bajaj, Kaavya Raghavan and Sherien Kaul

I  INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

In India, the recently introduced Consumer Protection Act 2019 (CPA 2019) has defined product liability as the ‘responsibility of a product manufacturer or product seller, of any product or service, to compensate for any harm caused to a consumer by such defective product manufactured or sold or by deficiency in services relating thereto’. Before this, the term had not been specifically defined under any statute.

There are other statutes, and multiple general and sector-specific laws exist, 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 Consumer Protection Act 2019;
b  the Sale of Goods Act 1930 (SGA); and
c  the Indian Contract Act 1872.

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 supply of defective products, 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 in Section II of this chapter).

There are also regulations, such as the ones under the Bureau of Indian Standards Act 2016 (the BIS Act), which set out mandatory and voluntary standards and specifications applicable to products across different sectors and industries.

1  Vivek Bajaj is a partner, and Kaavya Raghavan and Sherien Kaul are associates at AZB & Partners.
2  The CPA 2019, which seeks to replace the Consumer Protection Act 1986 (CPA 1986) has been passed by the Indian legislature, but has not been brought into force yet. It has introduced specific provisions on product liability in India, and includes particular grounds under which a product manufacturer, product service provider and product seller may be held liable.
3  The BIS Act 2016 replaced the Bureau of Indian Standards Act 1986.
In addition to the foregoing, specific industries such as the food, pharmaceuticals, automotive and electronics have specific laws that govern and regulate product standards, product safety and liability in these 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. The BIS Act allows the central government to notify certain goods, articles, processes, systems or services, or any essential requirements for such 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 considers them necessary for:

- public interest;
- the protection of human, animal or plant health;
- safety of the environment;
- prevention of unfair trade practices; or
- national security.

The 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, steel and steel products, domestic gas stoves, and certain valves and cylinders, manufacturers, importers, distributors, retailers, sellers, lessors and any person who applies his or her trademark on such goods or service are required to ensure compliance with these standards before the goods or services are manufactured, imported, distributed, sold, leased, stored or exhibited in India. If the BIS is convinced that goods or articles bearing standard marks do not conform to the requirements of the relevant standard, it has the power to direct the certified body or licence holder or its representative to stop the supply and sale, and may recall the non-conforming goods or articles. The BIS Act also provides for penal consequences, including fines and imprisonment for non-conformance with prescribed standards and other acts of non-compliance.

The CPA 2019 provides for the establishment of the Central Consumer Protection Authority (CCPA), a body to promote, protect and enforce the rights of consumers as a class. The CCPA regulates matters relating to the violation of consumers’ rights, unfair trade practices, and false or misleading advertisements. Among other things, the CCPA has the authority to refer instances of violations of consumer rights or unfair trade practices to investigating authorities, and pass orders to recall goods or withdraw services that are dangerous or hazardous; ensure reimbursement of the price for such goods or services to the purchasers; and discontinue practices that are unfair or prejudicial to consumer’s interests.

4 Food Safety and Standards Act 2006 (FSSA).
5 Drugs and Cosmetics Act 1940 (the Drugs Act).
6 Motor Vehicles Act 1988 (MVA).
7 Electronics and Information Technology Goods (Requirements for Compulsory Registration) Order 2012.
In addition to the foregoing, the drug, automotive and food industries are some of the notable sectors governed by industry-specific regulators, which are discussed below.

i  **Drugs and medical devices**

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.

The Union Ministry of Health and Family Welfare (the Ministry of Health) notified the Medical Devices Rules 2017 (the Devices Rules), which came into force on 1 January 2018. These rules 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. Pursuant to these rules, medical device manufacturers are required to follow the essential principles of safety and performance of medical devices and conform to standards that may be specified by the Ministry of Health or the BIS, from time to time. 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 Standardization or the International Electrotechnical Commission, or any other pharmacopoeial standards. In the absence of these international standards, medical devices should conform to the validated manufacturer’s standards. In 2019, the Ministry of Health proposed setting up an online system for the registration of medical devices.

Manufacturers or suppliers 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 manufacturers or authorised agents to recall medical devices (manufactured or imported) that are likely to pose a risk to users’ health, indicating reasons for the recall; and inform the competent authority of the relevant details. Contravention of the provisions could result in penal consequences, including fines, imprisonment, cancellation, suspension or debarment of the licence holder.

ii  **Automobiles**

Under the MVA, the Ministry of Road Transport and Highways (MoRTH) is the primary authority for regulation of the automotive industry in India. It has overarching powers, including laying down standards on automotive safety, construction and equipment of motor vehicles, which have to be complied with by automobile manufacturers. Pursuant to these powers, MoRTH, 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.
In 2019, the MVA was amended to permit a motor vehicle manufacturer to initiate voluntary recalls, and empower the MoRTH to order recalls. A direction to recall motor vehicles of a particular type may be made if a defect is found in the vehicle that may harm the environment, driver, occupants or other road users, or if the defect is reported to the MoRTH by a certain percentage of vehicle owners (as decided by the MoRTH), a testing agency or any other source. Where the defect lies in a motor vehicle component, the MoRTH may direct a motor vehicle manufacturer to recall all motor vehicles that contain the component, regardless of the type or variants of the motor vehicle. The manufacturer of the motor vehicles that have been recalled will be liable to reimburse the buyers the full amount, replace the defective motor vehicle with another motor vehicle of similar or better specifications, or pay the prescribed fines.

Further, the manufacturers or importers of motor vehicles being sold, delivered, and offered for sale or delivery, or being used in a public place, are required to obtain a type-approval certificate for such vehicles. However, exemption from this requirement has been provided for vehicles only intended for export, display, demonstration or exhibition; being used by the manufacturer of the vehicles or for the purposes of research, data collection, or test by testing agencies inside a factory premises or in a non-public place; or that are exempted by the MoRTH.

Manufacturers that do not comply with the provisions of the MVA relating to construction, maintenance, sale and alteration of motor vehicles and its components will be liable to pay a fine, which may extend to 1 billion rupees, or imprisonment of up to one year, or both. Additionally, manufacturers, importers or dealers of motor vehicles that offer to sell, deliver or alter a motor vehicle; or any other person who sells or offers to sell, or permits the sale of a motor vehicle component notified as a critical safety component of a motor vehicle, in contravention of such provisions, will be punishable with imprisonment of up to one year, or with a fine of 100,000 rupees, or both, for every non-compliant vehicle or component.

iii Food

The Food Safety and Standards Authority of India (the Food Authority) was established under the FSSA to regulate the manufacture, storage, distribution, sale and import of food to ensure the 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, food labelling and recalls. The Food Safety and Standards (Food Recall Procedure) Regulations 2017 (the Food Recall Regulations), framed under the FSSA, contain detailed provisions and procedures for the removal of food that is unsafe, including by way of recalls, and require all food business operators (FBOs) engaged in the manufacture, import or wholesale supply of food to have an up-to-date recall plan. The Food Authority has issued guidelines to help FBOs develop a food recall plan, and also requires FBOs to maintain a recall management team. The Food Authority is required to monitor the progress of a recall and assess the effectiveness of the action taken by the FBOs. Under the provisions of the Food Recall Regulations, the Food Authority can

a  ensure removal of food under recall from all stages of the food chain;
b  disseminate information to the consumers and customers concerned; and
c  retrieve, destroy or reprocess food under recall.
Prior to the notification of the Food Recall Regulations, the Food Authority had used its inherent powers under the FSSA to recall defective or unsafe food. Under the FSSA, the manufacture, storage, sale, distribution or import of food that is unsafe for human consumption is punishable by imprisonment and fines.

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, it refers to all circumstances or sets of facts that give rise to a right to sue or, if proved or admitted, would entitle the plaintiff (the 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. Under the CPA 2019, a cause of action for a claim in product liability arises when a consumer suffers ‘harm’ caused by a defective product manufactured by a product manufacturer or serviced by a product service provider or sold by a product seller.

A ‘defect’ for which the consumer may file for a claim includes any fault, imperfection or shortcoming in the quality, quantity, potency, purity or standard of the product that is required to be maintained as per law.

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 if elements of provisions of the IPC, such as those relating to negligence, fraud or cheating, are present in product liability cases.

IV LITIGATION

i Forum

Depending on the facts, the goods or services involved and the category of the aggrieved party (the consumer or buyer for commercial use), there are multiple forums 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 2019;
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.

8 Harm to the consumer may be proved if there was damage to any property, other than the product itself; the consumer suffered personal injury, illness or death; the defect or personal injury due to the defect in the product caused mental agony or emotional distress; there was any loss of consortium or services, not on account of harm caused to a product itself or any damage to the property on account of breach of warranty conditions or any commercial or economic loss, including any direct, incidental or consequential loss.
In addition to the foregoing, in certain circumstances, aggrieved parties can also approach a jurisdictional high court if the distribution of defective products has resulted from a breach of duty or inaction by a statutory authority.

Further, in 2015, Parliament enacted the Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act 2015 (the 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 was amended in 2018, and provides for the constitution of:

a. commercial courts at a district level, though in areas where the high court exercises ordinary original civil jurisdiction the state government may specify the limits of the commercial courts’ pecuniary jurisdiction; and

b. 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:

a. of a specified value of not less than 300,000 rupees or such other value as notified; and

b. 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 commencing proceedings across various Indian states.

In India, dispute resolution through adjudication by courts and arbitration are completely distinct and independent processes that rarely overlap. If 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. Mediation, as a method of alternate dispute resolution, is also gaining popularity in India. The recent amendment to the Commercial Courts Act makes pre-institution mediation mandatory in all cases where the parties do not require immediate intervention by courts.

ii) Burden of proof

The Indian Evidence Act 1872 (the Evidence Act) 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 claims relating to defects in products, depending on the factual circumstances, the burden of proof will be on the aggrieved party to prove:

a. the presence of a defect in the goods;

b. breach of warranty or condition (implied or expressed); or

c. 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 2019;
c the purchaser of the product is not a ‘consumer’ as defined under the CPA 2019;
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.

A product liability action cannot be brought against a product seller, if at the time of harm, the product was altered, misused or modified. A product manufacturer will not be liable for failure to instruct or warn about a danger that is obvious or commonly known to the user, taking into account the characteristics of the product. Additionally, the product manufacturer will also not be liable for failure to provide adequate warnings or instructions if:

a the product was purchased by an employer for use at workplace and warnings or instructions of usage had been communicated to the employer;
b the product was sold as material to be used in another product, warnings or instructions of usage had been communicated to the purchaser and harm is caused by the end product;
c the product is legally meant to be used under supervision of an expert and reasonable means have been employed by the manufacturer to communicate the warnings or instructions of usage to those experts; or
d the consumer under the influence of alcohol or any prescription drug not prescribed by a medical practitioner.

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.

Further, in addition to 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. The CPA 2019
provides for a limitation period of two years from the date of the cause of action; however, the CPA 2019 gives the consumer court the discretion to entertain complaints filed beyond the limitation period if it is satisfied with the reasons for the delay.

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 Code of Civil Procedure (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 persons or movables, in the jurisdictional court of the local limits where the cause of action took place, in part or full; or 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 (e.g., 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, Indian courts can ignore 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 the 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*, 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 who the first party should have considered while directing its acts or omissions (irrespective of whether any contractual relationship exists), and have assumed jurisdiction over the first party upon 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 must form an opinion on foreign law, science, art and handwriting. Indian criminal courts are also vested with the

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9  [1932] AC 562.
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 2019, the consumer courts have the power to appoint experts to examine defective products manufactured, sold or distributed if the defect cannot be determined without proper analysis or testing of the goods.

The consumer courts may also appoint experts to assist them if such courts are of the opinion that an issue involves the larger interest of consumers.

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

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 to save costs. If the information or documents are not produced before the court and no legitimate reason is provided for this 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 the 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 the case. 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 if the parties have, acting in concert, committed a wrongful act resulting in loss or damage to the affected person or, when not acting in concert, have, by their individual wrongful acts, caused loss or damage to the affected person. In exceptional cases, courts have apportioned the liability between multiple tortfeasors on the basis of material evidence available on record, indicating the degree of liability of each tortfeasor. Further, in consumer complaints under the CPA 2019, 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 sale of defective products.
Mass tort actions

India does not have a codified system of tort law. 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, if 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 the suit, with the prior permission of the court in which the suit is required to be instituted. In this regard, interest is said to be similar or common when the plaintiffs have a common grievance against the defendant and the relief sought is in its nature beneficial to all persons interested in the suit.

The CPA 2019 recognises the right of the CCPA to initiate a class action, including enforcing recall, refund and return of products when necessary, to prevent detrimental effects to the consumer’s interests. The definition of a ‘complainant’ under the CPA 2019 includes one or more consumers or a voluntary consumer association to file a complaint against a single manufacturer, dealer, distributor, etc., on behalf of, or for the benefit of, numerous consumers having the same interest. The complainants are required to obtain prior permission from the relevant forum for adjudication of disputes under the CPA 2019 before instituting such proceedings. Additionally, the CPA 2019 provides the district, state and national fora the power to grant relief to several consumers who are unidentifiable. This power is typically exercised in the event of loss or injury being suffered by a large number of consumers as a result of defective goods or services, and where the consumers cannot easily be identified.

Damages

The general law of economic damages in the Indian context is covered under the SGA, Contract Act, the CPA 2019 and tort law. The Contract Act provides for the payment of damages or compensation by the defaulting party to the aggrieved party for any loss or damage that arose as a natural consequence of a breach; or that the parties were aware, at the time of entering into the contract, would possibly result from a breach. In this context, the Contract Act does not allow damages for remote, indirect or incidental loss.

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 the 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. The CPA 2019 permits awards of punitive damages in circumstances deemed fit by the consumer courts. Further, under the CPA 1986, the courts have in the past awarded 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. However, the amount of damages awarded under consumer protection laws 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 these 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.

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. 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

Two major milestones in Indian product liability law in 2019 were the enactment of the CPA 2019, which includes a chapter on product liability, and the amendment of the MVA.

The Food Authority recently initiated recall and passed orders to stop the production of packaged food that contained a toy in it that posed a choking hazard to children. Further, the Food Authority is also exploring the possibility of setting standards for Ayurvedic food as a part of its food supplement regulation. However, no regulations have been notified in this regard.

In 2019, drug manufacturer GlaxoSmithKline voluntarily initiated recall of the heartburn drug Ranitidine and Zinetac tablets (150mg and 300mg), which came under the radar of the CDSCO for containing carcinogenic substances. The supply of Atorvastatin was also banned in certain states in India after it was declared to be not of a standard quality by the CDSCO.

Six years after the cancellation of Johnson & Johnson’s (J&J) import licence for hip replacement devices that were faulty, J&J had been ordered by the Ministry of Health to pay compensation (ranging between 3 million and 12.3 million rupees) to patients who had received the faulty hip implant. A committee was formed by the Ministry of Health that calculated the compensation payable based on a formula using a person’s age and the extent of disability. J&J challenged the committee’s decision on grounds of lack of transparency and opportunity to be heard, which still remains pending before the Delhi High Court. Pending judgment, J&J has agreed to pay 2.5 million rupees each to identified patients as interim compensation. An expert subcommittee has been constituted to review and appropriately
recommend provisions for compensation in the case of faulty devices under the Devices Rules. There is also a proposal by the CDSCO to include all medical devices under the regulatory provisions of the Devices Rules.

In 2019, prior to the amendment of the MVA, several car companies initiated voluntary recalls of their car owing to various defects discovered in the cars’ components, including safety issues in certain circumstances. The recall was initiated under the Voluntary Code on Vehicle Recall prescribed by the Society of Indian Automobile Manufacturers. Hyundai Motors has recalled over 16,000 cars due to a fault in the compressed natural gas filter assembled in the cars; Mahindra and Mahindra recalled a total of 16,908 cars due to improper metallurgical condition of the suspension component, and Maruti Suzuki issued for the recall for over 40,000 vehicles suspected of fuel hose fouling with metal clamp, which could lead to fuel leakage. On account of the amendment to the MVA in 2019, the recalls will now be under the MVA, and will no longer be under the Voluntary Code on Vehicle Recall.

In relation to the global emission scandal involving Volkswagen, a public interest litigation (PIL) was filed against Volkswagen in India before the National Green Tribunal (NGT, which is the forum set up in India for expeditious disposal of cases relating to environmental and conservation-related issues) towards the end of 2015. The PIL sought a ban on sale of the cars in India, and Volkswagen, as part of its ongoing global recall, continued to carry out a voluntary recall of its cars affected in India. While a committee constituted by the NGT to estimate the quantum of environmental loss caused by Volkswagen recommended a fine of 1.7 billion rupees, the NGT holding Volkswagen liable under the polluter pays principle, precautionary principle and the principles of sustainable development, imposed a fine of 5 billion rupees on Volkswagen while ordering the Central Pollution Control Board to take further actions as may be required under applicable statutory regime. This penalty has been challenged before the Supreme Court of India, and an interim order has been passed directing the NGT to not take any coercive steps against Volkswagen.

Until the recent statutory framework for recall of cars, voluntary product recalls was the main mechanism adopted by manufacturers and dealers to avoid or limit liability. Voluntary product recalls have continued being carried out across several industries. In particular, pursuant to obligations such as the duty of care under tort and consumer protection laws, manufacturers, dealers and distributors across various sectors undertake these actions as strategic initiatives to limit and curb potential liability arising because of defects in products.
Chapter 7

ITALY

Daniele Vecchi and Michela Turra

I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK


With regard to the general rules on product safety and to the legal standards governing the manufacture, distribution and sale of products, the provisions of the Consumer Code only apply to those products that are not covered by other sector-specific legislation (e.g., toys, machinery, pharmaceuticals and food). The Consumer Code also complements the provisions of sector-specific legislation, where the latter does not cover certain matters such as, for instance, the powers of the relevant public authorities in charge of safety issues.

II REGULATORY OVERSIGHT

In Italy, the administrative body that is tasked with overseeing various aspects related to product liability is the Ministry of Economic Development, and specifically its directorate-general for market, competition, consumers, surveillance and technical legislation. Furthermore, Italian law provides for a series of duties for several authorities and public bodies to ensure that products placed on the market are safe and to adopt all necessary measures to guarantee public safety (including ordering product recalls or prohibiting their sale), depending on which kind of products are involved (e.g., the Ministry of Health for medical or pharmaceutical products).

The Ministry of Economic Development is also the main contact point for all safety issues related to products. If manufacturers or distributors discover that a product is not compliant with the due safety standards, they must notify the Ministry. Notifications must also be filed with the relevant authority or public body in charge of the matter, depending on the nature of the product in question.

Besides the Consumer Code, the main legal framework that manufacturers and distributors have to take into account to identify how to fulfil their obligations with regard to product safety are the guidelines adopted by the European Commission in relation to safety issues. In particular, Decision 2019/417EU provides guidance for the management of the EU rapid alert system for dangerous non-food consumer products (the RAPEX system) and

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for notification to the competent authorities. Said Decision also constitutes the fundamental framework that manufacturers and distributors have to refer to in assessing the level of risk posed by a product.

III CAUSES OF ACTION

In general terms, pursuant to the Consumer Code the manufacturer of a product is liable for damage that defects of said product might cause to the consumer. To this purpose, the ‘product’ is any movable good, even if incorporated in another movable or immovable good; the ‘manufacturer’ is whoever manufactured the finished product, or a component of the same, or the raw materials used in manufacturing the product. If the consumer cannot identify the manufacturer, he or she can claim the liability of the distributor. To this end, the ‘distributor’ is any professional operator that, as part of its business, supplies the product on the market as part of the supply chain of a product, provided that it does not impact the safety of the same product. However, the liability of the distributor has a residual nature. The distributor can escape liability if it allows the identification of the manufacturer of the product or of the supplier from which it purchased the product in the first place. Possible liability also extends to the importer of the product in the EU, should the manufacturer have no representative established in the EU.

Therefore, the consumer who suffered damages caused by a defective product may claim compensation of said damages from the manufacturer or the distributor of the product in question. The statute of limitation to bring said claim is three years from the date when the damaged party became or should have become aware of the damage, the defect of the product and the identity of the liable subject. In this regard, see Section IV.iii.

In most serious cases, the manufacturer and the distributor of a product that turned out to be defective and caused serious damage to consumers could also incur criminal liabilities (e.g., personal injuries or manslaughter). In the case of criminal proceedings, the civil claim for product liability could be raised within the same proceedings.

From an administrative perspective, the Ministry of Economic Development, as well as the authorities and public bodies in charge of the relevant monitoring activities, depending on the nature of the product, enjoy a series of powers aimed at guaranteeing that only safe products are available on the market. These powers include:

- controlling the products after they have been put on the market;
- requesting the transmission of information by concerned parties;
- taking samples of the products for monitoring purposes;
- prohibiting the placement of products on the market; and
- ordering the enactment of measures to render products safe.

