

Reflection on Developmental Risk Defence Under Product Liability Law

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Abstract: Product manufacturers are held culpable for defects associated with their product. However in order to promote product innovation particularly in the area of biotech, pharmaceutical and other related area of human endeavour which impact positively on human safety and sustainability of the environment; the European Economic Community in 1985 promulgated Directive 85/374 EEC which introduced strict liability principle as an additional theoretical principle of liability in resolving product liability claim; introduced the developmental risk defence (known as state of the art defence in other jurisdictions). The adoption of this defence was made optional for member states. Since the philosophy behind the adoption of strict liability is to enhance human safety and promote sustainable development, the introduction of developmental risk defence to some extent diminished this gain; because where the defence is sustainable the product manufacturer is absolved of liability where the defect which occasioned harm is unknown and undetectable at the time the product was manufactured. It is likely that these type of risks would have become more or less uninsurable under the strict liability regime introduced by the Directive; thus having the negative effect of slowing down product innovation and such scenario slow down human development. From the consumer's point of view, the defence is seen as a disappointment; while to the manufacturer it is a catalyst to enhance human development. In view of the above contending views, this papers sets out to examine the implication of this defence in product development.

Keywords: Developmental Risk Defence, Law, Product Liability, Sustainable Development.

Introduction

In order to protect the interests of consumers, a strict liability principle was introduced as an additional theoretical principle of liability to complement the existing legal regime in resolving product liability claims. Strict liability is a regime which does not require proof of the producer's negligence, but instead requires the existence of a defect in the product, the harm, and the causal relationship between the two. The adoption of strict liability was done through Directive 85/374/EEC.¹ Under this regime, a producer is absolved of any liability if he/she is able to 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." This is known as the developmental risk defence. The rationale for the developmental risk defence as a defence under the strict liability regime is to encourage product development and innovation. The adoption of developmental risk attracted considerable protest, while some groups supported it.

The opposition from the consumer point of view can be summarized as follows: that strict liability is necessary to protect consumers from unforeseeable and unknown risks; the exclusion of a form of liability for these categories of risk would constitute a gap in the consumer protection; manufacturers can recoup compensation paid for this type of

¹ See generally Council Directive 85/37/EEC on the Approximation of Laws, Regulations and Administration of Provisions of the Member States Concerning Liability for Defective Products.

risk by increasing the price of their products; insurance can be taken out for this type of risk; and, finally, the inclusion of such defence will diminish the gains of strict liability.²

The producers/manufacturers, on the other hand, were of the view that developmental risk defence should be included in the Directive because its exclusion would discourage scientific and technical research and the marketing of new high-tech products. Finally, they argued that it is necessary to protect manufacturers/producers from the unpredictable consequences of liability bearing in mind that such would discourage producers and manufacturers from innovating.³

While the importance of developmental risk defence in promoting product innovation, both in developed and developing countries, cannot be over emphasized, it tends to diminish the gains of the strict liability regime introduced as an additional theoretical principle of liability for resolving product liability claims because it relieves manufacturers or producers of liability under certain circumstances. It must also be noted that the provisions of the developmental risk in the Directive is ambiguous and, therefore, susceptible to some interpretational difficulties.

It is against this background that this paper sets out to discuss the importance of development risk defence, to identify some of the controversial area of the defence [the nexus between developmental risk defence and sustainable development within the subject of product liability], to discuss the utility of risk defence and also identify some of the controversial areas of the defence. The paper will be divided into four broad sections which consist of the following:

- (a) Meaning, evolution and development of product liability under English law and developmental risk defence;
- (b) Developmental risk defence and sustainable development;
- (c) Some controversial areas of developmental risk defence; and
- (d) Conclusion.

Conceptual clarification

This section at the outset gives a brief insight into the evolution and development of product liability law and developmental risk, and, thereafter, it gives an insight into the meaning associated with some of the principal words to be employed in this paper.

Meaning, Evolution and Development of Product Liability

It must be stated from the outset that the gradual evolution of product liability law is associated with the promotion of sustainable development in all its ramifications. Its focus is to ensure the protection of the welfare of consumers.

The term product liability has been described as referring to, or is understood to refer to, "the civil liability of manufacturers and others where damage or loss is caused by products which fail to meet the standards claimed expressly or implicitly for them or which are dangerous or otherwise defective."⁴ This definition is wide enough to accommodate defects which belong to the province of contract or sales law.

