

## Full Harmonization, Consumer Protection and Products Liability: A Fresh Reading of the Case Law of the ECJ\*

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**Abstract:** It is debated whether the European Products Liability Directive (85/374/EEC) (EPLD) is meant to protect victims of product-related accidents or to create a level playing field. This article proposes to solve this controversy by making two separate, but inter-linked claims. Taking advantage of a brand-new case and focusing on issues of burden of proof, it first identifies a trend in the recent case law of the ECJ to decide in favour of the consumer. Secondly, and more importantly, the article demonstrates that the question about the aim of the EPLD can be answered at two different levels of abstraction. In line with the legal basis of the directive (former Art. 100 EEC, current Art. 115 TFEU), the ECJ has always pressed the point that the EPLD, taken as a whole, is fully harmonizing within its scope – even to the detriment of consumers. Within this perimeter set by the ECJ, however, the directive undeniably counts as a consumer protection device. Not only the overall equilibrium struck by the directive bears witness to this phenomenon. It is also clearly manifested in the way the ECJ interprets the directive within the boundaries of the full harmonization.

**Résumé:** La directive 85/374/CEE sur la responsabilité du fait des produits défectueux vise-t-elle au développement du « level playing field » ou à la protection du consommateur ? Voilà une question fort contestée dans la doctrine juridique européenne. En vue d'éclaircir ce problème, cet article consiste en deux thèses différentes, mais toutefois corrélées. Prenant comme point de départ un nouvel arrêt de la Cour de justice de l'Union européenne (CJUE) sur la preuve en matière de la responsabilité du fait des produits défectueux, l'article démontre d'abord que la jurisprudence récente de la CJUE sur ce sujet est caractérisée d'une volonté de la Cour de statuer en faveur du consommateur. En plus, l'article avance la thèse que l'on peut répondre à la question sur le but de la directive sur deux niveaux d'abstraction différents. Bien démarquant la liberté des États Membres d'avantager les consommateurs au-delà des provisions de la directive, la CJUE est toujours restée fidèle à sa base juridique, l'ancien article 100 de la CEE (l'article 115 TFUE), provision qui ne permet à l'Union de promulguer que de directives harmonisant complètement les matières qu'elles gouvernent. Néanmoins, au-dedans des contours de l'harmonisation complète, il n'existe aucun doute que la directive cherche à protéger les victimes d'accidents causés par des produits défectueux. Cela s'avère de l'équilibre maintenu par la directive entre les intérêts des différentes parties et de la jurisprudence de la CJUE sur d'autres thèmes que l'harmonisation.

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**Zusammenfassung:** In der Lehre wird diskutiert, ob die Richtlinie vom 25. Juli 1985 über die Haftung für fehlerhafte Produkte (85/374/EWG) Verbraucherschutz oder Rechtsharmonisierung in der EU bezweckt. Dieser Artikel schlägt zur Lösung des Problems zwei gesonderte, aber verbundene Thesen vor. Ausgehend von einem neuen EuGH-Urteil über Fragen der Beweislast wird dargelegt, dass der EuGH in den letzten Jahren oft zugunsten von Verbrauchern entschied. Zweitens, und wichtiger, weist dieser Artikel nach, dass die Frage über das Ziel der Produkthaftungsrichtlinie auf zwei unterschiedlichen Abstraktionsniveaus beantwortet werden kann. Der EuGH hat immer betont, die Rechtsgrundlage der Richtlinie (Artikel 100 EWG-Vertrag, jetzt Artikel 115 AEU-Vertrag) erfordere Vollharmonisierung im Anwendungsbereich der Produkthaftungsrichtlinie - auch wenn dies zum Nachteil von Verbrauchern gereiche. Trotzdem, verleiht dient die Richtlinie zweifelsfrei als Verbraucherschutzinstrument. Das zeigt sich nicht nur an der Interessenabwägung der Richtlinie selbst, sondern auch an der Art, wie der EuGH die Richtlinie innerhalb des Vollharmonisierungsparadigmas interpretiert.

**Key words:** European Products Liability, European Tort Law, Burden of proof, European Court of Justice, Harmonization, Consumer protection.

## 1. Introduction

1 After thirty years and five cases before the ECJ<sup>1</sup> France still has not lost its uneasiness with the European Products Liability Directive (hereafter ‘EPLD’).<sup>2</sup> In a recent case the ECJ scrutinized a French rule concerning the use of presumptions by the plaintiff to prove the defect in the product and the causal link between the defect and the damage.<sup>3</sup>

Aside from providing a short introduction to European products liability and a summary of this new case, this article makes two separate, but interlinked claims. The first half of the commentary is devoted to questions of proof in products liability. I will track how the Court has consistently lowered the burden of proof in the last few years, thereby catering to decades of consumer demands. In the second half I reconstruct the existing case law of the ECJ on products liability in

