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RESEARCH ARTICLE

Product Liability in an Age of Development Risks: Should South Africa Reconsider Adopting a Development Risk Defence?

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Abstract
To provide protection against harm caused by defective, unsafe products and to promote product safety, the law of product liability has developed as a specialized area of the law of delict (tort). The vexing question is, who should bear such liability? This contribution interrogates the notorious EU development risk defence, which exonerates manufacturers that meet certain stringent requirements for undiscoverable development risks in products that consequently inflict harm on consumers. In particular, it considers the election by South Africa, which recently adopted a "strict" product liability regime with the introduction of the Consumer Protection Act 2008, *not* to adopt such a defence. The purpose of this contribution is to consider the nature and scope of the development risk defence as contained in article 7(e) of the European Union (EU) Product Liability Directive and to determine whether it was prudent for South Africa to steer clear of incorporating a similar defence in its new statutory product liability regime.

Keywords: Defective products; developmental risk; developmental risk defence; hybrid regime; product liability; strict liability

Introduction

The modern consumer market is characterized by the continuous supply of products that have become increasingly sophisticated and complex. Although these products are generally beneficial, there are instances in which they may be defective, unsafe and harmful. This applies to consumer goods as well as medical and pharmaceutical products despite the rigorous testing the latter is subjected to. Geistfeld aptly comments that "[p]roduct risk is pervasive, increasingly so in the modern economy. Automobiles can crash. Drugs can cause harmful side effects. Chemicals can be carcinogens. Even seemingly benign products pose the risk of serious physical harm. Food, the most basic of all products, can be contaminated. Or a bottle of soda can explode".[1]

In order to protect against harm caused by defective, unsafe products, the law of product liability has developed as a specialized area of the law of delict (tort). Product liability law not only seeks to protect consumers by providing redress for harm but also seeks to promote the production of safer

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1 M Geistfeld *Principles of Product Liability* (1st ed, 2011, Foundation Press) at 7. See also E Van Eeden and J Barnard *Consumer Protection Law in South Africa* (2nd ed, 2017, LexisNexis) at 381.

products.[2] At the heart of the evolution of product liability law is the question of who should be the bearer of such liability.[3] Many attempts have been made to answer this question by interrogating the rationale behind and the goals of product liability.[4] It has proven to be a very difficult question to answer because of the many competing interests. These vary from consumers who buy a product, persons who receive the product as a gift, users of a product belonging to someone else, an innocent bystander injured by a defective product, as well as the interests of manufacturers and those of the broader community who stand to benefit from innovative products that may, for example, save lives. Although there are instances when a victim should personally bear the risk of injury caused by a product, such as when a person deliberately throws a glass bottle against a pole and the shrapnel from the bottle injures him. Owen points out that consumers, sometimes passively and unknowingly, confront other product risks, such as being exposed to toxic chemicals or defective pacemakers, where they cannot, from a moral perspective, be expected to bear liability for the damage they suffered in the process. He thus cautions that "the product liability paradigm is more complex than merely stating that because a manufacturer produces and sells products, it should by necessary implication compensate a person who has suffered harm as a result of using that product."[5]

Recent decades have witnessed the rise of various "strict product liability" regimes that impose faultless liability on manufacturers of goods and, in many instances, on the whole supply chain. The rationale behind introducing these purportedly strict regimes is, inter alia, that it will open up redress to victims of defective, unsafe products who will no longer be required to prove negligence on the part of the manufacturer.[6] Notably, however, these "strict" regimes generally introduce specific statutory defences that manufacturers and other suppliers may rely on to avoid liability for the harm caused by defective, unsafe products in certain limited instances – thus making them hybrid rather than strict regimes.

One such defence, which has been met with much controversy over the years, is the so-called "development risk defence", which, simply put, seeks to exonerate manufacturers for undiscoverable development risks in products that subsequently inflict harm on consumers. While the European Union (EU) has become notorious for the development of risk defence in its strict product liability regime, South Africa, which has only recently transitioned to a strict product liability regime with the introduction of the Consumer Protection Act 2008, has chosen *not* to adopt such a defence. The purpose of this contribution is, therefore, to consider the nature and scope of the development risk defence as contained in article 7(e) of the EU Product Liability Directive (the Directive)[7] and to determine whether it was prudent for South Africa to steer clear of incorporating such a defence in its new statutory product liability regime.

2 BJ Riordan "Unravelling the mystery: A comparative introduction to product liability law in the US and Europe" (2013) 1 *South Carolina Law Journal of International Law* 27 at 27.

3 DG Owen "Products liability: Principles of justice for the 21st Century" (1990) 11 *Pace Law Review* 63 at 63.

4 RW Wright "The principles of product liability" (2007) 26 *The Review of Litigation* 1067 at 1067 remarks that more than any other area of tort (delict) law, the law of product liability has been the subject of continuing debate regarding the interrelated issues of its proper rationales and grounds of liability.

5 DG Owen "Moral foundations of product liability" (1993) 68 *Notre Dame Law Review* 427 at 461 (emphasis added).

6 G Howells "The new product liability law: The relevance of European and United Kingdom reforms for the development of the Australian law" (1996) *Competition and Consumer Law Journal* 1 at 7 remarks that there are essentially four types of product liability standards. The contractual or warranty standard involves products which fail to meet the promised standard or to comply with a term implied by law. The negligence standard judges the conduct of the defendant in light of the risks and benefits which result from his conduct. The strict liability standard focuses on the product and not on the conduct of the producer. The last standard is the absolute liability standard, although he submits this standard is not applied in practice.

7 European Council Directive 85/374/EEC of 25 July 1985 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products, available at: <https://europa.eu/european-union/eu-law/legal-acts-eu.pdf> (last accessed 5 April 2022).

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Development risks defence in the EU Product Liability Directive

Background

Prior to the introduction of the Directive, consumer protection was a "Cinderella policy of the European Communities".[8] As pointed out by Murray, the EU lacked, inter alia, safeguards on the quality and safety of products to prevent defective goods from reaching the market.[9] There was also a clear need for consolidated consumer protection in the EU as the then-existing consumer protection measures differed considerably from one member state to another, resulting in suppliers being subject to differing degrees of liability. This fragmentation of consumer protection laws resulted in the distortion of competition and restriction on the movement of goods within the common EU market.[10]

However, it was not until the "thalidomide disaster" that the move towards greater consumer protection in the EU gained serious momentum. Thalidomide was a pharmaceutical drug patented by Grunenthal in Germany in 1954, initially as an antidote to nerve gas poisoning. It was, however, launched in October 1957 as a sedative, pain killer and an anti-emetic suitable for treating morning sickness in pregnancy. The following year, it was licensed in the UK and most other countries, the main exception being the USA, which insisted on seeing more pre-clinical studies on the effects of the drug.[11] In the pre-clinical testing of the drug in Germany, no tests had been performed on pregnant animals to check the impact of the drug on foetuses. Such testing was not usually undertaken as the belief was held *at the time* that drugs would not cross the placenta and harm the foetus. However, between 1957 and 1961, when the drug was withdrawn, more than 10,000 children in 46 countries were born with congenital deformities caused by the drug. The immediate consequences of the thalidomide tragedy were that testing all drugs for teratogenicity (possible ill effects on the foetus in pregnant animals) became universal. A further consequence was that the drug licensing procedures became much more rigorous, lengthier and far more expensive.[12]

