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Law

Objections to the Development Risk Defence

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Abstract. In Europe the Council Directive of the European Community relating to product liability was enacted in 1985. The Directive allows the producer to use six defences. One of these is particularly interesting: '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 defence, set out in Article 7 (e) had a turbulent history. Would it or would it not be included? The tug-of-war between its supporters and its opponents almost resulted in a complete split. For a long time it seemed as if the development risk defence would block the establishment of the entire directive on product liability [1]. But that would have been much more than it deserved. Eventually those in favour of the defence tugged their opponents over the line, but it is doubtful whether this has turned out to be a real victory. It might seem so, now that the defence has been enshrined in almost all of the national legislation. But isn't this merely the outward appearance?

Initially it seemed unlikely that the development risk defence would end up in the Directive. The 1976 version even ruled explicitly against it: no defence. The classical arguments against the defence were certainly strong. The Directive simply happens to relate to strict liability, in which a development risk defence would be a totally alien element. As the American Robb concisely states: 'the risk is a clear cost of doing business, and the product manufacturer is in the better position both to absorb the risk and to prevent it' [2].

Against this stood the arguments which had traditionally been raised in favour of the defence. Would it be fair [3] if producers were also held liable for those defective products whose defect could in no way be discovered at the time they were put on the market? Would not such an absolute liability also form an obstacle to innovation? Who would still dare to put new products onto the market? Basically, the manufacturer would in this way become the insurer of his own products. Lastly, the preventive argument just mentioned was also reversed. The producer would - if the defence were not available - perhaps start to think: what does it matter whether or not I conduct extensive research into my new products? I'm liable anyway!

These were the types of arguments for and against which played a strong role in the discussion on the 1976 draft directive. That version - as said - still explicitly rejected the defence. But it was above all three recommendations (all in favour of the defence) which brought about a U-turn [4] the recommendation of the Economic and Social Committee, that of the Economic and Monetary Committee and that of the Legal Committee, the two latter being committees of the European Parliament.

Of great interest is the fact that the Economic and Monetary Committee remarked that one (could) ask oneself to what extent it is really necessary to lay down rules for this problem of development damage. In fact, not ~~one~~ delegation in the working group (consisting of British, Irish, Dutch, Belgian, German and Italian representatives) was able to advance a single instance of development damage based on their own practical experience! [5].

'American Mess'?

During the discussion conducted in Europe about product liability, the fear of being confronted with American situations certainly made itself felt. It is reflected in the advice given by the various committees. Often the opinion about America is probably left unsaid, but none the less it plays an implicit role when decisions are taken, in the form of a vague feeling of 'we don't want that sort of thing over here'.

In this context the terminology itself poses an immediate threat. Europeans talking about the development risk tend quite often to use the expression 'state of the art defence', a term that apparently refers to 'the state of scientific and technical knowledge'. Yet it would be much better if we continued to refer to it as the development risk defence' [6]. For there is a danger of wide-scale confusion, a confusion which America has known for many years [7]. The 'state of scientific and technical knowledge' ('state of the art') can be a decisive factor in answering two questions: whether the product can be said to be defective, and whether development damage exists. .

In fact, the crucial factor in deciding whether a product is defective is whether, taking all circumstances into account, that product offers the safety that can be expected of it. One of those circumstances is the date when the product was put into circulation [8]. The latter is important, as is also reflected in Article 6: 'A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including: a) the presentation of the product; b) the use to which it could reasonable be expected that the product would be put; c) *the time when the product was put into circulation*' [9].

The second question then is whether the producer - given the defectiveness of the product - can successfully plead the development risk defence. The fact that this involves two different questions is quite often overlooked. Consequently, I feel it is likely that producers got the shock of their lives when they believed at the time - incorrectly - that the 'state of the art' would no longer play a role of importance in the legislation of product liability. But what was involved was the 'state of scientific and technical knowledge' in respect of the development risk: a look-alike railway station, but one stop further down the line. Yet the person whizzing by too readily thinks he has seen only one station.

'State of the Art' in America

The same terminological confusion exists in America. With regard to the development risk pure and simple the judges in the US normally rule that strict liability does not extend so far that the producer is also liable for damage caused by defects 'not knowable' by the defendant in the light of its not even having been then known to the scientific community' [10]. The producer is 'obligated to keep informed of scientific knowledge and discoveries concerning that field . . .' [11]. If he complies with this condition, then he gets off scot-free.

But things do not always end up so favourable for him. In the famous case of *Beshada v Johns-Manville Products Corp* (1982) the judge ruled against the defence. This was one of the asbestosis cases in which a number of asbestos workers (or their next-of-kin) were claiming damages from a producer [12]. Nevertheless, this judgment - plus several others [13] - forms an exception to the rule that the producer is allowed to defend himself and is thus not liable for development damage [14]. For instance, the new Uniform Product Safety Act, which is not yet in force, also contains a development risk defence.