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- 1 ECJ 13 January 1993, ECLI:EU:C:1993:4, *Commission v. France*, curia.europa.eu/juris/documents.jsf?num=C-293/91; ECJ 25 April 2002, ECLI:EU:C:2002:252, *Commission v. France*, curia.europa.eu/juris/documents.jsf?num=C-52/00; ECJ 14 March 2006, ECLI:EU:C:2006:173, *Commission v. France*, curia.europa.eu/juris/documents.jsf?num=C-177/04; ECJ 4 June 2009, ECLI:EU:C:2009:351, *Société Moteurs Leroy Somer v. Société Dalkia France & Société Ace Europe*, curia.europa.eu/juris/documents.jsf?num=C-285/08; ECJ 21 December 2011, ECLI:EU:C:2011:869, *Centre hospitalier universitaire de Besançon v. Thomas Dutreux & Caisse primaire d’assurance maladie du Jura*, curia.europa.eu/juris/documents.jsf?num=C-495/10.
  - 2 Dir. 85/374 of 25 July 1985 on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products, eur-lex.europa.eu/legal-content/ALL/TXT/?uri=CELEX:31985L0374.
  - 3 ECJ 21 June 2017, ECLI:EU:C:2017:484, *N.W, L.W & C.W v. Sanofi Pasteur MSD SNC, Caisse primaire d’assurance maladie des Hauts-de-Seine & Carpimko*, curia.europa.eu/juris/documents.jsf?num=C-621/15.

order to demonstrate that full harmonization and consumer protection<sup>4</sup> largely go hand in hand under the EPLD – contrary to what is often said or at least implied.

## 2. Synopsis of European Products Liability Law

2 The EPLD<sup>5</sup> is a maximally harmonizing<sup>6</sup> directive that embodies the principle that the producer shall be liable for damage caused by a defect in its product (Art. 1 EPLD) – a product being a movable good, including those incorporated into other movable or immovable goods and including electricity (Art. 2 EPLD). Every manufacturer of a finished product, producer of raw material or of a component part, and every person who presents himself as producer by putting his name, trademark or other distinguishing feature on the product is liable under the regime of the EPLD. Equally liable are actors importing a product from outside the EU. In case the EU producer or the importer cannot be identified, the liability rests upon the supplier of the product (Art. 3 EPLD). If more than one person qualifies as ‘producer’, they are jointly and severally liable (Art. 5 EPLD). Liability under the directive only covers damage caused by death or personal injury, and damage to or destruction of goods intended for private use and consumption and mainly used by the injured person for these purposes (Art. 9 EPLD). Exemption clauses limiting the liability of the producer towards the injured person are prohibited (Art. 12 EPLD), but the producer’s

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- 4 Some might consider the term ‘consumer protection’ a misnomer in the context of the EPLD. The EPLD does not only protect consumers – it offers compensation for death and personal injury and damage to non-professional goods (Art. 9 EPLD). The plaintiff does not have to be a consumer in whatever legal sense. However, the directive itself mentions consumer protection as a goal in the preamble and the ECJ also uses the phrase at various instances. It seems as if the European legal community is more and more considering the EPLD part of consumer law. See also S. WHITTAKER, ‘Introduction to Fault in Product Liability’, in S. Whittaker, *The Development of Product Liability* (Cambridge: Cambridge University Press 2010), p (1) at 9.
- 5 For recent and thorough discussions of the regime of the EPLD, see D. FAIRGRIEVE, G. HOWELLS, P. MØGEVANG-HANSEN, G. STRAETMANS, D. VERHOEVEN, P. MACHNIKOWSKI, A. JANSSEN & R. SCHULZE, ‘Product Liability Directive’, in P. Machinkowski (ed.), *European Product Liability – An Analysis of the State of the Art in the Era of New Technologies* (Cambridge: Intersentia 2016), pp 17-108 or H. MICKLITZ, ‘Liability for defective products and services’, in N. Reich, H. Micklitz, P. Rott & K. Tonner (eds), *European Consumer Law* (Antwerpen: Intersentia 2014), pp 239-284 (with useful bibliography at p 241). Some older sources are C. HODGES, *Product Liability: European Laws and practice* (London: Sweet & Maxwell 1993) and H. TASCHNER, *Produkthaftung: Richtlinie des Rates vom 25. Juli 1985 zur Angleichung der Rechts- und Verwaltungsvorschriften der Mitgliedstaaten über die Haftung für fehlerhafte Produkte (85/374/EWG)* (München: Beck 1986).
- 6 ECJ 25 April 2002, ECLI:EU:C:2002:255, *María Victoria González Sánchez v. Medicina Asturiana*, curia.europa.eu/juris/documents.jsf?num=C-183/00, paras 23 et seq.; ECJ 25 April 2002, curia.europa.eu/juris/documents.jsf?num=C-52/00, paras. 13 et seq.; ECJ 25 April 2002, ECLI:EU:C:2002:254, *Commission v. Greece*, curia.europa.eu/juris/documents.jsf?num=C-154/00, paras. 9 et seq.

liability may be reduced in case the victim or a person for whom the victim was responsible was itself at fault (Art. 8, para. 2 EPLD).

3 A product is considered defective under the regime of the EPLD ‘when it does not provide the safety which a person is entitled to expect, taking all circumstances into account’ (Art. 6 EPLD). From a comparative law perspective this criterion is a version of the so-called consumer expectations test, which is commonly opposed to the risk-utility test.<sup>7</sup> The directive is only concerned with the product’s ‘safety’, so not with its fitness for use, aesthetics, or other characteristics.<sup>8</sup> Three elements are explicitly mentioned as relevant. The first is the ‘presentation of the product’ (Art. 6, para. 1, (a) EPLD), which ranges from advertising to product warnings and instructions for use.<sup>9</sup> Also relevant is the ‘use to which [the product] could reasonably be expected to be put’ (Art. 6, para. 1, (b) EPLD). It can reasonably be expected, for instance, that small children will try to put toys in their mouth rather than just play with them. Lastly, the directive mentions ‘the time when the product was put into circulation’ as a relevant factor (Art. 6, para. 1, (c) EPLD), to avoid that a producer is held liable if ‘a better product was subsequently put into circulation’ (Art. 6, para. 2 EPLD).