The EU community pressured the European Commission (EC) into introducing legislative reform that would protect consumers across member states against harm arising from unsafe products.[13] In 1972, the Hague Convention addressed the conflict of laws in product liability among the EU member states.[14] Subsequently, in 1974, the Committee on Legal Corporations (CCJ) of the Council of Europe proposed a Convention on Product Liability (the Strasbourg Convention) imposing strict liability on manufacturers in personal injury and death cases.[15]

A preliminary draft EU Directive was subsequently presented in August 1974, modified in 1975, and officially proposed on 9 September 1976, followed by another amendment in 1979.[16] The EC submitted the proposal to the European Parliament and the Economic and Social Committee (ECOSOC), where it was met with harsh criticism as being too consumer-friendly because it imposed strict liability whenever a product failed to provide the safety a person was entitled to expect.[17] The EU Parliament and ECOSOC held the view that any future Directive had to provide

8 C Murray "Product safety: The new Directive" (1992) 3 *International Company and Commercial Review* 426 at 426.

9 Id at 427.

10 M Ueffing "Directive 85/374: European victory or a defective product itself?" (2013) 4 *Europeanisation of Private Law, Marble Research Papers* 373 at 375.

11 PJ Lachmann "The penumbra of thalidomide, the litigation culture and the licensing of pharmaceuticals" (2012) 105 *International Journal of Medicine* 1179 at 1179; and N Vargesson "Thalidomide-induced teratogenesis: History and mechanisms" (4 June 2015) *National Library of Medicine: National Center for Biotechnology Information* at 140, available at: <https://pubmed.ncbi.nlm.nih.gov/26043938/> (last accessed 25 August 2023).

12 Lachmann "The penumbra of thalidomide", above at note 11 at 1197.

13 J Stapleton "Restatement (Third) of Torts: Products liability, an Anglo-Australian perspective" (2000) 39 *Washburn Law Journal* 363 at 367. See also Ueffing "Directive 85/374", above at note 10 at 373.

14 Ueffing, id at 375.

15 See EC (CCJ), TS No 91, Strasbourg 27.l.1977. See also Ueffing, id at 375.

16 Ueffing, id at 376.

17 Ibid.

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some exculpatory provisions in favour of producers because the industry should not be liable for defects in products that could not have been manufactured to a safer standard at the time that they were put into circulation.[18] Both Parliament and the Council urged for the inclusion of a "development risk defence" that would limit the liability of producers to defects that were foreseeable, based on the scientific knowledge available at the time the product was introduced to the market, which would provide substantial protection, especially to new and innovative firms.[19]

Throughout the 1980s, the finalization of the proposed Product Liability Directive seemed doubtful, given that earlier debate had not reached a resolution as many national governments demanded amendments to the proposed Directive in order to preserve their sovereignty. The result was that the Commission eventually struck a compromise by which an array of options was left to member states, inter alia, relating to aspects such as choosing whether or not to adopt the development risk defence and limitations on the total liability of producers.[20]

The EU Product Liability Directive was eventually introduced on 25 July 1985.[21] The introduction of a general strict product liability regime in the EU was justified in the preamble of the Directive, which provides that "liability without fault on the part of the producer is the sole means of adequately solving the problem peculiar to our age of increasing technicality of a fair apportionment of risks inherent in modern technological production."[22]

Save for a few exceptions, the Directive, in most respects, imposes maximum harmonization[23] and an instruction[24] that all member states have to incorporate the strict liability provisions of the Directive into their national legislation.[25]

EU Product Liability Directive

Article 1 of the Directive provides that "the producer" shall be liable for damage caused by a "defect" in their product. A "producer" is defined as a manufacturer of a component part or finished product. A person who makes raw materials presents themselves as such by attaching their name, trademark, or other identifiable feature to the product.[26] Article 3(2) further provides that, without prejudice to the liability of the producer, "any person who imports into the community a product for sale, hire, lease or any form of distribution in the course of its business shall be deemed to be a producer within the meaning of the Directive and shall be responsible in accordance with the Product Liability Directive as a producer."

18 Ibid.

19 See the European Council, Council Resolution embodying the Opinion on the Proposal for a Council Directive Relating to the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products – OJ No C 114, 7.5 (1979) as updated by COM/2018/246.

20 Ueffing "Directive 85/374", above at note 10 at 381.

21 Stapleton "Restatement (Third) of Torts", above at note 13 at 367. Ueffing "Directive 85/374", above at note 10 at 373 remarks that "in recent years the EU Product Liability Directive has become something of a global smash hit, providing not only a template for EU Member States but also an international blueprint used by countries worldwide, including South Africa, Australia, Brazil and countries in the ASIA Pacific Region when reforming their product liability regimes".

22 See the preamble to the Directive, recital 18.

23 T Verheyen "Full harmonization, consumer protection and products liability: A fresh reading of the case law of the ECJ" (2018) 26 *European Review of Private Law* 119 at 121 indicates that the EU Product Liability Directive is a "maximally harmonising directive".

24 Arts 19 and 20. The Directive is binding by virtue of the Treaty of Rome (Treaty establishing EEC (1957) *U.N.T.S* 11). See Stapleton "Restatement (Third) of Torts", above at note 13 at 370 and 373.

25 However, C Hodges "The product liability Directive" (2000) 6 *European Lawyer* 33 at 33 states that despite the member states being required to implement the Directive into their national laws by March 1988, most countries were late, with France as late as 1998.

26 Recital 4 read with art 3(1).

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Article 1 is qualified because the product's producer or importer must be identifiable before being held strictly liable.[27] Where the producer of a product cannot be identified, liability is extended by providing that each supplier of the product must be treated as the producer unless they inform the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him with the product.[28] Suppose more than one person in the supply chain is held jointly and severally liable for the same damage. In that case, the consumer may claim full compensation from any of them "without prejudice to the provisions of national law concerning the rights of contribution or recourse".[29]

Interestingly, the Directive does not define the term "consumer" or limit the application of the Directive to consumers only. Instead, it provides that a "person" injured by a defective product may claim compensation under the Directive. Although the preamble to the Directive refers in numerous recitals to "the protection of the consumer", the reference to "the injured person" in the articles of the Directive has the result that "the remedy afforded by the Directive appears to be available to any person harmed by a defective product, whether that person is the purchaser of the product, a bystander or a defendant who suffers loss as a result of harm caused by a defective product to another person".[30]

The Directive only applies to products, not services.[31] For the purposes of the Directive, "product" was initially defined to mean "all movables, with the exception of primary agricultural products and game, even though incorporated into another movable or into an immovable", thus including component parts of a finished product.[32] "Primary agricultural products" were defined as "the products of the soil, of stock-farming and of fisheries, excluding products which have undergone initial processing". "Product" also includes electricity.[33] However, after the "mad cow" disaster in the 1990s,[34] the definition of "product" was amended by discarding the exception relating to primary agricultural products.[35] Liability for nuclear injury or damage is excluded if covered by special rules of member states.[36]

It is further required that the alleged defective product must have been "ordinarily intended"[37] and "used"[38] by the injured party for private use or consumption, as confirmed by the European Court of Justice (ECJ) in *Moteurs Leroy Somer v Dalkia France and Ace Europe,*[39] where it was

27 See C Hodges "Product liability of suppliers: The notification trap" (2002) 27(6) *European Law Review* 758 at 759.

28 Directive, art 3(3). EC Staff Working Paper *Evaluation of Council Directive 85/374/EEC* (May 2018) 51 (EC Green Paper (1999)) available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52018SC0157> (last accessed 25 August 2023) at 4 points out that the victim is obliged to formally notify the supplier concerned so that he can, within a reasonable time, provide details of the producer or previous supplier. Note should be taken of the decision in *Commission v France* Case C 52-00 where it was held that a supplier will be free from liability under the Directive where such supplier identifies the producer or upstream supplier and that member states cannot restrict this "defence" through any provisions of domestic law.

