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Practical cross-border insights into product liability

# Product Liability 2022

## 20th Edition

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# Expert Analysis Chapters



# Q&A Chapters

# England & Wales


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## 1 Liability Systems

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

Product liability claims may be made under the Consumer Protection Act 1987 ("CPA"), in negligence or arising from a breach of contract. Although claims can be made in respect of the breach of some statutory obligations, such as certain duties imposed by product safety and health & safety legislation, consumer fraud laws do not give rise to private law rights to claim compensation.

The CPA implemented the Product Liability Directive, 85/374/EEC, in the United Kingdom ("UK"). Following the withdrawal of the UK from the European Union ("EU"), the CPA continues to apply in the UK, subject to amendments made by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations (SI 2019/696). However, the CPA will no longer be updated in line with changes to the EU Product Liability Directive and does not have to be interpreted in line with decisions of the Court of Justice of the European Union ("CJEU") made after the UK's withdrawal from the EU. Case law of the CJEU which preceded the UK's withdrawal is part of retained EU law and continues to be binding on UK Courts unless and until the Supreme Court or some other appellate courts issue a judgment explicitly departing from it. No significant changes to the UK regime are anticipated in the short term, but there is plainly scope for the EU and UK product liability regimes to diverge in future.

The CPA imposes liability on the producer of defective products for damage caused by the defect. A product is defective if it is not as "safe as persons generally are entitled to expect", taking account of all of the circumstances, including any instructions or warnings provided with the product and the manner in which it has been marketed.

Recent authority suggests that the assessment of defect depends on the facts of the case, but that a wide range of factors may be relevant circumstances, including compliance with regulatory requirements, whether the risks could be avoided and, in the case of medicinal products where safety is always relative, the risk-benefit balance (*Wilkes v Depuy International Limited* [2016] EWHC 3096). This conflicts with an earlier decision that adopted a much narrower approach to the assessment of defect (*A and Others v The National Blood Authority and Others* [2001] 3 All ER 298 (the so-called "Hepatitis C" case)). The approach to defect in *Wilkes* was followed in another English case involving allegedly defective hip prostheses: *Gee & Others v DePuy International Limited* [2018] EWHC 1208 (QB), by the Scottish Court of Session in *Hastings v Finsbury Orthopaedics and Stryker UK Ltd* [2019] CSOH 96, and has also been approved by the Court of Appeal in *Bailey & Others v GlaxoSmithKline UK Limited* [2019] EWCA Civ 1924. Liability is strict: it is not necessary to prove that the manufacturer was at fault in causing the defect. A claimant need only prove the presence of a defect and a causal relationship between the defect and the injury.

Claims may only be brought under the CPA in respect of products put into circulation (i.e. entering the distribution chain) after 1 March 1988. Claims relating to products supplied before this date must be brought in negligence or breach of contract. Even if the dispute is governed by English law, the CPA may not apply to non-EEA claims (*Allen v Depuy International Ltd* [2014] EWHC 753 (QB), where the court held that the CPA did not apply in circumstances where the damage was caused outside the European Economic Area ("EEA"), the claimants had no connection with the EEA, and the defective product was supplied outside the EEA).

In order to establish negligence, it is necessary to prove that the defendant owed a duty of care to the claimant, that he breached that duty by failing to take reasonable care, and that the breach caused the damage complained of. Such claims are commonly brought against the manufacturer of a defective product, although they may also be brought against other parties in the supply chain, if fault can be established.

Claims for breach of contract may only be brought against the immediate supplier of the defective product to the person injured. Liability is strict where the contract has been breached, but this will depend upon the terms of the contract agreed between the parties or implied into the contract.

Consumer contracts are regulated by the Consumer Rights Act 2015, which provides consumers with certain statutory rights. All contracts to supply goods include a term that the goods are of satisfactory quality and comply with the description applied to them or a sample supplied. The goods must also be fit for any particular purpose made known by the consumer to the seller before the contract is concluded. However, the seller will not be liable for faults drawn to the buyer's attention prior to the contract, or which should have been revealed by the buyer's examination of the goods. There is a presumption that goods that malfunction during the first six months after delivery were in breach of contract at the time of supply. Public statements made by manufacturers, importers, distributors and retailers of the product – for example, in labelling and advertising – must also be factually correct and form part of the retailer's contract with the consumer. These statutory rights may not be excluded. Additional rights apply in respect of standard terms not individually negotiated with consumers.

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

Claims for breach of statutory duty can be brought where the courts are satisfied that a statute was intended to create a private law right, actionable by an individual harmed by the breach. It is well established that claims can be made in respect of damage caused by the breach of many product safety and health & safety regulations. However, no such rights have been found to arise from breach of consumer statutes such as the Trade Descriptions Act 1968, the Consumer Protection from Unfair Trading Regulations 2008 and the Business Protection from Misleading Marketing Regulations 2008, which regulate unfair commercial practices and the provision of trade descriptions and advertisements to consumers. To date, there has been no UK litigation similar to the consumer fraud litigation pursued in some US states.

### 1.2 Does the state operate any special liability regimes or compensation schemes for particular products e.g. medicinal products or vaccines?

Under the Vaccines Damage Payments Act 1979, a fixed payment of £120,000 is provided to persons suffering severe disablement as a result of certain listed vaccinations. In general, injured persons are eligible to receive a payment under the scheme only where the relevant vaccination was administered to a person under the age of 18 years, in the context of an outbreak of the disease in question in the UK or related to certain specified vaccinations. On 3 December 2020, the Vaccine Damage Payments (Specified Disease) Order 2020 added COVID-19 as a disease to which the Act applies, meaning that those suffering severe disablement as a result of COVID-19 vaccination are potentially eligible to receive compensation. Compensation schemes have also been set up to resolve specific claims, e.g. the schemes relating to HIV and Hepatitis C contamination of blood products.

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

Under section 2 of the CPA, liability principally rests on the "producer" (the manufacturer), the importer of the product into the UK, or an "own brander" (i.e. any person who, by labelling or the use of trademarks, holds himself out as being the producer of the product).

The supplier (whether the retailer, distributor or a wholesaler) may be liable in place of the manufacturer if he fails to identify the producer or at least the person who supplied the product to him. In Case C-358/08, *O'Byrne v Aventis Pasteur SA*, the CJEU said that the requirement is that "the supplier, against whom proceedings are brought by an injured person, inform the latter, on its own initiative and promptly, of the identity of the producer or its own supplier". Whether these conditions are met is a factual matter to be determined by the court. Under the CPA, the obligation to identify is triggered by a request from a claimant. Following the withdrawal of the UK from the EU, it is possible that UK courts will, in future, find that the plain words of the UK statute do not impose any requirement on a supplier to do more than respond to a request; however, any deviation from CJEU case law applicable at the withdrawal date would require a decision by the Supreme Court or other relevant appellate court.

Where a claim is brought in negligence, liability falls on the party that has breached its duty of care to the claimant; this can be any person or organisation in the supply chain.

Contractual liability may be passed down the supply chain through a series of contractual agreements between the manufacturer, distributor, retail supplier, customer and others, depending on proof of breach of the contractual terms in each case and subject to any exclusion clauses.

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

In England and Wales, a public body charged with exercising a regulatory function in relation to public welfare may be liable for breach of statutory duty if a right to sue for breach of statutory duty is provided by or may be inferred from the relevant legislation.