4 Issues of evidence will be discussed at greater length in section 4 of this article. As an introduction it suffices to note that the injured person is required to prove the damage, the defect and the causal link between defect and damage (Art. 4 EPLD). The producer avoids liability if she proves one of the elements listed in Article 7, *i.e.*, that she did not put the product into circulation, that the defect did not exist at the time when the product was put into circulation, that the product was not manufactured for sale or any other form of distribution with economic purpose nor manufactured or distributed by her in the course of her business, that the defect is due to compliance of the product with mandatory regulations issued by the public authorities, that the state of scientific and technical knowledge at the time when she put the product into circulation was not such as to enable the existence of the defect to be discovered, or in case of the manufacturer of a component, that 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.

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7 M. REIMANN, ‘Liability for Defective Products and Services: Emergence of a Worldwide Standard?’, in International Academy of Comparative Law (ed.), *Convergence of Legal Systems in the 21st Century* (Brussel: Bruylant 2006), pp (394–397) at 367.

8 H. TASCHNER, ‘Product Liability: Basic Problems in a Comparative Law Perspective’, in D. Fairgrieve (ed.), *Product Liability in Comparative Perspective* (Cambridge: Cambridge University Press 2005), p (155) at 159.

9 For a thorough account, see S. PAPE, *Warnings and Product Liability: Lessons Learned from Cognitive Psychology and Ergonomics* (Den Haag: Eleven International Publishing 2012).

### 3. The Case

5 After being administered three injections of a hepatitis B vaccine produced by Sanofi Pasteur between December 1998 and July 1999, Mr W. began to present symptoms of multiple sclerosis (M.S.) in August 1999. Mr W. and his family subsequently brought a claim before the *tribunal de grande instance de Nanterre* (regional court of Nanterre) based on the French provisions incorporating the EPLD. They sustained that the vaccine that W. had received had been defective and had caused him to develop M.S.

6 The plaintiffs supported their claim with the following proof: (1) the period between the vaccination and the occurrence of the first symptoms was suspiciously short; (2) there was no family history of M.S. According to the plaintiffs, this gave rise to serious, specific and consistent presumptions as to the existence of a defect in the vaccine and a causal link between the injection of the vaccine and the occurrence of M.S. In fact, the case law of the *Cour de cassation* (Court of cassation) concerning liability of pharmaceutical companies for their vaccines allowed plaintiffs to prove defect and causal link relying on these presumptions.<sup>10</sup> After being upheld in the first instance, the claim was dismissed on appeal. The plaintiffs then appealed to the *Cour de cassation*, which quashed the judgment on appeal and sent it to the *cour d'appel de Paris* (court of appeals Paris) to rule on the merits.<sup>11</sup> The *cour d'appel de Paris* again overturned the judgment in the first instance, mainly relying on the fact that the link between hepatitis B vaccination and M.S. was not scientifically proven, that research suggested that the pathophysiological process of developing M.S. commences several months or even years before the first symptoms, and that 92% to 95% of the patients had no family antecedents of the disease.

7 After a new appeal before the *Cour de cassation*, the latter decided to submit three preliminary questions to the ECJ.<sup>12</sup> The first question concerns two distinguishable issues, that are each dealt with in a separate second and third question. The first question the *Cour de cassation* submitted was whether Article 4 of the EPLD (on burden of proof) precluded:

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- 10 *Cour de cassation* 1<sup>er</sup> civ. 22 May 2008, *X/Laboratoire Glaxosmithkline*, [www.legifrance.gouv.fr/affichJuriJudi.do?oldAction=rechJuriJudi&idTexte=JURITEXT000018868823](http://www.legifrance.gouv.fr/affichJuriJudi.do?oldAction=rechJuriJudi&idTexte=JURITEXT000018868823); J.-S. BORGHETTI, 'Product Liability in France', in P. Machinkowski (ed.), *European Product Liability – An Analysis of the State of the Art in the Era of New Technologies* (Cambridge: Intersentia 2016), pp (224–225) at 205. This case law has been picked up by a Belgian court in a similar case (although in this case the court ruled for the producer): *Hof van Beroep* (court of appeals) Luik 9 October 2014, *RGAR (Revue Générale des Assurances et des Responsabilités)* 2015, nr. 15.153.
- 11 *Cour de cassation* 1<sup>re</sup> civ. 26 September 2012, *X/Sanofi Pasteur*, [www.legifrance.gouv.fr/affichJuriJudi.do?oldAction=rechJuriJudi&idTexte=JURITEXT000026432064](http://www.legifrance.gouv.fr/affichJuriJudi.do?oldAction=rechJuriJudi&idTexte=JURITEXT000026432064).
- 12 Cass. civ. 1<sup>er</sup> 12 November 2015, *X/Sanofi Pasteur*, ECLI:FR:CCASS:2015:C101243, [www.legifrance.gouv.fr/affichJuriJudi.do?oldAction=rechJuriJudi&idTexte=JURITEXT000031478159](http://www.legifrance.gouv.fr/affichJuriJudi.do?oldAction=rechJuriJudi&idTexte=JURITEXT000031478159).

‘in the area of liability of pharmaceutical laboratories for the vaccines that they manufacture, a method of proof by which the court ruling on the merits, in the exercise of its exclusive jurisdiction to appraise the facts, may consider that the facts relied on by the applicant constitute serious, specific and consistent presumptions capable of proving the defect in the vaccine and the existence of a causal relationship between it and the disease, *notwithstanding the finding that medical research does not establish a relationship between the vaccine and the occurrence of the disease* [emphasis added]’.<sup>13</sup>

The first part of the question concerns the acceptability of the use of presumptions in cases involving an allegedly defective vaccine. The second, emphasized part concerns the status of scientific evidence in the courtroom.