29 Recitals 4 and 5; and art 5.

30 C Kriek "The scope of liability for product defects under the South African Consumer Protection Act 2008 and common law: A comparative analysis" (LLD thesis, University of Stellenbosch, 2017) at 153.

31 EC Green Paper (1999).

32 Directive, art 2.

33 Ibid.

34 Medically termed "bovine spongiform encephalopathy". See P Salzmann and LM Tierney "Mad cow disease. An opportunity for preventive medicine?" (1997) 167/6 *Western Journal of Medicine* 417.

35 EC Green Paper (1999) par 1.1[2]. Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999 amending Council Directive 85/374/EEC. Article 1 of the 1999 Directive amends the Product Liability Directive by replacing the original article 2 with the following article: "For purposes of this Directive, 'product' means all movables even if incorporated into another movable or into an immovable, 'Product' includes electricity".

36 Preamble, recital 14.

37 Art 9(b)(i).

38 Art 9(b)(ii).

39 [2009] ECR l-04733, paras 2 and 9–11. This case was heard in France in 2006 prior to the ECJ being approached for a preliminary ruling. Damage was caused to a hospital generator due to the alternator overheating. The alternator was manufactured and put into circulation by Leroy Somer. Dalkia France installed the product, whereas Ace Europe was

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stated that "an item of property intended for professional use and employed for that purpose, is not covered by the term 'damage' for the purposes of Directive 85/374 and, consequently, cannot give rise to liability of the producer under Article 1 of that Directive".[40]

In line with the stated intention of the Directive to introduce a strict product liability regime at the EU level, article 4 provides that, for purposes of founding a product liability claim, the injured person is required to prove "the damage, the defect and the causal relationship between defect and damage".[41] A product is "defective" for the purposes of the Directive when it does not provide the safety which a person is entitled to expect, *taking all circumstances into account*, including:[42]

(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.

Article 6(2) specifically provides that a product shall *not* be considered defective for the sole reason that a better product is subsequently put into circulation.

Although the EU product liability regime is regarded as a strict regime, it is, in fact, a hybrid regime given that six statutory product liability specific defences are available to producers under the Directive. These defences are set out in article 7, which states that a producer shall not be liable if they prove:

(a) that they did not put the product into circulation;
(b) that, having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by them or that the defect came into being afterwards or
(c) that the product was neither manufactured by them for sale or any form of distribution for economic purposes nor manufactured or distributed by them in the course of their business or
(d) that the defect was due to compliance of the product with mandatory regulations issued by the public authorities or
(e) that the state of scientific and technical knowledge at the time when they put the product into circulation was not such as to enable the existence of the defect to be discovered or
(f) in the case of a manufacturer of a component, the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product.

the insurer. Upon Dalkia France and Ace Europe compensating the hospital, they reclaimed the money from Leroy Somer.

40 [2009] ECR 1-04733, paras 17 and 28.

41 In *NW v Sanofi Pasteur MSD SNC* [2017] Case C-621/15, the ECJ examined the requirement in article 4 of the Directive requiring a claimant to prove a causal link between his damage and the defect in a product. This matter concerned a hepatitis vaccine which the plaintiff claimed caused his subsequent contraction of multiple sclerosis. The French courts had previously allowed proof of causation by way of evidentiary presumptions in similar types of matters where the plaintiff had no family history of the disease and the onset of the disease occurred soon after the vaccine was administered to the plaintiff. These presumptions thus enabled plaintiffs to establish causation even though there was a notable lack of scientific or medical evidence that hepatitis could actually cause multiple sclerosis. The ECJ held that national courts have a wide discretion to determine what evidence a plaintiff must present to prove causation, subject only to ensuring that the evidential requirements do not have the effect of reversing the onus of proof under article 4. Accordingly, the ECJ held that the use of presumptions to establish causation was permissible under article 4. See further Verheyen "Full harmonization, consumer protection and products liability", above at note 23 at 123–26 for a discussion of this case.

42 Art 6(1).

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Article 8(1) further provides that, without prejudice to the provisions of national law concerning the right of contribution or recourse, the liability of the producer shall not be reduced when the damage is caused *both* by a defect in the product and by the act or omission of a third party. The producer's liability may, however, be reduced or disallowed when having regard to all the circumstances when such damage is caused *both* by a defect in the product *and* by the fault of the injured person or any person for whom the injured person is responsible.[43]

The Directive provides for compensation to be claimed for damage caused by death or personal injuries and for damage to, or destruction of, any item of property, with a lower threshold of 500 ECU, provided that the item of property is of a type ordinarily intended for private use or consumption and that it was used by the injured person mainly for his own private use or consumption.[44] Furthermore, member states may also award compensation for pain and suffering and other non-material damages where appropriate, as made effective in terms of their national law.[45] Thus, the Directive does not affect the member states' laws regarding economic loss damages.[46]

Member states must provide in their domestic legislation a limitation (prescription) period of three years from the date the plaintiff became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer.[47] Article 11 contains a "period of repose", which provides for the expiry of the rights of the plaintiff to institute a product liability claim against the producer, which takes effect ten years from the date on which the producer put the product into circulation.[48]

In terms of article 12, the producer's liability arising from the Directive vis-à-vis the injured person may not be limited or excluded by a provision that restricts the producer's liability or exempts them from liability. The Directive also does not affect any rights that an injured person may have according to the rules of the law of contractual or non-contractual liability or a special liability system existing in member states.[49] Member states may further provide that a producer's total liability for death or personal injury arising from identical products with the same defect must be limited to a maximum of 70 million ECU.[50]

Notably, article 18(2) requires the EC to issue a report on the workings of the Directive every five years.

Development risk defence

As indicated, article 7(e) provides a defence, popularly referred to as a "development risks defence", for the producer if they can prove that "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".[51] The development risks defence is controversial; the 1976 version of the Products Liability Directive initially ruled explicitly against incorporating this defence.[52] The defence was,

43 Art 8(2) (emphasis added).

44 Art 9(a) and (b).

45 Recital 9.

46 Kriek "The scope of liability", above at note 30 at 156.

47 Art 10(1).

48 The EC Green Paper (1999) paragraph 3.2.4 states that "this limitation of liability is mainly justified by the fact that strict liability puts a higher burden on producers than liability under the traditional systems of contractual or extra-contractual liability. Therefore, the liability period is limited in order not to discourage technical innovation and to allow insurance cover".

49 Art 13.

50 Art 16(1).

51 Emphasis added.

52 CJ Stolker "Objections to the development risk defence" (1990) 9/2 *Journal of Medicine and Law* 783 at 783. See further M Arbour's "Portrait of development risk as a young defence" (2014) 59 *McGill Law Journal* 913 at 913 who refers to the "infamous" development risk defence.