An Insurance Crisis?

The dread of 'American situations' or of a liability crisis is inextricably linked to the fear that producers will no longer be able to obtain adequate insurance cover in return for reasonable premiums. That insurance aspect has been raised in the 'European discussion'. For instance, in a memorandum from the general secretariat of the European Insurance Committee in Paris, which says that no real problems are expected [15].

And let us bear in mind here that the version which the Insurance Committee was advising on was one in which the manufacturer would also be liable for any development damage. However, that version did apply a liability limit. The Committee commented that it assumed 'that it will in general be possible for the development risk to be insured' [16]. Support for this view can, incidentally, be found in the situation regarding the West German 'Arzneimittelgesetz' (Medical Products Act). Upon introduction of this Act, in which in all probability a liability for development damage will also be imposed, the premiums initially climbed sharply, but they have since fallen substantially again [17].

How do things now stand as regards medicines? In a Supplementary Memorandum the European Insurance Committee provides some insight into the premiums which would be applicable [18]. As far as medicines are concerned, a premium could be expected of somewhere between 0,50 and 6,00 (expressed as thousandth parts of the sales). To give an illustration: for a medical product costing 25 dollars the premium will amount to between 1 cent and 15 cents. These may seem very low amounts, particularly if we realise that producers of medicines are already paying premiums. Moreover, the experience with the West Germany 'Arzneimittelgesetz' has shown that the premiums were initially estimated at much too high a level.

The Importance of the Defence

The most interesting question, of course, arises when a producer successfully pleads the development risk defence. So, let us now take another, somewhat closer look at the text of the relevant article. The producer has 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 defect to be discovered'. This is an objective touchstone: the defect could not have been discovered by this one producer, nor by any other producer [19]. It is also indisputable that the producer cannot claim that - given the state of technical and scientific knowledge - his product complied with the practical and reasonable criteria which were then applicable. Nor is his liability lessened in any way by claiming that he lacked the manpower to carry out certain research work, or was constrained by financial problems [20].

The criterion is therefore a strict one, much stricter than, say, the British Government would have us believe in its Consumer Protection Act [21]. The enactment of the Directive in UK legislation reads as follows: 'that the state of scientific and technical knowledge at the 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' [22].

This is certainly a very liberal interpretation of the original text. One British author points, and rightly so in my view, to a 'material difference and ... a victory for the producer's lobby' [23]. However, another Englishman, Christopher Newdick, discusses this question in detail and feels that the interpretation is 'correct' [24]. But he loses sight of the fact that the words 'might be expected' in the English text can definitely not be reconciled with the words 'was not such as to enable the existence of the defect to be discovered'. The Dutch version even uses the word "onmogelijk" - impossible to discover. Here there is some similarity with what is happening in the Netherlands where a new Civil Code is being prepared. On the one hand there is the clear wish to make a number of *tortious* liabilities into *strict* liabilities (for goods, dangerous substances, etc), but, when it comes to the crunch, the strict liability provision as drafted is again toned down at the last minute.

The discussion frequently focuses on the question of whether the producer, if he wishes to plead with success, should have been aware of the entire body of technical and scientific knowledge everywhere in the world [25]. One of the examples given was that of a monograph written in Finnish. Or of the findings of a top secret research project conducted in a laboratory in the US. No, some people believe, that would be going too far; it would be just the same as requiring the producer to be aware of 'abweichende, Aussenseiter- und Mindermeinungen' - divergent, outsider and minority opinions [26]. For, it is argued, one cannot then claim that the defect 'was not such as to enable the existence of the defect (not) to be discovered'.

And yet, those who interpret the text of the Directive in this way are making a mistake. They are in my view asking themselves the wrong question. What is at stake is:

whether the defect could have been discovered. So, if a Finn or an American has produced relevant research findings, it would apparently have been possible to have discovered the defect. If a Finn could have made these relevant findings, then the Dutch or West German manufacturer could have arrived at these relevant findings, as well. Except where this involved a pure fluke discovery by the Finn [27]. The proper question therefore is not whether a Dutch or British producer should have discovered the results of the Finnish research work, but whether it was possible to discover the defect. This is what is at stake. Therefore, if it is established in legal proceedings that on the date when the product was put into circulation the findings of a relevant Finnish research project already existed, the defence is doomed to failure. If this is correct, then the use of the word 'impossible' in the Dutch text in fact gives a more precise indication of how little latitude the defence allows the producer [28].