Prior to the evolution of what could be termed modern day product liability, problems associated with product defects were dealt with under various legal fields, such as the law of contract and tort.⁵ Liability in contract was delimited by the requirements of privity. This meant that the buyer of a product could not sue anyone other than the immediate seller, such as a wholesaler or manufacturer, in contract. In addition, only the buyer could sue in contract, and not a third person who had been harmed by using the product, irrespective of any possible close connection with the buyer and the product.⁶

Liability in tort at inception was also restricted by the privity requirement. This principle is illustrated by the case of *Winterbottom v Wright*.⁷ In this case, the plaintiff sustained an injury as a result of a defect attributed to the product

²Jane Stapleton, "Bugs in Anglo – American Product Liability" in Duncan Fairgrieve ed. *Product Liability in Comparative Perspective* (2005) 300

³*Ibid*

⁴ Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) para 1.01.

⁵ Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) para 1.03.

⁶ Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) para 1.06; Stapleton *Product Liability* (Butterworths, 1994) 15-16.

⁷ (1842) 10 M&W, 109. In this case, the claimant was employed by a third party who had contracted with the Post Master General to run a coach for the mail delivery between Harford and Holyhead. In the said contract with the Post Master General, the defendant, had undertaken to keep the coach in good

in question. He instituted a claim in tort which was dismissed on the ground that he was not a party to the contract from which the injury arose. Most probably, if he had been a party, liability would have been imposed on the contractor. The non-liability rule determined that non-parties to a contract were not entitled to claim in tort for injuries sustained from such a contract.⁸

The facts of the *Winterbottom* case may be contrasted with those of *Longmeid v Holliday*.⁹ The issue for resolution in this case was whether one who was not a party to a contract was entitled to claim. The claimant in the case sustained injury from an explosion caused by a lamp purchased by her husband from the defendant retailer. Baron Parke, who delivered the decision of the Exchequer Court, agreed that liability might be incurred, and he stated as follows:

"And it may be the same when one delivers to another without notice an instrument by its nature dangerous, or under particular circumstances, such as a loaded gun which he himself loaded, and that other person to whom it is delivered is injured thereby, or if he places it in a situation easily accessible to a third person, who sustains damage from it. A very strong case to that effect is *Dixon v. Bell*. But it would be going much too far to say that so much care is required in the ordinary intercourse of life between one individual and another, that, if a machine not in its nature dangerous – a carriage for instance – but which might become so by a latent defect entirely unknown, although discoverable by the exercise of ordinary care, should be lent or given by one person, even by the person who manufactured it, to another, the former should be answerable to the latter for a subsequent damage accruing by the use of it."¹⁰

It has been argued that the *dicta* in this case, along with similar authorities in that line, seem to have established the rule that liability will exist where dangerous things are supplied without any previous warning of their true nature.¹¹

Subsequent cases over the years have shown that there was a gradual extension of the duty relation leading to the imposition of liability in cases relative to defective products. In the case of *George v Skivington*,¹² the plaintiff bought a bottle of hair wash produced by the defendant for his wife. The plaintiff's wife sustained injury when she used the product. The court acknowledged and affirmed the existence of a duty in the case.¹³

The recognition of a limited duty, as evidenced by the trend of decisions in the cases mentioned above concerning dangerous goods, continued until the late nineteenth century when the decision in the case of *Heaven v Pender* was delivered.¹⁴ In this case, the defendant, a dock owner who supplied staging and ropes, was held liable for the injury sustained by the employee of a ship painter because the supplied appliances were defective. Liability in this case was premised on the ground that the defendant had invited the injured employee to his premises to use the defective and dangerous appliances which were under his exclusive control. Brett MR observed as follows:

"[W]henever one person supplies goods or machinery or the like for the purpose of their being used by another person under such circumstances that everyone of ordinary sense would, if he thought, recognise at once that unless he uses ordinary care and skill with regard to the condition of the thing supplied or the mode of supplying it, there will be a danger of injury to the person or

condition. This obligation was held by the court to be owed to the Post Master General and not the defendant who had a separate contract with the contractor.

⁸ Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) paras 1.08
1.10; Stapleton *Product Liability* (Butterworths, 1994) 16-17.

⁹ (1851) 6 Ex 761.