The first issue regarding the use of presumptions is again addressed in the second question, in which the *Cour de cassation* asked whether Article 4 precludes a system of presumptions where the causal relationship between the attributed defect and the damage will ‘always be considered to be established where certain indications of causation are found’.

The second issue regarding the status of scientific evidence is taken up again in the third question, in which the *Cour de cassation* asked whether the causal link between the defect and the damage can only be considered proven by the judge ruling on the merits if it is established scientifically.

8 The answer of the ECJ can be summarized as follows. The directive only maximally harmonizes ‘the matters regulated by it’ (paras. 20-21). Not all matters of proof fall under its scope. The ways in which evidence is to be elicited, what evidence is admissible before the national courts and questions about the probative value and level of proof are all matters that are left to national law (para. 25). A few conditions have to be met, however.

First of all, the burden to prove defect, causation and damage has to remain with the plaintiff. A reversal of the burden of proof is not allowed, neither as a matter of law (para. 27), nor as a matter of fact: ‘principles characterizing [national evidentiary rules] must not be applied by the national courts in such a way that they introduce, to the detriment of the producer, unjustified presumptions liable to

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13 In French: ‘L’article 4 de la directive 85/ 374/ CEE du Conseil, du 25 juillet 1985, relative au rapprochement des dispositions législatives, réglementaires et administratives des Etats membres en matière de responsabilité du fait des produits défectueux s’oppose-t-il, dans le domaine de la responsabilité des laboratoires pharmaceutiques du fait des vaccins qu’ils produisent, à un mode de preuve selon lequel le juge du fond, dans l’exercice de son pouvoir souverain d’appréciation, peut estimer que les éléments de fait invoqués par le demandeur constituent des présomptions graves, précises et concordantes, de nature à prouver le défaut du vaccin et l’existence d’un lien de causalité de celui-ci avec la maladie, nonobstant la constatation que la recherche médicale n’établit pas de lien entre la vaccination et la survenance de la maladie ?’



infringe Article 4 [of the EPLD] or even undermine the very effectiveness of the substantive rules laid down in that directive' (para. 34).

Secondly, the courts have to be able to freely assess whichever piece of evidence the parties present them (para. 38). This requirement seems to apply to both factual<sup>14</sup> and legal presumptions, as well as to both rebuttable and irrebuttable presumptions (paras. 52-55). Quoting the words<sup>15</sup> of the opinion of the A.G., the ECJ states that it would undermine the effectiveness of the system if 'national courts apply evidentiary rules in an overly rigorous manner by accepting irrelevant or insufficient evidence' (para. 35). 'Immediate and automatic presumption[s]' once 'one or more types of factual evidence [are] presented together' are not allowed (para. 36). This is why the court has to 'ensure that the evidence adduced is sufficiently serious, specific and consistent' so that the 'defect and causal link may reasonably be considered to be established' (para. 37). This also pertains to the substantive conditions of liability. If automatic presumptions were applied, two of the three conditions for the producer to be held liable - defect and causation - 'would not be sufficiently examined by the national court' (para. 35 and similarly, paras. 52-55).

Lastly, the ECJ ruled that national courts cannot require scientific proof of the causal link, because this would go against the effectiveness of the system laid down in the directive. Such a rule would 'render practically impossible or excessively difficult the exercise of rights conferred by the EU law', *i.e.*, by the EPLD (para. 26). In paragraph 31 this principle of 'effectiveness' seems to be interpreted as referring to the goal of holding the producer liable if the defect in her product caused damage. Requiring scientific proof would also go against the 'objectives' of the directive, *i.e.*, to reach a 'fair apportionment of the risks inherent in the modern technological production between the injured person and the producer' and 'protecting consumer health and safety' (para. 32).

9 The answer of the Court can be interpreted in two ways. A first interpretation focuses on the specific problem addressed by the ECJ: the burden of proof and the freedom of Member States to regulate evidence law in products liability cases.<sup>16</sup> The Court has approved the use of presumptions by national courts in products liability law, as long as they are not automatic and do not reverse the burden of proof - at a minimum concerning liability for defective vaccines. Scientific proof, moreover, is not required. A second interpretation looks at the case from the

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14 Factual presumptions are more commonly known as 'circumstantial evidence' (Opinion of Advocate General Bobek, ECLI:EU:C:2017:176, [curia.europa.eu/juris/documents.jsf?num=C-621/15](http://curia.europa.eu/juris/documents.jsf?num=C-621/15), paras. 28-36).

15 Although the meaning of the term 'rigorous' seems to be different in the judgment and in the opinion.

16 Opinion of Advocate General Bobek, [curia.europa.eu/juris/documents.jsf?num=C-621/15](http://curia.europa.eu/juris/documents.jsf?num=C-621/15), para. 15.

perspective of previous case law of the ECJ. In the last few years, the ECJ has ruled in favour of the consumer on quite a few occasions. The second interpretation of this case relates this consumer-friendly attitude to the other grand theme in the case law of the ECJ on products liability: the numerous cases where the Court enforces the maximally harmonizing character of the EPLD to the detriment of consumers. In this second interpretation, *Sanofi Pasteur* can be considered an indication that consumer protection and maximal harmonization do not always conflict in this area of law.

