Liability for unknown risks

Articles

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Liability for Unknown Risks: A Common Law Perspective

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Abstract: In this article, I address the issue of liability for unknown risks from a Common Law perspective. My observations are made principally with English law in mind, but there is also reference to the (mixed) legal system of Scotland as well as to US Common Law (in relation to product liability). In order to set the scene, and in particular to explain the concept of unknown risks, some recitation of basic tort law principles is desirable.

I Basic tort law principles

Tort law rests upon the idea of fault: a defendant is liable because he ought not to have acted in the way he did. Strict liability is of course an exception to this basic principle. Fault implies that one could have, and should have, behaved differently. The defendant could have and should have *foreseen* the risk of, that is, likelihood of, harm occurring, and therefore could have and should have taken steps to avoid this risk materialising.

Foreseeability of injury is clearly predicated upon the premise that the defendant was able to conceive of the risk of injury occurring. Self-evidently, that premise is defeated in cases where the defendant could not have done so, because the necessary information about the likely risk of harm was unavailable to it. Crucially, however, it is not the inability of the individual defendant to foresee the risk of injury which is ultimately at issue – rather, in the Common Law, it is the inability of the imagined reasonable person in the circumstances of the defendant which is at issue in the fault enquiry. Typically, therefore, in Common Law judgments a finding of liability is framed in terms that the 'defendant knew, or ought to have known of' the risk of harm, and a finding of no liability in terms that the defendant 'did not know, and could not reasonably have known of' such a risk.

Such formulations allow a terminological distinction to be drawn between 'unknown' and 'unknowable' risks:[1] an unknown risk can be said to be one of which the *specific* defendant in an action did not, *as a matter of fact*, have knowledge; whereas, an unknowable risk can be said to be one of which no person in the circumstances of the defendant could reasonably have been aware. Such lack of

[1] This particular semantic distinction is not, so far as I am aware, one of art, and it is simply offered here as an aid to legal analysis.

knowledge of the risk by an imagined person in the defendant's shoes might be on account of the fact that only a limited class of person is in possession of knowledge of the risk (for example, someone having particular skills which the reasonable person in the defendant's shoes was not expected to have), or because no one, at the present time, has knowledge of the risk (for instance, because it relates to scientific or medical knowledge which has yet to be acquired by anyone, or at least anyone outside a very limited class – perhaps a discoverer who has yet to make his or her discovery public). This distinction between unknown and unknowable risks is not especially crucial in relation to the liability of a defendant in a fault-based claim, because, as I have noted, to avoid such liability a defendant must both not, as a matter of fact, have known of a risk *and* not reasonably be expected to have known of it. But, as we shall see later, in relation to the defence of *volenti non fit injuria* (to a willing person, no injury is done), the distinction is important, as it is only known risks which can trigger the defence, not ones which ought reasonably to have been known but were, as a matter of fact, unknown.

These suggested definitions provide one way of approaching the distinction between the actual defendant's knowledge and what a reasonable party in the defendant's shoes ought to have known. An alternative way of approaching matters would be simply to use the term 'unknown' risks to describe both cases, and speak of risk 'unknown to the defendant' and risk 'unknown to the reasonable party in the defendant's shoes' (the latter being the circumstances I have described as unknowable risks). This approach is discernible in some of the other articles in this edition of the journal, and represents a perfectly reasonable alternative to the definitional distinction I have drawn.

The above discussion of foreseeability, and of unknown/unknowable risks, gives rise to several consequences:

i. A risk is not unforeseeable merely because the defendant's inattentiveness or carelessness prevented him from appreciating the risk – on the contrary, it is that very inattentiveness or carelessness which constitutes the fault.
ii. A risk is not unforeseeable merely because a cause intervened between the harm and the defendant's conduct (something more is required to constitute what has traditionally been called a *novus actus interveniens*[2]).
iii. A risk is not unforeseeable merely because the specific defendant lacked the ability or capacity to foresee the risk, so long as the ordinary person in the defendant's shoes could reasonably have done so. As Kitto J put it in the Australian High Court: 'The standard of care being objective, it is no answer … to say that the harm [the defendant] caused was due to his being abnormally slow-witted, quick-tempered, absent-minded or inexperienced.'[3] Concession is however made for risks which are not appreciated on account of medically recognised mental incapacity or because of youthfulness: in the case from which the quoted statement of Kitto J comes, a twelve year old defendant was only held to the standard of foresight of an 'ordinary boy of twelve' and not the more mature, reflective foresight of risk which an adult in his circumstances might

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[2] Though a number of scholars, including the present writer, have argued that the traditional causal language is not best suited to describe the issues relevant to determining the impact of intervening causes upon responsibility for harm.

[3] *McHale v Watson* [1966] High Court of Australia (HCA) 13, (1966) 115 Commonwealth Law Reports (CLR) 199, per Kitto J at para [6] of his judgment.

have had. However, no concession is made for a lack of capacity to appreciate a risk which results from the voluntary intoxication of the defendant.[4]

iv. A risk is not unforeseeable merely because the full extent of the harm which might result was not appreciated by the defendant. So, for instance, the so-called 'egg-shell skull rule' means that a defendant must accept the risk that a specific claimant has a condition which made him susceptible to otherwise unforeseeable harm or to harm of a more severe degree than would otherwise be foreseeable. The locus classicus of this rule is the English case of *Smith v Leech Brain & Co Ltd*,[5] in which Lord Parker stated: '[i]f a man is negligently run over ... it is no answer to the sufferer's claim for damages that he would have suffered less injury ... if he had not had an unusually thin skull or an unusually weak heart.'

A further difficult matter is the *extent of the risk* which must have been foreseeable in order for neglect of it by a defendant to constitute negligence. This issue does not directly relate to the question of whether the risk was unknowable, so it will not be discussed at length here, but in assessing negligence it is an important issue. Suffice to say that the answer has to be teased out from a number of significant cases, including the House of Lords' judgment in *Bolton v Stone*,[6] in which Lord Reid stated that the risk had to be 'material' or 'substantial', and the judgment of the Privy Council in *The Wagon Mound (No 2)*,[7] in which their Lordships used the language of a risk which was 'real' (and hence not 'far-fetched' or 'fantastic'). The appropriate formulation of the level of risk required has been subject to much academic debate.[8] Even where the harm which should have been avoided is itself formulated in risk-based terms, as the 'loss of a chance' of avoiding harm in the real world, the courts have said that the chance lost must be 'real or substantial' (and not 'speculative') in order to be claimable.[9]

II Unforeseeable risk of harm

The risk of harm may have been unforeseeable to the reasonable person in the shoes of the defendant because (1) the harm was of a *type* not reasonably foreseeable in the circumstances (even though harm of other sorts may have been), (2) the *mechanism* by which the harm was caused was not reasonably foreseeable (even though harm by other mechanisms may have been), or (3) harm to someone in the *position of the claimant* was unforeseeable (even if harm to others may have been). These basic propositions are well known, so only a summary of the relevant law is necessary. A few cases exemplify these rules in practice.

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4 For US law, see Restatement (Third) Torts: Liability for Physical and Emotional Harm, § 12, comment c. See, for further discussion, *J Goudkamp*, Tort Law Defences (2013) 52.

5 [1962] 2 Queen's Bench (QB) 405.

6 [1951] Appeals Cases (AC) 850.

7 *Overseas Tankship (UK) Ltd v The Miller S.S. Co ('Wagon Mound (No 2)')* [1967] 1 AC 617 (PC).

8 See, for instance, *RW Wright*, The Standards of Care in Negligence Law, in: DG Owen, Philosophical Foundations of Tort Law (1997) 159–182.

9 See judgment of Stuart Smith LJ in *Allied Maples plc v Simmons & Simmons* [1995] Court of Appeal (Civil Division) (EWCA Civ) 17.