¹⁰ *Per* Parke B 767. See also the decision in *Dominion Natural Gas Co Ltd v Collins & Perkins* (1909) AC 646 where the Privy Council upheld a decision in favour of the plaintiffs on the ground that, in cases of dangerous articles, there is a particular duty to take precautions imposed upon those who send forth or install such articles when other parties will of necessity come within their proximity.

¹¹ Bohlen FH "Liability of manufacturers to persons other than their immediate vendees" 1929 45
LQRev 343.

¹² (1869) LR 5 Exch 1.

¹³ This decision, however, has also been subjected to criticism, and the view has been expressed that it should have been overturned; see Bohlen FH "Liability of manufacturers to persons other than their immediate vendees" 1929 45 *LQ Rev* 343.

¹⁴ (1883)11 QBD 503.

property of him for whose use the thing is supplied and who is to use it, a duty arises to use ordinary care and skill as to the condition or manner of supplying such thing."¹⁵

This position permitted of two exceptions to the general rule recognized by Lord Sumner in the case of *Blacker v Lake and Elliot*¹⁶ where the state of the law prior to the decision in the *Donoghue* case was stated as follows:

"The breach of the defendant's contract with A to use care and skill in and about the manufacture or repair of an article does not of itself give any cause of action to B when he is injured by reason of the article proving to be defective."

The two exceptions, recognised in respect of this general rule, were that (a) liability would arise where the article is inherently dangerous and (b) where the article is not itself dangerous, but becomes dangerous as a result of some defect in it or owing to any other reason. Where such a fact is known to the manufacturer, liability would be imposed on such a manufacturer.¹⁷

The famous judgment in *Donoghue v Stevenson*¹⁸ represented a landmark development in English product liability law. The appellant visited a café in Paisley where she drank some ginger beer that had been served from an opaque bottle. When the remainder of the contents of the bottle was poured into her glass, a decomposed snail also came out of the bottle. The appellant alleged that the sight of the decomposed snail and the impurities in the ginger beer made her suffer shock and severe gastro-enteritis. The respondents acknowledged that they were the manufacturers and bottlers of the ginger beer, but they contended that it had been produced in a sealed bottle with a metal cap. They equally acknowledged that it was their duty to ensure that impurities did not get into the bottle, but they contended that this was done by ensuring that their bottles were inspected before they were filled. They argued that the appellant's claim disclosed no cause of action.

The court of first instance found the manufacturer liable. The manufacturer's appeal to the court of second instance was successful in that the court upheld their contention and held that the claimant's claim disclosed no cause of action. The claimant, who was dissatisfied with the decision, appealed to the House of Lords. The House of Lords upheld the decision of the court of first instance to the effect that the appellant's claim disclosed a cause of action and the case was remitted back for trial. While the issue of the presence of the decomposed snail in the bottle of ginger beer was never determined since it seems that the producers died before proof, the case was, however, settled out of court upon the payment of £100.¹⁹

The House of Lords recognised that a manufacturer owes the consumers of its product a duty of care and could be held liable if he/she is found wanting in his/her duty. Lord Atkin outlined the extent of the producer's or manufacturer's liability as follows:

"A manufacturer of products, which he sells in such a form as to show that he intends them to reach the ultimate consumer in the form in which they left him with no reasonable possibility of intermediate examination, and with the knowledge that the absence of reasonable care in the preparation or putting up of the products will result in an injury to the consumer's life or property, owes a duty of care to the consumer to take that reasonable care."

The significance of this case in the area of product liability can be summarised in three points.²⁰ It abandoned the strong privity requirement of the contract-based product liability²¹ which had, prior to the decision, gradually been eroded. It, furthermore, jettisoned the long-standing exceptions of liability which hinged on the inherently dangerous requirement²² and the exception relating to defective appliances within the premises of the tortfeasor.²³ Finally, the decision served as an impetus under English law which influenced the expansion of the scope of liability under the

¹⁵ *Heaven v Pender* (1883) 11 QBD 503 510.

¹⁶ (1912) 106 LT 533.

¹⁷ See Howarth DR and O'Sullivan JA Hepple, Howarth and Matthews *Tort: Cases and Materials* (2002 Butherworth) 29.

¹⁸ [1932] AC 562.

¹⁹ See Heuston RFV "Donoghue v Stevenson in Retrospect" 1957 20 *MLR* 1.