In limited circumstances, a regulatory body may be liable in negligence for the careless performance of its statutory duty. However, while a claim is possible in principle, the courts are generally reluctant to find that a duty of care arises. In *Smith v Secretary of State for Health* [2002] Lloyd's Med LR 333, no duty of care was found to arise in relation to an allegedly negligent failure by the UK medicines regulatory authority to issue a timely warning about the risks of aspirin in children and adolescents. This decision indicates that no duty of care is owed by a regulator in relation to its own policies, but that a duty of care may be owed in relation to proper implementation of a policy. Other more recent cases involving public authorities, e.g. police or local councils, have tended to follow this approach.

The courts will generally not impose new private law duties of care, except incrementally by analogy with established case law; however, where an authority creates a risk of injury, it may owe a duty to protect individuals against the danger it has created (*Michael v Chief Constable of South Wales Police* [2015] UKSC 2; *Robinson v Chief Constable of West Yorkshire* [2018] UKSC 4; and *Poole BC v GN* [2019] UKSC 25).

The judgment of the CJEU in Case C219/15 *Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH* concerned the liability of a regulatory body (a notified body responsible for assessing conformity of certain products before being placed on the market) for harm caused by faulty breast implants. While indicating that notified bodies were under a duty of sorts, the case essentially confirmed that such liability was a matter of national law competence.

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

Claims for a failure to recall may be brought under the CPA, in negligence and in contract. A duty to withdraw unsafe products underpins the CPA as this imposes strict liability for defective products. Manufacturers/retailers may owe a duty of care in negligence to institute a recall or product withdrawal in appropriate cases. They owe a duty to keep the products they produce/supply under review and to warn of risks that come to light after the product has been supplied. If warnings are not adequate to manage the risk, the product may need to be modified or withdrawn.

Under the General Product Safety Regulations 2005 (the "GPS Regulations"), producers must ensure that they only place safe products on the market, and must take measures to manage any risks that are identified including, in appropriate cases, issuing warnings or withdrawing or recalling the product from the market. The GPS Regulations impose an obligation on producers and distributors to inform the authorities if a product is unsafe. Although the regulations provide for criminal penalties, breach of the requirements may also be of evidential value in supporting a civil claim.

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

Yes. Criminal sanctions are imposed for breach of the GPS Regulations. It is an offence for a producer to offer or agree to supply or otherwise place an unsafe product on the market, punishable on conviction with an unlimited fine and/or a 12-month term of imprisonment. A range of penalties apply to other breaches of the GPS Regulations. The enforcement authorities also have the power to issue notices compelling the producer to take certain actions, e.g. compelling the withdrawal or recall of products or requiring the provision of warnings.

The GPS Regulations apply to all products to the extent that these are not subject to other specific safety requirements in product- or sector-specific regulations. Separate regulations apply to specific types of products, such as medicines, medical devices, foods, toys, cosmetics, machinery and electrical equipment, and this legislation imposes its own criminal sanctions.

## 2 Causation

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

A claimant has the burden of proving his/her case on the "balance of probabilities".

Under the CPA, a claimant must prove that the product is defective, and that the defect caused damage to the claimant. The claimant does not need to prove the cause of the defect or why the product failed, or to identify the defect with precision. He only needs to prove in general terms that a defect exists and that it caused the damage complained of (*Hufford v Samsung Electronics (UK) Ltd* [2014] EWHC 2956 (TCC)).

In *Al-Iqra and others v DSG Retail Ltd* [2019] EWHC 429 (QB), the High Court held that a faulty electric heater, which led to a household fire causing the claimants significant injury, ignited by reason of a defect under section 3 of the CPA. It did not matter that the claimants were unable to identify the specific mechanism or cause of the ignition. The judge noted that, given the ferocity of the fire and the fact that not all the component parts of the heater were recovered, it was unsurprising that there had been no definitive identification of the actual defect. This judgment, whilst creating no new law, serves as a useful reminder of the meaning of "defect" under section 3 of the CPA and how the courts apply this test.

(See also in *Baker v KTM Sportmotorcycle UK Ltd and another* [2017] EWCA Civ 378: a judge had been entitled to find that there must have been a defect in a two-year-old, fully serviced motorcycle which caused the brakes to seize, resulting in personal injury to the claimant. The claimant was not required to identity the specific defect to successfully bring a claim under the CPA.)

Where the producer relies on defences under the CPA, including the development risks defence, the producer has the burden of proving that defence: see the answers to questions 3.1 and 3.2 below.

In negligence, a claimant must prove that the defendant breached the duty of care he owed to the claimant, and that this negligence caused damage to the claimant.

In contract, a claimant must establish that the defendant breached his contract with the claimant by supplying product(s) that did not meet the terms and conditions of the contract, and that such breach caused damage to the claimant. The burden of proving breach of contract is reversed in the case of consumer contracts if the product malfunctions in the first six months after delivery; the product is presumed not to conform to the contract at the time of supply.

### 2.2 What test is applied for proof of causation? Is it enough for the claimant to show that the defendant wrongly exposed the claimant to an increased risk of a type of injury known to be associated with the product, even if it cannot be proved by the claimant that the injury would not have arisen without such exposure? Is it necessary to prove that the product to which the claimant was exposed has actually malfunctioned and caused injury, or is it sufficient that all the products or the batch to which the claimant was exposed carry an increased, but unpredictable, risk of malfunction?

A claimant has the burden of proving, on the balance of probabilities, that the defendant's product caused or materially contributed to the claimant's injuries. The traditional test of causation is the "but for" test: a claimant must prove that, but for the defendant's negligence, or (as the case may be) supply of a defective product, the claimant would not have sustained the injury. This continues to be applied in most cases, for example in the recent case of *Claire Busby v Berkshire Bed Co. Ltd* [2018] EWHC 2976 (QB) in which the court rejected a claim after the claimant sustained tetraplegia following a fall from a bed. Although the bed was not of satisfactory quality as it had two feet missing, the missing feet had not caused or materially contributed to the claimant's fall.

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

What amounts to a material contribution depends on the facts. Where the alleged injury is non-divisible and there are several possible causes, but it cannot be established which of them caused the injury, causation may not be established (*Wilsher v Essex Area Health Authority* [1988] AC 1074). However, in the case of a divisible injury, such as pneumoconiosis, where the injury is caused by multiple factors which have an additive or multiplicative effect, and the tortious cause materially contributed to the

injury, causation may be established (*Bonnington Castings Limited v Wardlaw* [1956] AC 613), but liability is likely to be apportioned to reflect the extent of the tortfeasor's liability for the injury. Where the defendant caused or contributed to an indivisible injury, the defendant will be held fully liable, even though there may well have been other contributing causes (see *Williams v Bermuda Hospitals Board* [2016] UKPC 4). These principles have not been applied to product liability claims, as yet, but are as likely to be relevant to these as they are to clinical negligence claims.