#### **4. The Burden of Proof in Products Liability Law**

##### **4.1. *Where Do We Come from? Antecedents to the Judgment of 21 June 2017***

10 It is a truism that the distribution of the burden of proof is as important as the substantive conditions of liability. The distribution of the burden of proof arms the parties in the dispute. This holds even more for products liability, today as much as in the past. From the moment industrial mass-production of widgets took off, judges and lawmakers have always felt pressure to reduce the information asymmetry between victim and producer.<sup>17</sup> In a first possible interpretation, the ruling of the ECJ deals exactly with this concern. It demarcates the freedom of Member States to regulate proof in products liability law. More specifically, the ECJ approves the rule adopted by the French *Cour de cassation* that the plaintiff is allowed to offer serious, specific and consistent presumptions as a proof of defect and causal link in cases of liability of pharmaceutical companies for the vaccines they manufacture.

11 In the early days of products liability,<sup>18</sup> its recognition as a cause of action distinct from negligence law and contractual warranties revolved around reducing the proof requirements for the plaintiff.<sup>19</sup> In the years prior to the EPLD the then EEC Member States had already devised doctrinal ways to reduce the burden of proof of the victim of a product-related accident. The basic rule of Belgian negligence law for instance is clear. The behaviour of the defendant has to be

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17 See for instance, in the US context, J. Traynor in his concurring opinion in Supreme Court of California 5 July 1944, *Escola v. Coca-Cola Bottling Co.*, 150 P. 2d 436: ‘The inference of negligence may be dispelled by an affirmative showing of proper care. If the evidence against the fact inferred is clear, positive, uncontradicted, and of such a nature that it cannot rationally be disbelieved, the court must instruct the jury that the nonexistence of the fact has been established as a matter of law’. [...] An injured person, however, is not ordinarily in a position to refute such evidence or identify the cause of the defect, for he can hardly be familiar with the manufacturing process as the manufacturer himself is.’

18 For a general overview of the history of products liability law in the European context, see S. WHITTAKER, in *The Development of Product Liability*, pp 1-50.

19 For a summary of relevant causes of actions, see C. HODGES, *Product Liability*, pp 3-8.



measured against the standard behaviour of a hypothetical reasonable person in the same circumstances.<sup>20</sup> However, several courts have already considered *per se* wrongful the sale of a defective good or of a dangerous good without further requirements of proof.<sup>21</sup> On the European level, the lawmakers adopted the consumer expectations test of Article 6 EPLD in order to avoid that victims would have to prove negligence of the producer.<sup>22</sup> We see the same pattern in the US,<sup>23</sup> where courts at first applied the doctrine of *res ipsa loquitur* to infer negligence of the producer. This happened for instance in the famous *Escola v. Coca-Cola Bottling Co.* case, where a waitress was injured by an exploding Coca-Cola bottle.<sup>24</sup> In the same case concurring Traynor, J. advocated a strict liability test ‘when an article that [a manufacturer] has placed on the market, knowing that it is to be used without inspection, proves to have a defect that causes injury to human beings’. In 1963 the same Traynor, J. firmly established the principle of strict liability of the manufacturer in *Greenman v. Yuba Power Products, Inc.*<sup>25</sup>

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- 20 M. KRUIHOF, ‘Tort Law’ in M. Kruithof & W. De Bondt (eds.), *Introduction to Belgian Law* (Alphen aan den Rijn: Wolters Kluwer International B.V. 2017), pp (249-250) at 243; P. VAN OMMESLAGHE, *Les Obligations – Volume II, Sources des Obligations* (Brussel: Bruylant 2013), p 1220.
- 21 Sale of a defective good = wrongful: *Hof van Beroep* (court of appeals) Brussel 16 June 1951, *RGAR* 1951, nr. 4.833; *Hof van Beroep* (court of appeals) Brussel 27 November 1963, *JT (Journal des Tribunaux)* 1964, pp 74-75; *Hof van Beroep* (court of appeals) Gent 13 May 1988, *TBBR (Tijdschrift voor Belgisch Burgerlijk Recht)* 1990, pp 219-224, note K. BYTTEBIER & P. DEBRUYNE; *Rechtbank van Koophandel* (commercial court) Ieper 24 June 2002, *RW (Rechtskundig Weekblad)* 2005-2006, pp 1229-1232 (in this case, no fault was deemed proven, however). Sale of a dangerous good = wrongful: *Hof van Cassatie* (Court of cassation) 12 December 1958, *Arr. Cass. (Arresten van het Hof van Cassatie)*, pp 326-328; *Hof van Beroep* (court of appeals) Brussels 9 Februari 1955, *JT* 1955, p 683; *Hof van Beroep* (court of appeals) Brussel 21 April 1955, *JT* 1956, p 163; *Hof van Beroep* (court of appeals) Brussel 12 November 1973, *RGAR* 1973, nr. 9.177; *Hof van Beroep* (court of appeals) Liège 7 November 2005, *TBBR* 2006, pp 620-624, note E. MONTÉRO; *Rechtbank van Koophandel* (commercial court) Hasselt 16 maart 2004, *RW* 2006-2007, pp 107-110. A recent case goes against this trend: Politie rechtbank (Police Tribunal) Antwerpen 22 maart 2016, *RW* 2016-2017, pp 115-116.
- 22 D. FAIRCRIEVE et al., in *European Product Liability – An Analysis of the State of the Art in the Era of New Technologies*, p (17) at 73 (quoting the Commission); C. VAN DAM, *European Tort Law-Second Edition* (Oxford: Oxford University Press 2013), p 298; C. HODGES, *Product Liability*, p 5.
- 23 See for a more elaborate account of this history J. HENDERSON, A. TWERSKI & D. KYSAR, *Products Liability – Problems and Process – Eighth Edition* (New York: Wolters Kluwer 2016), pp 3-16.
- 24 Supreme Court of California 5 July 1944, *Escola v. Coca-Cola Bottling Co.*, 150 P.2d 436.
- 25 Supreme Court of California 24 January 1963, *Greenman v. Yuba Power Products, Inc.*, 377 P.2d 897. With the Restatement, Third of Torts (Products Liability) this has changed, because it introduced as a rule a *risk-utility* balancing for design and warning defects, which is to a large extent the reasonableness test from negligence law (Restatement of the Law, Third, Products Liability, § 2, comment a). I will not address this issue here.