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nevertheless, subsequently added to the Directive as a "balancing defence" as it was feared that strict liability would have impacted the industry too harshly.[53] Arbour thus remarks that the premise underlying the development risk defence is "surprisingly simple: Overly broad liability chills innovation, threatens to make certain products entirely unavailable, and increases insurance premiums". Hence, the defence aims to strike an "acceptable compromise" to avoid these negative effects.[54]

Member states can exclude the development risk defence, but most have opted to include it in their product liability regimes.[55] In simple terms, the development risks defence entails that, in a particular instance, one cannot expect the producer of a defective product to have discovered the relevant defect *at the time that the product was put into circulation* due to the absence of accessible scientific and technical knowledge *at that stage* which would otherwise have allowed the discovery of the defect.[56]

As a point of departure, a number of aspects should be noted about the defence. First, it is a defence available to the producer of goods covered by the scope of the Product Liability Directive. Second, it relates to the absence of scientific and technical knowledge, which would have made the defect discoverable. Third, the crucial point in time with regard to which the availability of scientific and technical knowledge for purposes of the defence should be established is the time that the product is put into circulation.

The development risk defence raises many questions of interpretation. As a point of departure, it can be asked whether the defence should be availed to the whole supply chain or whether it should be strictly construed and made only available to the *actual* manufacturer of the goods who, it is submitted, is the party that designed the product and intended to benefit from it, and on whom the obligation to conduct the vast research that is implied by the defence would arguably reasonably rest. If not, does this mean that every time a subsequent supplier in the supply chain receives the product for purposes of further circulation, they incur the responsibility to ensure that, in line with available scientific and technological knowledge, the product does not contain an undiscoverable defect? If so, it would mean the duty to guard against so-called development risks is a continuous duty imposed on the whole supply chain, and it can be asked whether imposing such a duty on suppliers other than the actual manufacturer would be fair, let alone practical. It may also be asked whether this defence can be raised with respect to any defect or whether its very nature limits its application to certain types of defects. Similarly, the question as to the exact "state of scientific and technical knowledge" required by the defence and how this element will be proved poses interpretational challenges.

The reference to the time that the product is "put into circulation" appears to mean that it will not be sufficient for the producer to indicate that he could not have discovered the defect when the product was manufactured. This defence obliges him to keep abreast of scientific and technical knowledge until the product is finally put into circulation. Notably, Hodges points out that the development risk defence relates to *both* scientific and technical knowledge. He remarks that these two types of knowledge are distinguishable and that *both types* must be satisfied for the development risk defence to become available. He further explains that scientific knowledge derives from systematically observing and testing phenomena and formulating hypotheses, principles and rules to explain and predict such phenomena. On the other hand, technical knowledge concerns applying such principles and rules; thus, the defect must not be scientifically knowable or technically discoverable.[57] Accordingly, neither science nor technology must have been in a state of development when the product was put into circulation so that the defect could have been detected.

53 Recital 7 in the preamble of the Directive.

54 Arbour "Portrait of development risk", above at note 52 at 927.

55 Art 15(1)(b).

56 Art 7(e).

57 C Hodges *Product Liability: European Laws and Practice* (1993, Sweet & Maxwell, UK) at 78.

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The lack of guidance provided by the Directive with respect to the exact scope and application of the development risk defence also impeded the interpretation that oscillated between views that the defence requires "absolute undiscoverability" (the so-called narrow interpretation) as opposed to views that the defence merely requires "undiscoverability by reasonable means" (the so-called wider interpretation).[58]

Various views exist on the meaning of the words "state of scientific and technical knowledge". Hodges opines that, on the face of it, the development risks defence is absolute – merely asking whether the state of scientific and technical knowledge at the time when the product was put into circulation enables the existence of the defect to be discovered. Hodges remarks that it would seem that the relevant knowledge for purposes of the defence is that of the technical and scientific community at large, not just that of the given producer, and that the discoverability of the defect is to be measured by reference to the highest scientific and technical levels of intelligence and deduction. Consequently, he states that "the objectivity of this wording may set a standard which is almost *impossibly high* for producers to attain".[59] Stapleton is also critical of the development risk defence, arguing that:

> "[O]nce the criterion for discoverability involves leaps of curiosity or creativity, a succession of value questions are introduced, the inevitable consequence of which is that liability should exist only in respect of defects discoverable by reasonable means, for there is no logical halfway house between absolute undiscoverability (rendering the defence nugatory) and undiscoverability by reasonable means (aping the negligence standard)".[60]

The meaning of the words "state of scientific and technical knowledge" was eventually clarified to some extent in 1997 when the matter of *Commission v United Kingdom*[61] came before the ECJ. This case concerned an application for a declaration that, by failing to take all the measures necessary to implement the EU Product Liability Directive, particularly article 7(e) thereof, the UK had failed to fulfil its obligations under the Directive and under the EC Treaty by not correctly transposing article 7(e) of the Directive into its Consumer Protection Act 1987.[62] First, the ECJ observed that article 7

58 M Mildred "The development risk defence" in D Fairgrieve *Product Liability in Comparative Perspective* (2nd ed, 2005, Oxford University Press) 167 at 170.

59 Hodges *Product Liability*, above at note 57 at 79.

60 J Stapleton "Bugs in Anglo-American product liability" in D Fairgrieve (ed) *Product Liability in Comparative Perspective* (2nd ed, 2005, Oxford University Press) 295 at 332.

61 *Commission of the European Communities v United Kingdom of Great Britain and Northern Ireland* [1997] C-300/95 ECR 1-2649.

62 *Commission v United Kingdom*, paras 10–17. The UK Consumer Protection Act 1987, sec 4(1), which purports to implement article 7(e) of the Directive, reads as follows:

> "In any civil proceedings by virtue of this Part against any person … in respect of a defect in a product it shall be a defence for him to show. … (e) 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".

The UK argued that, although the wording of section 4(1) was different from that of article 7(e); member states were entitled to choose appropriate wording when implementing a Directive, provided that the intended result of the Directive was achieved. The Commission argued that the UK legislature had broadened the defence under article 7 (e) of the Directive to a considerable degree and had converted the strict liability imposed by article 1 of the Directive into a mere liability for negligence. It submitted that the test in article 7(e) is objective in that it refers to a state of knowledge and not the capacity of the producer of the product in question or to that of another producer of a product of the same description to discover the defect. However, the Commission's view was that, by using the words "a producer of products of the same description as the product in question [who] might be expected to have discovered the defect", the UK Consumer Protection Act 1987, section 4(1)(e) presupposed a subjective assessment based on the behaviour of a reasonable producer. Under section 4(1)(e), it was easier for a producer to demonstrate that *neither he nor a producer of similar products* could have identified the defect at the material time, "provided the standard

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(e) is not directed at the practices and safety standards in use in the industrial sector in which the producer is operating but "unreservedly, at the state of scientific and technical knowledge, including the *most advanced level of such knowledge*, at the time when the product in question was put into circulation". Second, article 7(e) does not contemplate the state of knowledge of which the producer in question "actually or subjectively was or could have been apprised" but the "objective state" of scientific and technical knowledge of which the producer is presumed to have been informed.[63]

The ECJ further pointed out that it is *implicit in the wording of article 7(e)* that the relevant scientific and technical knowledge must have been *accessible* at the time when the relevant product was put into circulation.[64] Accordingly, in order to have a defence under article 7(e), the producer of a defective product must prove that the *objective* state of scientific and technical knowledge, including the *most advanced* level of such knowledge, at the time when the relevant product was put into circulation was "*not* such as to enable the existence of the defect to be discovered". In addition, it must be shown that "such knowledge was *not accessible* when the relevant product was put into circulation".[65] The court further confirmed that the burden of proof for purposes of the development risk defence lies with the producer.[66]

From *Commission v United Kingdom*, it is thus clear that it will generally not be easy for a producer to prove the development risk defence. It entails a heavy evidential burden, which requires proof of the objective state of the most advanced scientific and technical knowledge when the product was put into circulation and evidence that such knowledge was not accessible. In addition, it must be proved that the defect in the product could not have been discovered due to the absence of such objective, most advanced scientific and technical knowledge. Conversely, if the objective state of the most advanced scientific and technical knowledge that was accessible would have allowed the discovery of the defect at the time of circulation, a producer who was *unaware* of such state of knowledge, for whatever reason, would *not* be able to rely on the development risk defence.