The CJEU considered the position on causation where a product is part of a batch of potentially faulty products in *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt*, Case C-503/13, which involved a claim under the Product Liability Directive. In its decision in that case, which is currently binding on UK courts, the CJEU ruled that if a product, such as a pacemaker, has a potential defect, products belonging to the same production series may also be classified as defective without the need to establish that each individual product is faulty. In reaching its decision, the CJEU found that the safety which persons are entitled to expect from medical devices, such as the pacemakers and implantable cardioverter defibrillators at issue in the proceedings, was particularly high in light of their function and the particularly vulnerable situation of patients using them. Although the decision is concerned with the legal test of "defect", it supports the view that a court may find a defendant liable without proof that the specific product in issue has actually malfunctioned and caused injury.

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

At present, the position remains that, where it cannot be established which of several possible producers manufactured the defective product, the claimant's evidential burden cannot be met and the claim will be dismissed. The English courts have not adopted so-called "market-share" liability. In *Fairchild* (see the answer to question 2.2 above), Lord Hoffman considered this issue and stated *obiter* that market-share liability did not fall within the scope of the present law on causation as the existence of several manufacturers supplying the same defective product did not materially increase the risk of injury. However, he indicated that the issue should be left for further consideration. In *Barker v Corus* he drew a comparison between the *Fairchild* principle and market-share liability, but again declined to decide the point. It remains to be seen whether the English courts will extend the *Fairchild* decision to impose market-share liability where the manufacturer of the defective product cannot be identified.

In this context, an important distinction needs to be made between liability based only on marketing a product ("market-share liability") and on a fact-pattern closer to *Fairchild* in which the claimant has been exposed to the same product, such as a medicine, made by different manufacturers and the actual dose or doses of the drug which caused or materially contributed to the cause of the injury cannot be identified.

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

A failure to warn may give rise to liability both under the CPA and in negligence.

The CPA specifically identifies the "get up" of the product and any instructions or warnings relating to its use as part of all the circumstances to be taken into account in assessing if the product is defective. In *Palmer v Palmer* [2006] All ER (D)86, the court found a device, designed to allow some slack on a seat belt to enhance comfort, to be defective on the basis that the instructions were incomplete and encouraged misuse, thereby compromising the effective operation of the seat belt itself.

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

This decision, combined with the decision in *Webster v Burton Hospitals NHS Foundation* [2017] EWCA CIV 62, can reasonably be viewed in the medical product field as increasing the spotlight upon the activities of the learned intermediary and, in practice, making it more likely that a claimant will focus a claim on the negligence of the clinician, rather than advance a speculative claim against the manufacturer that he is strictly liable for injury arising, despite the regulatory authorities having approved the product and the information supplied with the product.

In *Webster*, the Court of Appeal determined that there was an overriding obligation for a healthcare professional to advise the patient directly on any material risks associated with a proposed treatment and reasonable alternative treatment, unless there was good evidence that this information would itself "damage the patient's welfare". In so doing, the court effectively set aside decades of jurisprudence that treated a doctor as not negligent in the counselling provided to a patient, if the doctor could show that a body of expert opinion would have behaved in the same way as the defendant in fact behaved. This test likely caused many claimants to advance a product liability claim for injury against a manufacturer based on strict liability (or even negligence) rather than seek to prove clinical negligence against a doctor.

In negligence, manufacturers and suppliers owe a duty to take reasonable care to provide adequate warnings and instructions with their products. There is no duty to warn of dangers that are obvious or a matter of common knowledge (see, for example, *B (A Child) v McDonald's Restaurants Ltd* [2002] All ER (D) 436, where the court found that McDonald's were not negligent in supplying cups of hot tea and coffee without a warning, as consumers generally knew that there was a risk of scalding if hot drinks were spilled). Manufacturers owe a duty to warn of dangers identified after the product was first supplied. Failure to warn of design defects identified after marketing may give rise to issues surrounding the application of the development risks defence (see question 3.2 below).

In some circumstances, warnings provided to learned or responsible intermediaries may be sufficient to discharge the

manufacturer's duty of care in negligence. Whether such a warning is sufficient will depend on factors including the likelihood and gravity of the risk and the practicality of providing a personal warning to the ultimate consumer. The learned intermediary doctrine has become less important in cases involving medicinal products, as manufacturers of medicines are required to provide patient information leaflets with their medicines unless the warnings and information can be included on the container or outer packaging of the product.

A failure to warn in breach of duty may sometimes be sufficient to establish liability even if it cannot be shown that the inadequate warning caused the damage suffered by the claimant. In *Chester v Afshar* [2005] 1 AC 134, the House of Lords found that a neurosurgeon was liable for his negligent failure to warn of a rare, but serious, complication of spinal surgery even though the risk was unavoidable and the claimant would probably have had the surgery in any event, even if later. The court considered that a remedy should be available where there was a failure to obtain informed consent. It is unclear whether the same principles would be extended beyond the facts peculiar to that particular case, or would be adopted in a product liability context in relation to a company's obligation to warn in product information.

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

## 3 Defences and Estoppel

### 3.1 What defences, if any, are available?

Under the CPA, the following defences are available:

- the defect is due to compliance with legal obligations imposed by UK or retained EU law;
- the defective product was not supplied by the defendant;
- the product was not supplied for profit and in the course of business;
- the defect did not exist at the time the product was supplied;
- the so-called "development risks defence" applies: the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the allegedly defective product might be expected to have discovered the defect if it had existed in his products while they were under his control; and
- a producer of component products will not be liable if he can show that the defect was due to the design of the final product, or to defective specifications provided to the component producer by the producer of the final product.

The defendant has the burden of proving each of these defences. Such defences have rarely been successful. However, in *Terence Piper v JRI (Manufacturing) Limited* [2006] 92 BMLR 141, the Court of Appeal found that the manufacturer of a defective hip prosthesis was not liable when the prosthesis fractured after implantation, as the prosthesis was not defective at the time it was supplied to the hospital. The court was satisfied, based on evidence of the manufacturer's inspection and quality control systems, that a defect in the surface of the prosthesis would have been detected prior to delivery, even though there was no evidence of inspection of the specific prosthesis. It was not necessary for the manufacturer to prove the actual cause of the defect and when it arose.

Liability under the CPA and in negligence may also be limited by the principles of contributory negligence (see the answer to question 3.6 below).

In negligence, it is a defence if the claimant freely and voluntarily agreed to run the risk of injury in full knowledge of the nature and extent of the risk (*volenti*). Otherwise, the defendant will defeat the claim if the claimant cannot establish each of the elements of negligence. Thus, if the defendant can show that no duty was owed, or his conduct was reasonable, or the negligent act or omission was not causally related to the damage, or that no damage was in fact sustained, he will escape liability. Proof that the fault in the product was not discoverable based on the state of scientific knowledge at the time of supply is often described as the "state of the art" defence (see the answer to question 3.2 below).

In contract, no specific defences arise, but the claim will fail if the claimant cannot establish the breach of contract and damage due to that breach.

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

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

Yes, there is a development risks defence. The UK Government opted to include it in the CPA: see the answer to question 3.1 above. Under the CPA, it is for the producer to prove that the defect was not discoverable.

The scope of the defence has been controversial. The correct transposition of the wording of the Product Liability Directive into UK law was challenged by the European Commission, although the European Court of Justice concluded that the Commission had failed to make its case that UK implementation of the defence was incorrect (*Commission v United Kingdom* (Case C-300/95)).