Should it be assessed that an unsafe product has been marketed, the Ministry of Economic Development may order either that the product be immediately withdrawn from the distribution, adequately informing consumers, or the recall of the product from the consumers, depending on the seriousness of the case. The measures in question may be adopted with regard to the manufacturer and the distributor. Both of these subjects have a duty to promptly inform the Ministry of Economic Development if they are, or should be, aware, based on the information at their disposal and in their capacity as professional
operators, that the product they placed on the market or made available to consumers does not comply with due safety standards. Criminal charges can also be brought against the manufacturer or distributor that either:

- placed dangerous products on the market;
- violated a ban from government authorities not to market a certain product;
- did not make efforts to ensure that a certain product was safe or that consumers were warned about the possible connected dangers; or
- did not cooperate with the Ministry of Economic Development and the authorities or public bodies involved, in the performance of their surveillance. (See Section IV.ix.)

**IV LITIGATION**

**i Forum**

In the Italian legal order, product liability cases, like all other civil cases, are tried either before a justice of the peace or a court, depending on the value of the plaintiff's requests. More specifically, if the claim is lower than €5,000, the case shall be tried before a justice of the peace (said threshold will increase to €30,000 from 31 October 2021). If the claim is higher than the above-mentioned amount, the case shall be tried before a court.

In general terms, in the field of product liability, ordinary civil proceedings of first instance are held by a single judge. Class action proceedings of first instance are held before a court, ruling in a panel of judges. Appeal proceedings are held before a court of appeal and the decision is rendered by a panel of judges. If the first instance decision is rendered by a justice of the peace, the same may be challenged before a court, where the relevant proceedings are held by a single judge. Appeal decisions may, in turn, be challenged before the Court of Cassation – the Italian Supreme Court – where the proceedings are held by a panel of judges as well. In class action proceedings, orders of second instance ruling over admissibility cannot be further challenged before the Court of Cassation. Juries are not contemplated in civil proceedings.

**ii Burden of proof**

A consumer who claims to have been injured by a defective product has the burden of proving the defect of the product, the damage suffered and causation in terms of existence of a causal relationship between the defect and the damage claimed.

Several merit courts over the years have stated that the existence of the defect of a product could be inferred by the existence of the damage and of the causal link between the use of the product and the damage itself. In other words, in accordance with this case-law trend, the mere fact that the use of the product caused the damage would be enough to infer the existence of the defect of the product. Thus, no specific evidence of the defect would be needed.

Nonetheless, this case-law trend appeared to be overturned, following a benchmark decision of the Court of Cassation. In accordance with the rulings of the Supreme Court, the existence of a defect of the product must be proved. The plaintiff, therefore, must provide evidence that the product lacks the general safety conditions that are required and can be expected with regard to the common use for which the product has been manufactured and marketed (Court of Cassation Decision No. 6007 of 15 March 2007; this stance was more recently confirmed by Court of Cassation Decision No. 29828 of 11 November 2018).
In this regard, the proof that the damaged party must provide largely depends on the nature of the alleged defect. Assuming that the relevant product is generally safe and only a single item, to which the damaged party was exposed, malfunctioned or was defective, the damaged party must prove the existence of the defect (however, some argue that said burden of proof could be satisfied by demonstrating the single item differs from all other products of the same set). However, should the injury derive from a defect that is common to all similar products (i.e., the product itself is unsafe or has been wrongfully designed, or there is a lack in the information provided by the manufacturer), it will be sufficient for the damaged party to prove that the entire category of products is defective; they are not required to demonstrate the existence of the defect of the single product he or she entered in contact with.

If the proof of the defect is not easily attainable, presumptions may be considered sufficient by judges. In this regard the Court of Cassation found that once a ‘secondary fact’ is demonstrated, judges may indirectly infer from that fact the existence of the ‘main fact’, such as the existence of defect of the product. However, this is only if the secondary facts on which the presumption is built are clearly and specifically demonstrated (Court of Cassation Decision No. 29828 of 11 November 2018).

iii Defences

As a general principle, the manufacturer of a product is liable for damage caused by defects of the same product. For the purposes of product liability provisions, the definition of ‘manufacturer’ includes anyone manufacturing the product in the EU (either the finished product, or a component of the same, or its raw materials).

The distributor may also be held liable, if the manufacturer is not identified or identifiable. A distributor is any professional operator that is part of the supply chain of a product.

In the case of claims being brought against them by consumers, the manufacturer and the distributor should demonstrate facts that may exempt them from liability under the Consumer Code. Namely, liability is excluded if at least one of the following occurs:

a the manufacturer did not place the product on the market. In general, a product is considered as marketed if it is delivered to the purchaser, to the user or to an assistant of one of them (this also includes the delivery of samples or products to be viewed or tested only);

b the defect that caused the damage did not exist at the time 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 exercise of its business;

d the defect is because of the compliance of the product with a mandatory legal provision or with binding public measures; and

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.

In addition, the distributor can escape liability by allowing the identification of the manufacturer. Further to that, Italian law does not provide for any special immunity for particular categories of defendants.
Without prejudice to the above, liability is also excluded if the damage was attributable to the consumer. Specifically, compensation is excluded if the consumer, despite having been aware of the defect of the product and the related risks, voluntarily exposed himself or herself to them, thereby accepting such risks. Furthermore, if the consumer who was damaged by the defective product contributed to the causation of the relevant damage, compensation is reduced proportionally having regard to the seriousness of the negligence attributable to the consumer and the extent of the relevant consequences.

As briefly highlighted above, the limitation period for product liability claims is of three years. This period starts running from either:

a. the day when the consumer was allegedly damaged by the defective product;
b. the day when the consumer became aware or should have become aware of the damage or defect; or
c. the day when the consumer became aware of the identity of the liable party.

The running of the limitation period can be interrupted. In general, this occurs whenever proceedings are initiated to raise the relevant claim or at least a final demand letter is sent to the manufacturer or the distributor by the allegedly damaged party, denouncing the harmful event and asking for compensation. In the case of interruption, the limitation period starts running again afresh as soon as a binding decision is issued as an outcome of aforesaid proceedings. In any event, the right to be compensated for the defect of a product expires after 10 years from the day when the manufacturer or the importer within the EU placed the product on the market.

Without prejudice to the above, the consumer may consider bringing an action based on general tort liability as governed by the Italian Civil Code, instead of a product liability action. In this case, the limitation period is five years running from the date of the detrimental event. In litigation it is very common for the consumer to submit both a claim for product liability and, alternatively or subordinately, a claim for general tort liability, in relation to the same events. If the claim concerns a product that is dangerous in itself, owing to its inner nature (e.g., gas cylinders, fireworks, pharmaceuticals), the consumer may ground his or her action on rules concerning liability for dangerous activities, which is a kind of strict liability. Nonetheless, it is worth considering that, based on the case law of the Court of Justice of the European Union and of the Italian courts, it is disputable whether the applicability of the rules on product liability derived from EU law to cases of damages caused by the use of a product excludes the possibility of applying another kind of strict liability regime to the same case, such as the rules on liability for dangerous activities mentioned above.

A particular situation occurs when the consumer can obtain the product only from an intermediary, which then has a personal duty to evaluate the suitability of the product and inform the consumer of the possible consequences of its use. In this case, the intermediary, in light of its professional skills and knowledge, may incur personal liability if it made an inappropriate evaluation or failed to provide the consumer with adequate information with regard to the products, thus preventing him or her from making an informed choice as to the type of product to use. However, the intermediary’s liability would not per se exclude the manufacturer’s liability should the relevant product turn out to be defective. This hypothesis is particularly relevant, for instance, in the medical field with regard to products such as prescription drugs or medical devices (prostheses, heart valves, etc.), which the consumer cannot have access to without a physician’s intervention. In this hypothesis, according to the case law, the manufacturer of the product in question must make available to medical
professionals all relevant information concerning the product. The physician, in turn, is responsible for assessing which product is better suited for his or her patient's case and for informing the same of possible side effects of the product. In this scenario, should prejudicial effects derive to the patient as a consequence of the use of the product, the manufacturer may be exempt from liability, provided it had properly informed the physician of the possibility of such prejudicial effects. The ratio behind this reasoning is that the physician is in the best position, knowing the patient's medical history and the case to be treated, to weigh the risks and the benefits of the product and decide whether to use it. This reasoning does not apply if the product in question turns out to be defective, in which case the manufacturer may be held liable for damages consequently suffered (Court of Cassation Decision No. 20895 of 8 October 2007; Court of Cassation Decision No. 25148 of 11 October 2018). It may also not apply to the case of medical or pharmaceutical products to which consumers have free access, without the need of the intervention of a physician (Court of Cassation Decision No. 15734 of 2 July 2010).

iv Personal jurisdiction

Jurisdiction over product liability cases is governed by EU Regulation No. 1215 of 2012, as well as by Law No. 218 of 1995, setting forth conflict of law provisions.

In general terms, based on the provisions mentioned above, for Italian courts to have jurisdiction over claims for compensation of damages, including the case of damages caused by a defective product, the damages claimed must have been caused by an event that occurred in Italy, irrespective of the fact that the claimant or the defendant is domiciled or resident in Italy, and of where the product was manufactured, sold, or advertised. For instance, assuming that a product was manufactured in a foreign country and advertised only abroad or on the internet, if the damaging event occurred in Italy, Italian courts would have jurisdiction over claims for compensation of the damage.

Furthermore, Italian courts have jurisdiction over claims raised by a claimant who is not domiciled or resident in Italy against any defendant who is domiciled or resident in Italy.

v Expert witnesses

The parties to a proceeding can appoint their own retained experts to draft written reports to support their claims or defensive arguments. These reports are filed as exhibits in the case. In general, there is no restriction on the nature or the extent of the use of this kind of evidence. Also, the parties can ask the court to hear their own retained experts as witnesses.

Should the case require specific technical knowledge, the judge may appoint, also upon a party's request, one or more experts (a judicial technical consultant (CTU)) to act as the judge's assistants and provide technical expertise on the matter. The CTU cannot make legal assessments, establish the existence and meaning of legal provisions, assess documentary evidence or provide evidence of the facts at issue (in place of the parties). His or her role is strictly limited to the technical questions posed by the court.

The CTU is selected from lists of experts filed in each court. If the CTU is not chosen among the experts included in such lists, the appointment has to be previously authorised by the president of the court. Each party can oppose the appointment of the CTU on proper grounds, such as risk of impartiality or bias.

Each party can appoint its own retained expert to work together with the CTU (party-appointed experts (CTPs)).
The results of the expertise proceeding are put in writing. After his or her investigations, the CTU shares a preliminary report with the CTPs, which are then allowed to submit their remarks or comments; subsequently the CTU files a final report, including the CTPs’ comments.

The content of the CTU’s final report is not binding for the judge, who may disagree with its outcome in his or her final ruling, provided he or she has adequate grounds in support of this decision.

vi  Discovery

US-style discovery procedure, by which each party can access its counterparty’s entire internal documentation, has ever existed in Italy.

Recently, Law No. 31 of 2019 has reformed the existing provisions concerning class actions, introducing for the first time to the national legal system a procedural tool that is similar to US discovery (see Section IV.viii). Indeed, one of the main novelties introduced by this Law, which will become effective in October 2020, regards evidence-gathering. First of all, the court will be entitled to use statistical data and simple presumptions to ascertain the liability of the respondent. Furthermore, upon reasoned request by the petitioner, the court may order the resistant (only) to produce relevant evidence and documents within its possession. This order may also cover ‘categories of evidence’, identified by the common features of the evidence falling within their scopes (e.g., the time at which they were formed, the subject matter and contents of the evidence requested to be produced). If the resistant refuses or fails, without good reason, to comply with the relevant order to produce evidence, it may be sentenced to a fine of between €10,000 and €100,000.

In relation to ordinary proceedings, during evidence-gathering activities, the judge may, upon a party’s request, order the counterparty or any third party to exhibit documents. If the counterparty or any third party refuses to do so and fails to provide a valid reason to support the refusal, the judge may infer from its conduct to rule on the case. Furthermore, the judge may also order the parties to the proceedings or third parties to subject themselves to inspections on their own persons or on goods in their possession, if such inspections are essential to assess the facts under dispute and may be put in place without serious detriment to the parties or third parties. Should one of the parties refuse to allow said inspections, the judge may infer from such conduct to rule on the case.

The Italian legal system does not provide for the possibility of US-style depositions. However, parties are allowed to file documents containing statements from third parties on facts that are relevant for the purposes of the proceedings, such as affidavits, or in any event to ask the judge to allow for third parties to be heard as witnesses during the proceedings.

The parties to the proceedings cannot be heard as witnesses; on the contrary, they can be heard through formal questioning. In this case, their statements have to be considered as evidence for the purposes of the judge’s decision.

Last, Italian law allows for the possibility of international evidence-gathering procedures if evidence needs to be gathered in a foreign country.

vii  Apportionment

Under the Consumer Code, if several subjects jointly caused the damage, each of them is considered liable to compensate such damage. The liability of each subject has to be determined by the judge, taking into account a series of factors: the extension of risk, the seriousness of the wrongdoing and the relevant consequences attributable to each subject. Should this
If the damage claimed is not caused by a common activity but by a single manufacturer, the burden to identify that single manufacturer lies with the plaintiff. No form of market-share liability is applicable.

In general terms, under Italian law, if a subject takes over the enterprise or company that has manufactured, distributed or marketed the defective product, the acquiring subject becomes liable for any damage that the acquired enterprise or company might have caused in the performance of its business, including any damage caused by a defective product manufactured by the same. However, attention should be paid to the content of the agreement for the acquisition of the company, by which the parties might stipulate that certain liabilities, up to the date of the acquisition, shall not pass over to the acquiring subject.

viii Mass tort actions

Since 2008, Italian law has provided for the possibility to resort to class actions as tools to seek damage compensation in relation to certain kinds of multiple claims, including claims for product liability arising from the defect of a certain product. Class actions can be brought in relation to wrongful events that occurred after 15 August 2009.

Class actions can be initiated by any single consumer as a class representative, providing there is evidence that the claim raised is worthy of being litigated as class actions owing to the existence of homogenous rights within the potential group. Homogeneity of rights under dispute is an essential condition for the admissibility of the class action.

In Italy, class actions are based on an opt-in system. The relevant procedure consists of a preliminary admissibility stage (certification), during which the homogeneity of the rights claimed by the members of the group is assessed. If the class action is considered admissible, the merit stage follows for the assessment of liability and damage.

The decision of the court, ruling in panel, can provide for a direct condemnation or set forth the criteria to calculate the amount due to the members of the group or the minimum amount due to each of them. In this second case, the assessment of individual damage can be remitted to a subsequent settlement or litigation between the individual and the respondent.

Since the introduction of class actions in Italy, an average of 10 proceedings per year have been brought. This is a very small result, considering that approximately four million new civil cases are initiated in Italy every year. Moreover, out of those actions, only a limited number of them have been certified.

Very recently, Law No. 31 of 2019 has reformed the existing provisions concerning class actions. This reform, which will become effective starting from October 2020, has significantly modified the class action tool, with regard to both its scope of application and its functioning from a procedural perspective. The new set of provisions will apply to unlawful conduct that is carried out after the Law enters into force. Therefore, the class action would become a general remedy, which would be available not only to consumers, but to everyone claiming compensation for the violation of ‘homogeneous individual rights’. Thus, professional operators (natural and legal persons) will be also entitled to promote a class action. Further to that, the main novelties introduced by the reform are the following: opting-in will also be permitted after the publication of the decision ruling on the case and the establishment of the liability of the resistant; by the decision ruling on the merits of the
case, the court appoints a common representative of the class members, in charge of preparing a distribution project for the class members, taking a position on each individual request; the unsuccessful respondent must pay the common representative and the plaintiff’s attorney a ‘reward fee’, set as a percentage of the total amount due to the members as compensation. This last point is one of the most highly debated aspects of the reform; in fact, the business community is concerned that the reward fee may result in punitive damages and that the high amounts involved may render class action – as it is in the US – a relevant money-making business (see also Section IV.vi).

The Consumer Code also provides for the possibility of a representative action being brought by consumer associations, acting for the protection of the collective interests of consumers. By this action, consumer associations may request the court to order the concerned business to refrain from conduct harming the interests of consumers and to adopt measures to remove the prejudicial effects of previous conducts. The above-mentioned Law No. 31 of 2009 for the amendment of class action rules also provides for the reform of representative actions. According to this law, individuals will also be entitled to directly seek injunctive or declaratory relief (see Section IV.ix).

Before the introduction of class actions, Italian mass tort litigation was generally characterised by lawsuits jointly brought by single subjects who had suffered damage in connection to the same product, all acting as plaintiffs in the same proceedings or giving mandate to a single person to act on their behalf, as their representative in the proceedings. In our experience, following the introduction of class action, this practice has generally diminished. However, some lawyers tend to introduce ‘strands’ of lawsuits, in other words, bring a series of lawsuits having all the same objects, each one on behalf of a single consumer.

ix Damages

In general, product liability claims can be raised to seek compensation for personal damage (death or physical injuries), as well as for damage to objects normally used for private purposes and damaged by the defective product. In general terms, compensation is allowed only as restoration of damage actually suffered as a consequence of the defective product. Otherwise, in principle, no compensation is possible.

Both economic and non-economic damages suffered by the consumer as a consequence of the defective product are recoverable. For some decades now, both case law and authors have identified four categories of compensable damage:

a material (economic) damage, consisting of monetary damage due to pecuniary loss or loss of profits;

b non-economic damage, namely:

• biological damage, affecting the physical or psychological integrity of a person, directly related to his or her health;
• moral damage, essentially consisting of pain and suffering, to be awarded only in cases provided for by law (mainly as a result of a criminal offence); and
• existential damage, a type of damage created by case law to allow for compensation of damage not included within the above category of moral damage and essentially consisting of any event that negatively affects someone’s quality of life.

By a stand-out ruling, the Joint Sections of the Court of Cassation maintained that non-pecuniary damage is compensable only in cases provided for by the law, in other words, whenever compensability is expressly acknowledged in a provision of law and whenever,
even lacking such a provision, the damage entails the violation of a personal right that is constitutionally safeguarded (Court of Cassation Decision No. 26972 of 2008). In view of the above and on the basis of such ruling, existential damage is no longer compensable as an autonomous category of damage, but rather as a component of non-material damage. In this regard, decisions from Italian courts, even those issued by the Supreme Court, do not amount to binding precedents, even though they may have a persuasive effect on judges that have to rule on similar cases. So far, the trend of lower level courts has been to follow the above interpretation.

It is up to the judge to quantify compensable damage that should be awarded to the damaged party, based on the evidence submitted by the parties. As to the quantification of non-economic damage, the most recent practice of the courts has been to base their assessment on tables setting forth criteria for such quantification depending on several objective elements. Reference is made, in particular, to the tables drafted on a yearly basis by several Italian courts with regard to the compensation of non-economic damage derived from physical and psychological harm and of damage linked to the loss of a relative.

In general terms, Italian law does not allow for punitive damages to be awarded in the field of product liability and, more generally, in the field of tort liability. However, by an unprecedented judgment, dealing with a case of product liability, the Joined Sessions of the Court of Cassation clarified that punitive damages is not per se incompatible with the Italian legal order and with the nature and function of tort liability under Italian law (Law No. 16601 of 5 July 2017). In the relevant case, the Court found that punitive damages should be granted if Italian judges are called to enforce a foreign decision rendered by a judge belonging to a legal order in which punitive damages are allowed. No similar cases have followed so far.

So far, the Consumer Code does not allow individual consumers to seek injunctive or declaratory relief; this possibility is granted only to consumer associations. This is one of the aspects being dealt with by Law No. 31 of 2019, for the reform of class action rules (see Section IV.viii). Pursuant to said Law, starting from October 2020, individuals will become entitled to directly seek injunctive or declaratory relief too.

From a criminal law perspective, should an unsafe product cause harm to its user, the manufacturer of the product in question might face criminal charges, depending on the facts of the case and the seriousness of the damage caused by the product (e.g., personal injury, manslaughter). In this case, criminal proceedings may begin and the consumer may also bring civil action in the criminal proceedings to seek compensation for the damage suffered.

Furthermore, Italian law provides for other more specific penalties if a manufacturer or distributor places dangerous products on the market and fails to adopt measures aimed at remediating the risks deriving from an unsafe product, as ordered by the Ministry of Economic Development or the authorities or public bodies involved. More specifically:

a. unless the conduct constitutes a more severe criminal offence (e.g., if the defect causes death), the manufacturer or distributor that markets dangerous products, or violates a ban issued by a government authority to market a product, may be punishable with imprisonment up to one year and pecuniary sanctions ranging from €10,000 to €50,000;

b. unless the conduct constitutes a more severe criminal offence, the manufacturer or distributor that does not conform with an order issued by the competent authorities to act to make sure that a certain product is safe or that consumers are warned about the possible connected dangers may be punishable with pecuniary sanctions ranging from €10,000 to €25,000;
the manufacturer or distributor that does not cooperate with the competent authorities in the performance of their monitoring and surveillance activities may be punishable with pecuniary sanctions ranging from €1,500 to €40,000; and

if a more serious crime is also involved (e.g., injury or manslaughter), the relevant criminal provisions will also apply.

In any event, under Italian law, criminal liability cannot be imposed on corporations, but only to responsible individuals.

V YEAR IN REVIEW

In general terms, in Italy, product liability rules as set forth by the Consumer Code have not yet found an extensive application in judicial litigation, whereas general tort liability rules are more frequently resorted to.