However, *Commission v United Kingdom* did not provide answers to all the questions regarding the EU development risk defence. Mildred, for example, remarks that the ECJ did not resolve the classic difficulty of defining the "*state* of scientific and technical knowledge".[67] It also remains a concern for Mildred that, given the apparent no-fault liability nature of the Directive, a court that hears a product liability matter is likely to exclude consideration of the producer's conduct (ie whether he was negligent or not) at the instance of either party. He thus points out the anomaly that the conduct of the producer is to be disregarded for purposes of ascertaining whether a product had a defect but that the producer's conduct may, however, be taken into account for purposes of article 7(e).[68] In fact, many scholars are of the opinion that the development risk defence has blurred the line between strict liability and negligence in EU product liability.[69]

precautions in the particular industry were taken and there was no negligence" other than to show, under article 7(e), "that the state of scientific and technical knowledge was such that *no-one* would have been able to discover the defect" (emphasis added). The UK government did not challenge the Commission's interpretation of article 7(e) as setting out an "objective" and not a "subjective" test but argued that section 4(1)(e) introduced an objective test and did not provide for liability founded on negligence. The court eventually rejected the Commission's view as it opined that the Commission selectively stressed particular terms in section 4(1)(e) without having demonstrated that the general legal context of section 4(1)(e) failed effectively to secure full application of the Directive. See also G Howells "Defect in English law: Lessons for the harmonisation of English product liability" in D Fairgrieve (ed) *Product Liability in Comparative Perspective* (2nd ed, 2005, Oxford University Press) at 149; and Mildred in "The development risk defence", above at note 58 at 173.

63 *Commission v United Kingdom*, para 27–28 (emphasis added).
64 Authors' emphasis.
65 *Commission v United Kingdom*, para 29 (emphasis added).
66 Id, para 34.
67 Authors' emphasis.
68 Mildred "The development risk defence", above at note 58 at 188.
69 K P Borra "Products liability in the 21st Century" (2013) 3 *Juridical Review* 1 at 6.

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It is submitted that, on this point, the following statement by Advocate General Tessauro, who appeared on behalf of the Commission in *Commission v United Kingdom*, is pertinent: "*the Council opted for a system of strict liability which was no longer absolute but limited*, in deference to a principle of the fair apportionment of risk between the injured person and the producer, the latter having to be only quantifiable risks, but not development risks which are, by their nature, unquantifiable".[70] This statement makes it clear that the EU Directive, despite being propounded as having introduced a strict product liability regime and despite the academic speculation that it reintroduces fault via the development risk defence, has indeed created a regime that is, in fact, *a hybrid of strict liability and fault-based liability*. The development risk defence thus captures the essence of the balancing that occurred in the EU between consumer interest and the interests of industry in order to sustain competition across EU member states.

However, Borra points out that, despite the ECJ's decision in *Commission v United Kingdom*, the interpretation of the development risk defence led to conflicting decisions across EU member states on the same subject. For example, in the UK case of *A v National Blood Authority,*[71] blood suppliers who supplied blood infected with Hepatitis C were not able to rely on this defence while, in the Netherlands, a blood supplier who supplied blood infected with HIV was able to rely on the defence in *Scholten v Foundation Sanquin of Blood Supply*.[72]

Due to the controversies surrounding the interpretation and application of the development risk defence, the Italian research institution Fondanzione Rosselli was commissioned in 2004 to examine the economic impact of this defence. In recommending that the defence remain in the Directive, the report by Fondanzione Rosselli concluded that:

> "[T]he Development Risk Clause is a significant factor in achieving the Directive's balance between the need to preserve incentives to innovation and [the] consumer's interests. There is in fact evidence that the Development Risk Clause protects incentives [for] innovation by reducing the innovation related risks, not diverting resources from (research and development) to insurance policies and pushing firms to acquire state of the art knowledge".[73]

Regarding the question of whether the development risk defence applies across the board to any type of defect, it should be noted that neither the Commission nor the ECJ has pronounced on this issue. Having regard to the nature of the defence, it is submitted that it seems to be directed at design defects and, by necessary implication, to warning defects, given the close interrelation between these two. Notably, the German Bundesgerichtshof held that the development risk defence does not apply to manufacturing defects. However, one should be cognizant of the following remarks by Stapleton, who is critical of excluding the application of the development risk defence to manufacturing defects and regards it as a deep anomaly:

> "On its face, however, the development risk defence applies to *all claims,* not merely those in relation to design and warnings: the literal readings of the statutory provisions would appear to allow the manufacturer of a product with a manufacturing error to escape liability where the state of scientific or technical knowledge at the time it was supplied was not such as to enable that the defect be discovered".[74]

70 *Commission v United Kingdom*.

71 [2001] 3 All *ER* 289.

72 See 3 February 1999, unreported, County Court of Amsterdam; and Borra "Products liability", above at note 69 at 6.

73 *Analysis of the Economic Impact of the Development Risk Clause as Provided by Directive 85/374/eec on Liability for Defective Products: Final Report* (2004, Fondanzione Rosselli) available at: <https://ec.europa.eu/docsroom/documents/7104?locale=en> (last accessed 17 July 2024).

74 J Stapleton "Restatement (Third) of Torts", above at note 13 at 383.

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Regarding the question of whether it is only the *actual* producer that can rely on the development risk defence, it is submitted that, logically, it makes sense to only avail the defence to such producers. One would expect designers and manufacturers to conduct all the time-consuming and costly research during the development of the said product that would eventually render the product safe for use. However, it should also be borne in mind that the Product Liability Directive, by virtue of article 3, affords an extended interpretation to the concept of "producer", which includes the importer of the product and, if the producer cannot be identified by virtue of the inquiry provided for in article 3(3), would include other suppliers such as distributors and retailers. Arguably, the words "put into circulation" cannot be interpreted restrictively and would depend on the context of a particular supply and on *who* puts the product into circulation. Thus, it appears that putting a product into circulation is not a one-off event; they are putting it into circulation every time a further supplier releases the product down the supply chain. Therefore, although the development risk defence appears to have been introduced with the actual producer of a product in mind, the effect would be that, where such a producer cannot be identified, a subsequent supplier should theoretically be able to rely on the development risk defence. On a practical level, however, it is submitted that a later supplier will likely face insurmountable obstacles in proving the defence. They would not possess the necessary information required to prove the defence; only the actual producer would be privy to such information. Accordingly, even if it can be said that this defence is available to the whole supply chain, the practical reality is that, generally, only the actual producer (manufacturer) will be able to adduce the evidence necessary to prove the development risks defence.