The defence was considered by the English courts in the Hepatitis C case (see the answer to question 1.1 above), which found that its scope is limited. Based on current authority, the defence applies if the defect was not discoverable in the light of the scientific and technical knowledge at the time the product was supplied. The defendant's conduct is irrelevant to this assessment. The court found that the defence was not available if the existence of the defect in the product was, or should have been, known. It was irrelevant whether or not the defect could be avoided because measures to identify and rectify the defect were impractical or impossible; once the defect was known, the defence became unavailable. (Such factors may, however, be relevant to the assessment of defect – see the *Wilkes v Depuy International* and *Gee v DePuy International* cases cited above.)

In negligence, whether the defendant exercised reasonable care in relation to the design/development, manufacture, supply, marketing and, in appropriate cases, licensing of the product, will be assessed in light of the state of scientific and technical knowledge at the time these activities were carried out. Manufacturers also owe a continuing duty to warn of any faults identified after the product has been supplied and, where a warning is not sufficient, to modify or withdraw the product. If the defendant manufacturer is able to show that he acted in the way that a reasonable

manufacturer would have done, this is often described as the "state of the art" defence. It is significantly wider than the development risks defence outlined above, because the court must assess the defendant's conduct; not just whether the defect was discoverable. Factors such as whether the defect could be avoided and compliance with statutory obligations are relevant.

These issues are not relevant to claims for breach of contract.

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

It is a defence to proceedings under the CPA if the manufacturer can show that the defect is due to compliance with UK laws or retained EU obligation. Otherwise, there is no general defence under the CPA, in negligence, or in contract, in circumstances where the manufacturer is able to demonstrate compliance with regulatory and statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product.

Such compliance is, however, of evidential value, and may help in the defence of negligence claims by demonstrating that the manufacturer exercised reasonable care. It is also a relevant circumstance for the purpose of determining what persons are generally entitled to expect in relation to the safety of a product for the purpose of proceedings under the CPA. In the *Wilkes* case, the court held that compliance with regulatory standards carried considerable weight because these "have been set at a level which the … [regulator] has determined is appropriate for safety purposes". Similarly, the court held that compliance with broader regulatory requirements was evidence of the level of safety of the product that persons are entitled to expect.

Although the defendant's conduct is generally irrelevant for the purpose of CPA claims, evidence that it had in place appropriate systems to detect any defects in the product and for post-marketing surveillance may also be relevant to the question of whether a defect was "discoverable" for the purpose of establishing whether the development risks defence is applicable. Such systems are commonly mandated by statute; for example, in the field of medicines and medical devices.

However, failure to comply with a regulatory standard, compliance with which is not required by law, may not be decisive in determining liability. In *Tesco v Pollard* [2006] EWCA Civ 393, Tesco was not liable for supplying a bottle of dishwasher powder with a screw top, where the child-resistant cap fitted did not meet the British Standard, as there was no statutory requirement for such a cap to be fitted and all that the public could legitimately expect was that the bottle would be more difficult to open, which it was.

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

In general, a final judgment or order is conclusive as between the parties to the proceedings and their successors (save where the judgment can be set aside; for example, because of fraud, or because the decision was not based on the merits). An estoppel arises that prevents the parties from re-litigating in subsequent proceedings the decision or any issues that were an essential part of the legal basis of the judgment. In group litigation, a judgment or order is binding on the parties to all claims that are on the group register at the time the judgment or order is made, unless the court orders otherwise.

In principle, an estoppel cannot arise in proceedings involving non-parties. However, in certain circumstances, it may be possible to defeat a challenge to a prior decision by a party to that decision on grounds of abuse of process. Even if the doctrines of estoppel and abuse of process do not apply, the prior findings of another court based on similar facts are likely to be persuasive.

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

Yes. Claims for contribution or indemnity can be made against a third party where the third party is liable to the claimant for the same damage as the defendant. Such claims can be brought either in the same proceedings (by means of a "Part 20" claim) or in subsequent proceedings. In the case of subsequent proceedings, the claim must be brought within two years from the date of judgment in or settlement of the claimant's claim.

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

Yes. Liability under both the CPA and in negligence can be limited if the defendant can prove that the claimant's negligence caused or contributed to the damage.

See *Howmet Ltd v Economy Devices Ltd* [2016] EWCA Civ 847 (a negligence claim): fire had been caused by a defective thermolevel manufactured by EDL. Howmet alleged that the thermolevel had failed to switch off the heater of the tank in which it was immersed, causing the tank to catch fire. The Court of Appeal unanimously dismissed Howmet's appeal for want of proof of causation. The effective cause of the fire had not been the defective thermolevel, but the failure of the system which Howmet had put in place to protect the tank following the malfunction of the thermolevel. In addition, given that Howmet had discovered the defect before the damage took place, EDL did not owe Howmet a continuing duty in respect of the safety of the thermolevel.

### 3.7 Are there any examples in your jurisdiction of legislation providing exemptions from product liability in respect of products produced and/or deployed in the context of a public health emergency?

Regulation 345 of the Human Medicines Regulations 2012 provides that, in the instance that a medicinal product is used off label in response to a confirmed spread of a pathogenic agent, toxins, chemical agents or nuclear radiation (any of which could cause harm), marketing authorisation holders, manufacturers and healthcare professionals will not be subject to civil liability for any consequences of that use. This does not, however, affect potential liability for a defective product. Media reports, however, indicate that the UK Government has offered contractual indemnities to the manufacturers of certain medicinal products used in the context of the COVID-19 pandemic in relation to such claims.

Also during the COVID-19 pandemic, the UK Government allowed manufacturers to apply for exemptions from certain regulatory requirements for medical devices, including personal protective equipment, ventilators and COVID-19 testing kits. Again, UK product liability rules were not altered as a result; however, in April 2020 the UK Government announced that it

would protect manufacturers of rapidly manufactured ventilator systems ("RMVS") intended to treat COVID-19 patients, from the financial burden of potential legal claims, including product liability claims resulting from defective equipment. Details of such indemnities have not been disclosed.

## 4 Procedure

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

Trials are by a judge.

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

Yes. The court can appoint one or more assessors to assist the judge, to enable him to reach a properly informed decision on matters in which the assessor has skill and expertise. The assessor does not have judicial status and does not play a part in deciding the case; his role is to educate and assist the judge.

In product liability claims, assessors have not been appointed to assist the court in deciding issues of liability; on the whole, in such cases, the court prefers to leave technical issues to the experts called by the parties themselves and to evaluate the experts' evidence having heard it tested in cross-examination.

Under the Civil Procedure Rules ("CPR"), which lay down procedural rules for the conduct of proceedings in England and Wales, the parties to any proceedings must be notified of the appointment of the proposed assessor and may raise objections.

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

Yes. Where claims give rise to common or related issues of fact or law, the court has the power to make a group litigation order ("GLO") enabling it to manage the claims covered by the order in a co-ordinated way. Many group claims have been brought over the last 30 years in relation to defective products and medicines, cases of industrial disease and sudden accidents or disasters.

The procedure is "opt-in". Claims managed under a GLO remain individual actions in their own right. However, the court will usually order that one or more actions that are representative of the rest of the claims cohort are tried as lead actions. The outcome of the lead actions does not, in theory, determine liability in the remaining cohort of claims, but those actions will establish findings of law and fact that may, in practice, allow the parties to compromise or simplify resolution of the remainder of the litigation by focusing further proceedings on clarifying any remaining points of principle.