The first example is the Scottish House of Lords appeal *Bourhill v Young*,[10] in which psychiatric harm suffered by a passer-by who witnessed a road accident was held to be unforeseeable from the perspective of the negligent (and deceased) victim of the accident. From his point of view, the *type of harm* suffered by someone *in the position* of the pursuer was not reasonably foreseeable. The pursuer had not witnessed the accident in which the defender was killed, but only its aftermath. She suffered what was described as 'nervous shock', but would nowadays be called psychiatric harm or injury. The court held that, from the deceased's point of view, harm of this sort to someone in the pursuer's position was unknown, and could not reasonably have been known.[11]

A second Scottish case addressed the somewhat slippery issue of what aspects of the mechanism by which the injury was caused need to have been reasonably foreseeable. In *Hughes v Lord Advocate*,[12] in holding the defender liable, the House of Lords arguably imposed liability for a risk of harm the mechanism of causing which had been unknown to the defender. Two boys had suffered burns in an explosion, caused when they knocked a paraffin lamp into an open manhole. The explosion (the mechanism by which the harm occurred) had been unforeseeable, but their Lordships held it was enough for liability to be imposed that the sort of injury sustained (burns) had been foreseeable, given the presence of the paraffin lamp. There is a troubling inconsistency with the approach taken in the slightly later decision of the English Court of Appeal in *Doughty v Turner Manufacturing*,[13] where an explosion was caused by an accidental knocking of an asbestos lid into a cauldron of molten metal. Here the court focused not on the harm sustained (burns) but on the mechanism (the explosion), to hold the injury to have been unforeseeable.[14] One can attempt to reconcile the judgments: so, for instance, it can be argued that in *Hughes* the burning lamp was a 'known source of danger'[15] (of harm generally), whereas in *Doughty* the lid was not. This is not entirely convincing, however, as lids can clearly cause harm too: if they are heavy, they can fall on people; or if they fall into vats of molten liquid, they can splash people (as the plaintiff's counsel in *Doughty* argued). Alternatively, one can argue that in *Hughes* the House of Lords, in stating that burns were foreseeable, was also focusing on the mechanism of the harm (injury caused *by the means of burning*), but again that is not entirely convincing: any type of harm might be re-phrased as harm arising by the mechanism of the operation of that type of harm (for example, 'cancer' could be re-phrased as 'harm arising by means of the development of cancerous cells'). In *Hughes*, their Lordships were attempting, by means of semantic fancy footwork, to ignore the actual mechanism by which the harm was caused, the explosion. The result is two cases which are difficult to reconcile, and

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10 [1942] United Kingdom House of Lords (UKHL) 5, [1943] AC 92, 1943 Session Cases, House of Lords (SC (HL)) 78, 1943 Scots Law Times (SLT) 105.

11 As Lord Wright put it in his speech: 'I cannot accept that [the deceased] could reasonably have foreseen, or, more correctly, the reasonable hypothetical observer could reasonably have foreseen, the likelihood that anyone, placed as the appellant was, could be affected in the manner in which she was' (1942 SC (HL) at 93).

12 [1963] UKHL 8, 1963 SC (HL) 31, [1963] AC 837.

13 [1964] 1 QB 518.

14 As Diplock LJ (summarising the finding of the judge at first instance) put it in his judgment: 'this was not a risk of which the defendants at the time of the accident knew, or ought to have known' (QB at 530).

15 For discussion of this analysis, see the judgment of Lord Pearce in *Doughty* (QB at 526).

law which is as a result rather unsettled on the question of what a defendant needs to know about the mechanism by which a risk may eventuate in harm.

The third case is an English Court of Appeal decision concerning negligent damage to property (as well as trespass to goods), *National Coal Board v J E Evans & Co (Cardiff) Ltd*.[16] The defendants, in carrying out digging operations, damaged an underground cable owned by the plaintiffs. In an action for damages against them, the court found in the defendants' favour, holding (in respect of the negligence claim) that they had not been negligent: the presence of the cable was unknown to the defendants, having been laid by the plaintiff without the knowledge or consent of the landowner, such that no one in the defendants' shoes could have known it was there, and their lack of knowledge was in no way culpable. So, both the type of harm and the mechanism by which it might occur in this case were unknowable to the defendants.

A final example from the cases concerns circumstances of environmental pollution, *Cambridge Water v Eastern Counties Leather plc*.[17] The defendants were leather manufacturers who used a chlorinated solvent in their production process. Their business was located 1.3 miles away from the plaintiffs' borehole, from which water was drawn for domestic purposes. The defendants' solvent leaked into the ground beneath their premises, and eventually contaminated the borehole. The plaintiffs sued for damages (1) in negligence, (2) in nuisance, and (3) under the rule in *Rylands v Fletcher*.[18] The House of Lords found in the defendants' favour, overruling the decision of the Court of Appeal. Their Lordships held that foreseeability of harm of the relevant type by the defendants was a pre-requisite for recovery in both nuisance and under the rule in *Rylands v Fletcher*, and that, on the circumstances of this case, 'it was plain' (said Lord Goff) that 'nobody at E.C.L. could reasonably have foreseen the resultant damage which occurred at C.W.C.'s borehole'.[19]

It is worth adding, in relation to this final example of environmental damage, that in addition to any tortious claims by victims of such damage, in England (following transposition of the EU Directive on Environmental Damage[20]) such damage may be required to be remediated by order of a local or other designated authority.[21] One of the grounds specified for an appeal against an order to remediate incorporates a somewhat amended version of the state-of-the-art defence which will be examined in more detail later in relation to product liability: the relevant defence states that the operator of the activity which caused the environmental damage 'was not at fault or negligent and the environmental damage was caused by an emission or activity or any manner of using a product in the course of an activity that the operator demonstrates was not considered likely to cause environmental damage according to the state of scientific and technical knowledge at the time when … the activity took place'.[22] This version of the state-of-the-art defence is more favourable to the operator

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16 [1951] 2 King's Bench (KB) 861.

17 [1993] UKHL 12, [1994] 2 AC 264, [1994] 2 Weekly Law Reports (WLR) 53.

18 [1868] UKHL 1, (1868) Law Reporter (LR) 3 HL 330. The 'rule' being that a person who 'for his own purposes, brings on his land, and collects and keeps there anything likely to do mischief if it escapes, must keep it in at his peril, and, if he does not, he is *prima facie* answerable for all the damage which is the natural consequence of its escape' (Blackburn J in *Rylands*).

19 [1994] 2 AC at 306.

20 Directive 2004/35/CE of 21 April 2004, Official Journal (OJ) L 143, 30.4.2004, 56–75.

21 See the Environmental Damage (Prevention and Remediation) Regulations 2009.

22 Reg 19(3)(e). This is a transposition from the EU Directive: see art 8(4)(a).

than the version employed in relation to a manufacturer's liability for defective products, because in the latter context it operates (as will be seen) to excuse liability only where the state-of-the-art renders harm undiscoverable, rather than just (as here) unlikely.

As these cases demonstrate, the fault-based requirements that the harm suffered (1) was a type of harm, and was caused by a type of mechanism, which was reasonably foreseeable as a likely consequence of the defendant's fault, and (2) was caused to a party falling within the class of people reasonably foreseeable as likely victims of the defendant's fault, act as a break on fault-based recovery, protecting defendants who were not culpably in ignorance. In other words, tort law requires there to have been be a risk of harm of a sort, and to a class of people, which was knowable and which ought to have been known by a reasonable person in the defendant's shoes.

III Strict liability

Beyond the realm of fault-based liability, there is strict liability. Strict liability may be said to exist wherever it is accepted that a defendant behaved reasonably (that is, met the necessary standard of care in the circumstances), yet liability for harm is nonetheless imposed. In cases where the defendant could not reasonably have known of a risk of injury, because it would have been unknowable to a reasonable person in the defendant's shoes, or indeed because it was presently unknowable to anyone (there being no relevant information in existence and no known way of obtaining it), then the defendant cannot be said to have been at fault; if liability is nonetheless imposed, this is strict liability. Under strict liability, the burden of unknown risk rests upon the causer of harm (whether that party is careful or negligent), tort law making that party, in effect, an insurer in respect of any loss caused through materialisation of the unknown risk.