²⁰ See in general Ferrari 1994 <http://digitalcommons.law.ggu.edu/cgi/viewcontent.cgi?article=1003&context=annlsurvey> accessed on 2 December 2016.

²¹ The claimant in the *Donoghue* case was not contractually connected to the contract of purchase.

²² See the case of *Langridge v Levy* (1851) 6 Ex 761.

²³ See the case of *Heaven v Pender* (1883) 11 QBD 503.

law of tort, in that the courts in cases after the decision in the *Donoghue* case interpreted the principle enunciated in the case broadly, particularly in the area involving personal injury and damage to property.

This position represented the state of English law on product liability until the 1970s when steps were taken towards reforming product liability law by the European Economic Community. This eventually led to the promulgation of Directive 85/374/EEC.²⁴ The reform introduced through this Directive was greatly influenced by earlier common law development in the United States by the provisions of section 402A of the Second Restatements of Torts (Restatement 2nd).²⁵ This document greatly inspired, and also served as a model for, the advocates of reform of the law in this area of English law. The quest for reform was influenced by a variety of reasons, prominent amongst which were economic growth influenced by the Industrial Revolution, the challenges and inadequacies of the fault regime which was brought to fore by the Thalidomide tragedy in Europe,²⁶ and a variety of other reasons.²⁷ The steps towards reforming product liability in Europe were a series of pragmatic efforts which began in the 1970s. This reform began with the Law Commission and the Scottish Law Commission. Both bodies were charged with the responsibility of considering whether the operating regulating laws which guide compensation for personal injury, damage to property or any other loss occasioned by defective goods were adequate. These bodies were also to recommend possible improvements in this area of the law, improvements which were needed to ensure that additional remedies were provided and against which such remedies should be available.²⁸ The Royal Commission, headed by Lord Pearson, also worked towards reforming product liability in the jurisdiction under review. This Commission was to consider to what extent, in what circumstances, and by what means, compensation should be payable in respect of death or personal injury (including ante-natal injury) caused by the production, supply or use of goods or services.²⁹

The above-mentioned bodies in their reports recommended the adoption of a strict liability system in cases involving death or personal injury caused by defective products. They also recommended that such liability should be imposed on the manufacturers or producers of defective products.³⁰ While the above reform exercise was on-going, the Committee of Ministers of the Council of Europe simultaneously, in September 1976, adopted the *Strasbourg Convention on Product Liability* that focused on the area of personal injury and death. The obligation imposed on the signatories of this Convention was that strict liability should be imposed on the manufacturers of defective products which caused death or personal injury.³¹

The major development and achievement towards reforming product liability law which superseded the *Strasbourg Convention* was that of the European Economic Community.³² This body, starting from August 1974, worked assiduously towards reforming product liability law. A series of proposals and draft directives arose from their efforts, and this eventually culminated in the adoption, on 25 July 1985, of *Council Directive 85/374/EEC* (the Directive).³³ Worthy of note is the fact that agreement was reached about the fact that member states could derogate from the provisions of the Directive in three important controversial areas. These areas included primary agricultural products and game,³⁴ a defence based on the state of scientific and technical knowledge,³⁵ and, finally, the

²⁴ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations administrative provisions of the Member States concerning liability for defective products OJ 1985 L210/29.

²⁵ Stapleton *Product Liability* (Butterworths, 1994) 4.

²⁶ Use of the drug Thalidomide led to the birth of children who were deformed. These children could not claim under contract and so they relied on the tort of negligence. The operating fault regime, however, seemed inadequate particularly in the area of establishing the fault of the producer. See Goldberg *Causation and Risk in the Law of Torts: Scientific Evidence and Medicinal Product Liability* 7 and also Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) para 7.06.

²⁷ See Stapleton *Product Liability* (Butterworths, 1994) ch 3.

²⁸ See Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) para 1.24.

²⁹ See Hansard, HC Deb Vol. 848, Col 111 9 (19 December 1977).

³⁰ See Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) para 12.5.

³¹ See Miller CJ, *Product liability and Safety Encyclopedia* (1979-2004 Butterworths) Div V, para 172.

³² Later the European Union; https://europa.eu/european-union/about-eu/eu-in-brief_en accessed 15 February 2017.

³³ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations administrative provisions of the Member States concerning liability for defective products OJ 1985 L210/29.

³⁴ See Art 2 of the Directive, which permits members to derogate, while Art 15(1)(a) permits its inclusion.