Proceedings can be brought by any party that has a claim, whether an individual, a company or another legal entity. There is currently no mechanism by which claims can be brought by a representative body on behalf of a number of claimants (see also the answer to question 4.4 below).

Once a GLO has been made, a group register will be established on which details of the individual claims to be managed under the GLO are entered. A managing judge will also be appointed with overall responsibility for case management of the litigation. He may be assisted by a Master or District Judge appointed to deal with procedural matters.

Co-ordinating judges have an extremely wide discretion to manage the litigation as they see fit. The court will usually make directions, including directing the transfer of claims to the court that will manage the litigation, giving directions to publicise the GLO so that claimants may join the group register, and imposing a cut-off date during which claims proceeding under the GLO must be issued. The court often also appoints lead solicitors to act on behalf of the claimants and defendants.

Claims can also be pursued in a representative action where one representative claimant or defendant acts on behalf of a group of individuals. The procedure is rarely used, as it is only available where the group of litigants have the same interest in one cause of action; it is not available if they have different defences or remedies. The court also has power to consolidate a number of individual proceedings into one action, or order that two or more claims should be tried together.

A recent judgment (*Lloyd v Google LLC* [2021] UKSC 50) has confirmed that, while representative actions are a flexible tool of convenience in the administration of justice, where each represented person has a separate cause of action or where the relief claimed consists of damages, such actions are not appropriate where the assessment of individual harm would vary across the claimants. The court suggested, however, that the representative action route could be used as part of a "bifurcated approach", whereby common issues of law or fact are decided through a representative claim, leaving any issues which require individual determination, whether they relate to liability or the amount of damages, to be dealt with at a subsequent stage of the proceedings. Such an approach has not, to date, been considered appropriate in any product liability litigation.

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

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

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

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

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

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

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

Timing depends on the complexity of the case and the value of the claim. According to the Civil Justice Statistics Quarterly for October to December 2021, published by the Ministry of Justice, unitary civil actions proceeding in the County Court (excluding certain small claims which are fast-tracked), on average, took 74 weeks from the issue of proceedings until trial. Equivalent statistics are not available for High Court actions, but these cases are generally more complicated and therefore take longer to come to trial. Complex group actions may take many years to come to trial. Delay is largely a result of the conduct of the parties and is not inherent in the court system.

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

Yes. In accordance with general case management powers, the judge may order the trial of preliminary issues of law and fact in separate proceedings prior to the main trial, and may decide the order in which issues are to be tried in the main trial. In a suitable case, the court also has power to give a summary judgment dismissing a claim which has no realistic prospect of success.

### 4.8 What appeal options are available?

An appeal may only be made with the permission of the court (either the appeal court or the lower court that made the decision subject to appeal) and such permission will only be granted if the appeal appears to have a real prospect of success or there are other compelling reasons why it should be heard.

The appeal will usually be limited to a review of the lower court's decision, but the court retains the power to order a re-hearing in the interests of justice. An appeal will be allowed where the decision of the lower court was wrong (because the court made an error of law, or of fact, or in the exercise of its discretion) or was unjust because of a serious procedural or other irregularity of the lower court. However, in practice, the courts will rarely disturb findings of fact made by the trial judge who had the benefit of hearing at first hand the witness and expert evidence.

The appeal court may affirm, vary or set aside any order or judgment made by the lower court, order a new trial or hearing, or make any other appropriate order.

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

Experts are generally appointed by the parties to litigation rather than by the courts. No expert may give evidence, whether written or oral, without the court's permission and the court may, in appropriate cases, dispense with expert evidence or require that evidence on a particular issue be given by a single joint expert. (The court will select a joint expert from a list prepared by the parties if they cannot agree who should be instructed.)

The extent of the expert evidence that is permitted will depend on the type and value of the claim, with more extensive evidence permitted in complex cases. In all personal injury cases, the claimant must serve a medical report with his or her Statement of Case substantiating the injuries alleged in the claim.

Expert evidence should be independent and comprehensive. An expert owes an overriding duty to assist the court on matters falling within his expertise; this duty overrides any obligation to the party instructing the expert. Experts may only give evidence on matters of opinion falling within their expertise.

Evidence must be provided in the form of a report disclosed to the other parties. The Court Rules give the parties a right to put written questions to an expert about his or her report in order to clarify the report. Where several experts are instructed, it is usual for experts in particular disciplines to meet on a "without prejudice" basis, after the exchange of reports and before giving oral evidence, in order to explore areas of agreement and narrow the matters in dispute.

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

The factual and expert evidence that the parties intend to rely upon at trial must be provided in the form of witness statements and expert reports that are disclosed by the parties prior to the trial. The court may make directions limiting the scope of factual and expert evidence by, for example, identifying those disciplines or issues to which such evidence may be directed. Evidence is usually mutually exchanged, but the court may, in appropriate circumstances, direct that it is served sequentially.

Factual and expert witnesses are required to give oral evidence at the trial unless the court orders otherwise. However, the witness can only amplify the evidence given in his/her written statement or report with the court's permission. Expert evidence is usually given sequentially, but the court may order that it is given concurrently (so-called "hot-tubbing").

Witnesses are not generally required to present themselves for pre-trial deposition. However, the court may order evidence to be given by deposition if the witness is unable to attend the trial. The increased use of video conferencing facilities has reduced the use of depositions in proceedings in England and Wales. Evidence can be taken by video if the witness is abroad or unable to attend court as a result of illness. During the COVID-19 pandemic, much court business, up to and including final hearings, has been conducted remotely using videolink technology. The experience of this seems likely to result in increased use of such technology in future.

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

In claims involving personal injuries, the general rule is that a

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

A document is in a party's control if he has, or had, physical possession of it, a right to possession of it, or a right to inspect and take copies of it. The obligation may therefore extend to documents in the hands of a party's professional advisers or an associated company, provided control can be established.

"Document" means anything on which information of any description is recorded and includes paper records, drawings, microfilms, information held on tape, video, CD or DVD, and electronic documents such as emails and metadata (including electronic documents that have been "deleted" which are held on servers and back-up systems).

The parties are required to conduct a reasonable and proportionate search for disclosable documents. The obligation to give disclosure continues until the action is at an end, and applies to documents created while the proceedings are underway. Additional obligations apply in the case of the disclosure of documents held in electronic form, and the Court Rules require the parties to exchange information about the electronic documents that they hold, and to seek to agree the scope of searches for electronic documents.

The duty to disclose the existence of documents is a strict one and is enforced by the court. A party may not rely upon any documents that it does not disclose. Moreover, if a party withholds documentation that should have been disclosed, the court may impose cost penalties or draw an adverse inference.

Disclosable documents are identified in a List of Documents served on the opposing party. All disclosed documents can be inspected save for those which are privileged from inspection. Two of the most important types of privilege are "legal advice privilege", which applies to confidential communications between a lawyer and his client made for the sole or dominant purpose of seeking or giving legal advice and assistance, and "litigation privilege", which applies to documents between the potential party, his lawyer and any third party, created after litigation is contemplated or pending, for the sole or dominant purpose of seeking or giving advice in relation to the claim, or collecting evidence for use in the litigation. Legal advice privilege only applies to lawyer-client communications with company employees who are regarded as the "client" (generally senior managers or the in-house lawyer), not all employees. Litigation privilege will only apply if there is a real likelihood of litigation, rather than a mere possibility.