In 2019, courts rendered decisions on cases of product liability, with regard to different kinds of products (i.e., cars, bicycles, drugs and paints). All the relevant actions were brought by individual consumers. Generally, insurance companies do not bring claims on behalf of consumers. It is common practice for businesses to stipulate insurance policies, also covering product liability.

The majority of the decisions issued in the past couple of years focused on the topics of the causal link between the defect of the product and the damage suffered by the consumer and the allocation of the relevant burden of the proof between the parties, as well as on the kind of evidence that the plaintiff should provide to demonstrate the existence of the causal link. The most relevant ruling in this regard is Decision No. 29828 of 11 November 2018 from the Court of Cassation, which concerned the use of ‘presumptions’ to demonstrate the existence of the claimed defect of the product. See Section IV.ii.

One of the most relevant cases initiated in Italy in the past few years on consumer law concerns the automotive sector and relates to the aftermath of the affair known as ‘Dieselgate’. After the recall of the vehicles involved on the part of the manufacturer, an Italian consumer association promoted two class actions in the name of the purchasers of said vehicles for breach of contract and unfair commercial practices. Both class actions were declared admissible. According to the press, more than 95,000 people exercised their right to opt in the actions and the aggregate value of the cases is reported as around €400 million, likely making these the biggest class actions in Europe.

Besides the above-mentioned case, the majority of product withdrawal or recalls in Italy concerned food products and beverages, toys and electrical appliances (especially low voltage devices).

As to recent Italian legislative developments in the field of consumer law and product liability, the most relevant ones concern Law No. 391 of 2019 for the reform of the class action, which will become effective starting from October 2020. See Sections IV.vi, IV.viii and IV.ix in this regard.

In 2018, the European Commission set up an expert group focused on product liability and new technologies. In this regard, the Commission announced that, owing to the work of this expert group, it will issue guidance on the Product Liability Directive and a report on the broader implications for liability and safety in relation to the employment of artificial intelligence, the Internet of things and robotics.

Based on our experience, businesses nowadays tend to pay an ever-increasing amount of attention to the topic of product and safety liability. A lot of them have developed internal policies of monitoring, control and audit to reduce related risks.
Chapter 8

JAPAN

Akihiro Hironaka, Kazuyuki Ichiba and Hidenori Sato

I  INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

Japan is a civil law country, with 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.

Initially, the core source of civil liability for defective products was tort liability under the Civil Code, Law No. 89 of 1896 (CC). However, to mitigate difficulties faced by victims of defective products in establishing tort claims against manufacturers and other entities responsible for product defects, the Product Liability Act, Law No. 85 of 1994 (the PL Act) was enacted to create strict liability (i.e., requiring no proof of negligence in association with the defect) in product liability claims. Tort liability can also be pursued even if 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:

a  to prevent defective products from being distributed in the market (e.g., government approval and licensing systems);

b  to prevent defective products in the market from causing damage or injury to consumers (e.g., recall and remedy systems); and

c  to provide prompt and effective relief to consumers who have actually suffered losses as a result of defective products (e.g., special measures or relief for losses caused by 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, as described in Section I. With respect to the administrative regulations, various administrative authorities oversee the safety of different categories of products, as explained below.

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1 Akihiro Hironaka is a partner, Kazuyuki Ichiba is a counsel, and Hidenori Sato is an associate at Nishimura & Asahi.
2 PL Act, Article 6.
i  Food safety

The Food Sanitation Act, Law No. 233 of 1947, governs administrative matters to prevent 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 (CAA). This Act provides standards for methods of producing, processing, using, cooking or preserving foods and additives, standards for the ingredients used in foods and additives, and procedures for investigating the causes of food poisoning and for reporting the results of investigations. In 2013, the Food Labelling Act, Law No. 70 of 2013, was enacted to regulate the mandatory labelling system for foods and additives, incorporating the regulations provided by the Food Sanitation Act, the Act Concerning Regulation of Agricultural Goods and Appropriate Labelling of Qualities, Law No. 175 of 1950, and the Act to Promote Health, Law No. 103 of 2002. The Food Labelling Act entered into force in 2015, and its regulations on foods and additives are administered by the CAA.

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. 145 of 1960, as amended by Law No. 84 of 2013 (the PMD Act). The MHLW administers the PMD Act. The PMD Act provides regulations concerning labelling, manufacturing methods, and false or exaggerated advertising of products. It is necessary to obtain approval from the minister of the MHLW to manufacture and market drugs and quasi-drug ingredients covered by this Act.³ The Pharmaceutical and Medical Devices Agency conducts safety testing of these products.

iii  Industrial products safety

An important statute establishing regulations for industrial products is the Consumer Product Safety Act, Law No. 31 of 1973 (the CPS Act). The Ministry of Economy, Trade and Industry (METI) and the CAA administer the CPS Act. The CPS Act provides a certification system called ‘PSC marks’, which mandate that manufacturers of products that pose high risks to the lives and bodies of consumers must comply with technical standards determined by the government, and require the placement of labels that satisfy national standards on such products.⁴ If a product lacks the required labelling, the government can order that certain measures be taken, including the recall of the products.⁵ If a product has caused a serious accident, the manufacturer and importer of the product must report the occurrence to the CAA.⁶ The CAA may then announce these incidents to the public.⁷ The CPS Act also provides certain measures to prevent accidents caused by prolonged use of products.⁸ Incidents that are not serious must be reported to the National Institute of Technology and Evaluation.

Other important, relevant statutes are the Electrical Appliances and Materials Safety Act, Law No. 234 of 1961; the Act on the Securing of Safety and the Optimisation of

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.
Japan

Transaction of Liquefied Petroleum Gas, Law No. 149 of 1967; and the Gas Business Act, Law No. 51 of 1954. The METI administers these acts, which also provide for 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 ensure the safety of vehicles. The Ministry of Land, Infrastructure, Transport and Tourism (MLIT) administers the RTV Act. The RTV Act requires that users of vehicles comply with mandatory safety standards that are issued by the MLIT under the RTV Act9 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 The RTV Act was revised in 2019 to include additional provisions to ensure the safe operation of autonomous vehicles.11

v  The Consumer Safety Act and the Consumer Affairs Agency
The administrative regimes explained above, depending on the category of the products, had shortfalls by which defective products were not regulated because the relevant products or defects 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 relating to 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.12 The CAA then collects information on the accident and responds with responsive measures.13

III  CAUSES OF ACTION
The PL Act defines a ‘product’ as a movable item that is manufactured or processed.14 Therefore, unprocessed agricultural products are not subject to the PL Act. The PL Act applies to manufacturers, processors and importers (the Manufacturer).15 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 in a manner that misleads others into believing that he or she is its Manufacturer.16 The PL Act also applies to any person who provides his or her name, trademark or other indication on a product and who may be considered substantially as the Manufacturer of a product in light of the manner and other circumstances under which the product is manufactured, processed, imported or sold.17 The PL Act will not

9  RTV Act, Article 40 et seq.
10  id., Articles 63-2 and 63-3.
12  Consumer Safety Act, Article 12(1).
13  id., Article 13 et seq.
14  PL Act, Article 2(1).
15  id., Article 2(3)(i).
16  id., Article 2(3)(ii).
17  id., Article 2(3)(iii).
provide a cause of action against distributors or sellers of a product if those persons are not among the entities specified above. Therefore, civil claims against distributors and sellers of a defective product (i.e., entities that may owe direct contractual liability to consumers) must be brought based on a warranty against defects, breach of contract or tort under the CC.

To prove liability under the PL Act, a plaintiff must establish:

a. a defect in the product;
b. damage to life, body or property; and
c. a causal link between the defect and the damage (i.e., causation).18

‘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 circumstances concerning the product.19 ‘Defect’ is interpreted to include defects in manufacture, design, and instructions or warnings. As mentioned above, it is said that the PL Act creates strict liability. However, the Supreme Court of Japan reviewed the foreseeability of the injury from the perspective of the defendant company, and denied the existence of defective instructions or warnings, in re Iressa, where a Japanese subsidiary of a UK pharmaceutical company was sued for an 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.’20

The Acts described in Section II provide for administrative sanctions against the responsible party where applicable. With respect to criminal liability, if a failure to exercise due care causes death or injury, a criminal penalty may be imposed on the responsible individual under the Penal Code, Law No. 45 of 1907.21

Conflict-of-law issues often arise in cross-border product liability cases. Japanese courts determine the applicable law by applying the Act on General Rules for Applications of Laws, Law No. 78 of 2006 (AGRAL), the Japanese code concerning conflict-of-law rules. AGRAL establishes the 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 claim shall be governed by the law of the place where the victim received delivery of the product.22 However, AGRAL also provides for an exception to this general rule, stating that if delivery of the product at a certain place is ordinarily unforeseeable, the law of the principal place of business of the manufacturer (or the other entities mentioned above) shall apply.23

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18 id., Article 3.
19 id., Article 2(2).
21 Penal Code, Articles 209-11.
22 AGRAL, Article 18.
23 id.
IV LITIGATION

i Forum

Civil product liability claims are determined by professional judges in national courts. No jury system exists for civil litigation in Japan.

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 civil product liability claims through ADR; for example, the Electric Home Appliances PL Centre and the Automotive Dispute Resolution Centre. In addition, 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 (the degree of proof), the Supreme Court of Japan defined the required degree of proof in Miura v. Japan, a medical malpractice case. In that case, the Supreme Court found causation of a patient’s injury resulted from 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, given the standard of ‘proof of a high degree of probability’. The Japanese standard is generally considered to be higher than a preponderance of evidence, but less than beyond a reasonable doubt.

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 (the ‘development risk’ or ‘state of the art’ defence). Furthermore, where the product is used as a component of or ingredient for another finished product, a manufacturer of the component or ingredient that is named as a defendant may be exempt from liability if the defendant successfully proves that the defect occurred primarily owing to compliance with instructions that were given by the manufacturer of the finished product, and that the defendant was not negligent with respect to the occurrence of the defect.

24 For general explanations of Japanese civil procedure, see Yasuhei Taniguchi, et al. eds., Civil Procedure in Japan (3rd ed.) (Juris Publishing, 2018), to which Akihiro Hironaka, one of the authors of this chapter, is a contributor.
26 PL Act, Article 4(i).
27 id., Article 4(ii).
In addition, the PL Act provides for the following limitations on the period after which a claim under the PL Act will be extinguished:

a  if the victim does not exercise his or her claim within three years (five years, if there was harm to life or body) of the time when he or she (or his or her legal representative) becomes aware of the damage and the party liable for the damages; or

b  10 years have elapsed from the time the product was delivered. In cases involving damage caused by substances that become harmful to human health when they accumulate in the body, or damage whose symptoms appear after a certain latent period, this 10-year period is calculated from the time when the damage occurred.28

As with tort claims under the CC, the prescriptive period is three years (five years, if there was harm to life or body) from the time the victim (or his or her legal representative) becomes aware of the damage and the identity of the perpetrator.29 A tort claim also cannot be brought when 20 years (or more) have elapsed from the time of the tortious act.30

Plaintiffs’ own negligence may be considered upon the determination of the amount of damages, and can be asserted in defending a product liability claim as a defence of comparative negligence, either under the PL Act or as a tort claim under the CC.31

Compliance with applicable regulations is considered one of the important factors in determining whether there is a defect in a product; however, non-compliance or compliance with applicable regulations, by itself, will not automatically give rise to or preclude liability.32

A majority of US states recognise the ‘learned intermediary doctrine,’ which states that a manufacturer of prescription medications and devices is released of its duty to warn users of the risks associated with its products upon warning the prescribing physician of the proper use and risks of the manufacturer’s product. The Supreme Court of Japan, in re Iressa, in denying the existence of defective instructions or warnings, stated that ‘it was known at least among physicians engaged in anti-cancer therapy targeting lung cancer that when interstitial pneumonia occurred owing to the administration of these drugs, including anti-cancer drugs, it could be fatal’.33 This ruling of the Supreme Court is similar to the ‘learned intermediary doctrine’ referenced above, in that the Court considered the knowledge of the addressee of the information in determining whether a defect existed in the instructions or warnings for the product.

iv  Personal jurisdiction

No specific provision for product liability claims

The Japanese Code of Civil Procedure, Law No. 109 of 1996 (CCP), contains a set of rules for domestic and international jurisdiction applicable to litigation in Japanese courts, but does not include an express provision for product liability claims. Under the prevalent view, product liability claims are classified as tort claims for purposes of determining jurisdiction.

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28  id., Article 5.
29  CC, Article 724(i), 724-2.
30  CC, Article 724 (ii).
32  See CAA, Consumer Safety Division, Chikujyô Kaisetsu Seizôbutsu Sekininhô (a commentary on the Product Liability Act) 82-83 (Shôjihômu, 2d ed. 2018).
With respect to international jurisdiction over tort claims, the CCP provides that the Japanese court has jurisdiction if the tort took place in Japan, unless the claim involves a wrongful act committed in a foreign country where the resulting damage occurred in Japan and the occurrence of such a result in Japan was ordinarily unforeseeable. Jurisdiction over international product liability claims will be determined pursuant to this provision. The stream-of-commerce doctrine, discussed in US courts, was not introduced when the CCP was revised to include international jurisdiction provisions in 2011.

The place where the tort took place

This phrase generally includes both the place where the wrongful act occurred and the place where the result occurred. The place of the wrongful act includes the place where the product was manufactured. Unless an advertisement on the internet constitutes part of the wrongful act, the advertisement itself does not constitute a basis for the jurisdiction of Japanese courts. On some occasions, allowing international jurisdiction at the place where the result of the tort occurred will cause substantial difficulties for the defendants. In such circumstances, it is likely that Japanese courts will not exercise international jurisdiction over the defendants, as an exception to the general rule.

Experts

The CCP has a set of provisions providing procedures for the examination of court-appointed experts. Where the issues to be determined by judges are highly specialised and difficult, the court can appoint experts to assist the judges with fact-finding. The court may order the expert to provide his or her opinion to the court in writing or orally. When an expert provides his or her opinion orally, the court may give both parties an opportunity to examine the expert, for purposes of impeaching an unfavourable opinion or to restore the credibility of a favourable opinion.

In Japanese practice, parties to 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 the court. Technically, these private experts are classified as ‘witnesses’ rather than ‘experts’ under the CCP, because they are not appointed by judges. However, these private experts also perform an important role.

The court may request assistance from experts not only for fact-finding purposes, but also to clarify issues and to increase the efficiency of proceedings. To enable the court to obtain such assistance, the court may appoint an expert commissioner in the proceedings.

Discovery

No extensive discovery system (as exists in the United States) exists in Japan; only limited document production requests are permitted. The Japanese discovery system, as explained below, is far from being an effective tool for litigants to request useful evidence from the other party or third parties.

34 CCP Article 3-3(viii).
35 Law No. 36 of 2011.
36 CCP Article 3-9. See also X v. Y, 70-3 Minshū 846 (Sup. Ct., 10 Mar. 2016) (claim dismissed in the Japanese court where related litigation was pending in Nevada state court in the US).
37 See CCP Article 213.
38 id., Article 92-2(1).
Request for document production order

A party may request that the court issue a document production order (DPO) against the other party or third parties. The CCP provides that the possessors of documents shall not refuse to produce the relevant documents in the following circumstances:

- where the possessor, as a party, has cited the document in his or her arguments in the action; the party applying for the DPO was otherwise entitled by law to possess or inspect the document; the document was executed for the benefit of the petitioner; or the document was executed with respect to a legal relationship between the petitioner and the possessor; and
- the document does not fall under any exemptions provided in the CCP.39

The exemptions provided for in (b) above are as follows:

- a document containing information with respect to which the possessor would have the right to refuse to testify, because the information is self-incriminating or incriminating to one’s family;
- a document containing a secret relating to a public officer’s duties;
- a document containing professional secrets, including documents obtained by lawyers and doctors through performance of their duties;
- a document containing technical secrets or secrets useful for occupations;
- a document held by the possessor exclusively for his or her own use; and
- 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,40 and courts meticulously scrutinise the necessity for issuing a DPO. If the court finds that the fact that the party is seeking to establish through a DPO is unnecessary for resolution of the dispute, the court will decline to issue the DPO. Japanese evidence law on civil cases does not have strict rules on admissibility of evidence. Therefore, in contrast with procedures in the United States, the court may admit evidence even if there is a danger that the evidence in question is unfairly prejudicial, confusing or misleading to the judges. Thus, whether a judge orders a DPO regarding ‘other similar incidents’ of a product defect, for example, depends on the judge’s interpretation of the ‘necessity’ of such evidence to deciding the issues in the current case.

Interrogatories

Before a lawsuit is instituted, or while the lawsuit is pending, a party may inquire of the opponent to request information regarding matters necessary for preparing allegations or proof.41 This system is analogous to the US interrogatory system, but in practice this process is not frequently used in Japan.

Depositions

No system for taking the depositions of parties, witnesses or experts exists in Japan.

39 id., Articles 220(i)–(iv).
40 id., Article 181(1).
41 id., Articles 132-2, 163.
Evidence preservation proceedings

A party (petitioner) may request that the court issue an order to preserve the evidence, if the petitioner provides prima facie evidence that circumstances exist in which it will be difficult to examine evidence, including circumstances where the other party may spoil evidence. The order is granted pursuant to an ex parte hearing requested by the petitioner, and the other party is notified of such an order only several hours before the judge implements the preservation order, which may avoid the other party spoiling the relevant evidence.

vii  Apportionment

When multiple entities are involved in a product liability case, the entities are jointly and severally liable for liability under the PL Act or in tort. A named defendant that has compensated the victim in excess of the damages that the defendant is required to bear may seek reimbursement 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. 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 torts. In practice, plaintiffs bringing mass tort actions have been solicited through announcements on the internet and by other methods.

In 2013, a new law relating to collective actions relating to consumer contracts was promulgated, which came in force in 2016: the Act on Special Measures Concerning Civil Court Proceedings for the Collective Redress for Property Damage Incurred by Consumers, Law No. 96 of 2013 (the Collective Redress Act). This Act provides for two-stage proceedings: during the first stage, a certified qualified consumer entity files a lawsuit and, if the defendant loses at the first stage, either entirely or in part, the certified qualified consumer entity files a second stage proceeding, to which individual consumers may opt-in to confirm their individual damages. This Act permits collective claims to be brought against business operators for recovery of damages suffered by consumers relating to consumer contracts. A plaintiff consumer generally must have privity of contract with the business operator for the relevant claims to be eligible under this system. Therefore, it is difficult to use this collective redress system to sue a manufacturer for product liability claims, where manufacturers usually lack a direct contractual relationship with consumers. Furthermore, lost profits, personal injury, and pain and suffering are expressly excluded from the scope of claims that can be brought under the Collective Redress Act. Therefore, in the context of this publication, the Collective Redress Act is relevant only when, for example, many consumers purchased defective products from a retailer, and the consumers collectively claim return of the purchase price of the product from the retailer. If the retailer loses the case, the retailer will seek...

42  id., Article 234; Rules of Civil Procedure, Article 153(3).
43  See CAA, Consumer Safety Division, footnote 32, at 137–38.
44  The Collective Redress Act, Articles 3(2)(i)–(vi).
reimbursement (for the damages paid) from the manufacturer responsible for the defect in a separate, regular lawsuit. Since the Collective Redress Act entered into force, only three collective redress cases have been filed, none of which is related to product defects.

ix Damages

Recovery of economic damages, including lost profits and non-economic damages such as pain and suffering, is permitted in product liability cases under Japanese law, regardless of whether the claim is brought in breach of contract, tort, or under the PL Act. The remedy for damages is monetary compensation. The amount of damages is determined by the judge because no jury system exists in Japan. There is no law limiting the amount of damages that may be ordered. However, Japanese law does not allow punitive damages. Punitive damages awarded in foreign litigation or arbitration will not be recognised in Japan, because they infringe upon public policy in Japan.

The PL Act limits its application to claims for damage arising from an infringement of life, body or property caused by a defect in a product. However, damages that occur only with respect to the defective product may be claimed only if they are aggregated with the other types of recoverable damages described above.

Criminal liability is explained in Section III.

V YEAR IN REVIEW

The first edition of the Product Regulation and Liability Review (2014) discussed mass damages to consumers caused by a facial soap, called ‘Droplet of Tea’, in Japan. The product at issue was a green tea-based cleansing bar of facial soap valued for its natural purity. This facial soap was treated as an over-the-counter drug and defined as a medication purchased without advice from pharmacists. The facial soap contained a hydrolysed wheat protein (product name: Glupearl 19S) and triggered immediate-type systemic wheat allergy; some users developed serious symptoms, including anaphylaxis and similar states of shock. The number of sufferers was reported to be approximately 2,000, approximately 1,300 of whom filed lawsuits in 28 district courts across Japan. Some courts rendered judgments in the first instance in 2018 and 2019.

These courts found that the facial soap was defective. For example, one court held essentially as follows: the frequency and seriousness of the damage significantly exceeded those expected during regular use of the facial soap, and the efficacy and social usefulness of the soap were not as imperative as medicines; moreover, the actual labelling on the soap could not be expected to prevent occurrence, or aggravating, of the damage, and Glupearl 19S was not indispensable to manufacturing a facial soap of the same efficacy. In addition, the damage exceeded the seriousness that common sense can tolerate.