Therefore, it appears that the development risk defence is not only significantly difficult to prove but that the high standard burden of proof motivates firms to go to great lengths to ensure that the products they put in circulation are safe. Notably, Mildred comments that:

> "[T]he controversy surrounding the introduction of the defence has *not been followed by its frequent invocation*. Further, there seem to have been *very rare successful pleadings* [*of*] *the defence*. This may be less to do with [a] clear definition of the meaning of the defence by the courts of the Union than the low volume of product liability litigation and the heavy pressure towards [the] settlement of disputes engendered by the very high cost of litigation. Indeed, as we have seen, unresolved questions of interpretation of the components of the defence predominate over settled jurisprudence."

However, he states that "the balancing exercise provided by the existence of the defence is likely to remain key to the acceptance of the Directive by [the] industry as a politically acceptable compromise on questions of the appropriate standard for liability without fault, and thus the opportunity for reform of the Directive by *removal of the defence is highly unlikely* to be taken".[75]

Product liability in terms of the South African Consumer Protection Act 2008

Strict product liability in terms of section 61

South Africa's new "strict" product liability regime, as introduced by the Consumer Protection Act 2008, came into operation in April 2010.[76] This statutory regime operates parallel to the existing fault-based common law product liability regime.[77] The product liability provisions in section 61 form part of chapter 2. Part H of the Consumer Protection Act 2008 deals with the right to "fair

75 Mildred "The development risk defence", above at note 58 at 188 (emphasis added).

76 The product liability provisions in the Consumer Protection Act 2008 came into operation on the Act's "early effective date", which was 24 April 2010. See *GN* 467 in *GG* 32186.

77 This is by virtue of sec 10(2) that preserves the common law rights of consumers.

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value, good quality and safety". Part H covers various aspects of this right and spans from section 53[78] to section 61. Section 61 introduces the new regime by providing that:

> "[E]*xcept to the extent contemplated in section 61(4)*, the producer, importer, distributor or retailer of any goods is liable for harm caused wholly or partly as a consequence of the supply of unsafe goods; a product failure, defect or hazard in any goods; or inadequate instructions or warnings provided to the consumer pertaining to any hazard arising from or associated with the use of any goods, regardless of whether the harm resulted from any negligence by the consumer".[79]

Section 61 thus imposes liability on the whole supply chain. It also applies to service providers,[80] and where more than one person is liable in terms of section 61, their liability is joint and several.[81] Section 61(4) introduces four statutory defences, thereby making the statutory product liability regime a hybrid one, namely: (1) that the defect in the product was wholly attributable to compliance with public regulations; (2) that the defect did not exist in the goods at the time of supply by the person raising the defence; (3) was wholly attributable to compliance by that person with instructions provided by a prior supplier or (4) that it is unreasonable to expect the distributor or retailer to have discovered the defect having regard to that person's role in marketing the goods to consumers or that the consumer's product liability claim has prescribed due to the time within which to institute such claim having elapsed. The "harm" for which a person may be held liable includes:[82]

> (a) the death of, or injury to, any natural person
> (b) an illness of any natural person
> (c) any loss of, or physical damage to, any property, irrespective of whether it is movable or immovable, and
> (d) any economic loss that results from harm contemplated in paragraphs *(a), (b)* or *(c)*.

Certain powers of the Court are set out in section 61(6) to determine whether "harm" has been established and adequately mitigated, to determine the extent and monetary value of any damages incurred, including economic loss or to apportion liability between suppliers who are jointly and severally liable.[83]

In addition to taking into account the Consumer Protection Act 2008's early effective date, it should be noted that section 5(1)(d) also provides that the Act applies to goods that are supplied "in terms of a transaction that is exempt from the application of the Act, but only to the extent provided for in section 5(5)". Section 5(5) stipulates that if any goods are supplied within the Republic to any person in terms of a transaction that is exempt from the application of the Consumer Protection Act 2008, "those goods, and the importer or producer, distributor and retailer of those goods, respectively, are *nevertheless* subject to sections 60 and 61."[84]

78 Consumer Protection Act 2008, sec 53 contains the definitions of the concepts of "defect", "failure", 'hazard" and unsafe", which serve to interpret the concept of defectiveness for purposes of product liability under sec 61.
79 Emphasis added.
80 Sec 61(2).
81 Sec 61(3).
82 Sec 61(5) (emphasis added).
83 Section 61(6)(a)–(c).
84 See also Sec 5(1)(d). Sec 60 deals with safety monitoring and recall.

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Defence in Section 61(4)(c)

The section 61(4)(c) defence provides that, in this particular instance, "it is unreasonable to expect the distributor or retailer to have discovered the unsafe product characteristic, failure, defect or hazard, having regard to that person's role in marketing[85] the goods to consumers". Notably, the defence has a limited application as the Act only avails it to distributors[86] and retailers.[87]

The section 61(4)(c) defence has been shrouded in controversy since it was first introduced. Some authors are of the opinion that it appears to be "re-introducing negligence through the back door", and some also regard it as introducing some form of a "development risk defence" akin to the development risk defence contained in the EU Product Liability Directive.

To fully appreciate why this defence has been so controversial, it is necessary to refer to its initial introduction in the first draft of the Consumer Protection Bill released in 2006. This Bill provided, in clause 73(3)(c)(ii) (the then product liability provision), that liability of a person would *not* arise if:

> (c) it is unreasonable to expect the *distributor or supplier* to have discovered the product failure, defect or hazard, having regard to:
> (i) that the person's role in introducing the good to the consumer market; *and*
> (ii) the state of scientific and technical knowledge at the time the good was under the control of that person.

The Select Committee later replaced the word "supplier" with "retailer", which narrowed down the application of the defence to distributors and retailers only. In the later version of the Consumer Protection Bill,[88] as subsequently introduced in the National Council of Provinces, the statutory defences were set out in clause 61(5). The abovementioned defence was also contained in clause 61(5)(c), which provided that liability would *not* arise if:

> (c) it is unreasonable to expect the *distributor or retailer* to have discovered the unsafe product characteristic, failure, defect or hazard, having regard to:
> (i) that person's role in marketing the goods to consumers; *and*
> (ii) the state of scientific and technical knowledge at the time the goods were under the control of that person.

The aforementioned provisions thus appeared to introduce some development risk defence. However, when the Act was finally signed into law, section 61(4)(c) contained no reference to the "state of scientific and technical knowledge at the time the goods were supplied" and merely limited the availability of the defence to distributors and retailers on the basis that it would be unreasonable to expect them to have discovered the defect in the goods, given their role in the marketing (and not the development) of those goods.

The reason for first incorporating a type of development risk defence in the Consumer Protection Act Bill and subsequently discarding the reference to "the state of scientific and technical knowledge" has, unfortunately, not been well documented. Although the *Draft Green Paper on Consumer Policy* mentions the need to introduce a more protective consumer protection regime,

85 Consumer Protection Act 2008, sec 1 defines "market" as "to promote or supply any goods or services".

86 Consumer Protection Act 2008, sec 1 defines a distributor as a "person who, in the ordinary course of business - (a) is supplied with those goods by a producer, importer or other distributor; and (b) in turn, supplies those goods to another distributor or retailer".