Disclosure usually takes place after pleadings setting out the parties' cases have been served. In addition, a party may seek an order for disclosure of specific documents or classes of documents. However, the court also has power to order pre-action disclosure in appropriate cases in order to fairly dispose of the proceedings. Such disclosure may only be ordered in respect of specific documents or classes of documents that would have to be disclosed in any event once the proceedings are under way. Any documents disclosed in accordance with these rules may only be used in connection with the proceedings in which they are disclosed until such time as they are referred to at a hearing held in public, or the parties agree, or the court otherwise gives permission.

A revised disclosure regime which seeks to limit disclosure is the subject of an ongoing pilot scheme in some business and property courts. The key feature of the proposed new disclosure rules is that there will be no automatic entitlement to search-based "standard disclosure". Instead, "basic disclosure", limited to the key documents on which a party has relied and those that are necessary to enable the other parties to understand the case they have to meet, will usually be provided with the Statement of Case (pleading). At this stage, a party will be required to state whether it intends to seek "extended disclosure". The pilot scheme was planned to last for two years but has been extended to the end of 2022.

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

There are a variety of different methods of alternative dispute resolution ("ADR"), including mediation, arbitration and neutral evaluation, which can all be pursued as an alternative to litigation. Mediation is also commonly used during the course of litigation in an attempt to compromise the proceedings. The courts encourage the use of ADR to resolve disputes and the pre-action protocols to the Court Rules provide that the parties should consider whether some form of ADR is more suitable than litigation before commencing proceedings.

While the courts cannot compel the parties to use ADR procedures (*Halsey v Milton Keynes General NHS Trust* [2004] EWCA Civ 576), failure to follow the protocols or to respond to an invitation to participate in ADR may amount to unreasonable conduct and result in a cost sanction (*PGF II SA v OMFS Company 1 Limited* [2013] EWCA Civ 1288). Courts have refused to award costs to a successful party where they unreasonably refused to mediate (*Dunnett v Railtrack plc* [2002] EWCA Civ 303), and awarded indemnity costs against an unsuccessful party (*ICI Ltd v Merit Merrell Technology Ltd* [2018] EWHC 1577 (TCC)), although it has also been held that complex questions of law might make a case unsuitable for mediation and, if there is no realistic prospect of a successful outcome, it may not be unreasonable to decline to mediate (*Gore v Naheed* [2017] EWCA 369).

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

The UK, having left the EU, is no longer bound by the rules on jurisdiction in cases involving parties domiciled in the EU under the Recast Brussels Regulation (EU) 1215/2012. UK national law post-Brexit retains certain provisions from the Brussels regime applicable to consumers and in employment cases (broadly permitting consumers and employees to sue where they are based). Otherwise, the effect of the European regime ceasing to apply in the UK is that jurisdiction will be determined by a combination of the existing common law and statute (which has always applied to cases falling outside the European regime) and, if applicable, the Hague Convention. (These arrangements are set out in more detail in the explanatory memorandum to the Civil Jurisdiction and Judgments (Amendment) (EU Exit) Regulations 2019 (SI 2019/479).)

One change going forward will be that UK-domiciled defendants can challenge the jurisdiction of the English courts on the

basis that England is not the appropriate forum for the resolution of the dispute (which was only possible in limited circumstances under the Recast Brussels Regulation). The English courts will also be able to grant anti-suit injunctions restraining parties from pursuing proceedings in an EU Member State in breach of a jurisdiction or arbitration agreement.

It is possible to bring a claim before the English court against a non-domiciled party. Claimants need to seek the permission of the court to serve their proceedings out of the jurisdiction, relying on the grounds set out in Practice Direction 6B 3.1 of the CPR. This requires the claimant to establish that England is the appropriate place for the case to proceed, which may be the case, for example, in an action based in tort, where the loss or damage was sustained or caused by an act committed within the jurisdiction. Permission to serve on a non-domiciled defendant may be granted where they are a "necessary and proper party" to a claim that is proceeding against an English-domiciled defendant. The courts can also allow cases to proceed where a defendant submits to the jurisdiction of the English court (i.e. fails to object to its jurisdiction). The English courts generally have jurisdiction to hear cases brought against persons domiciled in England.

Proceedings may be brought in England and Wales by foreign claimants against English-based corporations or bodies based on their actions or those of their subsidiaries in other jurisdictions. For example, group actions have been pursued in England in respect of actions arising from exposure in South Africa to asbestos mined or processed by an affiliate of an English company (*Lubbe v Cape Plc* [2000] 1WLR 1545); by a group of claimants from the Ivory Coast against a British-based oil trader, Trafigura, for damage allegedly caused by the dumping of toxic waste; and by a group of Bangladeshi villagers against The Natural Environment Research Council, a British organisation which allegedly conducted a negligent survey, in respect of damage arising from contaminated groundwater (*Sutradhar v Natural Environment Research Council* [2006] UKHL 33). The court found that parent company control had been present in *Lungowe and Ors. v Vedanta Resources Plc and Konkola Copper Mines Plc* [2017] EWCA Civ 1528, allowing the claim to proceed in England and Wales.

In a recent decision *Okpabi and others v Royal Dutch Shell plc and another* [2021] UKSC 3, the Supreme Court took a fresh look at the ways in which parent companies in the UK could be held liable for the acts of their overseas affiliates. The Supreme Court focused on how multinational groups of companies are actually structured and managed. It recognised that groups which operate via integrated global business functions may, in practice, exercise more in the way of control over the acts and omissions of affiliates. An affiliate may be legally separate and theoretically a self-controlled independent legal personality, but it is appropriate to consider whether its relevant activities (in this case, operation of an oil pipeline) which are alleged to have caused loss to others are wholly or partly managed by the parent company or a global business division under the control of the parent. If so, there may be a case for bringing a claim against the parent. Following this case, the English courts may be willing to accept jurisdiction in relation to more claims against UK-domiciled entities.

## 5 Time Limits

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

Yes, see our answer to question 5.2 below.

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

Under the Limitation Act 1980, the basic limitation period for tortious actions (including negligence claims) and for breach of contract is six years from the date on which the cause of action accrued. Additional requirements apply in the case of latent damage caused by negligence.

Special time limits apply to personal injury claims for damages in respect of negligence, nuisance or breach of duty. In such cases, the claim must be brought within three years from the date on which the cause of action accrued (i.e. the date of injury or death) or the date of knowledge by the claimant of certain facts. The date of knowledge is when the claimant is aware of the identity of the defendant, that the injury was significant, and that it was attributable in whole or part to the alleged negligence, nuisance or breach of duty. Knowledge of attribution may be established where a claimant's subjective belief that his injury is capable of being attributed to the breach of duty/defective product is held with sufficient confidence to make it reasonable for him to begin to investigate whether he has a valid claim (*Ministry of Defence v AB and others* [2012] UK SC9). The court has a discretionary power to disapply this time limit where it would be equitable to do so. In doing so, it can take into account the merits of the case and whether the claim has a reasonable prospect of success (*Ministry of Defence* case above).