This should, in my opinion, be seen in conjunction with another very important factor. The reference date is the date when the product is put into circulation. And yet, upon closer consideration, that date is not the solution to all evils either. For this might in fact be a temptation to the less scrupulous producer: to conduct as little research as possible and to put his product on the market as quickly as he can. In concrete terms: suppose it is found that the producer, at the time he put his new product into circulation, could not have discovered its defectiveness. Suppose also that it is established (subsequently, that he could have discovered the defect if he had conducted further research. Would he then not be liable? Of course he would; not even strict liability would be needed for that. Well, if this is true, where does the borderline lie? At one year's extra research, at five years?

Burden of Proof

Yet another problem is formed by the burden of proof. The proof of the development risk lies with the producer [29]. He is the one who has to prove that it would have been impossible to discover the defect. None the less the victim may be expected during a case to prove that his claim is plausible, for instance with the aid of experts. Poor victim! Perhaps faced by the might of a big and financially strong producer! Here the words of Samuel Butler are highly appropriate: at the start of a case nothing is certain, except that it's going to cost money.

Lastly, it will not at all be easy to (have experts) look back and decide what the state of the art was five or ten years earlier. But that is what the judge is required to do! How difficult it is to do this can be in the Netherlands in court cases on soil pollution in which it always has to be established whether a soil polluter, at the time when contaminated material was tipped onto a landfill site many years ago, was or could have been aware of the consequences of his action [30]. That was also the finding reached by the Supreme Court of New Jersey in the *Beshada* case:

'Proof of what could have been known will inevitably be complicated, costly, confusing and time-consuming. Each side will have to produce experts in the history of science and technology to speculate as to what knowledge was feasible in a given year. We doubt that juries will be capable of even understanding the

concept of scientific knowability, much less be able to resolve such a complex issue. Moreover, we should resist legal rules that will so greatly add to the costs both sides incur in trying a case' [31].

The Wrong Battlefield

Even if the development risk were regarded as uninsurable, there is still one other possibility. One could, for medicines for instance - and that brings us to the most important category of potential development damage [32] - lay down a liability limit. I do feel that a limit for each type of product would be feasible [33]. Which brings me to my claim that - in their battle for the development risk defence - the producers have exhausted their forces by fighting on the wrong front: it's a Pyrrhic victory. I think that the only substantial victory would be won by including a liability limitation. This in fact applies not only to development damage but to *any* harm resulting from a defective product.

Where Do We Go From Here?

What should we do about the development risk defence? All arguments for or against the development risk defence are groundless or unconvincing. Ultimately, everything revolves around just two questions: is it fair to make the producer foot the bill for defects which it was impossible for him to discover? Is it fair that someone who has had the misfortune to become a victim of a development defect should be left to suffer the damage? For many people the answer to both questions will be: no, it's not fair. And yet a choice has to be made, and surely then the only valid argument in favour of whatever form of strict liability is: the possibility of obtaining insurance cover. Surely, the party who can best insure himself against the damage should be the one who has to bear the disadvantage? It seems to me that the best idea is not to include the defence in the national legislation. In the words of an English author: 'New legislation never solves all the problems, and often raises new problems that did not exist in the old law.' [34]

References

- 1 PB no C 241/9 of October 14 1976. For a useful overview of the various versions, see J Schmidt-Salzer, Kommentar EG-Richtlinie Produkthaftung, Band 1: Deutschland, Heidelberg 1988, 35ff and 11ff
- 2 GC Robb, in Frumer and Friedman, Products liability (1987) par 2.26 (8) 1686. See the West German author R Sack, VersR 1988, 448.
- 3 This word is used, for example, in the recommendation of the Legal Committee of the European Parliament, Doc 1979-1980, doc 71/79, April 17 1979
- 4 For the history of the Directive see, inter alia: AJO van Wassenaeer van Catwijck, Produktenaansprakelijkheid 1986, 10ff with references to American sources (in Dutch); the same in The American Journal of Comparative Law 1986, 798ff and HC Taschner, Produkthaftung CH Beck'sche Verlagsbuchhandlung Munchen 1986 6ff
- 5 Economic and Monetary Committee of the European Parliament, Doc. 1979-1978, April 17 1979, 29ff