45 CC, Article 722(i), 417; PL Act, Article 6.
46 For punitive damages awarded in a foreign court, see Northcon I, Oregon Partnership v. Mansei Kōgyō Co Ltd, 51-6 Minshū 2573 (Sup. Ct., 11 July 1997).
47 PL Act, Article 3 proviso.
With regard to the ingredient Glupearl 19S, the conclusions in the courts’ decisions were split. Hydrolysed wheat protein is a generic material, which was contained in 19 medications and cosmetics at that time. Some courts found that Glupearl 19S was not defective.\textsuperscript{50} One court held that the relationship between Glupearl 19S and the final product was weak, and that the ingredient did not necessarily trigger the damage; this was considered largely due to the design of the final product.\textsuperscript{51} The other courts held that Glupearl 19S was defective.\textsuperscript{52} One court held that, considering the seriousness and probability of the damage, the material was defective.\textsuperscript{53}


\textsuperscript{53} X v. K.K. Yuuka, 2418 Hanrei jihô 38 (Fukuoka Dist. Ct., 18 July 2018).
I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK


As it is based on European Community (EC) Directives, the Portuguese product liability system is, therefore, based on strict liability; that is, liability without fault on the part of the manufacturer. This is an exception in Portuguese law, and the Product Liability Law provides for a unique liability system. In Portugal, there are two different but related liability systems: one based on the general rules on civil liability (contractual liability and liability in tort) and another formed by the special rules based on strict liability contained in the Product Liability Law.


Before the enactment of the Product Liability Law, there were only a few scholarly works on product liability. Recently, the number of publications by legal scholars on product liability has seen a marked increase, as has the case law.

In addition to these rules, Article 60 of the Portuguese Constitution includes the basic provisions governing consumers’ rights. According to Article 60(1):

Consumers shall have the right to the good quality of the products and services they consume, to education and to information, to the protection of their health, safety, and economic interests, as well as to the compensation for damage.

The first Portuguese Consumer Protection Law was passed in 1981 by Law No. 29/81 of 22 August. This Law has been repealed by the Consumer Protection Law, which was approved by Law No. 24/96 of 31 July 1996, as amended. Article 3 of the Consumer Protection Law acknowledges a number of rights for the benefit of consumers, such as the rights to:

a good quality of goods and services;

b protection of health and physical security;

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1 Joana Mota is a managing associate and Alexandre Pedral Sampaio is a senior associate at Uría Menéndez — Proença de Carvalho.
Based on the rights laid down in Article 3 of the Consumer Protection Law, Article 12 of the Law sets the specific provision on the right to the prevention of damage and recovery of damages. Under this provision, the consumer is entitled to be compensated for any property damage or personal injuries resulting from defective goods or services. The producer is also responsible, even if there is no fault on its part, for the damage caused by defects in products it places in the market.

Additionally, Decree-Law No. 67/2003 of 8 April, as amended (the Sale of Consumer Goods Law), applies to contracts for sale of consumer goods, including the repair and replacement of defective products.

In this respect, it is also important to refer to Decree-Law No. 69/2005, transposing the Product Safety Directive (Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety), which provides for general rules on consumer rights regarding the safety of products and services, pursuant to Article 60(1) of the Portuguese Constitution and of Article 5 of the Consumer Protection Law.

Finally, specific aspects that give rise to product liability are governed by provisions of the Civil Code, more specifically when the rules described above do not apply (e.g., pre-contractual liability, some aspects of contractual liability, termination of the contract).

II REGULATORY OVERSIGHT

In Portugal, the main authority responsible for enforcing consumer rights is the Directorate General of Consumers (DGC). This authority ensures the proper functioning of the European Consumer Centre in Portugal. Moreover, the DGC is the single liaison office for the purposes of application of Regulation (EU) 2017/2394 of the European Parliament and of the Council of 12 December 2017, in its current version, on cooperation between national authorities responsible for the enforcement of consumer protection laws. Also, the DGC is the national point of contact for the EU Rapid Alert System (the RAPEX System) for non-food dangerous products and is responsible for the management of the RAPEX network in Portugal, which is made up of the national market control entities.

Moreover, the Authority for Economic and Food Safety is the regulatory authority, and also the criminal police body, primarily responsible for supervising and preventing compliance with the regulatory legislation for the exercise of economic activities in the food and non-food sectors, as well as the evaluation and communication of risks in the food chain. It is the national liaison body, with counterparts at European and international levels.

Also, other sectorial administrative bodies, such as Infarmed (the National Authority for Pharmaceuticals and Health Products), have responsibility in monitoring and overseeing the quality and safety of medical products and medical devices.
Finally, although not public bodies, consumer protection non-government organisations, such as the Portuguese Association for Consumer Defence, play an important role in raising awareness of possible defects in products through independent testing and reviews.

III CAUSES OF ACTION

Manufacturers’ liability is based on strict obligations. According to Article 1 of the Product Liability Law, which states the basic principle applicable to this matter: ‘The manufacturer is liable, irrespective of any fault on its part, for damage caused by defects in the products it has put into circulation.’

Examining this provision, the relevant aspects are that:

a) the manufacturer’s product must have been put into circulation;
b) there must be a defect in the product;
c) there must have been damage; and

d) this damage must have been caused by the defect in the product.

In such cases, the manufacturer will be liable, even if there is no fault on its part, which, as given above, is an exception in Portuguese private law. Article 483(1) of the Civil Code states the general principle on liability in tort:

Any person who, either deceitfully or negligently, unlawfully violates somebody else's right or any legal provision aimed at the protection of the interests of others, shall be bound to indemnify the injured person in respect of the damage caused by the violation.

Article 483(2) of the Civil Code states that ‘only where specifically provided for by the law shall there be an obligation to indemnify beyond fault.’

The concept of a defect is defined by Article 4 of the Product Liability Law. Article 4(1) states:

A product is defective when it does not provide the safety which may be legitimately expected from it, taking all circumstances into account, including its presentation, the use to which it is reasonably expected to be put, and the moment it was put into circulation.

This definition adopts the provisions of Article 6 of the Product Liability Directive, which is that a defective product is one that lacks safety and is likely to cause damage to persons and property. However, what is important is not so much the product’s fitness for the purpose for which it is intended, but the degree of safety that consumers may legitimately expect from the product.

This safety must be ascertained taking into account all relevant circumstances – with special reference being made to the presentation of the product, its expected use and the moment when the product was put into circulation.

The concept of manufacturer used by the Product Liability Law is very broad, as is mentioned expressly in the preamble to the Law.

According to Article 2 of the Product Liability Law, ‘manufacturer’ means the producer of the finished product, of a component part or of any raw material (the effective manufacturer), as well as any other person who holds itself out as manufacturer by putting
its name, trademark, or any other distinguishing feature on the product (the apparent manufacturer). In addition, specific categories of importers and suppliers are deemed manufacturers (presumptive manufacturers) for the purposes of the Product Liability Law.

Strict liability is imposed on the manufacturer for damage caused by defective products, though specific defences are available to reduce or exempt liability. Strict liability requires only that the product was put into circulation, that there was damage or injury and that the defective product caused the damage or injury. When the defect may be attributed to others, such as the producer of components or raw materials, the liability may be joint and several.

The Product Liability Law provides that damages in the case of product liability are limited to those related to death or personal injuries and damage to any item of property other than the defective product itself. The Consumer Protection Law sets forth provisions for the right to recovery of damages, while the Civil Code governs contractual liability and liability in tort.

As regards contractual liability, under Article 2 of the Sale of Consumer Goods Law (as amended by Decree-Law No. 84/2008), the seller is required to comply with the sale and purchase agreement in respect of delivery of goods. According to Articles 4, 6 and 7 of the Sale of Consumer Goods Law, in cases of non-conformity, the consumer will be entitled to repair or replacement of the product, or to an appropriate price reduction, or termination of the contract.

The rules of the Civil Code regarding contractual liability apply when dealing with other products that are not consumer goods (e.g., in sales agreements for professional use). The remedies set forth in the Civil Code are very similar to the ones set forth in the Sale of Consumer Goods Law (see above).

IV  LITIGATION

i  Forum

In respect of civil proceedings, product liability claims may either be decided by a judge or a panel of judges:

- in a judicial court;
- by an arbitrator or an arbitral court; or
- by justices of the peace (if the value of the claim does not exceed €15,000).

There are no jury trials in civil proceedings under Portuguese law.

With respect to criminal proceedings, any potential criminal liability will be determined by a judge or a panel of judges in criminal courts following an indictment by the public prosecutor, a charge by the injured party, or both. Although there may be jury trials in specific criminal proceedings (depending on the type of crime) under Portuguese law, they are very rarely used and, most likely, would not have jurisdiction over product liability cases.

The organisation of the Portuguese judicial system, which is unitary and uniform throughout the territory, is regulated by Law No. 62/2013 of 26 August. Judicial courts are divided into courts of first instance (at least one per judicial district), courts of appeal (five throughout the country) and the Supreme Court of Justice. Although the Portuguese judicial system has three levels of ordinary courts, in civil matters the decisions of the courts of first instance could potentially only be subject to appeal if the value of the claim exceeds €5,000 and decisions of the courts of appeal could potentially only reach the Supreme Court (in which case the scope of review would be limited to the control of the application of the law).
if the value of the claim exceeds €30,000. In criminal matters, although there are no general limitations to appeals of court decisions, there may be specific limitations depending on the type of crime and the penalty incurred.

As mentioned above, civil liability in product liability cases may also be heard by an arbitrator or an arbitral court under the Portuguese Voluntary Arbitration Law (Law No. 63/2011 of 14 December), provided that both the claimant and the defendant agree to settle their dispute in this way. There are also consumer arbitration centres created under Decree-Law No. 425/86 of 27 December and Law No. 144/2015 of 8 September, as amended, although for some centres their jurisdiction is limited to cases where the value of the claim does not exceed €5,000.

Finally, certain product liability-related administrative offences may give rise to fines to be applied by the competent administrative authorities following administrative proceedings. These fines may be appealed against in an administrative court.

ii  **Burden of proof**

*Administrative and criminal liability and general remarks on civil liability*

In administrative and criminal proceedings, the burden of proof lies with the entity prosecuting the case, who must prove the facts that uphold its allegation.

In civil proceedings, as a general rule under Portuguese law, the burden of proof also lies with the party that makes the allegation and wishes to rely on the facts invoked in the claim. Although the obligation to indemnify (set out in Articles 562 et seq. of the Portuguese Civil Code) has a sole framework applicable both to contractual claims (whose general regime is set out in articles 798 et seq. of the Portuguese Civil Code) and tort claims (set out in Articles 483 et seq. of the Portuguese Civil Code), whereas in tort claims the damaged party must prove the fault of the alleged offender, this fault is presumed in contractual claims as per Article 799 of the Portuguese Civil Code. Apart from this, in both tort and contractual liability claims the damaged party must prove:

- a voluntary action or omission of the offender (corresponding to a breach of a general obligation in tort claims or of a contract in contractual claims);
- the unlawfulness of such action or omission;
- a damage; and
- the causal link between the damage and the action or omission, which is assessed according to the adequate causation theory in light of Article 563 of the Portuguese Civil Code, which states that ‘[t]he obligation to indemnify shall only exist in respect of those damages that the damaged party would probably not have suffered should the injury not have taken place.’

*Product Liability Law*

Under the Product Liability Law, given the strict nature of the manufacturer’s liability, the damaged party shall only bear the burden to prove the damage, the defect in the product and that the defect was the relevant (adequate) cause of the damage.
**Sale of Consumer Goods Law**

Under the Sale of Consumer Goods Law, even though the seller's or the manufacturer's liability (or both) is not strict, its fault in the non-conformity of the goods sold under the terms of the relevant contract is presumed if the goods:

- do not comply with the description given by the seller or do not possess the qualities of the goods that the seller has provided to the consumer as a sample or model;
- are not fit for the specific use that the consumer applies to them, provided that the consumer made the seller aware of such use and the latter accepted it;
- are not fit for the use for which goods of the same type are normally used; or
- do not have the standard qualities and performance of goods of the same type and that a consumer could reasonably expect, based on the nature of the goods and, if applicable, to their public presentation (in particular, advertising or labelling).

In light of the above and considering that fault is presumed, the consumer only bears the burden to prove the non-conformity of the goods with the contract and the causation between such non-conformity and the damage caused to it (this being the impossibility of using the goods as expected).

**iii Defences**

**Product Liability Law**

Article 5 of the Product Liability Law provides for several defences available to the manufacturer. In particular, it shall not be held liable if it proves one (or more) of the following:

- that it did not put the defective product into circulation;
- that, having regard to the circumstances, it is probable that the product was not defective at the time it was put into circulation;
- that 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 its business;
- that the defect is due to compliance of the product with mandatory regulations issued by the public authorities;
- that the state of scientific and technical knowledge at the time when it put the product into circulation was not such as to enable the existence of the defect to be discovered; and
- that, in the case of a component of a product, 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.

Another defence available to the manufacturer is provided by Article 7(1) of the Product Liability Law, according to which the liability of the manufacturer may be reduced or disallowed when, having regard to all the circumstances, the damage is caused both by a defect in the product and by the fault of the damaged party. However, no such defence shall apply and hence, the manufacturer's liability shall remain in full effect, if:

- although, having contributed to the damaged caused by the defective product, the damaged party did not act with intent, recklessly or with serious negligence; or
- the fault that contributed to the damage was of a third party.
Should there be such a contributory fault by the damaged party, the court (or other authority hearing the case) may, taking into consideration the circumstances of the case, either:

a determine the full indemnification of the damages (if contribution or fault of the damaged party was not relevant when compared to the defect of the product); or

b reduce or even disallow the payment of an indemnity (if, on the contrary, the defect of the product played a very minor role in the damage when compared to the contribution of the damaged party).

There are also certain situations that are not mentioned in the Product Liability Law but that could constitute defences available to the manufacturer. In particular, when a person has assumed the risk of using a defective product despite having been made aware of its defectiveness, the manufacturer should not be held liable for the damages caused by the product. In addition, it is currently understood that the force majeure defence is available to a manufacturer of defective products and that his or her liability may be reduced or even excluded as a consequence of this.

On a separate note, Article 11 of the Product Liability Law provides for a three-year limitation period for the right to claim damages, starting from the date on which the damaged party became aware, or should have become aware, of the damage, defect and identity of the manufacturer. In addition, according to Article 12 of the Product Liability Law, the rights of the damaged party to recover damages will lapse 10 years after the date the product was put into circulation, unless he or she has submitted a claim to court (or to another authority competent to hear the case) within this period.

Sale of Consumer Goods Law

Pursuant to Article 6 of the Sale of Consumer Goods Law, if the consumer directly demands that the manufacturer of a defective product repairs or replaces it, and provided that such demand is not impossible or disproportionate taking into account the value the product would have if there were no lack of conformity; the significance of the lack of conformity; and whether the alternative remedy could be completed without significant inconvenience to the consumer, the manufacturer may oppose the consumer’s claim based on any of the following grounds:

a that the defect results solely from the seller’s statements about the product and its use;

b that the product was not put into circulation by it;

c that, under the circumstances, it can be assumed that the product was not defective at the moment it was put into circulation;

d that the product was neither manufactured by it for sale or any form of distribution with the purpose of earning profit, nor manufactured or distributed by it in the course of its business; and

e more than 10 years have lapsed since the product was put into circulation.

iv Personal jurisdiction

Under Article 7 of Regulation (EU) No. 1215/2012 of the European Parliament and of the Council of 12 December 2012, applicable in Portugal as a Member State of the European Union, a manufacturer domiciled in the European Union may be sued in Portugal:

a in matters relating to a contract – if Portugal is the place of performance of the obligation in question (e.g., if the sale was made in Portugal or if the product was delivered or should have been delivered in Portugal, regardless of the fact that the product is, or is not, advertised in Portugal); and
in matters relating to tort, delict or quasi-delict – if Portugal is the place where the harmful event occurred or may occur. In claims of this nature, it is arguable whether the harmful event would be the actual occurrence of the damage caused by a defective product (in which case, the place where the product was manufactured, sold or advertised would play no role at all and the Portuguese courts would have jurisdiction to hear any claim where the damage occurred in Portugal) or if such harmful event would be the putting into circulation of the defective product (in which case, for the Portuguese courts to have jurisdiction over such claims the product would have to be either manufactured, sold or advertised in Portugal, or, at least, to a Portuguese audience).

If the manufacturer is not domiciled in a European Union Member State, pursuant to Article 62 of the Portuguese Civil Proceedings Code, the Portuguese courts would have jurisdiction to hear claims where:

- the element (or part thereof) that constitutes the cause of action to a claim was carried out in Portugal;
- the right invoked by the damaged party may not be effective unless the claim is brought to the Portuguese courts; or
- there are considerable difficulties for the damaged party to make a claim to a foreign court.

**v Expert witnesses**

There is no obstacle to the intervention of expert witnesses in Portugal. In fact, both the parties and the court or arbitrators may retain industry experts, or experts of another nature, to testify as part of their defence (in the former case) or to perform an independent expert analysis that would help the court or arbitrator to reach its decision (in the latter case).

The testimony, reports or evidence produced by experts are freely considered by the court or arbitrator and should not bind the latter.

**vi Discovery**

The common-law style of discovery is not available in Portugal, as there is no general disclosure procedure in the Portuguese legal system. However, pursuant to the inquisitorial principle and the principles of cooperation and good faith between all the parties intervening in the proceedings that, among other things, regulate Portuguese civil proceedings, whenever one of the parties justifiably claims a serious difficulty in obtaining a document, the court shall attempt to achieve the removal of that obstacle. For instance, the parties shall respond to or provide, as applicable, whatever is asked from them with relevance to the case and submit themselves to the necessary inspections ordered by the court. In addition, the parties are entitled to appoint as witness any person they wish, who is obliged to appear before the court or otherwise be subject to the payment of a fine. Parties can also request the deposition of the counterparty regarding unfavourable facts, for the purpose of obtaining a confession.

**vii Apportionment**

As a general rule under Portuguese law, if damage is caused by multiple parties, their liability is joint and several in tort claims and joint (but not several) in contractual claims.

When it comes to damage caused by defective products under the Product Liability Law, pursuant to Article 6 thereof, if several people are responsible for the damage they will
be jointly and severally liable. When it comes to the internal relations between such people, the circumstances of the case shall be taken into consideration, in particular the risk created by each person, the degree of fault of each person and the respective contribution for the occurrence of the damage. If there is doubt regarding the role played by each person involved, their liability shall be divided equally between them.

In the case of a lack of conformity of a product with the contract of sale under the Sale of Consumer Goods Law, as an exception to the general rule referred to above, in addition to the joint and several liability of the seller and the manufacturer of a product, the representative of the manufacturer in the area where the consumer is domiciled is also jointly and severally liable towards the consumer (the same defences referred to in Section IV. iii will be available to that representative). Also, pursuant to the Sale of Consumer Goods Law (Article 7), a seller before whom the consumer’s rights referred to in Section III have been exercised has a right of redress against the professional from whom the product was purchased for all damage caused by the exercise of the consumer’s rights.

Where the final seller is liable to the consumer because of a lack of conformity resulting from an act or omission by the manufacturer, a previous seller in the same chain of contracts or any other intermediary, the final seller is entitled to pursue remedies against the person or persons liable in the contractual chain.

viii Mass tort actions

Pursuant to Article 52.3 of the Portuguese Constitution, Article 2.1 of Law No. 83/95, of 31 August and Article 31 of the Portuguese Civil Proceedings Code, any citizen or association defending specific general interests, such as consumer rights, may submit claims to protect those general interests (citizen’s actions), including to request the corresponding indemnification on behalf of the damaged parties. In these citizen actions, the claimant represents, by its own initiative, all the remaining right-holders in question (who have not opted out after being given the chance to do so by the court) without the need for an express mandate or authorisation.

In addition to the citizen’s action referred to above, pursuant to Article 36 of the Portuguese Civil Proceedings Code, it is possible for several claimants to consolidate their claims into a single proceeding, without any limitation as to the number of claimants, provided that they have the same cause of action (e.g., the same type of defective product caused damage to several persons who bought it). However, the court may decide to separate the claims if it understands that a serious inconvenience would arise if the claims were to be heard jointly.

Some of the advantages resulting from both types of actions referred to above include:

- the reduction of legal costs to the interested parties;
- the reduction of the number of claims reaching the court system (this is particularly noticeable in citizen’s actions, due to the potentially large number of people covered by such actions) and;
- in relation to citizen’s actions, the fact that they may benefit people who would have never made an individual claim and, hence, would otherwise not have benefited from the result of the claim.