There are very few examples of strict liability in Common Law systems. They include liability for harm caused by defective products (discussed in detail below), by animals,[23] by emissions of radiation from nuclear installations,[24] by civil aircraft while in flight,[25] and in relation to the underground storage of gas.[26] In some systems, claims for medical injuries have been moved to a strict liability basis (as has happened in New Zealand); such a move has been contemplated in others.[27] There is support in some jurisdictions for the introduction of a system of strict liability for injuries to road users caused by drivers of motor vehicles.[28] In Scotland, it may be the case that there is strict liability for objects thrown from windows, if (as has been argued) the Roman *actio de effusis vel dejectis* (action of effusion or throwing down) was received into Scots law.[29] It is sometimes said that the vicarious liability of employers is an example of strict liability, but, while the imputation of liability to the

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[23] See, for English law, the Animals Act 1971; for Scotland, the Animals (Scotland) Act 1987.
[24] In the UK, under the Nuclear Installations Act 1965.
[25] In the UK, under the Civil Aviation Act 1982.
[26] In the UK, under the Gas Act 1965.
[27] The Scottish Government has expressed a view in favour of such a move, but no legislative proposals have been brought forward on the matter.
[28] The issue was debated in the Scottish Parliament on 29 October 2013, but no legislative proposals followed the debate.
[29] See discussion in *DM Walker*, The Law of Delict in Scotland, vol 1 (1966) 294.

employer occurs without reference to its fault, the employee for whom the employer is to be held liable must have behaved culpably. In general, strict liability is seldom employed, as it contravenes an intuitive moral sense that people who could not reasonably have behaved other than they did should be excused liability for harm caused by them.

Where strict liability *is* adopted, then only if a defence which relates to excusable lack of knowledge is provided for will a defendant faced with an unknown and unknowable risk of harm be able to avoid the consequences of such liability. Even without such a defence, it may be possible for a defendant to shift the burden of strict liability through the means of insurance. Insurance is compulsory in some areas: so, for instance, in the UK sec 1(1) of the Employers' Liability (Compulsory Insurance) Act 1969 requires employers to have in place 'insurance … against liability for bodily injury or disease sustained by [their] employees, and arising out of and in the course of their employment'. This provision extends to all harm sustained by employees, whether negligently or strictly caused. So, for instance, if one employee caused injury to another, the compulsory insurance required would cover the employer's liability even though it had not personally been at fault in relation to the occurrence of the injury.

Product liability cases present one example of an unforeseeable risk defence to strict liability, and are considered in detail in the following section of this article.

IV Product liability

A Product liability: the EU/UK

It is sometimes said that product liability under the EU regime, based on the EU Directive on Product Liability,[30] is strict liability. However, producers of goods may be entitled under national legislation to a defence – the state-of-the-art/development risks defence – and where this defence is available at a national level, liability is *not* in fact strict for producers. Suppliers and importers, who may in certain circumstances face liability, do not have the benefit of that defence, and so for them liability, where it is triggered, is strict.

Difficulties have arisen because of differences in the wording of the Directive and the UK statute implementing it. The definition of a defect in the Directive (in art 6) is that a product is defective when 'it does not provide the safety which a person is entitled to expect', taking all circumstances into account, including three specified matters.[31] The specification of the 'expectation' of safety of 'a person' creates a problematic test: it leaves it unclear as to which person is in question—is it the specific consumer in question in the case? Or perhaps a fictitious reasonable consumer? Moreover, what if the person (whoever it is) has no expectations about the

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30 Council Directive 85/374/EEC of 25 July 1985, OJ L 210, 7.8.1985, 29–33.

31 The three specified matters being: '(a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; (c) the time when the product was put into circulation' (see art 6(1) of the Directive).

safety of a product, or unreasonably high or low expectations?[32] The UK provision (as we shall see) does not improve much on this standard, but does adopt a somewhat differently worded test. As to the state-of-the-art defence, art 7(e) of the Directive provides that a producer of a product is not liable if 'the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered'. This wording is unclear as to whether it is the existence of the defect in specific products of a producer which is at issue, or whether it is products of that sort in general (a problem which had to be addressed in an English High Court judgment, discussed below).

The Directive was translated into UK law in the Consumer Protection Act 1987 (CPA). The CPA provides, in sec 2(1), for non-fault-based liability, stating that 'where any damage is caused wholly or partly by a defect in a product, every person to whom subsection (2) below applies shall be liable for the damage.'

This provision makes no mention of fault, so (on the face of it) it matters not that a defect capable of causing damage was unknown and unknowable. What makes a product defective? According to sec 3(1), it is 'if the safety of the product is not such as persons generally are entitled to expect.'

This standard (not an exact duplicate of, but as vague as, that in the Directive) pins the concept of a defect to general consumer expectations about safety – how safe would the public expect this product to be? That is a criterion with no obvious connection to the foreseeability of the risk of harm: my expectations of the safety of a product may well be formed without any regard to what a producer might know about the risk of harm created by use of the product. So, the Act does not introduce any element into the definition of defect which takes account of what potentially liable parties know or might be expected to know about risks (the approach of the US Restatement (Third) of Torts is different, as we will see). Therefore, unforeseeable harmful effects of a product could conceivably, under this section, give rise to liability under the Act. But, as discussed below, the Act creates a defence for producers which relates to the producer's ability to know about certain risks.

Both producers and importers are caught by the liability imposed by sec 2(1); suppliers of goods can, under sec 2(3), also have liability imposed on them, if a supplier is asked to identify the producer or importer and fails to do so within a reasonable period of time after the request. But a get-out for producers is found at sec 4(1)(e) where there is a defence that:

> 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 product in question might be expected to have discovered the defect if it had existed in his products while they were under his control.

This defence effectively creates an escape route for the producer whose ignorance of the risk of injury was not culpable: so long as a *fictitious producer of the same type of product* (note the discrepancy with the defence as stipulated in the EU Directive) could not have been expected to have known of the risk of injury, because *either* knowledge of such risk was not possible on account of the fact that the risk had not

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[32] Problems with a consumer expectation test are discussed, within the context of the history of US product liability, in *E Wertheimer*, The Bitter Bit: Unknowable Dangers, The Third Restatement, and the Reinstatement of Liability without Fault (2005) 70 Brook Law Review 889.

yet been discovered, *or*, if it had been discovered, because such risk had not been made public and was thus inaccessible to such a producer, then the producer will escape liability.

The nature of the '*or*' portion of the foregoing requirements for the defence – that, although the risk had been discovered, it had not been disclosed, and was therefore inaccessible to the fictitious producer of the same goods at the time the product was put into circulation – was clarified in the decision of the European Court of Justice (ECJ) in *Commission v United Kingdom*. The court stated that:[33]

> in order for the relevant scientific and technical knowledge to be successfully pleaded against the producer, that knowledge *must have been accessible* at the time when the product in question was put into circulation (emphasis added).

Common Law scholarship on the Act has further advanced the claims that, in addition to accessibility of the scientific or technical knowledge, it is also pertinent to consider *whose ideas* to include in the definition of such knowledge, as well as *the weight* to be given to those ideas.[34] If that is right (which it is suggested it is), this means that a specific risk of likely harm would not form part of the state of scientific and technical knowledge at the relevant time if it had simply been written in an as yet unpublished paper, or had been proposed by someone with little or no scientific training, or was controversial in the sense that it had (thus far) been rejected by a reasonable body of scientific opinion.

The defence conceivably covers medical products as much as it does other sorts of product. So, were a pharmaceutical product to cause harm to a consumer, the drug producer would be excused from the consequences so long as it met the requirements of this defence.[35] Of course, one would expect extensive clinical trials to have been carried out prior to the public marketing of any new medicinal product (where such trials are utilised, they are governed by an EU Regulation[36]). One would also expect appropriate warnings of side-effects on the packaging and instructions of

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[33] ECJ C-300/95, *Commission v United Kingdom* [1997] European Court Reports (ECR) I-2649, [1997] All England Law Reports (All ER) 481, para 29.

[34] See *J Stapleton*, Products Liability in the United Kingdom: The Myths of Reform (1999) 34 Texas International Law Journal 45, 59.

[35] In the wake of the world-wide Thalidomide scandal, harm caused to unborn children (which would include through maternal use of a pharmaceutical product) was made actionable at the suit of the child under the Congenital Disabilities (Civil Liability) Act 1976. However, the Act merely creates a right of action for the child, if born alive: it does not change the basis on which liability is imposed on the manufacturer (which would currently be governed by the CPA).