12 Turning the focus to the EPLD, its drafters considered ‘*actori incumbit probatio*’ (the burden of proof rests with the plaintiff) a basic principle of civil procedure of the Member States. However, in the decades leading up to the directive several legal impediments for the plaintiff had been consistently removed. Against this background, the European legislature wanted to re-emphasize the basic rule and decided to include Article 4 in the EPLD.<sup>26</sup> It provides that ‘the injured person shall be required to prove damage, the defect and causal relationship between defect and damage’. Other elements, such as the questions which evidence was to be admitted before national courts, the probative value of those pieces of evidence, etc. were to fall under the competence of the national legal system.<sup>27</sup>

Contrary to what Article 4 might seem to suggest, the plaintiff does not carry the burden of proof with regard to all the logical conditions for liability. For a few substantive conditions of liability, the burden of proof is already reversed by the EPLD in Article 7. It is up to the defendant to disprove that he put the product ‘into circulation’,<sup>28</sup> that the defect existed at the time he put the product into circulation and that the defective product was manufactured with an economic purpose or in the course of the producer’s business.

13 The directive did not end the discussion about the burden of proof. Both scholars<sup>29</sup> and lobbyists kept on debating the issue. The opposing lobbies are very well represented in the Commission’s quinquennial reports on the EPLD.<sup>30</sup>

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26 H. TASCHNER, *Produkthaftung*, pp 59-60.

27 H. TASCHNER, *Produkthaftung*, p 61.

28 This term does not carry the same meaning in all articles. The meaning in Art. 7 (grounds for exoneration) is different from its meaning in Art. 11 (on prescription). See ECJ 10 May 2001, ECLI:EU:C:2001:258, *Henning Vedfeld v. Århus Amtskommune*, curia.europa.eu/juris/documents.jsf?num=C-203-99 (on Art. 7) and ECJ 9 February 2006, ECLI:EU:C:2006:93, *Declan O’Byrne v. Sanofi Pasteur MSD Ltd & Sanofi Pasteur SA*, curia.europa.eu/juris/documents.jsf?num=C-127/04 (on Art. 11).

29 See from old to recent: H. TASCHNER, *Produkthaftung*, p 60 (defending the choice of the European legislature from the very beginning); C. HODGES, *Product Liability*, pp 66-70 (pointing to the problem and stating that the directive clearly solved it); G. HOWELLS, ‘Product Liability - A History of Harmonization’, in D. Fairgrieve (ed.), *Product Liability in Comparative Perspective* (Cambridge: Cambridge University Press 2005), p 215 (worrying that UK case law about evidence might ‘tak[e] us back to the dark days of negligence and the evidential difficulties that strict liability was intended to address’); D. FAIRGRIEVE, G. HOWELLS & M. PILGERSTORFER, ‘The Product Liability Directive: Time to Get Soft?’, *JETL (Journal of European Tort law)* 2013, pp (8-9) at 1 (pointing at the uncertainties); D. VERHOEVEN, *Productveiligheid en Productaansprakelijkheid* (doctoral dissertation University of Antwerp, to be published at Intersentia), p 189 (claiming that there are enough mechanisms already included in the directive that alleviate the burden of proof).

30 See from old to recent: Commission of the European Communities, *Report on the Application of Directive 85/374 on Liability for Defective Products*, 31 January 2001, COM(2000) 893 final (Second Report), eur-lex.europa.eu/legal-content/EN/TXT/?qid=1505138151112&uri=CELEX:52000DC0893, pp 13-16;

The consumer lobby noted the difficulties of proving defect and causation in cases involving highly technical products, particularly in the pharmaceutical sector. The manufacturing lobby submitted that lowering the burden of proof would lead to a high number of unwarranted claims and would reduce the number of cases that are effectively ruled on the merits.

In recent years<sup>31</sup> evidentiary questions have reached the ECJ on several occasions.<sup>32</sup> In fact, the judgment of 21 June 2017 is the third in a row. Strikingly, all cases involved medical products. As already indicated, the medical sector is what consumer organizations have always been most concerned about. Its particularity is also the reason why Article 13 EPLD allows for a special liability regime to co-exist with the general regime of the directive notwithstanding its maximally harmonizing character.<sup>33</sup>

14 In *Novo Nordisk Pharma*<sup>34</sup> the plaintiff based her claim on such a special liability regime, *i.e.*, the special liability regime for pharmaceuticals in Germany. After the directive came into force, a change in the regime reduced the need to prove an actual causal link between the defect and the damage and introduced a right of the victim to obtain information about the medicine from the pharmaceutical company. The question submitted to the Court was whether this amendment was consistent with the maximally harmonizing character of the directive. The ECJ considered that the right to obtain information – which was at stake in this specific dispute – falls outside of the scope of harmonization. Moreover, it does not reverse

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Commission of the European Communities, *Report on the application of Council Directive on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products (85/374/EEC) of 25 July 1985, amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999*, 14 September 2006, COM(2006) 496 final (Third Report), eur-lex.europa.eu/legal-content/EN/TXT/?qid=1505138151112&uri=CELEX:52006DC0496, p 9 (A strange passage follows, in which the commission discusses the reversal of the burden to prove ‘fault’ in several European jurisdictions); European Commission, *Report on the application of 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 amended by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999*, 8 September 2011, COM(2011) 574 final (Fourth Report), eur-lex.europa.eu/legal-content/EN/TXT/?qid=1505138151112&uri=CELEX:52011DC0547, p 7.