The main disadvantages of these actions are their complexity and, possibly, the longer duration of the proceedings.
ix  Damages

Only damages that have been caused by defects in products (and not the matter of causation) are covered by the Product Liability Law. The general provisions concerning the obligation to indemnify, causation and indemnifiable damages apply, in particular Article 563 of the Portuguese Civil Code, as referred to in Section IV.ii. However, pursuant to Article 8 of the Product Liability Law, the recoverable damages in the case of product liability are limited to those related to death or personal injuries and to property other than the defective product, provided, in the latter case, that such damages exceed €500. In addition, recoverable damages are limited to those caused to property of a type ordinarily intended for private use or consumption and that has mainly been used in such way by the damaged party.

In specific cases, the ‘private use’ criterion may be of limited use, especially in respect to items of property normally used for both private and professional purposes. In any event, the damaged party will bear the burden of proving the prevalent private use of such items of property.

There is no maximum amount of damages that may be recoverable.

V  YEAR IN REVIEW

During 2019, Directive (EU) 2019/2161 of the European Parliament and of the Council of 27 November 2019, as regards the better enforcement and modernisation of EU consumer protection rules, was enacted. Member States shall transpose this directive into their legal systems by 28 November 2021 and apply the measures necessary to comply with it from 28 May 2022. In addition, Regulation (EU) 2017/2394 of the European Parliament and of the Council of 12 December 2017, on cooperation between national authorities responsible for the enforcement of consumer protection laws, which entered into force on 1 January 2019, commenced its application on 17 January 2020.

At a national level, no significant changes have occurred in the past year as regards product liability from a case law perspective.

The market for product liability is primarily based on injured parties suing producers or vendors directly. Insurance companies may be called upon to participate in judicial proceedings, mostly upon the request of the producers or vendors, and they generally adhere to the same line of defence prepared by them.
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 on the civil law tradition. The Civil Code is the basic source of law in many areas of private law, including tort law. Puerto Rican courts frequently rely on three sources of law: written law, judicial opinions and the work of treatise writers. Treatise writers are scholars who author detailed commentaries on the civil law, just like scholars who analyse the common law.

However, owing to Puerto Rico’s relationship with the United States, which began with the 1898 Treaty of Paris, common law has heavily influenced local legislation, judicial opinions and legal commentary. 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.’

Product liability is an area heavily influenced by common law. The doctrine of strict product liability cannot be found in the Civil Code; however, to ‘fill a gap in our body of laws’ 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.

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1 Albéniz Couret-Fuentes is a partner and Elaine M Maldonado-Matías is a managing partner at Sepulvado, Maldonado & Couret.
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 United States).
5 In re Dupont Plaza Fire Litigation, 687 F. Supp. at 727.
7 Isla Nena Air Servs., Inc. v. Cessna Aircraft Co., 449 F.3d 85, 92 (1st Cir. 2006).
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, the call fell on deaf ears. Hence, product liability law remains an area largely governed by case law.

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;

b the Department of Natural and Environmental Resources, which, among other things, is charged with implementing Puerto Rico's constitutional and statutory public policy on environmental matters 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.

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.

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." A plaintiff ordinarily needs to establish three elements: damage, the causal relationship between the damage and the act or omission, and that the act or omission was negligent or wrongful. 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.

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.
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.\(^\text{19}\) Puerto Rico law currently recognises the application of the strict liability doctrine for many claims involving:

a. design defects;

b. manufacturing defects; and

c. defects for failure to provide adequate instructions or warnings.\(^\text{20}\)

For these claims, the Court eliminated the requisite negligence factor of a general tort claim.\(^\text{21}\) 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.\(^\text{22}\)

In *González Pagán v. JR Seafood*,\(^\text{23}\) the Puerto Rico Supreme Court held that claims for damages caused by products that are not manufactured or fabricated (contaminated shrimp in that case) do not trigger the strict liability doctrine. The Court explained its conclusion by emphasising that, under Puerto Rico law, the doctrine of strict product liability seeks to protect the consumer from the manufacturer's failure to provide a safe product. Therefore, claims related to products whose dangerous condition was not caused by human intervention do not implicate the liability doctrine's protection.\(^\text{24}\)

**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'.\(^\text{25}\) Puerto Rico has generally adopted the principles of strict liability set out in the Restatement (Second) of Torts Section 402A,\(^\text{26}\) which provides that:

\[
\text{[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.}
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\(^{21}\) *Rivera Santana*, 132 D.P.R. at 126 n.5.

\(^{22}\) \(\text{id.}\)

\(^{23}\) 199 DPR. 234 (2017).

\(^{24}\) *González Pagán v. JR Seafood*, 285 F. Supp. 3d 502, 504-05 (D.P.R. 2018) (discussing the Puerto Rico Supreme Court's holding). The question answered by the Puerto Rico Supreme Court had been certified by the federal District Court via a process by which a federal court asks a state's highest court to clarify an unsettled question of 'state law'. See generally Jona Goldschmidt, *Certification of Questions of Law: Federalism in Practice* (1995).

\(^{25}\) *Malavé-Félix v. Volvo Car Corp.*, 946 F.2d 967, 971 (1st Cir. 1991).

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.27

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.28 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’.29 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’.30 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 outweigh the risk inherent in the design.31 Where the defect in question involves complex and technical issues, ‘particularly within the knowledge of the manufacturer’, the risk-utility analysis applies.32

In a negligent design claim the plaintiff must establish that:

a the defendant owed a duty to prevent the harm by conforming to a reasonable standard of conduct;
b the defendant breached that duty through a negligent act or omission; and
c the negligent act or omission caused the plaintiff’s harm.33

The plaintiff bears the burden of establishing the applicable standard of care and proving that the defendant acted below the standard.34

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, Inc35 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.’36

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. . . . 37 [A] product’s mere failure to function, in and of itself, is insufficient to prove a design defect.38

27 id., (citing Montero Saldaña).
29 Barker, 573 P.2d at 446.
30 Quintana-Ruiz, 303 F.3d at 77.
31 id.
32 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 [. . .]’).
34 Fremaint, 258 F. Supp. 2d at 28.
35 327 P.2d 897, 901 (Cal. 1962).
36 Rivera Santana, 132 D.P.R. at 127.
37 id., at 125–26 (quoting Greenman, 377 P.2d at 900) (internal quotation marks omitted).
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’.39 These claims require showing that:

a  the manufacturer knew or should have known of the product’s inherent risk;

b  warnings or instructions were not provided or those provided were inadequate;

c  the absence or inadequacy of the warnings made the product inherently dangerous; and

d  the absence of adequate warnings or instructions was the proximate cause of the injury.40

A negligent failure to warn claim requires a showing that the defendant ‘failed to exercise due diligence to avoid foreseeable risks’.41 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.42

In 2016, the Puerto Rico Supreme Court’s decision in Rodríguez Méndez v. Laser Eye43 addressed whether a manufacturer can be strictly liable for damages arising in relation to inadequate maintenance of a product after purchase. Rodríguez summarises and reiterates much of the prior case law on strict product liability but also provides 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 risks inherent in the inadequate use of the product, such as not providing proper maintenance, and did not warn or provide adequate instructions about such risks and about proper maintenance.44 In other words, insufficient instructions about adequate maintenance can lead to strict liability under a failure-to-warn claim.45 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.46

iv Breach of warranty

Articles 1373-1375 of the Civil Code47 require certain product quality warranties. A cause of action for violation of this duty requires showing that the defect: was hidden or concealed; was unknown to the purchaser at the time of the sale; is harmful to the utility of the product; and existed before sale.48 The purchaser may choose to rescind the contract (redhibitory action) or demand a proportional reduction of the sale price (quantí minorís action).49

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39 Rivera Santana, 132 D.P.R at 130.
42 Prado Álvarez, 313 F. Supp. 2d at 76.
43 195 D.P.R. 769 (2016).
44 id., at 784.
45 id., at 788.
46 id., at 783 (citing Hoover v. New Holland N. Am. Inc., 11 N.E. 3d 693, 702 (N.Y. 2014)).
47 31 L.P.R.A. Sections 3841–43.
49 Simonet, 506 F. Supp. 2d at 84. The consumer may also seek quantí minorís remedy when a product does not comply with an express warranty. id.
However, since the 1953 case *Castro v. Payco, Inc*, Puerto Rico recognised a cause of action for breach of implied warranties based partly in the Puerto Rico Food, Drugs, and Cosmetic Act, and modelled on the doctrine developed in Louisiana. These actions are, in essence, strict liability claims. 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.

**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 a federal court to demand a trial by jury, since Puerto Rican law does not provide for jury trials in civil cases. Mainly, plaintiffs can file a claim in a federal court either when:

a. it is asserted in a case that raises a federal question;

b. under the court’s diversity jurisdiction, when all the plaintiffs and the defendants reside in different ‘states’; and

c. under the court’s admiralty jurisdiction.

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50 75 D.P.R. 63 (1953).

51 In re Dupont Plaza Fire Litigation, 687 F. Supp. at 787.


54 See Gonzalez-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).

55 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)).

56 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).

57 id., Section 1333 (admiralty jurisdiction).
Cases filed in Puerto Rican courts that are nonetheless removable to a federal court 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 a federal court because the proceedings in Puerto Rican cases are mostly in Spanish. English-language proceedings in a 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.

ii  Burden of proof

Plaintiffs have the burden to establish the elements of the causes of action in Puerto Rican product liability cases. 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. Manufacturing defect claims where the 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, the plaintiff bears the burden of proving timeliness.

iii  Defences

Statutes of limitation

In Puerto Rico, the statute of limitations is substantive law, not a procedural matter. A one-year limitations term applies to product liability claims under Article 1802.
The limitations term begins when the injured person has actual or constructive notice of the injury and knowledge of the identity of the tortfeasor. 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.

The law on statutes of limitation has been subject to important developments during recent years. In its 2012 decision in Fraguada Bonilla v. Hosp Aux Mutuo, the Puerto Rico Supreme Court held that commencing an action against a tortfeasor no longer tolls the statute of limitations for claims against absent joint and several tortfeasors. Expanding on Fraguada, in the 2016 decision in Maldonado Rivera v. Suárez, the Court 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 from the final judgment.

Claims for breach of implied warranty owing to hidden defects under Articles 1373–1375 are subject to a six-month limitations term. The term runs from the day on which the parties’ efforts to solve the dispute are ‘interrupted’.

Intervening cause

‘Intervening causes can break the chain of causation if they are not foreseeable.’ 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”’.76

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. 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.

Comparative fault or negligence

Under Article 1802, a plaintiff’s fault or negligence causes a corresponding reduction of its compensatory damages. This doctrine applies to strict liability and negligence product liability claims.

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67 González-Pérez v. Hosp. Interamericano de Medicina Avanzada, 355 F.3d 1, 2 (1st Cir. 2004).
68 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).
71 195 D.P.R. 182 (2016).
72 Maldonado, 195 D.P.R. at 212.
73 Article 1379 of the Civil Code, 31 L.P.R.A. Section 3847.
74 Ferrer Delgado v. General Motors Corp., 100 D.P.R. 246, 256 (1971).
75 Malavé-Félix, 946 F.2d at 972 (citing Gines v. P.R. Aqueduct & Sewer Auth., 86 P.R.R. 518, 523 (1962)).
76 Marshall v. Pérez Arzuaga, 828 F.2d 845, 848 (1st Cir. 1987).
77 575 P.2d 1162 (Cal. 1978).
78 McPhail v. Municipality of Calemba, 598 F.2d 603, 606 (1st Cir. 1979) (citing Montero Saldaña).
79 Cárdenas Maxain v. Rodríguez Rodríguez, 125 D.P.R. 702 (1990).
Absorption of fault

Under the absorption theory, if a party is only slightly responsible for causing damage, the overwhelming negligence of another party ‘absorbs’ the minimal negligence of the former and the latter bears all liability.81

iv Personal jurisdiction

Puerto Rico’s long-arm statute extends personal jurisdiction to the full extent allowed under the US Constitution.82 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 United States).83

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.’84 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’.85 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.86 Mere ownership of a subsidiary is insufficient to justify asserting personal jurisdiction over the parent wherever the subsidiary is present.87

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.88 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’.89

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.90 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.91

81 Ruiz Troche v. Pepsi Cola of Puerto Rico, 161 F.3d 77, 87 (1st Cir. 1998).
82 P.R. Rule of Civil Procedure 3.1(a)(2).
86 id., Escude Cruz v. Ortho Pharm. Corp., 619 F.2d 902, 905 (1st Cir. 1980).
87 Donatelli, 893 F.2d at 465–66.
88 509 U.S. 579 (1993); see also Cruz-Vázquez v. Mennonite Gen. Hop., Inc., 717 F.3d 63 (1st Cir. 2013).
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’. 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. An aggrieved party may collect the entirety of the damages from one, some, or all the joint tortfeasors. Under Article 1098 of the Civil Code, joint debtors can demand payment for the amount that exceeds their share of responsibility for the damages.

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.

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. 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;
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;

93 Tokyo Marine and Fire Ins. Co., 142 F.3d at 5.
95 31 L.P.R.A. Section 3109.
98 P.R. Complex Litigation Rule 3(d).
Puerto Rico

the type of case including whether it involves product liability claims;
whether a complex appellate process is anticipated;
whether the cases have been certified as class actions;
whether the case involves claims resulting from natural disasters or catastrophic events; and
the anticipated complexity of the pretrial proceedings.99

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.100 Trial courts have broad discretion in determining the amount of damages and the appellate courts will only reverse an award if it is an abuse of the trial court’s discretion.

V YEAR IN REVIEW

In 2019, the Puerto Rico Supreme Court issued two decisions that touched on important issues of time-limitations law. Hamedo Castro v. Roldán Morales reiterated that, under the provisions of Articles 1835 and 1838 of the Civil Code,101 an agreement to waive statutes of limitations for claims based on future acts is legally unenforceable.102 The Court’s opinion reflects that, while the Civil Code was modelled on its counterpart in Spain, Puerto Rico’s legal system is influenced by other sources. The Court’s decision cites not only to the Civil Code of Spain and Spanish scholars but also judicial decisions from Louisiana (due to its system based on French civil law) and court opinions from common law jurisdictions in the United States.

In Cacho González v. Santarrosa, the Court also held that for an extrajudicial claim letter to toll the statute of limitations for damages claims under Article 1802 of the Civil Code, it only needs to contain sufficient details to communicate the unequivocal intent to set forth the claim and broadly notify the basis for the claim. This can be achieved by complying with the following: that the letter (1) is served within the limitations period; (2) is sent by the person with standing to assert the claim; (3) accurately communicates the nature of the claim; and (4) is served via a suitable mean.103

99 P.R. Complex Litigation Rule 5.
100 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).
101 31 L.P.R.A. Section 5246 and 5249.
102 2019 T.S.P.R. 176.
103 2019 T.S.P.R. 146, at *8.
Chapter 11

RUSSIA

Sergey Yuryev

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:

a) a defective design or formula or other defect in the goods, works or services; or
b) unreliable or insufficient information concerning the goods, works or services.

Strict liability is applied regardless of whether 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 these 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:

- a defective design or formula or other defect in the goods; or
- failure to provide a consumer with complete and reliable information concerning the 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 a defective design or formula or other defect in the goods, or failure to provide a consumer with complete and reliable information concerning the 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. Moreover, in 2017 administrative liability for failure to adopt product recall measures was introduced in Russia. This liability may be imposed on manufacturers, executors, sellers and authorised entities, and depends on which of the prescribed measures is not observed. For instance, failure to suspend the production and sales of defective products and recall them from sale may incur a fine up to 500,000 roubles.

The basic feature of 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.

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 that legal entity has repeatedly 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 to secure those rights;

b. applying to the courts in support of consumers and 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 IEs (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);

e importers (an entity or an IE engaged in importing products for their subsequent sale in Russia); and

f online marketplaces (an entity or IE, aggregating information about third parties’ products through its website or app and accepting payments from the consumers).

As noted above, 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. Since 1 January 2019, online marketplaces have also been liable for loss and damages incurred by the consumers owing to provision of incomplete or misleading information about products. However, the online marketplace should not bear any liability if it does not modify the information about products provided by the seller.

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 a defective design or formula or another defect in the goods, works or services, or unreliable or insufficient information concerning the 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 these 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; this administrative offence leads to a fine of up to 1 million roubles and seizure of the improper goods;

b deceiving consumers – 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 three 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), causing major damage or grievous injury to health or death. This is punishable by up to five years’ imprisonment;

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. These activities are punishable by up to 10 years’ imprisonment; and

c. circulation of falsified or defective pharmaceuticals, medical devices and food supplements. These activities are punishable by up to 12 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 50,000 roubles) 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 the damage was caused within either the established lifetime or shelf life of the product, or 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’, 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; for example, GOSTs (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. This defence is likely to be taken into account by the court for the purposes of determining the amount of compensation to be awarded. However, if damage is caused to a consumer’s health or life, the court will not accept this 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 bureaucratically acrimonious.

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:

a  the defendant’s registered office;

b  the place of the consumer’s residence (permanent or temporary); or

c  the place where 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.). As it is conducted by the seller (manufacturer, etc.), the use of such expertise is considered a way of protecting the consumer’s rights and it is undertaken where there is a dispute as to the origin of a product’s defects.

The consumer has the right to be present during the 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 that provides evidence of a breach of obligatory product requirements.

*Judicial examination*

Subject to procedural rules, the court will appoint experts if any questions arise during the case that require special knowledge in science, technology, etc. 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 the 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
Procedural legislation does not provide any special regime similar to the discovery or disclosure procedure in the United Kingdom or the United States. Owing to fundamental differences in procedural law, a Russian court has a much more significant role in the court hearing and the examination of evidence.

Subject to 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 both the circumstances relevant to the case and which party successfully proves their case. The court may also propose that 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
Witness 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 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

Since 1 October 2019, the concept of class actions has been implemented into Russian law and may be used in consumer disputes.

Under the new procedure, individuals with a similar claim (e.g., a claim to the same manufacturer arisen from the same defect of the similar product) will be able to unite together or with organisations into a group of at least 20, select a representative from the group and file a lawsuit against a respondent.

Information about the filing of a class action lawsuit must be published in the media so that other people can join the claim, by opting in, if they believe their rights and legitimate interests were also violated.

Previously, the Consumer Protection Law only allowed certain state agencies, local authorities and consumer protection associations to file lawsuits on behalf of an indefinite number of consumers. In those cases, however, a court might only issue an injunction against the wrongdoing rather than award damages. Also, the court might declare the activity illegal; such a declaration would have a res judicata nature and might 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 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) over and above economic 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 in failing to abide by the time limits for satisfying the aforementioned remedies. Although the law does not cap the maximum amount of this 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. Furthermore, in 2019, consumers obtained an additional legal remedy to protect their interests by means of class actions. 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.
I INTRODUCTION TO THE PRODUCT LIABILITY FRAMEWORK

In Singapore, there is no particular legislation solely setting out liabilities that might arise owing to the manufacture, distribution or supply of a defective product. Rather, product liability laws span 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 (SFA) and the Food Regulations issued pursuant to the SFA deal with food products. Medical devices and drugs (therapeutic products) are regulated under the Health Products Act and several regulations. 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 ambit of enforcement for these categories of products are examined in greater detail in Section II.

II REGULATORY OVERSIGHT

The 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 Competition and Consumer Commission of Singapore (CCCS), which protects consumers against unfair trade practices in Singapore;

e. Enterprise Singapore, which regulates general consumer goods and ensures that the consumer goods supplied are safe; and

f. the Singapore Food Agency, which regulates the import and sale of food.  

These 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) provides the
CPCS with the power to conduct an investigation if it has reasonable grounds 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, and the power to require documents, articles or information. 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) and Consumer Protection (Consumer Goods Safety Requirements) Regulations 2011 (CGSR), issued pursuant to the Consumer Protection (Trade Descriptions and Safety Requirements) Act (CPSRA), provide Enterprise 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 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, 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. The same applies for a contract where the transferor transfers the property in goods in the course of a business. 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.
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. 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 latter. 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. Next, the claimant must show that the MDS has breached that duty of care by acting below the required standard of care. In addition, the breach must have resulted in damage to the claimant. This damage can be physical, psychiatric or economic in nature. Finally, any resulting losses cannot be too remote and should be adequately proved and quantified.

iii Misrepresentation
A claimant can sue an MDS for fraudulent or innocent misrepresentation.

To establish fraudulent misrepresentation, the claimant must show that the MDS made a false representation and knew or believed the representation about the goods to be false, or did not believe in the truth of the representation, when it was made. 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 Section III.ii). Meanwhile, if the MDS had neither acted fraudulently nor negligently, the claimant may only be able to sue for innocent misrepresentation. Under the Misrepresentation Act, a person will be entitled to rescind a contract for innocent misrepresentation or claim damages in lieu of rescission.

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. An unfair practice is relevant to product liability insofar as a seller, 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

14 Spandeck Engineering (S) Pte Ltd v. Defence Science & Technology Agency [2007] 4 SLR(R) 100; [2007] SGCA 37 (Spandeck) at [21].
17 Spandeck at [21].
18 Spandeck at [115].
19 Spandeck at [21].
23 Misrepresentation Act, Section 2(2).
24 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. 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, though the amount claimed cannot exceed S$30,000. 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.

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.

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 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. The same punishment applies if an MDS does not recall controlled goods as required by Enterprise Singapore.