[36] Regulation EU (No) 536/2014 of 16 April 2014, OJ L 158, 27.5.2014, 1/1. Article 28 of the Regulation stipulates that a clinical trial may be conducted 'only where … (a) the anticipated benefits to the subjects or to public health justify the foreseeable risks and inconveniences', and no mention is made of the issue of unforeseeable or unknowable risks. The Regulation does not affect civil or criminal liability (see art 75), so that liability may still arise under the product liability regime, but art 76(1) adds that 'Member States shall ensure that systems for compensation for any damage suffered by a subject resulting from participation in a clinical trial conducted on their territory are in place in the form of insurance, a guarantee, or a similar arrangement that is equivalent as regards its purpose and which is appropriate to the nature and the extent of the risk'. In the UK, the Medicines for Human Use (Clinical Trials) Regulations 2004 stipulate that no person shall conduct a clinical trial 'otherwise than in accordance with the conditions and principles of good clinical practice' (Reg 28), one of such principles being that '[p]rovision has been made for insurance or indemnity to cover the liability of the investigator and sponsor which may arise in relation to the clinical trial' (Sch 1, Pt 2, principle 16).

medicinal products. But there remains the risk of harmful effects arising from new (or even established) drugs which could not have been detected using even the most stringent precautionary measures.

The defence has given rise to almost no British case law. The notable exception is the decision of the English High Court in *A v National Blood Authority*,[37] a case concerning the contraction by the claimants of the hepatitis C virus through infected blood and blood products delivered in blood transfusions and other medical operations. The parties were in dispute as to, inter alia, the proper application of the state-of-the-art defence: the defendants argued that a producer had to prove that the defect had not been and could not be discovered in *the specific products at issue* (that is, the batches of contaminated blood); the claimants argued that the producer had to prove that the defect had not been and could not be *discovered generally*, namely, in blood products in general. If the claimants were right, then the defence was not open to the defendants, as it was common ground between the parties that the existence of the defect in blood, that is, of the infection of blood *in some cases* by the hepatitis virus notwithstanding screening procedures, was known, and indeed known to the defendants.[38]

Significantly, the judge in the case (Burton J) concentrated almost exclusively on the wording of the Directive and not of the CPA, because (he said) this was mandated both by the judgment of the ECJ in *Commission v UK*, and by sect 1(1) of the CPA.[39] In analysing the proper approach to application of the defence, he commented negatively on the discrepancy between the drafting adopted by the UK Government in the CPA and the Directive, remarking that '… the CPA inappropriately sought to enact [the defence] in Section 4(1)(e) "*a producer of products of the same description as the product in question*"'.[40] This discrepancy between Directive and UK Act was not the root of the problem, however, because even the wording of the Directive did not provide a clear answer to the disputed matter, namely, of whether, in applying the state-of-the-art defence, a court is to consider knowledge of risk of the specific defective products or of products of this sort in general. Burton J was therefore forced to come to a conclusion based on the aims of the Directive, a comparative analysis of the approach in other jurisdictions, and academic commentary.[41] He concluded that:[42]

> It would, in my judgment, be inconsistent with the purpose of the Directive if a producer, in the case of a known risk, continues to supply products simply because, and despite the fact that, he is unable to identify in which if any of his products that defect will occur or recur, or, more relevantly in a case such as this, where the producer is obliged to supply, continues to supply without accepting the responsibility for any injuries resulting, by insurance or otherwise.

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37 [2001] 3 All ER 289, [2001] Lloyd's Law Reports Medical (Lloyd's Rep Med) 187, (2001) 60 Butterworth's Medico-Legal Reports (BMLR) 1.

38 See para 50 of Burton J's judgment.

39 That subsection reads: 'This Part shall have effect for the purpose of making such provision as is necessary in order to comply with the product liability Directive and shall be construed accordingly'.

40 Para 76.

41 He remarked (at para 81) that 'I am satisfied that my conclusions, if not all of my reasoning, are consistent with the decision of the BGH, and with the views of the majority if not all of the academic writers.'

42 Para 74.

So, the judge took the view that the state-of-the-art defence is *not* available to a producer whose argument is that the risk of harm is unknown only in the sense that the producer does not know which of its products may be defective, rather than in the sense of an absence of knowledge that the risk of harm may exist in any products of the type in question.[43] The mention of insurance in the last quoted remarks of Burton J is of interest: the view of the court is that, when a party is unable to screen against a known risk of harm affecting the manufacture of some of its products, that problem is – from the manufacturer's viewpoint – to be guarded against through private insurance; the victim of the materialisation of such a risk (the consumer) has, by contrast, the benefit of a claim in tort.

A v National Blood Authority involved a medical product (blood). But the defence has other field of obvious applicability: to new technology, such as consumer electronic goods – for instance, mobile phones (argued by some to cause risks to health, especially to developing brains) and e-cigarettes; and to new forms of energy generation, such as wind turbines (argued by some to give rise to a risk of a number of health problems[44]) and tidal generation units. Not all forms of new technology involve unknown risk, however. Consider, for instance, the on-going development of driver-less cars. Who would be to blame if such a vehicle were to malfunction and injure someone? If a passenger or another road user is injured if the vehicle crashes because it is defective, then under the CPA the producer would be liable. In such a case, there would however seem to be little room for the operation of the state-of-the-art defence: the risks presented by driver-less cars (principally software malfunction, mis-prediction of road conditions, and hacking) are currently well known to producers; it is simply a question of trying to make the technology perform so as to overcome these *known* risks.[45]

What about pure software? Is, for instance, a GPS map application a product? Apparently not: software seems not to fall within the ambit of the CPA, which defines a product as 'any goods or electricity', the reference to 'goods' generally being taken to be suggestive of things having a corporeal nature; an electronic string of 1s and 0s would not be enough.[46] Now, if the Act were to be altered to include software, some interesting questions would arise. A producer of GPS map software would then conceivably be liable for defects in it. Yet some GPS map apps (for example, Waze) allow *users* to make alterations to the map, which are then visible to all other users of the app. What if these user-generated alterations are wrong (such as if a user changes

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[43] The 2015 judgment of the Court of Justice of the European Union (CJEU) *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt — Die Gesundheitskasse Betriebskrankenkasse RWE*, joined cases C-503/13 and C-504/13 (ECLI:EU:C:2015:148) [2015] All ER (D) 88 (Mar) took this pro-consumer approach even further: the court said that 'where it is found that … products belonging to the same group or forming part of the same production series have a potential defect, it is possible to classify as defective all the products in that group or series, without there being any need to show that the product in question is defective' (para 41).

[44] 'Living too close to wind turbines can cause heart disease, tinnitus, vertigo, panic attacks, migraines and sleep deprivation…' (The Independent, 1 August 2009). The story related to research undertaken by an American physician, Dr Nina Pierpoint.

[45] The unavailability of the state-of-the-art defence in such cases does not however mean that, if an accident occurs involving a driver-less car, the cause will necessarily be a defect in the product: in some cases, an accident might be unavoidable even with perfect technology, for instance if a pedestrian dashes onto the road and the self-driving car brakes immediately. In such a case, the stopping distance might be too great to avoid injury even if the product is lacking any defect.

[46] See *J Stapleton*, Software, Information and the Concept of Product (1989) 89 Tel Aviv Studies in Law 147.

the direction of traffic for a one-way street) and cause harm – would the producer of the app be liable? Or the user who made the alteration? If the producer *were* to be held liable, then this would have the potential for imposing liability even though the producer might well have been unaware of the changes made to the map (that is, we would have a case of liability for an unknown risk). The producer in such a case might have a defence available to it other than the state-of-the-art defence, however: the defence, under sec 4(1)(d) of the CPA, that the 'the defect did not exist in the product at the relevant time'. When is the relevant time? It is the time when the product was supplied. So, if a user were to download the app *with the defect already in it* (because the defective correction had already been made by another user), then the producer could be liable. There is an evident danger here in allowing user-generated content within software products, even though allowing such content is precisely what makes many apps very attractive to consumers.