31 An early case involved the so-called ‘development risk defense’, which is also related to the burden of proof, but does not touch upon it directly: ECJ 29 May 1997, ECLI:EU:C:1997:255, *Commission v. United Kingdom*, curia.europa.eu/juris/documents.jsf?num=C-300/95.

32 ECJ 20 November 2014, ECLI:EU:C:2014:2385, *Novo Nordisk Pharma GmbH v. S.*, curia.europa.eu/juris/documents.jsf?num=C-310/13; ECJ 5 March 2015, ECLI:EU:C:2015:148, *Boston Scientific Medizintechnik GmbH v. AOK Sachsen-Anhalt — Die Gesundheitskasse (C-503/13) & Betriebskrankenkasse RWE (C-504/13)*, curia.europa.eu/juris/documents.jsf?num=C-503/13; ECJ 21 June 2017, curia.europa.eu/juris/documents.jsf?num=C-621/15.

33 EPLD, 13th recital.

34 ECJ 20 November 2014, curia.europa.eu/juris/documents.jsf?num=C-310/13.

the burden of proof; it only ‘eliminate[s] the significant imbalance’ between consumer and producer (paras. 22–33).

It is unclear why the ECJ felt any pressure to address the question on a right to information in general. After all, it had already indicated that it fell outside of the scope of the directive. Moreover, the right to information that was at stake here only applied to the special liability regime, falling outside of the scope of the directive by definition. Most likely, the ECJ wished to point out that such rules reducing information asymmetry did not necessarily recalibrate the ‘fair apportionment of the risk between the injured person and the producer’.<sup>35</sup>

15 In *Boston Scientific Medizintechnik*,<sup>36</sup> the producer of already implanted pacemakers and cardio defibrillators had advised its treating physicians to replace or alter them because a specific part of the devices could disintegrate prematurely or present dysfunctions. While it offered replacements free of charge, the manufacturer did not reimburse the medical expenses related to the surgery. The insurance companies tried to recover those expenses based on the EPLD. The legal problem they faced was that they could not prove that the specific device implanted in the bodies of their patients had been defective. They could only prove that it belonged to the affected group of devices.

In a very consumer-friendly judgment, the ECJ ruled that ‘where it is found that such products belonging to the same group or forming part of the same production series have a *potential defect*, it is possible to classify as defective all the products in that group or series, without there being any need to show that the product in question is defective (para. 41)’. This ruling makes it considerably easier for plaintiffs to prove that the product they suffered an accident from was defective. Apparently, the Court considers it sufficient that a product is *potentially* defective, because it belongs to a group of products some of which have been shown to be defective.

The personal injury and related costs caused by the replacement surgery can qualify as ‘damage’ (para. 55) caused by this defect if the national courts consider ‘the surgery necessary to overcome the defect in the product in question’. Even though the questions related to the concepts of ‘defect’ and ‘damage’, the scope of the judgment goes beyond these notions. The Court does not only lower the burden to prove a defect, but also partially removes the – analytically necessary – condition of proving causation. To win a products liability case, a plaintiff would in theory not only have to prove that the product – as a type – was likely to cause damage (the defect/general causation), but also that this specific – token – product with an individualized token defect caused the specific damage the plaintiff sustained.<sup>37</sup> The ECJ removed this evidentiary hurdle in *Boston Scientific Medizintechnik*

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35 EPLD, 7th recital.

36 ECJ 5 March 2015, curia.europa.eu/juris/documents.jsf?num=C-503/13.

37 On a recent application and account of the distinction between general and specific causation in a products liability context, see A. TWERSKI & J. HENDERSON, ‘Fixing Failure to Warn’, 90. *Ind. L.J. (Indiana Law Journal)* 2015, p (237) at 241. Advocate General Bobek also briefly touches upon

because apparently a potential defect qualifies as an actual defect under the directive. It is unclear whether this mode of reasoning can be applied outside of the specific context of the case and whether it applies to other types of damage than replacement surgery.<sup>38</sup> In any case, the judgment definitely testifies of the willingness of the ECJ to cater to the interests of consumers.

#### 4.2. *What Does the Judgment of 21 June 2017 Add?*

16 Where does this leave us? What does the judgment of 21 June 2017 add to this controversy? On a quick look, *Sanofi Pasteur* limits the freedom of Member States to regulate evidence law in products liability cases. A Member State cannot allow proof based on presumptions that reverse the burden of proof or are automatic, in that they do not allow the national court to assess all the evidence before it. Moreover, a Member State cannot require scientific evidence. The judgment focuses on what a Member State *cannot*, leaving ample room to regulate the other aspects of evidence. Reminiscent of the goal mentioned in the 7th recital to the directive, *i.e.*, to achieve a ‘fair apportionment of risk between the injured person and the producer’, *Sanofi Pasteur* also conveys the impression of moderation. There are not only limits to what Member States can do to favour consumers (reversing the burden of proof; automatic presumptions), but also to favour producers (demanding scientific evidence). What about the prohibition of reversing the burden of proof? This was the principle from the very beginning and it confirms the ECJ’s previous judgment in *Novo Nordisk Pharma*.