- 6 As was rightly stated by HC Taschner in NJW 1986 615 and in a French translation of the same article, *Revue du Marche Commun* 1986, 261/262 and in *Produkthaftung* 1986, 120/121
- 7 'Few phrases in the law of products liability have caused as much judicial frustration as the term "state of the art"', MS Shapo *The law of products liability*, Warren, Gorham & Lamont, Boston, New York, 10-1. The same view is also taken by Taschner: 'Die Bedeutung beider Begriffe (state of the art and development risk -cs) in der amerikanischen Rechtspraxis war und its unklar. Definitionen, wenn es überhaupt solche gibt, schwanken. Übersetzungen in andere eutopaische Sprachen ... trugen den unklaren Begriff nur weiter' *Produkthaftung* 1986, 112/113
- 8 See the instructive article on this by M Faure and W Vanbuggenhout RW 1987-1988, 11 (in Dutch)
- 9 *Bailey v Boatland* 585 SW2d 805 (Tex 1979) a famous case discussed in detail by D DeSimone, *Dunguesne Law Review* 1980 924 ff
- 10 As overview is given by CC Marvel, Ann. in 33 ALR4th 369 ff. Usually this relates to claims which are argued on the basis of a 'failure to warn'. One of the root causes of all the confusion is to be found in the text of section 402A of the Restatement (second) of Torts. This is also touched on by P Borer. Verlag Stampfli & Cie AG Bern 1986 172ff
- 11 Eg *Karjala v Johns-Manville Products Corp* 523 F2d 155 (Minn 1975)
- 12 447 A2d 539, 33 ALR4th 353 (NJ 1982). A detailed description of this case is given by Robb, quoted in note 2, p 1691 ff and R Dossick in *Rutgers Law Review* 1986, 505 ff. These two publications contain much information on 'state of the art'
- 13 Eg *Little v PPG Industries, Inc* 579 P2d 940 (Wash 1978). *Vide* Marvel quoted in note 10, p 379 ff and supplement (September 1987)
- 14 The same Supreme Court of New Jersey subsequently ruled in favour of the defence: *Feldman v Lederle Laboratories, in re pharmaceuticals*: 479 A2d 374 (NJ 1984)
- 15 Memorandum of the General Secretariat of the European Insurance Committee, Annex I to the report of the Legal Committee, 43ff
- 16 Insurance Committee, 45
- 17 The committee notes that obviously a number of data are still not available, so that the figures need to be treated with some caution. Moreover, the Committee was at the time still basing its ideas on a liability limit
- 18 For example, the Dutch Minister of Justice commented that the defence had to be given a 'restrictive' and 'limited' interpretation and said that the defence ought to be subject to 'very strict requirements', *Parlementaire Geschiedenis*, 19 636, no 6, p 20, p 18. Van Bronkhorst 735 refers to an 'enormous burden of proof', whilst Van Wassenaeer 74 speaks of 'extraordinarily onerous' and H Duintjer Tebbens, of 'very onerous'; 'practically, the proving of a negative fact' he adds, *NJB* 1986 (all in Dutch) 272. Taschner NJW 1986, 615
- 19 *Vide* eg Taschner, *Produkthaftung* 1986, 116: BM Hummel, EH Hondius and GMF, Snijders, *Tijdschrift voor Consumentenrecht* 1988, 213 (in Dutch) correctly point out that legal regulations cannot be regarded as reflecting the 'state of science and technology'

- 20 Details are given by the Belgian authors Faure and Vanbuggenhout, RW 1987-1988, 37 (in Dutch); they refer to an 'absolute impossibility'.
- 21 Consumer Protection Act 1987, Halsbury's Laws of England (4 ed) Supp, Vol 41, para 659 ff and reprinted in BW Harvey en DL Parry, The law of consumer protection and fair trading, London, Butterworths 1987, 394ff
- 22 Section 4(1)e
- 23 A Clark Modern Law Review 1987, 619. For this provision see also: Harvey and Parry, quoted in note 21, 1987, 150ff
- 24 Christopher Newdick, Cambridge Law Journal 1988, 460
- 25 *Vide* eg Van Wassenaer quoted in note 10 and Taschner, Produkthaftung 1986 116
- 26 This is apparently his belief, though he is not entirely clear, Taschner, Produkthaftung 1986 118/119
- 27 In other words: a discovery not based on the then state of science and technology.
- 28 Besides, it obviously does not detract from his general 'Produktbeobachtungspflicht' - 'obligation of product observation') eg Sack, VersR 1988 448; E Deutsch Arztrecht und Arzneimittelrecht, Springer-Verlag Berlin, Heidelberg, New York 1983, no 428. In detail: I. Schwenzer JZ 1987 1059ff
- 29 Parlementaire Geschiedenis, 19 636, no 6 18; the Dutch Minister of Justice remarks that his expectation is that the proof by the producer will have to meet 'stringent requirements'.
- 30 *Vide* the Dutch authors AG Castermans, in Milieurechtelijke aspecten van koop en verkoop van onroerend goed, Tjeenk Willink, Zwolle 1989 and JM van Dunne, Tijdschrift voor Milieuaansprakelijkheid 1989 (both in Dutch).
- 31 447 A2d 548
- 32 The assumption is that the development risk defence is only of importance for pharmaceutical and chemical products. Taschener, Produkthaftung 1986, 121
- 33 If a general limit is allowed, then there could also be a limit for one specific category of goods.
- 34 AL Diamond, in Comparative Product Liability, CJ Miller (ed) British Institute of Intenational and Comparative Law, (1986) 42