In the case of pure software, however, this is all speculative, for as mentioned, software seems currently to be excluded from the product liability regime. But, if software is bundled with hardware, the hardware imprinted with the software can be considered a product for the purposes of the CPA. So, the supply of a satellite navigation device with software on it would fall within the ambit of the Act, and some such devices also allow user-generated modifications to content, such as the TomTom satnav system used in many vehicles. So a TomTom device, if incorrect user-generated content is bundled with it when sold, might be a 'defective' product if 'the safety of the product is not such as persons generally are entitled to expect'.[47] If that is correct, but if we also think that allowing user-generated content to be uploaded to such devices is a good thing (because the benefits outweigh the risks), then perhaps an alteration needs to be made to the product liability regime. As matters stand, there is a danger that in this sort of case liability may be imposed for risks which are unknown to the producer.

Apart from this specific problem, there is the more fundamental point that the exclusion from the existing regime of pure software as well as services creates unevenness in consumer protection under tort law. Such unevenness is hard to defend: why should it matter whether the incorrect software upon which I reasonably relied was a stand-alone product I purchased or came with a device I purchased?

B Product liability: the USA

Characterising product liability in the USA is a somewhat complex exercise, as each state has its own regime. In some, liability still reflects the older model reflected in § 402A of the Restatement (Second) of Torts, which did not differentiate between types of defect, and (not unlike the UK/EU approach) adopted[48] a consumer expectation test for the defective quality of products. In other states, the law is more reflective of a new approach set out in the relevant sections of the Restatement (Third) Torts: Product Liability volume, which (as discussed below) distinguishes between types of defect, building in one of a number of variants of a risk/utility

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47 CPA, sec 3(1).

48 Not within the text of sec 402A itself, but in the official comments to the section: see comment g (Defective Condition).

standard for design defects.[49] The trend is towards adoption of the Restatement (Third) regime, or at least towards a design defects approach which builds in fault-based safeguards, but there is as yet no uniformity of approach.[50]

The Restatement (Third) Torts: Product Liability volume was issued in 1998. The initial provision (§ 1) has the appearance, at first glance, of strict liability, stating that:

> One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.

However, as will shortly be explained, liability is really only strict for one sort of defect, manufacturing defects. Unlike its predecessor, the Restatement (Second), which gave no guidance in the text of its § 402A as to what might make a product defective, the Restatement (Third) provides in § 2 that a product is defective 'when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings'. In providing further detail about how these types of defect are to be assessed, § 2 utilises the idea of foreseeability of harm with respect to two of the three types; for those types of harm, this has the effect of making liability fault-based. § 2 provides that:

(a) a manufacturing defect exists where 'the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product' (this is the provision of strict liability);
(b) a design defect exists where 'the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design[51] by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe'; and
(c) a defect in instructions or warnings exists where 'the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe'.

Lack of knowledge has no bearing on defect category (a) – manufacturing defects – so it doesn't matter that a manufacturer did not know that the products being produced did not match their design: you are expected to keep a proper watch on your production line to ensure that what is being made conforms to the product's intended design. But categories (b) and (c) – design defects and instructions/warnings defects – *do* take account of unknown risks: a defect exists in relation to such matters only

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[49] Though some jurisdictions allow application of *either* a consumer expectations test *or* a risk-utility test to demonstrate a design defect: the *locus classicus* of such an approach is *Barker v Lull Engineering Co* 773 Pacific Reporter, Second Series (P 2d) 443 (Cal 1978).

[50] For a survey of the individual state rules, see *JF Vargo*, The Emperor's New Clothes: The American Law Institute Adorns a 'New Cloth' for Section 402A Products Liability Design Defects – A Survey of the States Reveals a Different Weave (1996) 26 University of Memphis Law Review 493.

[51] This 'reasonable alternative' standard has been described as embodying a risk/utility approach: see discussion in *R Epstein/C Sharkey*, Cases and Materials on Torts (10th edn 2012), ch 8 (Products Liability).

where the *foreseeable* risks of harm could have been reduced or avoided by the stated remedial action.[52] So, if a risk of harm could not have been known by a reasonable party in the position of the defendant, the product will not be defective and liability will not arise.

Here we see a contrast with the UK (and EU) regime: under the approach in the Restatement (Third), it is in the definitions of two out of three separately described types of defect that a knowledge based limitation on the otherwise strict liability is found; in the UK Act, no such limitation is built into the unitary definition of defect, rather a more restricted knowledge-based limitation is created under the–state-of-the-art defence. So far as knowledge of risks is concerned, on the Restatement (Third) approach, it is for the plaintiff to argue (and prove) that there were foreseeable risks which should have been avoided or reduced; on the UK approach, it is for the defendant to argue (and prove) that it should be afforded the protection of the state-of-the-art defence.

A separate provision of the Restatement (Third) (§ 6) makes special provision for prescription drugs and medical devices. Liability under it is, again, prima facie strict, but it also differentiates between the three types of defects provided for in § 2, so that foreseeable risks are taken into account in relation to design defects and instructions/warning defects. In the case of this section, those two sorts of defect are however defined in a special way, by reference to reasonable safety: there is a defect if the prescription drug or medical device is not 'reasonably safe due to defective design' or is not 'reasonably safe due to inadequate instructions or warnings'.[53] Further definition is then given in § 2 as to what 'reasonably safety' means in these two cases, and it is at this level that reasonable foreseeability again makes an appearance:

> (c) A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.
>
> (d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided …

Again, therefore, the prima facie strictness of the liability is mitigated by reference to 'foreseeable risk', thus effectively rendering the liability fault-based in nature. Risks which could not reasonably have been known of do not give rise to liability.

Further separate liability is provided for in relation to producers of food products. Here the test employed for defectiveness in the manufacturing process (the liability imposed under § 2(a)) is akin to the consumer expectation test applied generally under the EU/UK regime: 'a harm-causing ingredient of the food product constitutes a defect if a reasonable consumer would not expect the food product to

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[52] 'It is perfectly clear from [§ 2(c)] that unknowable risks lie outside the duty to warn because they are not "foreseeable", a limitation which the *Restatement* justifies on grounds of fairness and efficiency': *D Owen*, Products Liability (3rd edn 2015) 684.

[53] § 6(b).

contain that ingredient'.[54] This test takes no account of what the producer of a food product knew or could reasonably be expected to have known about the risk of harm, so liability is stricter from the manufacturer's point of view. That is consistent with the Restatement Third's different treatment of manufacturing defects under § 2, but the introduction of the consumer expectation standard provides for a vague, very broadly defined test.

US law takes a different approach to contaminated blood than that taken in the UK (and discussed earlier in relation to the case of *A v National Blood Authority*): the vast majority of US states have enacted legislation adopting a negligence standard in relation to the supply of blood,[55] such that a supplier of blood would not be liable if there were no means available to screen out batches of blood affected by a specific contaminant.

C UK (EU) versus US: comparative remarks

Opinion is divided on whether the approach taken in the Restatement (Third) of providing different tests for different sorts of product, and for different types of defect, is a commendable one. It can be argued that there is sense in not extending to defects which are merely the result of mishaps in the manufacturing process (the category (a) type of defect) the benefit (from the producer's point of view) of being able to argue that the risk of harm could not have been foreseen. All producers can anticipate that well-designed products may be manufactured defectively, even if they may not foresee the specific problem with the manufacturing process which may arise on the facts of the case, and so it can be said that producers always need to take care to ensure that manufacturing processes do not create a risk of harm. But, on the other hand, manufacturing processes have changed over the years because certain risks inherent in now discontinued processes were not appreciated at an earlier stage of manufacturing history. The Restatement (Third)'s regime makes no concessions for this; under the UK Act, if the manufacturing process involved risks which the producer could not have been expected to have known about at the time, given the state-of-the-art, there would be a defence available to it.[56]

A difference of opinion also exists in relation to whether the issue of unforeseeable risk should be built into the definition of defect (the Restatement (Third) approach) or into a defence made available to producers (the UK/EU approach). The Restatement (Third) approach is more pro-producer, because the plaintiff consumer has (in cases of design or warning/instruction defect) to convince a court (or rather a jury) what a producer ought to have foreseen (and therefore needs to have investigated this question and obtained relevant evidence), the defendant producer having the right to respond to this by pleading that the risk of harm was unknowable.[57] The UK/EU approach is often said to be more favourable to

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54 § 7.