Non-controlled goods

If an MDS supplies goods that have been publicly declared as unsafe for failing to conform to prescribed safety standards 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. A second or subsequent offence will attract higher penalties.

25 CPFTA, Sections 12B(1)–(2).
26 CPFTA, Section 6(1).
27 CPFTA, Section 6(2) read with Section 6(6).
28 CPFTA, Section 6(5).
29 CPFTA, Section 8.
30 See First Schedule of the CPSRR.
31 CPSRR, Regulation 5.
32 CPSRR, Regulation 4(3).
33 CGSR, Regulations 3 and 4.
34 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 be held liable for the offence.35

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;36 and
c above S$250,000: High Court.

Any decisions made in these courts may subsequently be appealed to a higher court.37 An exception arises where the claim is below S$10,000 and can, therefore, be heard before the Small Claims Tribunal.38 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.39

ii Burden of proof
The burden of proof is generally on the party that initiates an action against an MDS. For instance, to claim that the implied contractual condition that the goods are of satisfactory quality has been breached, the claimant must show how the goods in question are not of satisfactory quality.40

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 six months of the date of delivery did not so conform as at the date of delivery, and it will be for the MDS to prove otherwise.41

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.42

35 CPSRA, Section 17.
36 Section 19(4) read with Section 2(1) of the State Courts Act (Cap. 321, 2007 Rev. Ed.).
38 Section 5(3) read with Section 2(1) of the Small Claims Tribunal Act (Cap. 308, 1998 Rev. Ed.) (SCTA).
39 SCTA, Section 5(4).
40 Compact Metal Industries Ltd v. PPG Industries (Singapore) Ltd [2006] SGHC 242 at [102].
41 CPFTA, Section 12B(3).
42 Section 6(1)(a) of the Limitation Act (Cap. 163, 1996 Rev. Ed.) (LA).
However, for a negligence action for damages, different rules apply:

- where the damages claimed consist of or include damages in respect of personal injuries to the claimant or any other person, an action may be brought within the later of:
  - three years of the date on which the cause of action accrued; or
  - three years of the earliest date on which the claimant has the knowledge required for bringing an action for damages in respect of the relevant injury;\(^\text{43}\) and

- for damages other than personal injuries, an action may be brought within the later of:
  - six years of the date on which the cause of action accrued; or
  - three years of the earliest date on which the claimant 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 the action.\(^\text{44}\)

Meanwhile, for an individual seeking to sue for unfair practices under Section 6 of the CPFTA, the action should be within two years of:

- the date of the occurrence of the most recent material event on which the action is based; or

- the earliest date on which the consumer had knowledge that the supplier had engaged in the unfair practice to which the action relates.\(^\text{45}\)

**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.\(^\text{46}\)

**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.\(^\text{47}\) 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.\(^\text{48}\) 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.\(^\text{49}\)

\(^{43}\) LA, Section 24A(2).

\(^{44}\) LA, Section 24A(3).

\(^{45}\) CPFTA, Section 12.


\(^{47}\) 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.\(^{50}\) 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 said risk,\(^{51}\) that the consumer had voluntarily assumed that risk\(^{52}\) 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 were partly owing to the claimant’s own fault. In this 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.\(^{53}\)

**iv Personal jurisdiction**
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 Singaporean 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;\(^{54}\) or

\(b\) the MDS has submitted to the High Court’s jurisdiction.\(^{55}\)

**Specific civil jurisdiction**
An MDS that is a corporate entity may be subject to the legal authority of Singaporean courts’ jurisdiction if the MDS was incorporated in Singapore,\(^{56}\) and service was effected on the MDS at its registered address.\(^{57}\)

Conversely, if the MDS was not incorporated in Singapore, it first needs to be present within Singapore and then receive service of the claimant’s originating process for the MDS to be under Singaporean courts’ jurisdiction.\(^{58}\)

\(^{50}\) CPFTA, Section 5(3)(a).
\(^{51}\) Thomas v. Quartermaine (1887) 18 QBD 685.
\(^{52}\) Williams v. Birmingham Battery and Metal Co [1899] 2 QB 338.
\(^{53}\) Section 3(1) of the Contributory Negligence and Personal Injuries Act (Cap. 54, 2002 Rev. Ed.).
\(^{54}\) Cap. 322, R 5, 2014 Rev. Ed.
\(^{55}\) Section 16(1) of the Supreme Court of Judicature Act (Cap. 322, 2007 Rev. Ed.) (SCJA).
\(^{56}\) SCJA, Section 17(c), read with Section 4(1) of the Companies Act (Cap 50, 2006 Rev. Ed.).
\(^{57}\) Companies Act, Section 387.
\(^{58}\) SCJA, Section 16(1)(a).
**Forum non conveniens**

Singaporean courts generally uphold choice of law and jurisdiction clauses in contracts and will apply the principle of *forum non conveniens* to determine whether 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. The expert should have scientific, technical or other specialised knowledge based on his or her training, study or experience. This knowledge should be connected with the questions that he or she has been asked to address and be something that the court is likely to derive assistance from.

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. However, the court may limit the number of expert witnesses who may be called at the trial.

**vi Discovery**

There are two key methods of discovery in civil actions initiated before Singaporean 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.

This list of documents comprises documents that:

- are or have been in the other party’s possession, custody or power, and on which the party relies or will rely; and
- could adversely affect the party’s own case, adversely affect the other party’s case or support another party’s case.

In either case, discovery must be necessary for disposing fairly of the cause or matter, or for saving costs.

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59 ROC, Order 40, Rule 1(1).
60 Section 47(2) of the Evidence Act (Cap. 97, 1997 Rev. Ed.) (EA).
61 ROC, Order 40, Rule 1(4).
62 EA, Section 47(1).
63 ROC, Order 40, Rule 1(1).
64 ROC, Order 40A, Rule 1(1).
65 ROC, Order 24, Rule 1(1).
66 ROC, Order 24, Rules 1(2)(a) and 1(2)(b)(i)–(iii).
67 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.68

Specific discovery
To supplement the process of general discovery, specific discovery is available if 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 action69 or even discovery against a non-party.70 These are, however, exceptional situations that require a party to show why it is just for the court to grant such an application.71

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.72 The interrogatories should be necessary either for disposing fairly of the cause or matter, or for saving cost.73

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.74 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.75

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.

69 ROC, Order 24, Rule 6(1).
70 ROC, Order 24, Rule 6(2).
71 ROC, Order 24, Rule 6(5).
72 ROC, Order 26, Rule 1(2).
73 ROC, Order 26, Rule 1(1).
74 ROC, Order 26A, Rule 3.
75 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 or her actions. In *TV Media Pte Ltd v. De Cruz Andrea Heidi and Another Appeal*, one of the defendants was held to have directed, authorised and procured a company’s negligence because of his involvement in all the company’s significant dealings with third parties, as well as his absolute control of the company.

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 or an implied agreement.

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:

- there must be an employer–employee relationship between the MDS and the individual;
- the individual must have committed a tort; and
- 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.

First, to determine whether 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.

Second, to decide whether 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 behaviour by their employees.

Once vicarious liability is established, the MDS can be held liable for the losses and damage arising from the individual’s tort. The MDS ultimately may not have to bear the liability if the MDS had previously sought an indemnity from its employee.

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78 *Skandinaviska Enskilda Banken AB (PUBL), Singapore Branch v. Asia Pacific Breweries (Singapore) Pte Ltd* [2011] 3 SLR 540 at [75].

79 ibid., at [87].
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.80
Any judgment or order subsequently given would then be binding on all the persons as representing those whom the claimants sue.81 These 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.82

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.83 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.84
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 this situation, the consumer may receive reliance damages instead.85

Claims under the CPFTA
Damages claimable under the CPFTA in respect of an unfair trade practice are subject to a limit of S$30,000.86 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 sustained.87 This may include (present and future) medical expense, loss of future income,

80  ROC, Order 15, Rule 12(1).
81  ROC, Order 15, Rule 12(3).
84  Van Der Horst Engineering Pte Ltd v. Rotol Singapore Ltd [2006] 2 SLR 586 at [54].
86  CPFTA, Section 6(6).
87  Chartered Electronics Industries Pte Ltd v. Comtech IT Pte Ltd [1998] 3 SLR 502 at [16].
future transport costs and future nursing care and nursing home expenses.\textsuperscript{88} With regard to non-pecuniary losses, the court may award damages for the claimant’s loss of amenities and for pain and suffering.\textsuperscript{89}

\textbf{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 the loss was foreseeable (and including all consequential losses as well).\textsuperscript{90} Similarly, the MDS would be liable for the same type of damages if it had made a negligent misrepresentation to a claimant that 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.\textsuperscript{91} If the MDS is found liable for innocent misrepresentation, the court may also order damages in lieu of rescission.\textsuperscript{92}

V \hspace{1em} \textbf{YEAR IN REVIEW}

\textbf{i \hspace{1em} Statutory developments}

On 1 April 2019, a new statutory board, the Singapore Food Agency, was formed to replace the AVA in overseeing food safety and security.\textsuperscript{93} The Singapore Food Agency combines food-related functions currently performed by the AVA, the National Environment Agency and the HSA.\textsuperscript{94} To this end, Parliament passed the Singapore Food Agency Act 2019\textsuperscript{95} and the National Parks Board (Amendment) Act 2019.\textsuperscript{96} The AVA has since been dissolved and transferred its non-food responsibilities to the National Parks Board.\textsuperscript{97} The aim is to enhance regulatory oversight over all food-related matters ‘from farm-to-fork’ and strengthen Singapore’s food safety regime.\textsuperscript{98}

\textbf{ii \hspace{1em} Case law developments}

There were no relevant case law developments in the area of product liability in 2019.

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\textsuperscript{88} Poh Huat Heng Corp Pte Ltd and others v. Hafizul Islam Kofil Uddin [2012] SGCA 31 at [7].
\textsuperscript{89} Tan Kok Lam (next friend to Teng Eng) v. Hong Choon Peng [2001] SGCA 27.
\textsuperscript{91} Misrepresentation Act, Section 2(1).
\textsuperscript{92} ibid., Section 2(2).
\textsuperscript{94} ibid.
\textsuperscript{95} G.N. No. S 11/2019.
\textsuperscript{96} G.N. No. S 10/2019.
\textsuperscript{97} See footnote 93.
\textsuperscript{98} ibid.
\end{flushleft}
iii Other developments

Recalls

CASE has yet to release statistics on consumer complaints and the action it took in 2018 and 2019.

Proposed guidelines on price transparency

On 30 September 2019, the CCCS released a set of proposed guidelines on price transparency, setting out the key ‘dos and don’ts’ in the pricing practices of suppliers from all consumer-facing industries.99 The proposed guidelines were developed following the CCCS’s findings from its market study of the online travel booking sector in Singapore, which revealed various concerning practices such as the use of pre-ticked boxes and pressure selling.

The guidelines expand on the meaning of ‘unfair practices’ under Section 4 of the CPFTA and further elaborate on a number of unfair practices listed in the Second Schedule of the CPFTA. Broadly, it includes various recommended practices to ensure that pricing strategies are made explicit to consumers up front. It also discourages misleading practices such as the use of engineered discounts and careless references to the word ‘free’ without disclosing subsequent or deferred charges.100

Public consultation on the proposed guidelines ran from 30 September 2019 to 21 October 2019. Further details on the guidelines following the public feedback are expected to be released in the course of 2020.

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100 ibid.
Chapter 13

SPAIN

Alex Ferreres Comella and Cristina Ayo Ferrándiz

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.

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
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 entry into force of the Defective Products Liability Act). However, a scenario calling for the application of these 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 from the date 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 Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) is the regulator, with nationwide competence, and the regional authorities are competent within their own territories.

However, this regulation will only apply to all product types in the absence of any specific existing regulation. Indeed, there are some specific products (i.e., food, cosmetics or medicines) that have specific safety regulation and sometimes need prior administrative approval to be put on the market.

Likewise, 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).

2 The National Consumer Institute was the competent regulator. Following a recent restructuring, the National Consumer Institute was merged with the Spanish Agency for Food Safety and Nutrition to create AECOSAN.

3 Dirección General de Consumo, in Andalucía; 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 in Sections I and II, 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.

To establish whether a given product is 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 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 to information defects, it may be argued that, by using the degree-of-safety test to establish whether a product is 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:

a the risks are obvious (e.g., a knife or a pair of scissors are cutting instruments);

b the risks are socially and culturally known by the public (e.g., risks associated with tobacco or alcohol consumption); or

c the manufacturer, in compliance with its duty to provide the necessary information about its product, had provided to the injured persons adequate instructions for the product’s use and information about the risks associated with its 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 at which it was put 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 as 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 the product into circulation was not such as would 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 the 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 in 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, rendering the judgments in these proceedings.

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 the court of appeal is divided into several sections, each sitting with three magistrates.

Apart from the Superior Courts of Justice (the highest court in each of the Spanish territory's autonomous communities), which, basically, are in charge of hearing motions for dismissal in connection with specific matters of law in their respective autonomous communities, 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 jurisdicational 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. The stream a case falls under will depend on the amount claimed: cases in which payment of compensation of up to €6,000 is sought are dealt with in verbal proceedings; and cases in which the amount claimed is more than €6,000 are dealt with 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*, the plaintiff is not required to set out the legal grounds in thorough detail, and 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 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.

If ordinary proceedings are initiated, once notified of the lawsuit, the defendant will have a 20-working-day period to file the brief of response. Subsequently, the court will call the

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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 proceeding, the court summons the parties to a hearing where the defendant presents its response orally and the evidence is 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.
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:

- a link between the consumption of rapeseed oil and the disease suffered by more than 20,000 injured parties had been epidemiologically determined;
- 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;
- none of the parties to the proceedings proposed any alternative causal hypothesis other than the consumption of rapeseed oil; and
- 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 three years of the time the victim sustained the injury or damage.
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 the 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:

- the product was not put into circulation by the relevant manufacturer or importer;
- 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;
- 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;
- the defect was the result of manufacturing the product in accordance with mandatory rules in force; or
- the state of scientific and technical knowledge at the time of putting the product into circulation was not such as would enable the existence of the defect to be discovered (i.e., the 'state-of-the-art' defence).

Under this exemption-of-liability clause, damage caused by a defective product is not compensable where the state of scientific or technical knowledge at the time the damage was caused was not such as would have enabled the damage to be avoided.

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 at that time was not such as would have enabled 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 the 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, which on jurisdiction, recognition and enforcement of judgments in civil and commercial matter. Under that article, any person who has suffered damage 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 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 in two specific situations.

If preliminary proceedings have commenced, the law provides for the option for the court to enter and search premises to obtain certain documents requested by the plaintiff in cases where the person or entity to which they refer, or who is in possession of the documents, refuses to disclose them.

During ordinary proceedings, the law provides for the option to request from the other parties disclosure of documents referring to the object of the proceedings. Should the party or parties unjustifiably refuse to disclose the requested private documents, the court may either attribute to the document the evidential value alleged by the requesting party or issue an express injunction for the documents to be furnished, when it is deemed advisable given the nature of the documents, the other evidence brought to the proceedings and the contents of the allegations and claims made.

However, unlike in preliminary proceedings, here the law does not provide for the entry and search of premises in the event of a refusal to disclose documents. 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 if several agents have contributed to the damaging event, where it is possible to determine the specific level of contribution of each agent; however, market share liability has not yet been applied by the Spanish courts.

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6 This is an exceptional procedure, simply aimed at preparing the proceedings (and, therefore, conducted prior to filing the lawsuit). Its purpose is for the potential plaintiff to verify the suitability of the defendant and the object of the claim.

7 In such cases, the requesting party must 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.
However, if it is not possible to determine the specific level of contribution of each agent to the damaging event (while it is certain that they all contributed to it to some – unknown – extent), 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 aforementioned succession of liability does not occur, however, where a company purchases a brand or a producer’s product line, 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 either a determined (or easily determinable) or 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 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 the impairment or loss affects the person’s natural vital attributes or his or her property or assets.

Indemnifiable damages include both strictly economic damages and also ‘non-material damages’ (including, for instance, for suffering or pain).8

Punitive damages are not contemplated in the Spanish legal system.

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8 Non-material damages are not economically assessable, although compensation for non-material damage is imposed by law. In practice, each court determines the economic value of the non-material damage according to each specific case, and this is generally proportional to the strictly economic damages that are granted.
Spain

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

In December 2019, the Supreme Court issued a decision dismissing the extraordinary appeal filed by an insurance company against the decision issued by the Court of Appeal of Álava that condemned it to pay a compensation for the damage suffered in the property’s garage as a result of a vehicle, that was parked in the garage, setting on fire, generated by an electrical problem. The reason underlying the appeal was basically the improper application of the Regulation of Civil Liability and Insurance in the circulation of motor vehicles, instead of applying the regulation of product liability. In view of this dilemma, the Supreme Court raised a preliminary ruling before the Court of Justice of the EU, which concluded that it falls within the concept of ‘vehicle traffic’ contemplated in the regulation of civil liability derived from the circulation of vehicles description, such as the one described: where a vehicle that is parked in a private garage of a property and used as a means of transport, starts to burn due to an electronic problem, causing damage to the property, even if the car has been parked for more than 24 hours.

On 4 July 2019, the Supreme Court issued a decision by means of which, among other questions, it recalled the applicable regime and the liability of the supplier of a product that has been declared defective (for not offering the security expected and causing personal damage) as a producer, in accordance with Article 138 of the Royal Legislative Decree 1/2007, which enacted the Consumers and Users Protection (Consolidation) Act, provided that the producer cannot be identified or is not identified by whomever claims to be the mere supplier. According to this regulation, a producer will be considered to be – in addition to the manufacturer of the good or service, or its intermediary or the importer of the good in the territory of the EU, or the person who appears as such in the product or packaging – ‘the manufacturer or importer in the EU (a) of a finished product, (b) of any element integrated in a finished product, (c) of a raw material’. In addition, if the producer cannot be identified, the supplier of the product will be considered as such, unless, within three months, he or she identifies the producer or who has supplied the product. The same rule shall apply in the case of an imported product, if the product does not indicate the name of the importer, even if the name of the manufacturer is indicated.

However, the Dieselgate case still remains active in Spain. At the beginning of 2018, a court in Mallorca issued a decision ordering Volkswagen to compensate a purchaser of a car that had been affected by the diesel scandal with an amount equivalent to the acquisition cost of the car.
Additionally, the Spanish Agency of Drugs and Medical Devices recently reported that drug and medical device recalls have increased in past years, compared with previous ones. The intensification of the prerequisites that the above-mentioned products must comply with and companies’ safety investment cuts may explain the increase.
Chapter 14

SWITZERLAND

Frank Scherrer, Andrea Schütz and Marcel Boller

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. 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. In addition, 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.

The following persons are deemed to be producers:

- the manufacturer (in whole or in part) of the defective product;
- any person who applied its name or trademark to the product;
- any person who imported the product for commercial distribution; and
- the person who supplied the product, if the producer (at items (a) to (c)) cannot be identified.

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:

- the ratio between benefit and risk;
- the method and manner used to present the product (particularly the product information);
- the use of the product that can be reasonably expected; and
- the point in time the product was placed on the market.

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1 Frank Scherrer is a partner, Andrea Schütz is a senior associate and Marcel Boller is an associate at Wenger & Vieli Ltd.
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. In a decision of 2013, the Federal Supreme Court clarified that a lack of functionality 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 lack of functionality does not concern the safety of the extinguisher as such.

The Product Safety Act (PSA) of 2009 and many other administrative laws and corresponding ordinances contain rules on conformity assessments and on standards and proceedings that specific products have to fulfil to be considered safe. To a large extent, these 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’ competence depends 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. The State Secretariat of Economic Affairs (SECO) is responsible for coordinating the enforcement of the PSA.

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 health or safety of the user or third parties. Notification can be made with the form provided on the SECO website. 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).

The competent authority can even prohibit products that are in line with applicable EU harmonised standards if the authority comes to the conclusion that a product does not meet health and safety requirements. In a case of 2017, the Federal Supreme Court held that first the product’s compliance with the requirements of the applicable harmonised standard has to be assessed. Second, it must be assessed whether the risks spotted by the competent

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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.
10 www.seco.admin.ch/seco/de/home/Arbeit/Arbeitsbedingungen/Produktsicherheit.html.
authority are addressed by the standard. If this is not the case, the producer must prove that the product meets safety requirements. If the risks in question are addressed by the standard, the presumption of conformity applies. This presumption may, however, be proven wrong by the competent authority. In the case at hand, the Court came to the conclusion that the machines in question did not meet the basic health and safety protection requirement that reasonably foreseeable mishandling should be taken into account when constructing the machines (a requirement that is not taken into account by the standard SN EN 474-1 on earth-moving machinery either).\textsuperscript{11}

Apart from the PSA, sector specific federal laws provide for similar rules. 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 competence for ensuring the safety of these products.