³⁵ Art 7(e) permits exclusion and Art 15(1)(b) of the Directive permits derogation.

imposition of a ceiling on liability for death or personal injury as a result of injury occasioned by identified items with a similar defect.³⁶ It must be noted that the area which permitted derogation in respect of game and agricultural products was subsequently removed from the provisions of the Directive.³⁷ This document directed member states to impose strict liability on the manufacturers of a defective product which causes death or personal injury. Implementation of the Directive led to the promulgation of the Consumer Protection Act 1987 in the United Kingdom. The Directive remains important because the Act requires Part 1 of its provisions, which deals with product liability, to be construed in line with the Directive.³⁸

Developmental Risk Defence

The developmental risk defence is contained in Article 7 (e) of the Directive which states as follows:

Article 7:

"The producer shall not be liable as a result of this Directive if he proves.....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 or..."

The inclusion of this defence attracted much controversy as was earlier observed in this work.³⁹ This led to the provisions of Article 15(b) of the Directive which allow member states to derogate from Article 7(e) and which provided for the development risk defence.⁴⁰

The defence is beneficial to all manufacturers of products. Its relevance is predominantly pronounced in the field of medicinal products, aerospace, biotech products and other industries in the forefront of scientific and technical knowledge.⁴¹

Where the defence is successfully invoked, the tortfeasor, who is the person proceeded against, will escape liability for the injury emanating from the defective product if he or she is able to establish that the state of scientific and technical knowledge at the relevant time was not such that a producer of similar products as the product in question might have been expected to have discovered such a defect had it existed in his or her products while under his or her control.⁴²

The wording of the Act is different from that of the Directive. While the latter focuses on the state of knowledge enabling discovery of a defect, the Act emphasises the conduct of the producer.⁴³

³⁶ See Art 16(1). See Dir 1999/34 of the European Parliament and of Council of 10 May 1999 [1999] OJ L141/20.

³⁷ See Directive 1999/34/EC of the European Parliament and the Council of May 1999 [1999] OJ L141/20.

³⁸ Section 1(1) of the Act provides: "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."

³⁹ While the European Commission supported liability for development risks, the Parliament supported the existence of the defence. On the preliminary steps and issues involved before the defence was finally included in the Directive, see Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) paras 13.26-13.30.

⁴⁰ It must be noted that all member states, except Luxembourg and Finland, have adopted the development risk defence, although Germany removed pharmaceuticals and Spain removed medicine, food or food products meant for human consumption from the scope of the defence. France excluded products derived from the human body. See Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) para 13.40.

⁴¹ Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) para 13.30.

⁴² Section 4(e) of the Act provides for this defence where: "...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." Art. 7(e) of the Directive makes provision for the Developmental risk defence. It provides *inter alia*: "... 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."

⁴³ Clark AM, *Product Liability* (1989 Sweet and Maxwell) 153. The difference in wording led to the initiation of infringement proceedings in the European Court of Justice, in the case C-300/95 *Commission v United Kingdom* [1977] ECR 1-2649. The case was initiated under Art. 169 based on the failure of the United Kingdom to implement the Directive correctly. The case was, however, dismissed. See further Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) paras 13.44-13.58; Miller *Medicinal Product Liability and Regulation* 176-182. It should also be noted that the words "a producer of

The application of this defence came up for consideration in *A v National Blood Authority*.⁴⁴ The case involved claims by persons who had received transfusions of blood infected with hepatitis C. The defendants contended that the defence would relieve them of liability from the defect in the blood which, although the risk thereof was known, the state of scientific technological development could not enable a producer to discover the existence thereof in a particular bag of blood at the time. The claimants argued that the defence is applicable only where there was no accessible knowledge through which the defect could be identified. Furthermore, once the defect was known, it became a "known risk". They also contended that "a known but unavoidable risk" was not within the scope of the defence offered by this provision.⁴⁵ Drawing inspiration from the decision of the European Court of Justice in *Commission v United Kingdom*,⁴⁶ Burton J held that the producer or defendant could not rely on the defence contained in Article 7(e) of the Directive and held as follows:

"If there is a known risk, i.e. the existence of the defect is known or should have been known in the light of non-Manchurianly accessible information,⁴⁷ then the producer continues to produce and supply at his own risk. 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... [T]he existence of the defect is in my judgment clearly generic. Once the existence of the defect is known, then there is then the risk of that defect materializing in any particular product."⁴⁸

Developmental Risk Defence and Sustainable Development

This section is devoted to a discussion of the nexus and contributions of developmental risk defence to sustainable development. The protection of human safety, enhancement of quality of human lives and the protection of the environment are all part of the principal interest sought to be protected by sustainable development, and this is in tandem with the objectives of the developmental risk defence.