55 For discussion, see *Epstein/Sharkey* (fn 51). See also see *Owen* (fn 52) 1050 f.

56 Though the view has been expressed that 'it is expected that U.K. judges will continue to impose covert strict liability for manufacturing errors': *Stapleton* (1999) 34 Texas International Law Journal 45, at 53.

57 Some US courts, recognising that adoption of a risk-utility approach (such as that found in the Restatement (Third)) in relation to design defects creates a high hurdle for plaintiffs to overcome, have provided for a shifting of the burden of proof onto defendants so long as causation of harm has been made out by the plaintiff: see fn 49, the *Barker* case, P 2d 443 (Cal 1978)..

consumers, as the issue of what the producer might reasonably have foreseen is irrelevant to whether a product is defective: so long as persons generally would reasonably have expected the product to be safer than it was, then it is defective. In setting out his case, a UK consumer does not need to have access to design processes, and knowledge of what risks these might or might not have made foreseeable; he need only speak of the entitled expectations of the public about safety, and therefore can rely on what (one might expect) is more generally available evidence about the level of safety of other products in the marketplace, and can appeal to the judge's own expectations, as a reasonable consumer, concerning the safety of products. That may be too optimistic a view of the position of some consumers, however: one can imagine cases where consumers generally may have widely divergent expectations, or indeed no expectations, about certain products. As the author of a leading US text on product liability has remarked:[58]

> it is difficult to know what the safety expectations are (or should be) with respect to food, biologics, and other products whose most basic properties have been fundamentally, microscopically created or reconfigured by new scientific techniques such as nano-technology and three-dimensional printing in ways that generate risks that even scientists and engineers cannot contemplate.

These remarks reinforce the earlier stated worry about the inherent vagueness of a consumer safety expectations test of defectiveness, and give cause for concern that the apparent pro-consumer approach of the UK/EU regime may be more problematic than it at first appears.

There is no obviously, objectively right answer to the question of which approach to dealing with unknowable product risks is best.[59] In any future reform of the EU product liability regime, the competing arguments of the pro-consumer and pro-producer lobbies over where the balance should lie in relation to unknowable risks is likely to feature large, as it has in the past.

V *Volenti non fit injuria* (assumption of risk defence)

Courts are naturally wary of allowing admittedly negligent defendants to shift liability for the consequences of their culpable conduct to the party injured by that conduct. One mechanism by which such a shifting of liability can be achieved is through a plea of *volenti non fit injuria*, that is a plea that the injured party knew of, and voluntarily accepted, the risk of injury.[60] A successful utilisation of this fully exculpatory defence necessitates an examination of whether a risk was unknown to the claimant. It has been said by English courts that the relevant question is what the *actual claimant* knew, not what a fictitious person in his or her shoes ought reasonably to have known. So, by contrast with the law which we have just been considering, the question of

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58 *Owen* (fn 52) 330.

59 Some have argued against the need for product liability altogether: see *AM Polinsky*/*S Shavell*, The Uneasy Case for Product Liability (2010) 123 Harvard Law Review 1437.

60 A defence will only require to be pled if the requirements for liability have been met. Those requirements might not have been met if, for instance, a party has given clear warnings of the risk of danger, eg of the danger to health attendant upon smoking tobacco. In such a case, a proper warning may well qualify as sufficiently careful conduct, so that no defence needs to be employed.

whether a risk might have been foreseen by a reasonable person in the claimant's shoes is irrelevant to *volenti*: all that matters is what *this* claimant *actually* knew, and whether, in the light of that knowledge, this claimant accepted the risk of harm.

In some circumstances, the courts do not even need to embark upon such an examination. Some statutes pre-empt the need for consideration of whether a defendant did or did know of the risk of harm by entirely excluding the operation of the *volenti* defence in some circumstances. Employment law provides one context where this occurs. In the USA, the defence is excluded at state level in worker's compensation statutes, and also under US federal employment statutes. An example of a federal statutory exclusion is chapter 2 of title 45 United States Code (USC) (relating to liability for injuries to employees of common railroad carriers), § 54 of which provides that, in an action in respect of injury to or death of an employee:

> such employee shall not be held to have assumed the risks of his employment in any case where such injury or death resulted in whole or in part from the negligence of any of the officers, agents, or employees of such carrier; and … in any case where the violation by such common carrier of any statute enacted for the safety of employees contributed to the injury or death of such employee.

In the UK, the courts have extended common law protection to employees injured through the fault of their employers. So, for example, the courts have held that if an employee continues to work, knowing of and having complained to his employer about a specific risk, he is not *volens* for the purpose of the *volenti non fit injuria* defence.[61] Furthermore, by statutory reform, deemed consent to the risk of harm caused by a fellow employee now no longer applies.[62]

Volenti non fit injuria has thus been largely squeezed out of employment contexts. However, in the UK the defence still applies where a risk of danger is caused by the employee's own conduct: thus, where an employee undertakes plainly dangerous conduct, in defiance of statutory safety requirements and employers' regulations, a court may conclude that the employee knew of and accepted the risk of injury. An example where that was so is *ICI Ltd v Shatwell*,[63] in which a qualified shot-firer agreed with his brother, a fellow employee and shot-firer, to test-fire an explosive shot without returning to the safety shelter provided, and while standing too close to the test subject. Both the plaintiff and his brother were injured when the shot exploded. The plaintiff sued his employer for damages, arguing that his injury was caused by his brother's negligence and breach of statutory duty, for which the employer was (even if not at fault itself) vicariously liable.

As the House of Lords held in this case that the plaintiff had accepted the risk of injury, the question of whether he knew of the risk was brought into focus. The judgments in the case illustrate the point that the question of risk in relation to *volenti* is what the actual claimant knew, not what a fictitious person in his shoes ought reasonably to have known. As Lord Reid put the matter in his speech:[64]

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61 For an early example of judicial development of such protection, see *Smith v Baker* [1891] AC 325.

62 Prior to 1948, such consent was deemed under the doctrine of 'common employment'. See now the Law Reform (Personal Injuries) Act 1948, sec 1(1).

63 [1965] AC 656.

64 [1965] AC 656, at 671.

> No one denied that a man who freely and voluntarily incurs a risk of which *he has full knowledge* cannot complain of injury if that risk materialises and causes him damage. (emphasis added)

As Lord Reid expresses the matter, it is the knowledge of the claimant (not some reasonable person in his shoes) which is at issue. Note that the claimant must have, says Lord Reid, 'full knowledge' of the risk. His Lordship added:[65]

> [The plaintiff] had a full appreciation of the risk … He knew that the risk was that a charge would explode during testing, and no shot firer could be in any doubt about the possible consequences of that.

The notion of risk clearly encompasses not just the likelihood of some consequence to an act, but also an appreciation of the sort of harm that might arise as well as the way in which it might come about (that is, of the mechanism of the harm), as the mention by Lord Reid of an explosion (mechanism of harm) and the 'possible consequences' thereof (the harm) indicate. Similar remarks had been made by Diplock LJ two years before *ICI*, when he spoke of the defence of *volenti* requiring of the plaintiff 'full knowledge of the nature and extent of the risk that he ran'.[66] There are reported cases where the court has held a claimant to have had some, but not full, appreciation of the risk, and accordingly excluded the operation of the defence.[67]

Because, in assessing *volenti*, a court is looking at what the *actual claimant* knew about a risk and whether he consented to it, it should follow that the court is not concerned with whether the claimant in question ought to have been more appreciative of the nature of a risk, to have (for instance) possessed the appreciation of a risk that a reasonable person in the claimant's shoes might have had. As Bowen LJ put it in *Thomas v Quartermaine*:[68]

> There may be a perception of the existence of the danger without comprehension of the risk: as where the workman is of imperfect intelligence, or, though he knows the danger, remains imperfectly informed as to its nature and extent.