As many different authorities are competent in the field of product safety, it is often not entirely clear for the distributor or manufacturer which agency has to be notified in the event of product defects or 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 the event of death or personal injury, or damage to things that are intended for private use or consumption and have been used mainly for private purposes. Under the PLA, the manufacturer is not liable for damage to the defective product itself. To prevail in a claim based on the PLA, the plaintiff must generally show the following elements: the damage; the defect; and 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: the damage; the breach of contract or breach of a protective legal provision; adequate causation of the damage by the breach of contract or breach of a protective legal provision; and a fault of the liable person (intent or negligence). In the 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 cases 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 extend to a 10-year custodial sentence (in cases of intentional serious assault).

The PSA provides penalties (a fine of up to 40,000 Swiss francs) for 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.

\textsuperscript{11} BGE 143 II 518, E. 5.8.
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.\textsuperscript{12} In such cases, a fine of up to 5 million Swiss francs can be imposed on the company.

IV LITIGATION

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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:

\begin{itemize}
  \item \textit{a} the local conciliation authority;
  \item \textit{b} the local court of first instance;
  \item \textit{c} the cantonal high court; and
  \item \textit{d} the Federal Supreme Court.
\end{itemize}

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 the canton or in a foreign country are exempt from the obligation to appear in person and may send a representative on their behalf.\textsuperscript{13} The conciliation authority can, on petition, issue decisions on monetary claims if the value of the claim does not exceed 2,000 Swiss francs.\textsuperscript{14} 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.\textsuperscript{15} 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.

\begin{itemize}
  \item \textsuperscript{12} Article 102 of the Swiss Criminal Code.
  \item \textsuperscript{13} Article 204 CPC.
  \item \textsuperscript{14} ibid., Article 212.
  \item \textsuperscript{15} ibid., Article 209.
\end{itemize}
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.16

Four 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.17 If only the defendant, but not the claimant, is registered in the commercial registry, 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).18

For any stage of a civil proceeding, the claimant or the party appealing 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).19 Orders by federal administrative authorities can be appealed before the Federal Administrative Court.20 Judgments of the Federal Administrative Court are subject to appeal before the Federal Supreme Court.21

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.22 Administrative authorities are often also vested with a certain competence 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 that 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.23 The defectiveness does not necessarily need to be proven by an expert opinion.

16 ibid., Article 8.
17 ibid., Article 6.
18 Article 77 et seq. of the Federal Law on the Federal Supreme Court (FCL).
19 Article 10 PSA.
20 Article 31 of the Federal Act on the Federal Administrative Court.
21 Article 75 FCL.
22 Article 122 of the Swiss Criminal Procedure Code.
23 BGE 133 III 81, E.4.2.2.
Defences

The producer is not liable for a defective product under the PLA if it proves any of the following:

- it did not market the product;
- the product was not defective when it was put into circulation;
- it did not manufacture the product for a business purpose or within the framework of its professional activity;
- the defect is attributable to compliance with compulsory, official regulations;
- 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
- 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.24

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 because all regulatory requirements have been complied with. However, as defectiveness is assessed based on all circumstances, compliance with regulatory requirements and the assessments of the experts of the regulatory authorities 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.25

The statute of limitations 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 of the day when the product in question was put on the market.

Since 1 January 2020, the statute of limitations period for product liability claims under general tort law has been increased from one year to three years from the day the injured person gained knowledge of the damage and the person liable, or 10 years from the day on which the damaging behaviour took place or ceased. In the case of death or personal injury, the statute of limitations is three years from the day the injured person gained knowledge of the damage and the person liable and 20 years from the day on which the damaging behaviour took place or ceased. In the case of a longer limitation period for a criminal act, this longer period would apply.

The general statute of limitations period for contractual claims is five (foodstuffs, everyday retail goods) or 10 years (other goods). The statute of limitations period for contractual claims based on defects of a purchased product, however, is generally two years from the delivery of the product. The buyer is obliged to examine the product and to notify the seller immediately when he or she discovers a defect. In the relationship between buyer and seller, claims under contract and tort law can exist in parallel with different limitation periods.

Apart from the statute of limitations there are additional defences against contractual claims or claims under general tort law.

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24 Article 5 PLA.
25 Article 5 PSA.
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) for defendants 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;\(^{26}\)
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);\(^{27}\)
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 the court has jurisdiction, under its own law, to entertain civil proceedings;\(^{28}\)
d  if a number of defendants are sued together, in the courts of the place where at least one of them is domiciled;\(^{29}\) and
e  in an action on a warranty or guarantee, or in any third-party proceedings, in the court of the primary proceedings.\(^{30}\)

If 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 that 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;\(^{31}\)
b  for claims based on a contract, the place of performance of the characteristic contractual obligation;\(^{32}\) and
c  for claims based on contracts with consumers, the domicile of the consumer.\(^{33}\)

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:

\(^{26}\) Article 5.3 Lugano Convention.
\(^{27}\) ibid., Article 5.1.
\(^{28}\) ibid., Article 5.4.
\(^{29}\) ibid., Article 6.1.
\(^{30}\) ibid., Article 6.2.
\(^{31}\) Article 129 PILA.
\(^{32}\) ibid., Article 113.
\(^{33}\) ibid., Article 114.
testimony, physical records, inspection, expert opinion, written statements and questioning as well as statements of the parties. The court forms its opinion based on its free assessment of the evidence.

According to the Federal Supreme Court, expert opinions commissioned by the parties themselves are not to be regarded as expert opinions within the meaning of the CPC. Such a 'private expert opinion' may not be treated as evidence by the courts but merely as a statement by the party that commissioned the expert opinion.

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. Parties generally have to gather the evidence they consider necessary to substantiate their claim or defend themselves, or request the court to collect such 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 this order, the court may weigh this behaviour against this party.

The CPC provides the possibility of the precautionary taking of evidence by the court if the applicant credibly shows that evidence is at risk or that he or she has a legitimate interest. If an expert opinion is to be a central piece of evidence in a future court proceeding, a party can request that the court commissions the expert opinion before an actual trial is commenced based on Article 158 of the CPC. The requesting party must cover the costs for the expert opinion.

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 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, if it loses the trial, turn towards a third party such as a manufacturer, it is possible either to invite the third party to join the process or to 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 the manufacturer, or where a doctor is liable on the basis of a contract and a manufacturer on the basis of product liability), they are jointly

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34 Article 168 CPC.
35 ibid., Article 157.
36 BGE 141 III 433.
37 Article 164 CPC.
38 ibid., Article 158.
39 BGE 140 II 16, E. 2.5.
40 BGE 140 III 30.
and severally liable and can each be sued for the full amount of the damage.\textsuperscript{41} The law states that the judge may determine to what extent they have recourse claims against each other.\textsuperscript{42} If two or more persons are liable based on different legal grounds, the law provides that the person having caused the damage through tort shall bear the liability for the damage primarily and the person being liable without fault and without contractual obligation shall bear the liability for the damage lastly.\textsuperscript{43}

\textbf{viii Mass tort actions}

Swiss law does not provide for class or mass actions. Several claimants can ask that their respective claims be joined and the proceedings conducted together, but the claims remain separate from each other and are judged separately.

In 2017, the Swiss Foundation for Consumer Protection started a ‘lawsuit project’ with about 6,000 claimants against Volkswagen/AMAG, combining individual claims for damages and a ‘group action’ by the Foundation based on the Unfair Competition Act, and backed by various legal expense insurers. This is the first combination of lawsuits of this kind and scale in Switzerland. The background is the Volkswagen emissions scandal and therefore is not a product liability issue, but if the procedural mechanics used proved successful, they could potentially also be used in product liability cases in the future. In July 2018, the Commercial Court of Zurich, however, refused to hear the claim based on the Unfair Competition Act for lack of interest of the Foundation for Consumer Protection. The Swiss Federal Supreme Court confirmed this decision. In December 2019, the Commercial Court of Zurich also refused to hear the combined individual claims brought to the Court by the Foundation for Consumer Protection as the purpose of the Foundation (‘safeguarding the interests of consumers’) did not legitimise the Foundation to take such legal action. The Foundation for Consumer Protection appealed this decision to the Swiss Federal Supreme Court.

Currently, the Swiss government is examining amendments to the CPC to facilitate class actions. However, if and when such a revision will be implemented into the CPC is not yet settled.

\textbf{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 current financial situation compared with this person’s hypothetical financial situation 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 in cases of material damage to things. 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; however, the damaging event must have occurred. Punitive damages are not available in Switzerland. Amends for non-economic damage such

\begin{itemize}
\item \textsuperscript{41} BGE 115 II 42, E. 1.
\item \textsuperscript{42} Article 50 CO.
\item \textsuperscript{43} ibid., Article 51.
\end{itemize}
as pain and suffering are available to the injured person or their next of kin. The amounts are usually moderate, but range from about 100,000 to 200,000 Swiss francs in cases of severe violations of physical integrity.

V YEAR IN REVIEW

Cases on product liability and safety decided by the Swiss Federal Supreme Court are rare. In 2019, in connection with the assessment of a prohibition of snus, the Federal Supreme Court confirmed that the Food Act takes precedence over the PSA as lex specialis (Decision 2C_718/2018).

The Federal Supreme Court also decided in 2019 that Article 10(4) in conjunction with Article 12 of the PSA (warning to the population by the authorities and duty of confidentiality of the authorities) provides a special legal provision that takes precedence over the Public Information Act (Decision A-5623/2017).

The mass tort action brought by the Swiss Foundation for Consumer Protection in 2017 on behalf of 6,000 claimants against Volkswagen/AMAG, combining individual claims for damages and a ‘group action’ by the Foundation based on the Unfair Competition Act, was not heard by the Commercial Court of Zurich. A first decision of the Commercial Court of Zurich was confirmed by the Swiss Federal Supreme Court; the second decision is still under appeal.
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 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 are the Consumer Product Safety Commission, which, as the name suggests, oversees the safety of consumer products; the Food and Drug Administration (FDA), which, inter alia, regulates the marketing and labelling of food and prescription drugs; the National Highway Traffic Safety Administration, which regulates motor vehicle safety; the Federal Aviation Administration, which governs all aspects of air transportation; the Federal Railroad Administration, which oversees trains and railways; and the Occupational Safety and Health Administration, which was created to prevent injuries...
in the workplace. 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. 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 manufacturing the product and followed all applicable procedures and protocols, but nonetheless ended up producing a product later adjudged ‘defective’.

To prevail on a claim of strict liability, a plaintiff must generally show the following elements: the product contained a defect; the defect existed at the time the product left the manufacturer’s control; the defect rendered the product unreasonably dangerous; and the defect actually and proximately caused the plaintiff’s injuries.

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. To prove a manufacturing defect, a plaintiff must show that a product became unreasonably dangerous because it did not meet manufacturing specifications or deviated from the great majority of otherwise identical products with the same design. 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. Some courts also apply a ‘consumer 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 ‘general causation’ – that a particular substance is capable of causing the injury at issue – and ‘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 ‘minimise the unavoidable danger’.20 A crashworthiness plaintiff need only show that ‘the defective product was the proximate cause of the enhanced injuries – not the proximate cause of the accident itself’.21

14 Perez v. VAS S.p.A., 115 Cal. Rptr. 3d 590, 603–04 (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’).


16 See Stall 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 Mazda Motor Corp., 706 A.2d at 530.

19 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’).

20 Mazda Motor Corp., 706 A.2d at 531.
ii Negligence
To prove negligence, a plaintiff must show that the defendant owed a duty to the plaintiff; the defendant breached that duty; and the breach actually and proximately caused the plaintiff’s injury. 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 actual conduct of the manufacturer.

As a general principle of tort law, every person has a duty to act ‘reasonably’. In keeping with this principle, a manufacturer has a duty to design and construct products that are reasonably safe for their foreseeable uses. 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.

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’. 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.

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.

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).
24 Robinson v. Brandtjen & Kluge, Inc., 500 F.3d 691, 696 (8th Cir. 2007) (discussing South Dakota law); Sexton v. Bell Helicopters, 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. Beamna 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. Eutler, 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’).
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
The exact elements needed to prove a failure-to-warn claim vary between states. Generally, however, a plaintiff must show that the manufacturer had a duty to warn and breached that duty, proximately causing the plaintiff's injuries.

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. 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. Importantly, many jurisdictions hold that manufacturers have no duty to warn of 'open or obvious' dangers in their products.

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).

See, e.g., Dietz, 598 F.3d at 815 (discussing Georgia law); Huggins v. Stryker Corp., 932 F. Supp. 2d 972, 986 (D. Minn. 2013).


See Robinson, 500 F.3d at 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").

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 a false representation (or, in some jurisdictions, omission) of a material fact; ‘scienter’, in other words, knowledge that the representation is false; intent to mislead; justifiable reliance on the misrepresentation or omission; and 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

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).


36 UCC §2-314(1); 18 Williston on Contracts §52:78 (4th ed.).

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, will only hear cases that arise under federal law, such as the US Constitution or federal statutes; 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 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

40 Federal ‘removal’ proceedings are governed by 28 U.S.C. §§1441 and 1446.
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. U.S. Const. amend. VII. Although this constitutional right applies only in federal courts, see Minneapolis & St. Louis R.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 Twp., 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 2015 term, the Court had a total of 7,535 cases on the docket, but heard oral argument in only 82 cases and reviewed and decided an additional 145 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, 2011 Through 2015’, available at www.uscourts.gov/sites/default/files/supcourt_a1_0930.2016.pdf.
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.\textsuperscript{46}

\subsection*{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.\textsuperscript{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’.\textsuperscript{48} In contrast, the defendant usually bears the burden to prove an ‘affirmative’ defence, such as a statute of limitations.\textsuperscript{49}

\subsection*{iii Defences}

**Statutes of limitation and repose**

A statute of limitations is a law that establishes a time limit for bringing a lawsuit.\textsuperscript{50} The length of time within which a plaintiff must bring suit (if at all) varies from state to state. Usually, limitation periods range from two to four years and begin 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’).\textsuperscript{51} Some states also have statutes of ‘repose’, which are laws that bar a claim after a specified time period even if the plaintiff has

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\textsuperscript{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 cmr. (stating that, under Rule 21, ‘every appeal, unless dismissed, will result in a decision on the merits’); see also West Virginia Judiciary, www.courts.wv.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’).


\textsuperscript{48} \textit{People v. Taylor}, 618 P.2d 1127, 1135 (Colo. 1980); see also \textit{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)).


\textsuperscript{50} \textit{Black's Law Dictionary} (9th ed. 2009).

\textsuperscript{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’. \textit{R.J. Reynolds Tobacco Co. v. Ciccone}, 123 So. 3d 604, 610 (Fla. Dist. Ct. App. 2013) (quoting Fla. Stat. §95.031(2)(b)), approved in part, quashed in part on other grounds by 190 So. 3d 1028 (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. §95.4. 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.
not yet suffered an injury. 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. Some states do not apply statutes of limitations and repose to claims against the state or government agencies.

**Contributory negligence, assumption of risk and comparative fault**

The doctrine of contributory negligence historically barred a plaintiff from any recovery if the plaintiff’s own negligence contributed in any way to the injury. 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. 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. 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. In a ‘pure’ comparative fault state, a plaintiff can recover

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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).
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’).
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 & Med. 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: when a federal statute specifically provides for pre-emption (express pre-emption); when federal law directly conflicts with state law and it is impossible to comply with both (conflict pre-emption); and 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. LeCoyer, 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. R.R. 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 U.S.C. §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 Montalto 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, 132 S. Ct. at 1264–68 (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).

Other defences

Product alteration or misuse

Generally, a manufacturer 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 (e.g., an experienced professional) 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, 619 A.2d at 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 defence 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 Haw. 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).

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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. The manufacturer’s duty runs solely to the learned intermediary (e.g., the prescribing doctor), not to the end patient or 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. 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.

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’. This may be a form of pre-emption in federal contractor cases.

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.
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 (i.e., 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 in the absence of 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 the forum state's deliberately far-reaching 'long-arm' statute77 and 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 The law of minimum contacts is constantly evolving, however,
and recent US Supreme Court cases have placed stricter requirements on a court’s ability to exercise personal jurisdiction over a claim – most notably, the US Supreme Court’s 2017 decision in *Bristol-Myers Squibb Co v. Superior Court*.\(^7\) That said, some courts have found that 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.\(^8\) 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 substantial business there such that it is ‘fairly regarded as at home’ (also known as ‘general’ personal jurisdiction).\(^9\)

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.\(^8\) As a result, product liability trials will often involve a ‘battle of the experts’, the outcome of which may dictate the jury’s verdict.\(^8\)

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\(^8\) See *Burger King Corp.*, 471 U.S. at 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 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 was 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. However, 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 contracts with the state. See *Daimler AG*, 134 S. Ct. at 754. If a company is incorporated in the forum state or maintains its principal place of 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.

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 assists the trier of fact; is ‘based on sufficient facts or data’; is ‘the product of reliable principles and methods’; and involves a reliable application of those ‘principles and methods to the facts of the case’. Before 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’. 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, and may be obtained through a number of methods, including depositions, written interrogatories (usually limited to 25), requests for production of documents, requests for inspection of evidence or premises and requests for admissions. A party may also move the court to obtain a physical or mental examination of the other party. 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 and proportional to the needs of the case’. In considering what discovery is ‘proportional’ to the needs of the case, courts must weigh ‘the importance of the issues at stake in the action, the amount in controversy, the parties’ relative access to relevant information, the parties’ resources, the

84 Fed. R. Evid. 702; see, e.g., Del. R. Evid. 702; N.C. R. Evid. 702(a); Ariz. R. 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).

85 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 ‘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: whether the expert’s theory or technique can be tested; whether the theory has been subjected to peer review and publication; the rate of error in the scientific technique; and 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).


importance of the discovery in resolving the issues and whether the burden or expense of the proposed discovery outweighs its likely benefit.90 Most states have modelled their procedural rules on the federal system and allow for similar methods and scope of discovery.91 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.92 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, attorney work-product doctrine or trade secret privilege.93

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 sometimes appoint a magistrate judge94 to preside over discovery matters. State and federal courts may also appoint a ‘special master’ to address unique or voluminous discovery issues.95

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.96 Thus, a plaintiff may join all tortfeasors in one action and choose which one to pursue for recovery.97 It is then up to the defendant to seek

94 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 U.S. 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 U.S.C. §636(c)(1)). Nonetheless, discovery matters and disputes in federal courts are frequently referred to magistrate judges.
95 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.
97 See Therrien, 830 A.2d at 37.
(by agreement or legal process) contribution by other defendants. A majority of states have abolished the doctrine of pure joint and several liability in favour of apportioning damages based on each party’s percentage of fault.98

Successor liability

Traditionally, a purchaser of a company’s assets (rather than stock) is not liable for the seller’s liabilities unless the successor company assumed the seller’s liabilities via an express or implied agreement; the purchasing company effectively merged with the selling company; the transaction was fraudulent; or the buying company was a mere continuation of the seller.99 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’.100 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.101

Market share 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 [the] market unless it demonstrates that it could not have made the product which caused plaintiff’s injuries’.102 This theory has been sparingly applied by the courts. In the majority of product liability cases, there remains a burden on the plaintiff to prove that he or she was injured by the defendant’s specific product.103

98 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)).


**Contribution and 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.\(^{104}\)

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### 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 the class is 'so numerous that joinder of all members is impracticable'; there are 'questions of law or fact common to the class'; the claims or defences of class representatives are 'typical of the claims or defenses of the class'; and the class representatives and their counsel can 'fairly and adequately protect the interests of the class'.\(^{105}\) Most states have similar requirements for class actions.\(^{106}\)

Class actions filed against product manufacturers can be brought on behalf of consumers residing in a single state, multiple states or nationwide. While plaintiffs' counsel often will seek to increase a defendant's exposure by filing a multi-state or nationwide class action, such classes have come under increasingly stringent review in recent years. Specifically, courts have held that variations in state law may predominate over 'common' issues or may create significant manageability problems such that a class action is not superior to other available methods for fairly and efficiently adjudicating the controversy.\(^{107}\)

One of the most important developments in the law of class actions in the past two decades was the enactment of the Class Action Fairness Act of 2005 (CAFA).\(^{108}\) 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.\(^{109}\)

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\(^{104}\) See *Bradley v. Earl B. Feiden, Inc.*, 8 N.Y.3d 265, 274–75 (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 Mach.*, 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').

\(^{105}\) Fed. R. Civ. P. 23(a).


\(^{107}\) For instance, the Ninth Circuit – widely regarded as the most class-action-friendly court of appeals – held that a district court abused its discretion in granting final approval to a nationwide class settlement because it failed to conduct a choice-of-law analysis to ensure that common questions outweighed individual issues. See *In re Hyundai & Kia Fuel Econ. Litig.*, 881 F.3d 679 (9th Cir. 2018). The Ninth Circuit subsequently ordered that the *In re Hyundai* cases be reheard *en banc* and that the opinion not be cited as precedent by or to any court of the Ninth Circuit. See *In re Hyundai & Kia Fuel Econ. Litig.*, 897 F.3d 1003 (9th Cir. 2018). The Ninth Circuit heard oral argument *en banc* on 27 September 2018.