While it is the goal of every society to establish local economies which are economically viable, environmentally friendly and socially and economically beneficial, as well as breaking new ground by adopting ideas, efforts geared towards achieving these objectives must equally ensure that the environment and human safety are adequately protected.

Towards achieving these goals there is need to strike a balance between the competing interests of producers/manufacturers and those of the consuming public, and so there is the need for the evolution of developmental risk defence.

As a catalyst for the breaking of new ground in terms of product improvement and product innovation, developmental risk defence has sustainable development in virtually all facets of human endeavour while one must also not lose sight of the multiplier effect of such contributions on human development. Some of the influences of developmental risk defence to sustainable development can be classified or summarized under the following sub-

products of the same description as the product in question" have been subjected to criticism on the grounds that they cloud the definition with complications and also limit the scope of the defence. See Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) paras 13.32-13.35 for other points of criticism.

⁴⁴ [2001] 3 All ER 289. See further Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) paras 13.94-13.97.

⁴⁵ The *A* case [2001] 3 All ER 289 para 50.

⁴⁶ Case C-300/95 [1977] ECR I-2 649.

⁴⁷ For a discussion of the so-called Manchurian example cited by the court, see paras Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) paras 13.54 and 13.87.

⁴⁸ The view has been expressed that, "if any, weight to Recital 7 of the Directive, which provides that: 'Whereas a fair apportionment of risk between the injured person and the producer implies that the producer should be able to free himself from liability if he furnishes proof as to the existence of certain exonerating circumstances...' Burton J merely referred to the purpose of Art. 7(e) as being 'plainly not to discourage innovation', and as protecting 'the producer in respect of the unknown (*inconnu*)'. See Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) para 13.96 n 289. For criticism, see Stapleton, 'Bugs' 53 *S C L Rev* 1225 1249.

heads: economic sustainability; technological sustainability; health and medicinal sustainability; and, last but not least, protection of the environment. An attempt will not be made to discuss each of the above.

Health and Medicinal Sustainability

The developmental risk defence has impacted positively on the medical sustainability of society. The havoc caused to date by unsafe products and the attendant liability which has arisen from them in terms of physical and financial liability until now has remained very grievous.⁴⁹ In order to facilitate, and provide, an enabling environment to promote research and safeguard human health, the developmental risk defence was introduced. It encourages researches into various medicinal fields which will benefit mankind. Until now it has encouraged pharmaceutical industries to embark on research. This has led to the production of new drugs which have increased longevity and reduced the complications associated with some dangerous diseases that are life threatening. Research has also stimulated sustainable design and development techniques in hospitals and health care facilities which promote healthier, safer, and eco-friendly atmospheres. It has also assisted in revealing that healthy behaviour, such as eating right and exercising, ward off diseases. These revelations are all the result of research stimulated by the developmental risk defence.

Economic Sustainability

Developmental risk defence has also positively impacted on the economic sustainability of the environment. With the breaking of new ground, new industries and services are established. This directly and indirectly stimulates economic growth, provides employment, and increases GDP (gross domestic product) in both developing and developed countries. One can imagine what an economy without growth would look like. In such an economy, there would be unemployment along with its attendant consequences. Essential facilities which would have promoted healthy living would be lacking, and the interests of future generations in all areas of human, economic and health benefits would be jeopardized or seriously curtailed. Equally, resources which ought to be deployed for the provision of such facilities would be diverted to other needs, such as the payment of welfare packages and the provision of essential necessities of life to the needy amongst a host of other obligations. Such a scenario would both directly and indirectly affect growth and equally affect sustainable development in all its ramifications.

Technological Sustainability

The environment and society have changed from what they used to be in the past. The existence of new products, including personal and household products, modern communication equipment, aerospace developments and the manufacture of new industrial products, are all the result of research made possible by developmental risk defence. These developments have, in no small way, contributed to the sustainability of the environment and also contributed to the enjoyment of life. None these would have been possible without the existence of developmental risk defence.