87 Consumer Protection Act 2008, sec 1 defines a retailer as "a person who, in the ordinary course of business, supplies those goods to a consumer".

88 Consumer Protection Bill B 19 of 2008.

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it does not deal with the details of such a contemplated regime.[89] The *Memorandum on the Objects of the Consumer Protection Bill* refers to product liability in general terms but contains no reference to or detail regarding the rationale behind the defence in section 61(4)(c).[90] In the context of the current section 61(4)(c) defence two main questions arise, namely:

(a) Given that the reference to scientific and technical knowledge that was initially part of this defence has been discarded, can one say that the defence subsequently enacted is a development of the risk defence?
(b) Is it appropriate that the section 61(4)(c) defence should be available to distributors and retailers but not to manufacturers and importers?

Loubser and Reid argue that the development risk defence is intrinsically incorporated into the section 61(4)(c) defence as it may not be reasonable to expect retailers and distributors to have discovered "development risks" inherent in the goods they have supplied. They explain that "development risks" refer to "defects resulting from risks which have only become apparent as new products have been used and were not foreseeable or discoverable at the time of supply".[91] They further provide an example of a development risk arising where a new pharmaceutical product turned out to have side effects undetected by tests or trials conducted before the marketing of the said product. They state that if an appropriately rigorous test is applied, the relevant level of knowledge "expected" of the distributor or retailer should be judged by an objective test, referring to the constructive as well as the actual knowledge of such distributor or retailer.[92] The standard is a normative one, namely what the reasonable distributor or retailer "ought" to have known, although the authors indicate that the defence must also take into account the accessibility of information about safety defects. As such, they indicate that the distributor or retailer cannot reasonably be expected to have discovered defects identified in unpublished research or documents not available to the general public or retained within a particular company's laboratory or research department. Moreover, they indicate knowledge that only became discoverable after the goods left the control of the distributor or retailer and should not be attributed to them. At the same time, concessions should not be made for particular informational or organizational constraints affecting individual distributors or retailers. Thus, they argue that the distributor or retailer should not be able to rely on mere negligence where scientific and technological knowledge is concerned.[93]

Loubser and Reid further comment that the section 61(4)(c) defence is broadly drafted and that sceptics may argue that it has, as pointed out above, the potential to readmit fault-based liability through the back door. They remark that the use of a "reasonableness test" that evaluates the conduct of distributors and retailers and removes liability for risks that could not reasonably have been anticipated brings the "strict" liability of the legislation back closer to the standards of the Aquilian liability, in which the duty to take into account "known and foreseeable risks" is built into the formulation of the general duty towards the consumer. In view of the policy considerations underlying the introduction of strict product liability for defective products, they remarked that it seems appropriate to set a high, although not unattainable, standard of reasonableness if this defence is to be admitted. However, they point out that, even when applying such standards, there are various categories of defects that one could not reasonably expect even a highly responsible distributor or retailer to discover.[94]

89 Green Paper on the Consumer Policy Framework 2004 available at: <https://www.gov.za/documents/consumer-policy-framework-green-paper-draft> (last accessed 27 August 2023).
90 Consumer Protection Bill B 19 of 2008.
91 M Loubser and E Reid *Product Liability in South Africa* (1st edition, 2012, Juta Publishers) at 133.
92 Ibid.
93 Id at 134.
94 M Loubser and E Reid "Commentary on Section 61 of the Consumer Protection Act 68 of 2008" in T Naude and S Eiselen (eds) *Commentary on the Consumer Protection Act* (2014 *et seq*, Juta Publishers) 61-11.

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Loubser and Reid consequently raise the issue of latent defects and state that the very general wording of section 61(4)(c) can be extended to provide a defence in other circumstances that are curiously at odds with the strict liability framework supposedly created by this part of the Consumer Protection Act 2008. For example, they ask, to what extent can one reasonably expect a distributor or retailer to detect a latent manufacturing or design defect in a product it supplied? They remark that patent defects are readily discoverable, and there should be no avoiding them if the distributor, retailer or its agents and employees fail to detect them. However, the position is less clear with regard to latent defects. For example, should a distributor or retailer be able to escape liability to an injured consumer if a bottle of carbonated drink fragments due to a hairline crack in the glass bottle? They refer to the wording of the EU Product Liability Directive that confines the defence to those circumstances where the current state of knowledge "was not such as to enable the existence of the defect to be discovered"[95] and point out that there is no defence in the European product liability regime if the possible existence of latent defects were known in principle, even if the defendant had the practical means to detect the presence of a defect in a particular sample of the goods.[96]

Loubser and Reid observe that it remains to be seen how narrowly the South African courts will interpret section 61(4)(c) but point out that the standard of what might reasonably be expected of a distributor or retailer seems significantly less exacting. In their view, it might plausibly be argued that, although distributors and retailers are in principle "able" to discover the potential existence of a latent defect, they could not "reasonably have been expected" to discover its presence in practice, having regard to their role in marketing the goods to consumers. Yet, they state that to permit all "reasonable" distributors and retailers to evade liability for latent defects opens a significant gap in the South African strict liability framework, and if producers and importers cannot be traced, they are of the opinion that it leaves consumers no better off than under fault-based liability.[97] Gowar also comments that this defence appears to place the consumer "in a worse position than [they] would have been under the common law system when it comes to sellers as experts"; a consumer would not be able to hold a seller (retailer), who professed skill and expert knowledge in the product, liable without fault.[98]

Considering the initial wording of the defence in the two draft Bills mentioned above, it is clear that the legislature had at some stage considered introducing a limited type of development risk defence into South African law but then discarded the idea in favour of the defence currently contained in section 61(4)(c). However, the section 61(4)(c) defence clearly poses a somewhat interpretational conundrum. On the one hand, it is arguable whether the defence in section 61(4)(c), as it is now worded, bears any relation to the development risk defence that is afforded to suppliers by the EU Product Liability Directive, given that section 61(4)(c) contains no reference to scientific and technical knowledge that lie at the basis of the EU development risk defence. Surely, a court that has to deal with this defence will, on a plain reading thereof, without being alluded to the initial wording in the draft Bills, *not* think that it is dealing with a "development risk defence". As appears from the above discussion of the EU position, the development risk defence is a defence afforded specifically to producers (manufacturers) of goods so as not to stifle innovation. Boldly applying such a defence in the context of distributors and retailers without affording it to manufacturers seems inappropriate, as the distributors and retailers did not "produce" or develop the goods. It may thus be argued that despite the probable initial intention of the legislature to afford a development risk defence that is only available to distributors and retailers (albeit that they did not develop the goods concerned), a section 61(4)(c) defence does not fit the mould of a development risk

95 Loubser and Reid *Product Liability*, above at note 91 at 136.
96 Id at 135.
97 Loubser and Reid "Commentary", above at 94 at 61-12.
98 C Gowar "Product liability: A changing playing field?" (2011) 32 *Obiter* 521 at 534.

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defence due to the absence of any reference to the state of scientific and technical knowledge at the time the product was supplied.