\(^{109}\) 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 U.S.C. §1332(d)(2), (d)(5)(B))); see also *Progressive W. Ins. Co. v. Preciado*, 479 F.3d 1014, 1015 (9th Cir. 2007).
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.\(^{110}\) This consolidation is referred to as multidistrict litigation (MDL) and is intended ‘to provide centralised management of pretrial proceedings and to ensure their “just and efficient” conduct’.\(^{111}\) Actions may be transferred to an MDL either by a specially created judicial panel or by motion of a party.\(^{112}\) At the conclusion of pretrial proceedings, MDL cases are transferred back to their home districts for trial or other resolution.\(^{113}\) Many states also provide similar mechanisms for aggregating certain actions before a single judge for pretrial proceedings.\(^{114}\) One popular venue for aggregated mass tort actions is the Philadelphia Court of Common Pleas.\(^{115}\)

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.\(^{116}\) 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.\(^{117}\)

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’.\(^{118}\) Non-economic or

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\(^{112}\) 28 U.S.C. §1407(c); In re Phenylpropanolamine (PPA) Prods. Liab. Litig., 460 F.3d 1217, 1230 (9th Cir. 2006).

\(^{113}\) See 28 U.S.C. §1407(a).

\(^{114}\) See Cal. Rule of Court 3.541 et seq.; Or. R. Civ. P. 32.K.

\(^{115}\) See www.courts.phila.gov/common-pleas/trial/civil.

\(^{116}\) 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 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).

\(^{117}\) AU Optronics Corp., 134 S. Ct. at 741–46.

\(^{118}\) 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.
‘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. Some states impose caps on the amount of non-economic damages available to plaintiffs.

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 in the absence of an injunction. 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 or inadequate label and will be able to avoid those dangers in the future. 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.

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.

119 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.

120 See, e.g., Mich. Comp. Laws §600.2946a (imposing a US$280,000 or US$500,000 cap on non-economic damages in product liability actions); Md. Code Ann. §11-108(b)(2) (imposing a US$500,000 cap on non-economic damages in actions for personal injury or wrongful death).


124 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 (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...
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.  

**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 a defective product to market. Notably, however, the Federal Food, Drug, and Cosmetic Act (FDCA) criminalises even the unintentional production or distribution of ‘adulterated or misbranded’ food, drugs and cosmetics.

### V YEAR IN REVIEW

#### i Notable court decisions

The US Supreme Court decided several notable product liability cases in 2019. In May, the Supreme Court issued its opinion in *Merck Sharp & Dohme Corp. v. Albrecht*, a case involving hundreds of plaintiffs who allege that the drug manufacturer Merck failed to adequately warn consumers that its osteoporosis drug Fosamax carried a risk of atypical femur fractures.  

Previously, the district court had held that the plaintiffs’ claims were pre-empted by federal law because there was ‘clear evidence’ that the FDA would not have approved the plaintiffs’ proposed warning. On appeal, the Third Circuit reversed, holding that the plaintiffs had produced sufficient evidence from which a reasonable juror could determine that it was not ‘highly probable’ that the FDA would have rejected the plaintiffs’ proposed warning. The Third Circuit reasoned that the ‘clear evidence’ standard was an evidentiary standard and posed a question of fact for the jury. In a nine to zero decision, the Supreme Court reversed and decided that ‘clear evidence’ was a question of law for the judge to decide. In answering the question, the judge must determine whether the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer

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127 See 21 U.S.C. §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)).


129 id.

130 id., at 1675–76.

131 id., at 1676.

132 id., at 1672.
that the FDA would not approve a change to the drug’s label to include that warning.\textsuperscript{133} Although this decision was viewed as a win for the pharmaceutical industry, the majority opinion – along with a concurrence in the judgment – nevertheless emphasised the high standard required for ‘impossibility’ pre-emption to apply in prescription drug cases.\textsuperscript{134}

Additionally, the Supreme Court decided \textit{Air & Liquid Systems Corp. v. Devries},\textsuperscript{135} a maritime personal injury action filed against the manufacturer of engines installed on Navy vessels.\textsuperscript{136} The estates of deceased sailors and their spouses alleged that the engines were insulated by materials containing asbestos, which contributed to the sailors’ cancer.\textsuperscript{137} The question on appeal was whether the defendants could be held liable for the sailors’ injuries even though the asbestos was fitted onto the defendants’ engines by third parties, well after the defendants distributed the engines to the Navy.\textsuperscript{138} The Supreme Court held that the manufacturer could be held liable if its product requires incorporation of a part, the manufacturer knows or has reason to know that the integrated product is likely to be dangerous for its intended uses, and the manufacturer has no reason to believe that the product’s users will realise that danger.\textsuperscript{139} The decision expands the general scope of product liability, which traditionally imposes liability only when the defendant manufactured, distributed or sold the actual product that was defective. The breadth of this decision, however, is limited since it was established as a matter of federal maritime law,\textsuperscript{140} whereas most product liability actions in the United States are brought under the laws of an individual state.

Beyond the US Supreme Court, there were several notable product liability decisions issued by lower federal and state courts last year.

In \textit{Oberdorf v. Amazon.com Inc}, a Third Circuit panel considered whether Amazon was a ‘seller’ of a third-party vendor’s product when the vendor uses Amazon’s website to facilitate the sale.\textsuperscript{141} The panel held that Amazon was the ‘seller’ and therefore liable for any product defects.\textsuperscript{142} The divided panel rejected Amazon’s argument that it was not the seller because it never took title to or possession of the third-party vendor’s product.\textsuperscript{143} If left undisturbed, the ruling would expand the potential liability of online retailers who sell third-party products in Pennsylvania – and potentially other states with similar product liability regimes. In August, however, the Third Circuit granted Amazon’s petition to rehear the case en banc, vacating the panel’s opinion and judgment.\textsuperscript{144} The Third Circuit’s decision to take the case en banc underscores the importance of this unsettled issue of state tort law.

Additionally, in \textit{Soto et al. v. Bushmaster Firearms International LLC}, the Supreme Court of Connecticut held that gun manufacturers could be held liable for certain marketing

\textsuperscript{133} id.
\textsuperscript{134} id., at 1678.
\textsuperscript{135} 139 S. Ct. 986, 991 (2019).
\textsuperscript{136} id.
\textsuperscript{137} id.
\textsuperscript{138} id., at 992.
\textsuperscript{139} id., at 991.
\textsuperscript{140} id.
\textsuperscript{141} 930 F.3d 136, 150–51 (3d Cir.), reh’g en banc granted, opinion vacated, 936 F.3d 182 (3d Cir. 2019).
\textsuperscript{142} id.
\textsuperscript{143} id., at 149.
\textsuperscript{144} \textit{Oberdorf v. Amazon.com Inc.}, 936 F.3d 182, 183 (3d Cir. 2019).
practices, notwithstanding the Protection of Lawful Commerce in Arms Act,\(^\text{145}\) a federal law that generally provides civil immunity for gun manufacturers and dealers when third parties use their products for unlawful purposes.\(^\text{146}\) The Supreme Court of Connecticut held that the act does not provide immunity when the manufacturer’s marketing practices inspire or intensify illegal, offensive uses of the products.\(^\text{147}\) The US Supreme Court denied certiorari, which allows the Connecticut decision to remain in effect within the state.\(^\text{148}\) It remains to be seen whether other state high courts will follow suit.

**ii Federal laws and regulation**

As 2019 drew to a close, federal lawmakers passed amendments to the federal Food, Drug, and Cosmetic Act to raise the federal minimum age of sale of tobacco products from 18 to 21 years.\(^\text{149}\) While this legislation comprised one of the few noteworthy product liability reforms enacted by Congress last year, federal agencies ushered in new regulations and guidance that could entail significant changes for certain product manufacturers.

For instance, the FDA has taken steps to investigate certain vaping products in the wake of several deaths associated with e-cigarettes containing tetrahydrocannabinol (THC).\(^\text{150}\) Data suggest that the majority of these injuries may be derived from pre-filled THC cartridges sold in states where neither medical nor recreational marijuana use has been legalised.\(^\text{151}\) The FDA also banned certain flavoured vaping products in an attempt to prevent the sale of nicotine products that disproportionately appeal to children.\(^\text{152}\)

Additionally, the Department of Transportation continues to provide guidance on autonomous vehicles.\(^\text{153}\) Notably, the National Transportation Safety Board has been investigating crashes involving automated vehicle technology to promote safety, harmonise regulatory policies and facilitate the integration of automated vehicles throughout the transportation system.\(^\text{154}\) The agency continues to rely on voluntary consensus standards to promote cost-efficient innovation.\(^\text{155}\)

146 id., at 116–17, 202 A.3d at 300–01.
147 id., at 157–58, 202 A.3d at 325.
151 id.
154 id.
155 id.
Finally, while federal lawmaking concerning product liability issues has been intermittent and relatively limited during the Trump administration, states are enacting substantial reforms to their tort laws. Last year, for example, Missouri adopted several sweeping tort reform measures, the most significant of which seeks to curtail the ability of plaintiffs to bring mass tort and class action cases in Missouri if their claims lack a sufficient nexus with the state. Reverberations may soon be felt in other jurisdictions, as the city of St Louis has become the epicentre of several mass tort actions, due to its reputation as one of the most plaintiff-friendly jurisdictions in the nation.

iii Multi-district litigation

2019 was another big year for multi-district litigation (MDL). Claims against pharmaceutical manufacturers about their alleged role in the opioid epidemic continued to dominate the headlines. There are several different categories of pending opioid cases. State attorneys general have often pursued their own actions in their respective state courts. For instance, Oklahoma has secured a US$465 million judgment against opioid manufacturers. Additionally, well over a thousand state and local governments have brought suits that are consolidated in the US District Court for the Northern District of Ohio. Finally, private parties, such as hospitals and individual consumers, have also filed suit, though these actions have generally garnered less publicity. Most notably, in the consolidated proceeding involving claims asserted by local governments, the MDL court recently approved a novel class action device called a ‘negotiation class’. Specifically, the court certified a class of 49 representative local governments authorised to negotiate a settlement with opioid manufacturers on behalf of all other local governments within the class. The result of the negotiation would bind any local government that did not ‘opt out’ of the settlement class. While the viability of such a device has yet to be tested on appeal, the novel prospect of certifying a ‘negotiation class’ – in which the court elides complicated questions of causation and liability among dozens of differently situated parties – could have a profound effect on mass-tort litigation if replicated elsewhere.

Other high-profile MDLs concern Monsanto’s Roundup, 3M’s military earplugs and Johnson & Johnson’s talcum powder, which are consolidated in federal courts in California, Florida and New Jersey, respectively. In the Roundup litigation, plaintiffs have filed suit over

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157 MO. REV. STAT. § 508.010 (incorporating Missouri Senate Bill 7 (2019 Regular Session)).
158 See e.g., Michigan v. Cardinal Health Inc., et al., case number 19-016896-NZ, in the Circuit Court for the County of Wayne.
159 Oklahoma v. Purdue Pharma L.P., et al., final judgment after non-jury trial, case number CJ-2017-816, in the District County of Cleveland County.
160 In re National Prescription Opiate Litigation, case number 1:17-md-02804, in the U.S. District Court for the Northern District of Ohio.
161 See e.g., Dallas County Hospital District et al. v. Purdue Pharma L.P., et al., case number DC-19-13794, in the District Court of Dallas County, Texas.
163 id., at 556.
164 id., at 554.
Monsanto’s Roundup weed killer, which contains a herbicide called glyphosate. Over 40,000 plaintiffs have alleged that long-term use of the product caused them to develop non-Hodgkin’s lymphoma. Jury verdicts in these cases include billion-dollar punitive damages awards, though many of these judgments have been judicially reduced in post-trial motions. The 3M military earplug litigation involves military veterans who allegedly suffered hearing loss, tinnitus and loss of balance after their use of 3M’s earplugs, which were designed to block loud noises that soldiers experience during combat. The manufacturer has already settled with the Pentagon, the government agency that originally purchased the earplugs. Now, the manufacturer faces personal injury suits brought by individual veterans who claim their injuries were caused by the allegedly defective product. Finally, in the talcum powder litigation, consumer product manufacturers are being sued over claims that their baby powder contains asbestos, which allegedly caused plaintiffs to develop various forms of cancer. Trials have produced mixed results thus far, with some juries awarding damages as high as US$4.6 billion, while other juries have rendered complete defence verdicts.

In short, the stakes in multi-district litigation continue to rise each year. And, not surprisingly, more cases than ever are consolidated in MDLs. Indeed, for the first time in history, multi-district litigation now accounts for a majority of the federal civil docket, with 52 per cent of the entire civil caseload consolidated in MDLs. Accordingly, product manufacturers doing business in the United States must be prepared to mobilise a defence strategy quickly if the company faces a potential viral litigation risk.
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In 2013, he was particularly active within product liability cases and issues, especially within the health sector in France and at the European level. Christophe notably managed many cases for several pharmaceutical companies in relation to the ‘contraceptive pill scandal’, as well as the furosemide case, and was entrusted with advising the pharmaceutical manufacturer on the criminal complaints issued against an oral anticoagulant medicinal product.

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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.
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Natasha Lioubimova is an associate in Clyde & Co’s London office. She has broad experience of advising on insurance coverage and liability issues relating to products, both in the context of defending claims, and pursuing subrogated recoveries. She has worked on a range of product liability cases including those concerning food, cosmetic products, industrial machinery and pet products. Recently, Natasha defended a company in a multiparty litigation concerning the supply of allegedly contaminated food products.

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 United States 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.

SHEENA MCKIE
Clayton Utz

Sheena McKie is a special counsel 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 United States, the European Union and New Zealand in advisory matters, including product recalls, as well as in the coordinated defence of similar claims internationally.

ELAINE M MALDONADO-MATÍAS
Sepulvado, Maldonado & Couret

Elaine M Maldonado-Matías is the managing partner at Sepulvado, Maldonado & Couret, in San Juan, Puerto Rico. Before joining Sepulvado, Maldonado & Couret, 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 in the labour and employment law practice group. Since joining Sepulvado, Maldonado & Couret 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.

JOANA MOTA
Uría Menéndez – Proença de Carvalho


Joana focuses her practice on the acquisition, protection and maintenance of national and international IP rights and has represented parties in related litigation proceedings. She has also advised companies on personal data protection issues.

Joana has a postgraduate qualification in IP law, awarded by the Portuguese Association of Intellectual Property Law in conjunction with the Faculty of Law of the University of Lisbon. She also has an advanced qualification in data protection law from the University of Lisbon.
CLARA NG
_Baker McKenzie. Wong & Leow_

Clara is an associate with Baker McKenzie. Wong & Leow. She assists and advises on a variety of contentious and non-contentious intellectual property, healthcare and consumer goods regulatory matters. She regularly advises on the full spectrum of regulatory issues in the healthcare industry, including compliance issues arising from the supply of medicines, medical devices and food products. Where consumer goods are concerned, she has assisted with product recalls and advised on various labelling issues for clients in all sectors, including those in the luxury goods and fast-moving consumer goods industries.

ALEXANDRE PEDRAL Sampaio
_Uría Menéndez – Proença de Carvalho_

Alexandre Pedral Sampaio joined Uría Menéndez – Proença de Carvalho as a trainee lawyer in 2013 and became an associate of the firm in 2015.

Alexandre currently focuses his practice on corporate and real estate law, in particular on the sale, purchase and development of real estate assets, mergers and acquisitions with an underlying real estate component, acquisition finance, refinancing and restructuring of firms in the real estate and hotel industries, and on the acquisition of REO and mortgage-backed loan portfolios, advising clients on the negotiation of complex commercial contracts in the fields in which he works.

Alexandre also has experience in matters relating to data protection, e-commerce and intellectual property.

KAAVYA RAGHAVAN
_AZB & Partners_

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

Kaavya received her BBA LLB (Hons) from School of Law, Christ University in 2016. She subsequently obtained an LLM with a specialisation in international financial law from the King’s College London in 2018 and began her career at AZB & Partners in 2019.

HIDENORI SATO
_Nishimura & Asahi_

Hidenori Sato is an attorney-at-law at Nishimura & Asahi. He has worked in the dispute resolution practice, including large-scale arbitration and tax disputes. He is also representing a reputable pharmaceutical company in a significant product liability case. He is a graduate of University of Tokyo (JD, 2015) and was admitted to the Bar in Japan in 2016.
FRANK SCHERRER
Wenger & Vieli Ltd
Frank Scherrer obtained his law degree from the University of Neuchâtel, Switzerland in 1991; his LLM in European legal studies from the University of Exeter, United Kingdom in 1993; his Dr.iur. from the University of Zurich, Switzerland in 1996; and he 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.
Mr Scherrer speaks German, English and French.

ANDREA SCHÜTZ
Wenger & Vieli Ltd
Andrea Schütz obtained her law degree from the University of Fribourg, Switzerland in 2003; her Dr.iur. from the University of Zurich in 2011; her LLM in health and medical law from the University of Melbourne in 2014; and her CAS in forensics from the University of Lucerne in 2016. She was admitted to the Bar in Switzerland in 2008.
Her areas of practice include pharmaceutical and health law, product liability law, life sciences, administrative law, data protection law, intellectual property law and administrative criminal law.
Recent mandates include advising and representing pharmaceutical companies in legal proceedings concerning product liability. Ms Schütz has advised and represented pharmaceutical companies in appeal proceedings regarding price decreases and revisions of marketing authorisations. She also advises companies on a regular basis regarding contracts, advertising, sponsoring and gifts, and data protection.
Ms Schütz is also performing the legal review of a multinational pharmaceutical company’s advertising and PR material for Switzerland.
She 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. Her clients include industry leaders in the automotive, electronics, hydronic, pharmaceutical and chemical industries.
MICHELA TURRA

Gianni, Origoni, Grippo, Cappelli & Partners

Michela Turra is managing associate at the firm and over the course of her career has built up extensive experience in the field of litigation, with a particular focus on civil and international actions.

She specialises in product and safety liability and over the past 17 years she has assisted and advised numerous domestic and foreign companies, providing full scope assistance in matters concerning consumers’ claims and multi-claimant group actions. Also, she assisted major companies in all processes for product recalls and withdrawals, also relating on their behalf with safety authorities.

She regularly contributes to international publications in her field of specialisation.


She speaks Italian and English.

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 lawyer 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. She currently serves as president of the Supreme Court Historical Society. She serves on the editorial board of Moore’s Federal Practice, a leading treatise about practice in federal courts.

JULIE VASSEUR

Intuity

After completing legal studies at McGill University, Pantheon-Sorbonne University and the University of Helsinki, Julie Vasseur joined Intuity in 2015.

She has had several opportunities to acquire experience in the healthcare sector. Prior to joining Intuity, Julie Vasseur was a research assistant at McGill, where she organised conferences for the McGill Research Group on Health and Law. She also worked in an international pharmaceutical company, where she drafted, reviewed and negotiated contracts, declared data to the French Data Protection Authority and advised the various business units in healthcare regulatory law through meetings and position papers.

Julie Vasseur has solid expertise in the regulatory and competitive positioning of pharmaceutical firms, as well as in their judicial and administrative defence against complaints involving allegedly defective products.
DANIELE VECCHI

*Gianni, Origoni, Grippo, Cappelli & Partners*

Daniele Vecchi, a partner in the litigation department of Gianni, Origoni, Grippo, Cappelli & Partners, practises general commercial and civil litigation, and is a specialist in product and safety liability. He has extensive experience in defending companies in consumer and group actions involving tobacco products, food and pharmaceuticals.

Over the course of his career, he has worked extensively with in-house counsel and lawyers in Italy and abroad, developing an international defence strategy with important expert witnesses.

Internationally recognised as a leading expert on product liability and class actions, he regularly contributes to international publications and speaks at national and international conferences.


He speaks Italian and English.

ARIEL YE

*King & Wood Mallesons*

Ariel Ye has more than 25 years of experiences in cross-border commercial dispute resolution. As a senior partner of King & Wood Mallesons’ arbitration and dispute resolution practice group, Ms Ye has long been recognised as a leading expert in PRC-related dispute resolution in the Asia-Pacific region.

Ms Ye focuses on international arbitration, China-related compliance work and cross-border dispute resolution. Ms Ye has represented domestic and foreign clients at the China International Economic and Trade Arbitration Commission; and Chinese clients before the Stockholm Commercial Arbitration Board, the Hong Kong International Arbitration Centre, the American Arbitration Association International Center for Dispute Resolution and the International Chamber of Commerce Court of Arbitration, etc.

Ms Ye received her LLB from the Peking University Law School and a master’s degree from the China Academy of Social Sciences law school, as well as an LLM degree from Harvard Law School. She has been admitted to practise in both China and New York State. Her working languages are Chinese and English.

SERGEY YURYEV

*CMS Russia*

Sergey Yuryev is a partner at 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 25 years’ experience advising clients in the practice areas of dispute resolution, general commercial law and product liability law. Leading CMS Russia's dispute resolution practice, he has vast experience in defending clients before the Russian regulatory authorities and courts on the product liability matters. Mr Yuryev has represented a range of clients on product liability and professional negligence matters in various industries, including automotive, retail, healthcare and pharmaceuticals. 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 Dedman School of Law of Dallas, Texas (1997). He is fluent in English.

One of the leading legal rankings *The Legal 500 EMEA* regularly recognises Sergey Yuryev for dispute resolution, arbitration and mediation in Russia.
Appendix 2

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