Environmental Sustainability

The existence of modern-day equipment to ascertain the safety of the environment is all the result of research facilitated by the developmental risk defence. Though the environment still faces many challenges, such as pollution in the air, water and soil, global warming, etc, the significant improvements made in terms of the safety of the environment would not have been possible had it not been for the existence of this defence. The presence of pollutants in the air, water and ground, along with the serious health implications, may have been going on unnoticed.

Some Controversial Areas of the Developmental Risk Defence.

A look at the provisions of Article 7 (e) which deals with developmental risk defence shows that it is ambiguous and susceptible to definitional difficulties. Without sounding repetitive, it will be necessary to reproduce the provision to enable us appreciate the issues canvassed under this section:

Article 7:

"The producer shall not be liable as a result of this Directive if he proves...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 or..."

From the above provision, "a producer of products of the same description as the producer in question" is ambiguous and susceptible to definitional difficulties. The view has been expressed that these words "cloud the definition with inherent complications". They prompt the further query of whether they "refer to all producers of say, medicinal

⁴⁹See <http://www.independent.co.uk/news/uk/home-news/mad-cow-disease-in-the-uk-what-is-bse-and-what-are-the-symptoms-a6675351.html>, on the mad cow disease, accessed on 18/6/17.

products or drugs of the same therapeutic class, or [whether] the definition embrace[s] a more comprehensive group of drugs."⁵⁰

Another major area of concern in respect of the interpretation of the defence, is how to assess the relevant state of scientific evidence. It has been observed that the defendant is not expected to establish a worldwide absence of knowledge of defect.⁵¹ The defence should be applicable when the defendant shows that there is no previous knowledge of the defect in the field with which he/she is expected to be familiar.⁵² The relevant time to apply the test as stated in the Act is basically to revolve around the time of supply of the product,⁵³ while, under the Directive, it is when the producer puts the product into circulation.⁵⁴ The issue of relevant time is bound to create a problem, and it is of importance in an area where the state of the art is rapidly increasing.⁵⁵ The developmental risk defence, in terms of its scope, does not cover unknown defects as a result of limited general knowledge as evidenced by the case of *Abouzaid v Mothercare (UK) Ltd.*⁵⁶ In this case, the lack of appreciation of the defect was not the result of a lack of scientific and technical knowledge. The question might be asked as to at what stage the issue of access to the state of scientific and technical knowledge would become relevant for the purpose of availing a defendant of the opportunity of the defence provided by section 4(e). In line with the decision of the European Court of Justice in the infringement proceedings, the court was of the view that such knowledge must have been accessible at the time the product in question was put into circulation.⁵⁷

It has been noted that uncertainty still surrounds the scope of this defence and its applicability in instances of defects or risks that are known in general terms but are entirely unpredictable and undetectable in their incidence.⁵⁸

Conclusion.

The development risk defence has had a positive impact on the sustainability of the environment generally. It strikes a balance between the competing interest of the society and those of the manufacturer/producers of products. As a catalyst for product innovation its contribution in this regard is of great benefit to both the present generation and

⁵⁰ Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) para 13.31.

⁵¹ Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) para 13.31.

⁵² Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) para 13.31.

⁵³ Some special instances are also provided for. Section 4(2) states: "In this section 'the relevant time', in relation to electricity, means the time at which it was generated, being a time before it was transmitted or distributed, and, in relation to any other product, means- (a) if the person proceeded against is a person to whom subsection (2) of section 2 above applies in relation to the product, the time when he supplied the product to another; and (b) if that subsection does not apply to that person in relation to the product, the time when the product was last supplied by a person to whom that subsection does apply in relation to the product."

⁵⁴ See Art. 7e of the Directive.

⁵⁵ Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) para 13.43.
⁵⁶ [2000] All ER (D) 2436.

⁵⁷ See case C-300/95 [1997] ECR I-2 649, I-2 670 para 29. There is, however, bound to be a problem in establishing what accessibility connotes. For instances of such problems see Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) paras 13.89-13.90. See also Griffiths (1987) *JBL* 222.

⁵⁸ Miller CJ and Goldberg RS *Product Liability* (Oxford University Press, Oxford 2004) para 13.104.

future generations. While not unmindful of the criticisms level led against the provisions of Article 7 (e), the benefit of the existence of this defence in terms of its contributions to sustainable development outweighs such criticisms.