So, a defendant cannot argue that, although the claimant did not know of and fully appreciate a risk, it ought to have done so, and therefore ought to have imputed to it knowledge (and acceptance) of risk. Support for this proposition is also found in observations of Lord Reid in *Smith v Austin Lifts Ltd*.[69] This means, for instance, that

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65 AC at 673. The latter part of this quotation, in making reference to other persons in the plaintiff's line of work, raises the suspicion that an objective element may have crept into the judicial assessment of the plaintiff's knowledge of the risk.

66 *Wooldridge v Sumner* [1963] 2 QB 43, at 69. Diplock J was quoting the earlier formulation of Wills J in *Osborne v The London and North Railway Co* (1881) 21 Law Reports, Queen's Bench Division (QBD) 220, at 223.

67 See, for instance, *Smith v Austin Lifts Ltd* [1959] 1 WLR 100, where Lord Simmonds commented that the plaintiff 'had, it is true, an apprehension of some risk, for he had given the door a preliminary tug, but he did not appreciate, nor could have reasonably been expected to appreciate, that, though resistant to a tug at the bottom, the door would give way if pressure was applied higher up'.

68 (1887) 18 QBD 865, at 696.

69 'In this case the appellant saw the position and realized that there might be danger … But in my view his appreciation of the danger fell a good deal short of what is required. Another man might have had a greater appreciation but as I read the speeches of the majority in *Horton's* case, the test which they require is subjective': [1959] 1 WLR 100, per Lord Reid at 112.

an intoxicated claimant, who is unable to appreciate the risk of harm created by the negligent defendant, cannot be subject to a plea of *volenti non fit injuria* by such a defendant. However, such a claimant might well have been contributorily negligent in putting himself at risk: the potential relevance of the fault-based plea of contributory negligence by a defendant in many circumstances where *volenti* might also conceivably be pled should not be overlooked, and is a reminder that the victim of harm cannot always avoid an enquiry as to the risks of which he should have been aware.

Though the English courts have thus emphasised a subjective, actual knowledge of risk by a claimant, they have also taken the view that a voluntary assumption of the risk inherent in an activity can be implied in the circumstances, and need not be express. Such an implied assumption is usually made in relation to the participation of a person in sporting events: participants are held to accept the risks ordinarily associated with a specific sporting activity (risk which would therefore be known to a reasonable person). Such implied consent may operate in relation to spectators of sporting events,[70] as well as participants. However, in a number of sporting cases where the defence of *volenti* might potentially have been applicable, courts have said that no breach of a duty of care has occurred (so that the defence of *volenti* did not require to be considered); such has been the finding in some cases involving cricket,[71] golf,[72] and horseracing.[73] In those cases, discussions of consent, and on assumption of risk, took place within the duty of care context, and not within the context of the application of the defence of *volenti*: as Diplock LJ put it in one case, '[t]he spectator takes the risk because such an act involves no breach of the duty of care owed by the participant to him. He does not take the risk by virtue of the doctrine expressed or obscured by the maxim *volenti non fit injuria*'.[74] It is difficult to map such discussions of risk onto the nature of the knowledge of risk required for the *volenti* defence, as such discussions are doing no more than stating the obvious point that, if no one owes me a duty of care to prevent me from being injured, I have to bear the risk of any injury which I may suffer. When such cases have discussed the defence of *volenti*, judges have continued to adopt the language of knowledge of the risk by the actual claimant.[75] So, one should be careful not to assume that, because some cases have held that a duty of care is not breached where a party is injured as a result of a risk inherent in an activity, this means that the defence of *volenti* requires a reasonable person's knowledge of the risk in question. That at least seems to be the lesson of the English cases, though the US common law may be different in this respect.[76]

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70 *Wooldridge v Sumner* [1963] 2 QB 43; *Wilks v Cheltenham Homeguard Motor Cycle and Light Car Club* [1971] 1 WLR 668.

71 *Bartlett v English Cricket Board Association of Cricket Officials* 2015 Westlaw Transcripts (WL) 5037730 (31 July 2015).

72 *McMahon v Dear* [2014] Court of Session, Outer House (CSOH) 100, 2014 SLT 823.

73 *Wooldridge v Sumner* [1963] 2 QB 43.

74 Per Diplock LJ in Wooldridge at 68 f. See, for a similar view, *Blake v Galloway* [2004] 1 WLR 2844, at 2853.

75 As seen in the remark of Diplock LJ quoted above in the main text at fn 66.

76 The position in the United States is often said to be summed up in this view of Cardozo J, given in a case relating to horseracing: '*Volenti non fit injuria*: One who takes part in such a sport accepts the dangers that inhere in it so far as they are obvious and necessary, just as a fencer accepts the risk of a thrust by his antagonist or a spectator at a ball game the chance of contact with the ball': *Murphy v Steeplechase Amusement Co*, 166 North Eastern Reporter (NE) 173 (NY 1929). This is redolent

From the above discussion, it will be appreciated that there is a contrast between the knowledge of risk enquiries directed at arguably culpable defendants on the one hand[77] and arguably risk-assuming claimants on the other. The enquiry directed against the arguably culpable defendant concerns its alleged fault, and in that enquiry what it knew, *and* what a reasonable person in its shoes would have known, is one part of what must be determined; the enquiry directed against the arguably risk-assuming claimant concerns what it alone knew of the risk and whether it accepted such risk, fault and the reasonable person playing no part in this enquiry (albeit that consent to risks ordinarily arising may in some circumstances preclude the imposition of a duty of care in the first place).

By way of summary, where the defence of *volenti non fit injuria* is not otherwise excluded, a claimant against whom the defence is pled is in a better position so far as unknown risks are concerned than the defendant in a fault-based action. Such a claimant is not required to have shared a fuller appreciation of the risk than he in fact did. In this area, risks unknown to the claimant are at issue, but not risks which though unknown ought arguably to have been so.

VI Remarks on Civilian and economic perspectives

It is clear from the discussion in the other articles in this edition of the journal that there is a considerable convergence between the approach of Civilian systems and the Common Law to the treatment of liability for unknown/unknowable risks. Some aspects of the comparative position, especially in areas of divergence, merit specific mention here.

Specific clusters of injury have resulted in specific responses to unknowable risks in some Civilian systems:

(i) Looschelders addresses the issue of liability for harm caused by pharmaceutical products in German law.[78] The German law, formulated in the wake of the Thalidomide (Contergan) scandal, is found in the Medicinal Products Act. The strict liability imposed under that Act (in sec 84) does not avail manufacturers of pharmaceutical products of the development risks/state-of-the art defence[79] (the same position applies in Spain, as Del Olmo narrates[80]). This contrasts with the UK, where the response to incidents of Thalidomide was not to create a new category of strict liability for medicinal products, but merely to give the victims

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of a more objective, reasonable person approach to the assessment of knowledge of risk in relation to *volenti* than that disclosed in the English jurisprudence discussed in the main text.

77 And, where contributory negligence is in issue, arguably culpable claimants also.

78 *D Looschelders,* Liability for Unknown Risks in German Law (in this issue).

79 The current state of knowledge does feature in one aspect of the liability imposed under the German statute: liability is only triggered if the 'product has harmful effects which exceed the limits considered tolerable in the light of current medical knowledge' (§ 84(1)). To a non-German observer this seems an odd way in which to factor in the current state of medical knowledge, ie to make it relevant in assessing what level of harm is considered tolerable (one might have imagined that it would be the views of those who might be harmed which would be used to assess the tolerability of harm, rather than the state of knowledge of the medical professional).

80 *P del Olmo*, Unknown Risks and Civil Liability in Spain: A Study of Spanish Law with Some French/Italian Comparative Remarks (in this issue).

of *in utero* injuries (if born alive) a cause of action against the parent and (where relevant) third parties; the cause of action itself would, in the case of harm caused by a pharmaceutical product, arise under the general UK products liability regime, which as we have seen *does* provide a state-of-the-art defence.

(ii) Del Olmo narrates that the specific spur to the passage of the Spanish Consumer Protection Act of 1984—toxic syndrome caused by denatured rapeseed oil—resulted in the development risks defence being excluded in relation to food destined for human consumption;[81] such an exclusion does not apply in the products liability legislation of the UK or Germany. Then again, German law has a separate regime (the Genetic Engineering Act of 1990) for genetically modified organisms (discussed in Looschelder's article). This regime does not provide for a development risks defence to the strict liability it imposes. By contrast, English law would again treat instances of harm caused from this source as falling under the general products liability regime of the CPA.