Another possibility is to regard the current section 61(4)(c) defence as being aimed at protecting the distributor and retailer against development defects that occurred when the product was designed and manufactured, to which they would not have been privy considering their role in marketing the goods to consumers, which is remote from the development of the product. However, given the broad wording of section 61(4)(c), its purpose appears to be more encompassing and actually seems to cover any defects, not merely those occasioned by development risks. Although Botha and Joubert argue that the section 61(4)(c) defence should not be afforded to distributors and retailers, it is submitted that affording them some defence against development risks that manifest in goods being defective is not inappropriate if one considers their role in the marketing of such goods and the fact that they did not "develop" those goods. Generally, distributors and retailers do not conduct research or perform tests on goods prior to their supply; such research and testing is usually the domain of the manufacturer responsible for creating the goods. However, given that the Consumer Protection Act 2008 imposes liability for defects in goods on the whole supply chain jointly and severally, one can comprehend the legislature's concern that it would be unfair to hold distributors and retailers responsible for defects that arose in the goods at the time of their development (ie their design) by the manufacturer and their subsequent release into circulation. Surely, they cannot be expected to conduct extensive research when it is the responsibility of the manufacturer who developed a new product, such as pharmaceutical companies.

It can be asked whether it makes sense to hold an importer responsible for defects that arose due to the design of goods not conforming with the most recent accessible scientific and technical knowledge when the goods were produced and put into circulation. It has been noted that there is a distinct interrelation between design and warning / instruction defects in the sense that if the design of goods is such that certain uses of those goods may render them unsafe, it is the duty of the manufacturer to provide warnings or instructions that enable their safe use. Accordingly, if a manufacturer is unaware of, for example, certain hazardous side effects that a pharmaceutical product may have, it logically follows that the manufacturer will not provide warnings or instructions regarding those side effects. Further, subsequent suppliers will not know that warnings or instructions should accompany these products for their safe use. In the context of a regime that provides a development risk defence, the question would then arise whether the manufacturer's ignorance can be excused at all, and the answer will depend on whether the manufacturer is able to prove that, having regard to the state of objectively accessible scientific and technical knowledge at the time the goods were released into circulation, they could objectively not have been aware that the goods contained a defect. It is further submitted that defects that arise as a result of development risks will, by their nature, be latent and that the application of a development risk defence, should a country opt to have such defence in their product liability regime, is not justified in the context of manufacturing defects that arise from goods not complying with the manufacturer's specifications.

In any event, regarding section 61(4)(c) as providing a development risk defence to distributors and retailers would be something of an anomaly in a regime that does not otherwise acknowledge a development risk defence, where the legislation makes no reference to the state of scientific and technical knowledge against which the defence must be tested. It would mean that South Africa does indeed have a development risk defence, even though the Consumer Protection Act 2008 is silent on the role of the state of scientific and technical knowledge and uniquely affords this defence, *not* to manufacturers (for whom the defence was actually created), but to suppliers further down the supply chain who had nothing to do with the development of the goods concerned.

It is submitted that labelling the current section 61(4)(c) defence as a development risk defence would be misguided. Doing so would require distributors and retailers to present scientific and technical evidence they cannot access. Even though one might argue that the history of section 61(4)(c)

shows that the legislature intended to provide distributors and retailers with a development risk defence, it is submitted that using the concept of development risks at the distribution and retail level is simply inappropriate. The defence retained in section 61(4)(c) cannot be equated to a "development risk defence proper" as the section 61(4)(c) defence is only given to persons who are not involved in that part of the production of goods where development risks can arise. Rather, it is submitted the broad defence in section 61(4)(c) should be viewed as a *sui generis* defence afforded by the Consumer Protection Act 2008 to distributors and retailers for *any* defects, including those that occurred in the development of the product, which they could not reasonably have discovered given their role in the marketing of the product. Therefore, the section 61(4)(c) defence should rather be referred to as a mere "non-discoverability" defence. Accordingly, section 61(4)(c) should not be subjected to the limitations inherent in the development risk defence; namely, that it requires proof of the most advanced state of technical and scientific knowledge or that it is not suited to manufacturing defects, but only to design and warning / instruction defects.

On a practical level, if a distributor or retailer is able to provide evidence regarding their role in the marketing of goods and evidence shows that they complied with all reasonably expected quality and safety control measures at the level of distribution and retail and that they could, for example, not have been expected to open pre-packaged goods and subject them to all sorts of tests to ensure that they were not defective, they should be able to rely on section 61(4)(c) defence, even if the defect was a manufacturing defect.

The vexing question that nevertheless remains is whether the South African legislature was justified in first affording, in clause 73(3)(c)(ii) of the 2006 Bill, a development risk defence to retailers and suppliers (which would have included manufacturers given the wide definition of supplier), thereafter limiting the development risk defence in the former clause 61(5)(c)(ii) to distributors and retailers, completely discarding the development risk defence prior to enactment of the Consumer Protection Act 2008. Put differently, is a manufacturer's lack of a development risk in the Consumer Protection Act 2008 a sound position from which to take a purportedly strict product liability perspective?

Conclusion

It is submitted that the pertinent question should be whether the watered-down section 61(4)(c) defence, which is not a development risk defence proper in its current format, should be retained at all. Further, and maybe even more importantly, what is the effect of the South African product liability regime in not providing a development risk defence to manufacturers? For South Africa, this is an important issue, not only insofar as the safety of general consumer goods is concerned but specifically in relation to pharmaceutical products that may be harmful. South Africa has a large population of vulnerable consumers who suffer from terminal illnesses such as AIDS, tuberculosis and various types of cancers; it is part of a continent that is plagued by other life-threatening diseases such as malaria and ebola and has, more recently, experienced the global COVID-19 pandemic.

Pharmaceutical products can save thousands of lives that would otherwise be lost to these diseases. Suppose producers of pharmaceuticals know that they would be operating in a regime where there is no option for undiscoverable development risks to exonerate them from liability, where their suppliers are jointly and severally liable, and class actions can provide collective redress to thousands of consumers. In that case, it is likely that they will either stop innovating or withdraw from that jurisdiction or only make their products available at a very high cost (necessitated by the need to insure themselves comprehensively against liability). As Goldring and Richardson aptly remark: "I wonder if Flemming would have introduced penicillin or Pasteur smallpox vaccination if in doing so they had known that they were risking all they possessed if unforeseeable adverse consequences resulted."[99]

99 J Goldring and M Richardson "Product liability and the conflicts of laws in Australia" (1977) 3 *The Australian Law Journal* 135 at 135.

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Introducing a development risk defence will serve as a check and balances measure that might encourage innovation, especially in the development of pharmaceutical products. It will serve the double-edged purpose of facilitating innovation in an environment where a manufacturer would at least have some security in that, if his research complies with the latest scientific and technical knowledge at the time the product is put into circulation, they will not be condemned for their efforts at improving or saving human lives through new pharmaceuticals. In any event, should a manufacturer be afforded a development risk defence, the stakes are still very high: the defence is notoriously difficult to rely on due to its high burden of proof. Couple this burden with the fact that we live in the era of the Internet, and the vastness of the burden of proof a manufacturer faces immediately becomes evident. Therefore, even where a manufacturer raises a development risk defence, the chances of proving the defence are slim, meaning that the opportunity for the defence to thwart a product liability claim established without the shackles of negligence will also be severely limited (to the point of impossibility). Actually, the introduction of such a defence will arguably not have the effect of negating the existence of the product liability regime introduced by the Consumer Protection Act 2008. Still, it may foster lifesaving innovation and should be seriously reconsidered.

Competing interests. None

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