Where proceedings are brought under the CPA, there is also a general long-stop provision. A right of action under the CPA is extinguished 10 years after the defective product was put into circulation, and this applies irrespective of the other provisions of the Limitation Act (including the requirements relating to the date of knowledge set out above). In Case C-127/04, *O'Byrne v Sanofi Pasteur MDS Limited and Sanofi Pasteur SA*, the CJEU held that "a product is put into circulation when it is taken out of the manufacturing process operated by the producer and enters a marketing process in the form in which it is offered to the public in order to be used or consumed".

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

Special rules apply to persons under a disability, during such period as they are a minor or of unsound mind. In general, time only begins to run for limitation purposes when the claimant dies or ceases to be under a disability. However, the 10-year long-stop for CPA claims still applies.

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

Where an action is based on a defendant's fraud, or a defendant has deliberately concealed any fact relevant to the claimant's right of action, the relevant limitation period does not begin to run until the claimant has, or could with reasonable diligence have, discovered the fraud or concealment.

## 6 Remedies

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

It is possible to seek a range of remedies, including monetary compensation (damages) and injunctive or declaratory relief. However, most claimants in product liability cases seek to recover damages.

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

Under the CPA, damage includes death or personal injury (including mental injury) or loss of, or damage to, property for private use and consumption (provided the damages recoverable in respect of property loss exceed the minimum threshold of £275). Damages are not recoverable in respect of damage to the defective product itself.

In negligence, damages are awarded to put the injured party into the position he would have been in if the negligent act had not occurred. Damages can be recovered for death or personal injury (including mental injuries) and damage to property. Pure economic losses which are not consequent on physical damage are not generally recoverable in negligence.

In contract, damages are intended to put the injured party into the position he would have been in if the contract had been performed. Damages are usually awarded for monetary loss (for example, in respect of damage to property and to the defective product itself), but they can include non-pecuniary losses, such as damages for death or personal injury (including mental injury), where this was within the parties' contemplation as not unlikely to arise from the breach of contract. Economic losses, such as loss of profits, are recoverable if these are a foreseeable consequence of the breach.

In the case of psychological harm, the English courts only permit recovery for recognised psychiatric injuries. Mere anxiety or distress are not actionable and are not, on their own, sufficient to ground a claim for damages (see *AB and Others v Tameside & Glossop Health Authority and Others* [1997] 8 Med LR 91).

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

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

Medical monitoring claims of the type pursued in the USA in recent years have not been litigated before the English courts. English law does not generally permit recovery of the cost of tests or investigations unless the product has actually malfunctioned and caused physical or psychiatric injury or damage. Such medical monitoring costs are recoverable only as medical expenses consequential upon the main injury or damage. In addition, the courts will not usually allow a claimant to recover damages where he/she sustains a recognised, but unforeseeable, psychiatric illness as a result of becoming aware that he/she is at risk of sustaining a disease/illness, or to recover the costs of future medical monitoring to determine if that disease/injury has arisen (*Grieves v FT Everard & Sons Ltd* [2008] 1 AC 281).

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

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

Punitive or exemplary damages are rarely, if ever, awarded. They are not generally available in respect of claims for breach of contract. Although they are available in tort claims (see *Kuddus (AP) v Chief Constable of Leicester Constabulary* [2001] 2 WLR 1789), exemplary damages will only be awarded in certain limited circumstances, including where the defendant's conduct was calculated to make a profit that exceeds the compensation recoverable by the claimant or where there has been oppressive, arbitrary and unconstitutional conduct by Government servants (see *Rowlands v Chief Constable of Merseyside* [2006] All ER (D) 298 (Dec)). Exemplary damages may be awarded in claims regarding infringements of competition law, but only where the breach was intentional or reckless and the defendant's conduct was so outrageous as to justify an award (*2 Travel Group Plc (in Liquidation) v Cardiff City Transport Services* [2012] CAT 19). Exemplary damages are not generally recoverable in circumstances where a defendant has already been fined in respect of his conduct (see *Devenish Nutrition Limited v Sanofi-Aventis SA and Others* [2007] EWHC 2394 (Ch)).

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

There is no such limit.

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

In general, a claimant may unilaterally discontinue all or part of his/her claim at any time. However, the court's permission is required for compromise or settlement of proceedings instituted against or on behalf of a minor (aged under 18) or an adult who is incapable of managing their own property and affairs. Court approval is also usually sought where there is a settlement or compromise of an unlitigated claim made by, or on behalf of,

or against, such a person, as a compromise is not enforceable without the approval of the court. There is no requirement to seek court approval in other circumstances; for example, on the settlement of the claims comprising a group action.

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

Yes. Under the Social Security (Recovery of Benefits) Act 1997, where compensation is paid in respect of an accident, injury or disease, the compensator is liable to repay to the Government state benefits paid to the claimant in respect of that accident, injury or disease. The scheme is administered by the Compensation Recovery Unit ("CRU"), which issues certificates setting out the recoverable benefits ("CRU payment"). The compensator can offset the CRU payment against certain types of compensation paid to the claimant (in respect of loss of earnings, costs of care and loss of mobility). No deductions can be made from the damages paid in respect of the injury/disease itself.

A similar scheme applies to the recoupment of National Health Service ("NHS") charges in accordance with the Health and Social Care (Community Health and Standards) Act 2003. Where the claimant has received NHS treatment or been provided with NHS ambulance services as a result of the injury which is being compensated, the costs of that treatment must be paid by the compensator in accordance with a statutory tariff.

## 7 Costs / Funding

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

The general rule is that the unsuccessful party pays the legal costs of the successful party (including expert fees and other incidental expenses such as court fees). However, Qualified One-way Cost Shifting ("QOCS") applies to claims for death or personal injuries (provided a funding arrangement was not entered into prior to 1 April 2013). This means that a defendant may only enforce an order for costs against a claimant, without the court's permission, to the extent of any damages and interest ordered in favour of the claimant. In practice, this means that in most personal injury claims an unsuccessful claimant will not be responsible for the defendant's costs, although this principle will not apply if the claim is struck out, or if the court determines that the claimant is fundamentally dishonest. If the claimant is successful, they may recover their costs from the defendant in the usual way, subject to a "set-off" of any costs orders made in the defendant's favour (provided such costs do not exceed the amount of damages awarded).

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

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

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

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

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

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

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

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

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

There are broadly two types of CFA: "no win, no fee" agreements; and "less (or nothing) if you lose" agreements. The precise terms of the CFA are strictly regulated and agreements that fall outside the legal requirements are unenforceable. Under a CFA, the client initially pays a reduced (or no) fee to his lawyers, but in the event of "success" the client becomes liable for the standard fees plus a percentage uplift on those standard fees. What is a "success" or "failure" is defined in the CFA, often by reference to a level of damages recovered. The uplift is based on the level of risk associated with the claim. Under a DBA, the lawyers' fees are set as a percentage of the sum recovered as damages in the claim, net of any costs recovered from the losing party.