The practical and legal questions which unknown/unknowable risks pose for insurers is considered by both Looschelders[82] and Faure, Visscher and Weber.[83] Looschelders mentions the challenge which is posed in actuarial terms by unknown risks,[84] noting that risks such as those created by nanotechnology are of unknown extent (both in terms of likelihood of occurrence and possible extent of damage), and the uncertainties that the introduction of driver-less cars creates for insurance arrangements (especially as between vehicle owner's and manufacturer's insurance liability). Risk-spreading among insurers, through reinsurance and co-insurance, and the application of financial limits on claims can operate to assist insurers dealing with some of the uncertainty, as both Looschelders[85] and Faure, Visscher and Weber[86] discuss. A crucial general point about insurance is of course that, in providing coverage against unknowable risks, it enables new activities to be adventured which otherwise might not be, or at least not with the same expedition.[87] This is an overall beneficial outcome, as the ultimate good it is hoped the new activity will achieve is considered to outweigh the harm which might eventuate if the risk materialises.

Del Olmo narrates the interesting history of very broad fault-based liability in Spanish delict law,[88] in which (in his words) 'sometimes fault was presumed and other times the required degree of care was raised so high that the defendant's exoneration was practically impossible'. This went hand-in-hand with a reticence to apply strict liability regimes, out of a concern that aspects of such regimes (such as maximum claim limits) unduly limited victim compensation. Such pecuniary limits, also mentioned by Looschelders,[89] are not found in UK law, and are an aspect of clear difference between UK and Civilian approaches. The Spanish approach to liability for

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81 *Del Olmo* (fn 80) xxx.
82 *Looschelders* (fn 78) xxx.
83 *M Faure/L Visscher/F Weber*, Liability for Unknown Risks: A Law and Economics Perspective (in this issue) xxx.
84 *Looschelders* (fn 78) xxx.
85 *Looschelders* (fn 78) xxx.
86 *Faure/Visscher/Weber* (fn 83) xxx.
87 A point made in *Faure/Visscher/Weber* (fn 83) ch III.V. An alternative argument is that the existence of liability for unknown risks acts as an incentive to undertake research, in order to discover what risks exist: see section 3.4 of their article.
88 *Del Olmo* (fn 80) xxx.
89 *Looschelders* (fn 78) xxx.

so-called *inmisiones* is also of interest for comparative purposes: del Olmo explains that once a claimant demonstrates such an *inmissio* emanating from the defendant's property, it is for the defendant to prove that the *inmissio* is not harmful;[90] if it cannot, for instance because the potential risks are unknowable at the present time, there is liability, regardless of fault. Liability in England, under *Rylands v Fletcher*, is different, the claimant having both to demonstrate that harm occurred, and that the source of the harm was something 'likely to do mischief'. In Scotland, which lacks *Rylands* liability, the pursuer in the nearest equivalent form of action, nuisance, can only bring an action for damages for harm caused on the basis of fault (though fault is not required for an interdict to prevent conduct likely to cause harm).[91] There are clearly divergent jurisdictional attitudes to liability for harm caused by neighbours.

Faure, Visccher and Weber present a detailed and closely argued case on the impact of cost-benefit analysis on liability for unknown risks. Controversially (to this observer, at least) they suggest that an economic argument can lead to the conclusion that, although certain risks are known about scientifically, the costs to a tortfeasor of informing itself about such risks might outweigh the benefits, so that even though the risk is known to science, one might still reach the conclusion that 'this tortfeasor did not have to know this risk, and hence that liability is not warranted'.[92] Some might well find that a mere economic argument of this sort is insufficient to outweigh the social and personal benefit of expecting actors to appraise themselves of publicly known information relating to the field of their action. Ultimately, given the existence of competing economic arguments, their conclusion is that it is not possible to give a clear answer to the question whether, in general, liability for unknown risks is socially desirable. However, they argue that where there is a clear social utility in certain activity (for example, developing new medicine), 'liability for unknown risks should be used cautiously'. The existing approach of the law seems to confirm this, by virtue of the availability of the state-of-the-art defence in relation to product liability.

VII Conclusions

By way of drawing some conclusions, let me begin by returning to an area discussed earlier in the article: environmental damage. In that field, we saw that tort liability and public regulation (including remedial orders) both operate, the latter being subject to a variety of the development risks defence. Public intervention makes sense in the realm of environmental damage because such damage has the potential to impact negatively not just on specific individuals, but on society (and future generations) more generally. The specific English legislation mentioned earlier[93] does not catch damage with a more diffused environmental effect, however: consider, for instance, the long term effects of widespread usage of the female contraceptive pill, which it is now suggested is having a negative effect on male fertility levels through the presence of increased oestrogen levels in drinking water.[94] As this previously unknown risk

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90 *Del Olmo* (fn 80) xxx.

91 *RHM Bakeries (Scotland) Ltd v Strathclyde Regional Council* 1985 SC (HL) 17, 1985 SLT 214.

92 See *Faure/Visscher/Weber* (fn 83) ch III.IV.3.

93 The Environmental Damage (Prevention and Remediation) Regulations 2009.

94 A concern which had been publicly raised by 2001: see a report discussing the issue on the BBC News website, available at <http://news.bbc.co.uk/1/hi/health/1495908.stm>. See, more recently, a

emerges into public knowledge, what may ultimately be needed is an outright ban on that particular form of contraception (or at least deployment of extensive and expensive counter-measures). The same can be said of the use of micro-plastics in cosmetic products, now that evidence is emerging of the risk posed by the presence of such micro-plastics throughout the marine eco-system (including the food chain). Decisive public intervention may be mandated in order effectively to negate these emerging risks.

Tort law cannot fix environment-wide harm, and its power to provide remedies to specific individuals injured as a result of such harm faces the challenge of demonstrating a causal connection between an individual tortfeasor and individual victim. Outside the environmental sphere, however, harmful conduct tends to have a targeted effect, impacting negatively on specific persons or property. Here it *is* tort which most obviously fits the bill as the appropriate way to repair the harm caused; the absence of a wider public impact undercuts the rationale for public authority intervention.

So what of tort and unknowable risk? If we believe that fault-based liability should be the general, default basis of tort law, then we must accept that liability for unknowable risk will be excluded: the concept of fault suggests that the reasonable person in the defendant's shoes should have behaved differently, and this cannot be expected of such a party to whom the risk of a specific type of injury was unknowable. So, unless we abandon fault-based liability, we must accept that unknowable risk will be irrecoverable.

We have already, of course, abandoned fault-based liability to some extent: strict liability allows for the imposition of liability for unknowable risks, though in the most common example of such liability (for defective products) an EU defence of development risk for some actors has been created which effectively shifts liability back towards a fault basis, albeit that the resulting duty is at a higher standard (even unlikely risks must be guarded against, though not unknowable ones). As we have seen, the availability of this defence is not uniform across systems: for instance, in Germany it is not available for developers of pharmaceutical products, whereas it is in the UK. Economic arguments cannot of themselves furnish the obviously correct answer to the question of the extent to which this defence should be available, or to other questions surrounding unknowable risks, such as whether (in the area of product liability law) the concept of unforeseeable risk should be built into the definition of a defective product (the US Restatement (Third) approach) or into a separate development risks defence (the UK/EU approach). The policy arguments at work here stretch beyond the economic.

I have argued in this article that the issue of unknowable risks is relevant to the position of the defendant in a tort action, and, to the extent that contributory liability is pled, to the claimant too. It is however not applicable in relation to the defence of *volenti non fit injuria* (assumption of risk by the claimant). In assessing whether this defence applies, English courts are concerned only with what a claimant actually knew about the risk of harm and not what a reasonable person in his or her shoes ought to have known. That is appropriate, as the nature of the defence relates to

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report on the issue in the Guardian newspaper, available at <http://www.theguardian.com/environment/2012/jun/02/water-system-toxic-contraceptive-pill>.

what the specific claimant allegedly did, and not to the reasonable standard of behaviour expected of parties generally.

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