Rules which came into effect in April 2013 have significantly changed the way CFAs operate, and have legalised DBAs (which were previously unenforceable). Prior to April 2013, a successful claimant could recover from their opponent the CFA uplift or success fee in addition to their standard costs, and also any premium payable to obtain After the Event ("ATE") insurance purchased to protect the client against exposure to the other side's costs in the event of defeat. Where agreements are entered

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

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

Yes, in certain circumstances. In *Arkin v Borchard Lines* [2005] 1 WLR 2055, the Court of Appeal made clear that, in principle, third party funding may be an acceptable means of funding litigation. However, certain third party funding arrangements may be unenforceable. In *R (Factortame) Ltd v Transport Secretary (No.8)* [2002] EWCA Civ 932, the court held that in deciding whether a funding agreement is objectionable (champertous) the courts will take into account whether the funder controls the proceedings, whether the agreed recovery rate is fair and whether the agreement facilitates access to justice. If the funder controls the proceedings, the agreement will usually be champertous and unenforceable. In addition, as he will generally be treated as if he were a party to the proceedings, he will be exposed to costs liability.

*Arkin* concerned the award of costs against a third party funder. The Court of Appeal held that in the case of an objectionable agreement the funder will be liable to pay his opponent's costs without limit if the claim fails; in the case of acceptable agreements, the funder's cost liability is limited to the amount of the funding he provided, although in *Sandra Bailey & Others v GlaxoSmithKline UK Limited* [2017] EWHC 3195 (QB) the cap was held not to apply and it was confirmed that it was within the court's discretion to order security in excess of the funding provided. In *Chapelgate Credit Opportunity Master Fund Ltd v Money* [2020] EWCA Civ 246 the court at first instance ordered the funder to pay the opponent's costs without limitation by reference to the amount of their funding. They appealed. The Court of Appeal held that the application of *Arkin* was not a binding legal principle, but a factor that had to be balanced against other factors.

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

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

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

Yes. In most cases commenced after April 2013, except for some types of high-value claims (where the sums in dispute exceed £10 million excluding interest and costs), the parties are required to file and exchange costs budgets after the defence is served or prior to the first procedural hearing, setting out their estimate of the costs they anticipate recovering from their opponent if successful. Strict time limits are applied to filing these budgets, and if these are not met the party in default may only recover court fees. If they are not agreed, the budgets will be reviewed by the court, which may make a costs management order. This may be revised as the litigation progresses, but only significant developments will justify such revisions.

In assessing the amount of recoverable costs at the conclusion of the litigation, the court will not depart from the agreed budget unless it is satisfied that there is good reason to do so. The budget therefore effectively acts as a cap on the level of costs which the winner may recover from the losing party. This does not restrict the freedom of the parties to investigate and litigate claims as they consider appropriate (the parties may exceed the amount of the court-approved budget if they wish to do so), but those costs will not be recoverable from the opposing party on the successful conclusion of the litigation.

The court can also impose a cap limiting the amount of future costs that a party may recover where there is a substantial risk that, without such an order, the costs incurred will be disproportionate to the amounts in issue and the costs cannot be adequately controlled through usual case management procedures (see *AB and Others v Leeds Teaching Hospitals NHS Trust and in the matter of the Nationwide Organ Group Litigation* [2003] Lloyds Law Reports 355).

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

## 8 Updates

**8.1 Please outline the approach taken to date by the courts in your jurisdiction in relation to product liability for new technologies such as artificial intelligence, machine learning, and robotics, and identify the ways in which this approach differs (if at all) from the approach taken with other products.**

To date there has been little experience reported in relation to the way that the courts are approaching questions of product liability in the context of new technologies such as artificial intelligence ("AI"). It seems that what is truly new about such technologies are the aspects of autonomy and self-learning. In other words, an algorithm could develop and take decisions, including operating machinery or manipulating data in ways that cause harm, but which are neither foreseeable nor conditioned by any human operator.

Some commentators consider that such developments will challenge the underlying basis of legal obligations according to present concepts of private law (whether contractual or tortious). Others take the view that existing liability mechanisms are likely to be adequate to the task. Suggestions have been made for alternative insurance arrangements applicable to, e.g., driverless cars and drones, but in general no specific case has been made as to why existing mechanisms for legal liability and redress might not cope with products and systems that incorporate AI, just as they have coped to date with other complex and technologically advanced products.

Other aspects of technological change may require the updating of product liability and associated legislation, such as connected products where the distinction between a product and a service may not be clear, and where software updating and cybersecurity

considerations may affect safety. The UK's Office for Product Safety & Standards ("OPSS") has consulted on product safety legislation and this process may inform developments in product liability law. The consultation, which specifically covered connected devices, closed in June 2021 and the OPSS reported in November 2021. Respondents indicated concerns about online sale of goods, the increased complexity of products involving new technologies and the difficulty in establishing liability for such products. The OPSS indicated that a long-term approach with regulatory changes might be needed to fully address the challenges raised by respondents, but did not highlight any proposed changes to the UK product liability regime as part of that. It remains to be seen what concrete proposals arise. The outcome of the European Commission's consultation on adapting liability rules to the digital age, AI and the circular economy, launched in October 2021, may also be influential.

In the related area of cybersecurity, the Government published the Product Security and Telecommunications Infrastructure Bill in November 2021. This aims to make consumer connectable products more secure against cyberattacks. Under this legislation, the Government will be able to set security requirements for consumer connectable products on a statutory footing. The draft legislation envisages criminal law enforcement, including substantial fines. While the legislation does not directly affect the civil product liability regime, increasing standardisation in this area is likely to provide a firmer basis for bringing civil claims in that it will be easier, by reference to standards and statutory requirements, to discern when a connectable product is defective or has been negligently constructed.

**8.2 Please identify any other significant new cases, trends and developments in Product Liability Law in your jurisdiction.**

Various cases and developments are discussed in the answers above, for example: *Wilkes v Depuy International Limited* [2016] EWHC 3096), *Gee & Others v DePuy International Limited* [2018] EWHC 1208 (QB), *Hastings v Finsbury Orthopaedics and Stryker UK Ltd* [2019] CSOH 96 and *Bailey & Others v GlaxoSmithKline UK Limited* [2019] EWCA Civ 1924 in question 1.1; *Al-Iqra and others v DSG Retail Ltd* [2019] EWHC 429 (QB) and *Baker v KTM Sportmotorcycle UK Ltd and another* [2017] EWCA Civ 378 in question 2.1; and *Howmet Ltd v Economy Devices Ltd* [2016] EWCA Civ 847 in question 3.6.

*Wilson v Beko Plc* [2019] EWHC 3362 (QB) considered whether a claimant could bring a claim in strict liability for breaches of obligations imposed by safety regulations made pursuant to Part II of the CPA. The claimant could not bring a claim under Part I of the CPA, as the limitation period had passed. The court held that the claimant could not circumvent the Part I product liability regime in this way. Breaches of obligation imposed by safety regulations made under Part II of the CPA were not separately actionable under the CPA if and to the extent that the breach of duty in question would fall within Part I of the Act. The case is understood to be proceeding to appeal.

**Adela Williams** is a partner in the London office of Arnold & Porter, specialising in product liability litigation (unitary actions and group litigation), principally involving life sciences clients and including claims involving unlicensed medical products in the research context as well as marketed products. Such litigation has often involved co-ordinating proceedings within Europe and advising on forum and other jurisdictional issues. Past cases include the fetal anticonvulsant litigation and the successful defence of group litigation involving more than 100 claims relating to the "third generation" oral contraceptive pill on behalf of two of the defendant manufacturers.
Adela also advises clients in relation to the regulation of medicinal products, medical devices, foods and cosmetics in the EU and acts on their behalf in litigation arising from the decisions of regulatory bodies. She is an Assistant Coroner.

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