Underneath this veil of impartiality, however, the ECJ has made a clear policy decision in favour of consumer-victims. The *Sanofi Pasteur* case ratifies national rules that considerably reduce the burden of proof of the plaintiff in a products liability case with regard to pharmaceutical products, and maybe in general. As we have seen, there has been long-lasting strife about the burden of proof between the consumer and producer lobby. This judgment, read together with *Novo Nordisk Pharma* and *Boston Scientific Medizintechnik* is the third in a row catering to consumers’ interests on this vital aspect of products liability law.

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the issue in his opinion in the *Sanofi Pasteur* case (Opinion of Advocate General Bobek, curia.europa.eu/juris/documents.jsf?num=C-621/15, para. 46).

38 ‘With regard to medical devices such as the pacemakers and implantable cardioverter defibrillators at issue in the main proceedings, it is clear that, in the light of their function and the particularly vulnerable situation of patients using such devices, the safety requirements for those devices which such patients are entitled to expect are particularly high.’ (ECJ 5 March 2015, curia.europa.eu/juris/documents.jsf?num=C-503/13, para. 39). See also B. VAN LEEUWEN & P. VERBRUGGEN, ‘Resuscitating EU Product Liability Law? Contemplating the Effects of Boston Scientific Medizintechnik GmbH v. AOK Sachsen-Anhalt and Betriebskrankenkasse RWE (Joined Cases C-503/13 and C/504/13)’, *ERPL (European Review of Private Law)* 2015, pp (908-910) at 899 and L. BERGKAMP, ‘Is There a Defect in the European Court’s Defect Test? Musings About Acceptable Risk’, *EJRR (European Journal of Risk Regulation)* 2015, pp (317-318) at 309.

It seems that the ECJ is becoming more and more sympathetic towards the demands of the consumer lobby.

17 This is even more apparent if we consider how the ECJ rephrased the first question of the *Cour de cassation* in paragraph 18 of the judgment. Recall that the question, as cited in the English version of the judgment, goes as follows:

‘[Does Art. 4 EPLD] preclude, in the area of liability of pharmaceutical laboratories for the vaccines that they manufacture, a method of proof by which the court ruling on the merits, in the exercise of its exclusive jurisdiction to appraise the facts, may consider that the facts relied on by the applicant constitute serious, specific and consistent presumptions capable of proving the defect in the vaccine and the existence of a causal relationship between it and the disease, *notwithstanding the finding that medical research does not establish a relationship between the vaccine and the occurrence of the disease* [emphasis added]?’

In paragraph 18 of its judgment, the ECJ recasts the question as:

‘whether Article 4 of Directive 85/374 must be interpreted as precluding national evidentiary rules such as those at issue in the main proceedings under which, when a court ruling on the merits of an action involving the liability of the producer of a vaccine due to an alleged defect in that vaccine, in the exercise of its exclusive jurisdiction to appraise the facts, may consider that, *notwithstanding the finding that medical research neither establishes nor rules out* the existence of a link between the administering of the vaccine and the occurrence of the victim’s disease, certain factual evidence relied on by the applicant constitutes serious, specific and consistent evidence enabling it to conclude that there is a defect in the vaccine and that there is a causal link between that defect and that disease [emphasis added]?’

Did scientific consensus on M.S. suddenly shift between 12 November 2015 and 21 June 2017?

The way the Court reformulates the question is telling of its desire to rule for the consumer. The evidence Mr W. and his family advanced appears to have been quite weak: the short time-span between the vaccination and the first symptoms of M.S. on the one hand and the lack of family members that had also contracted the disease on the other. Within the contours of the legal dispute, moreover, the plaintiffs were lucky that the French *Cour de cassation* had adopted such a low standard of evidence. Science spoke against them,<sup>39</sup> but according to

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39 Only the description of the case by the ECJ itself is relevant for its interpretation. The answer of the medical science is not. In the Court’s own description, science spoke for the defendants.



paragraph 13 of the judgment, the case law was very clear that these two elements could theoretically suffice as proof of defect and causal link in this context. It would not have been unreasonable to consider this rule a *de facto* reversal of the burden of proof. The ECJ decided to disregard this meagre proof. Instead, it modelled its limits to the freedom to regulate proof upon the French rule – a rule it wanted to approve of. The slight change in the question only added credibility to this ratification.

18 A possible critique of this claim could be that pharmaceutical products warrant a different treatment because of their (bio)chemical nature and because of the difficulties of proving causation once consumed. There have been advocates of a lower burden of proof for pharmaceutical products from the very inception of the directive. Article 13 was especially included in the EPLD because the European legislature did not want to hamper liability regimes addressing these issues. *Novo Nordisk Pharma*, *Boston Scientific Medizintechnik* and *Sanofi Pasteur* are just sketching the contours of a yet-to-be elaborated special products liability regime for drugs.

On the other hand, pharmaceutical companies would be eager to note that these special characteristics of pharmaceutical products lead to the opposite conclusion. Medicines are often ‘unavoidably unsafe’, in that their specific composition cures and prevents diseases while simultaneously causing side effects.<sup>40</sup> They are also highly regulated and subject to administrative approval.<sup>41</sup> Why should they be held liable if something goes wrong, when most people benefit from their products? Within the category of pharmaceutical products, vaccines are even more specific.<sup>42</sup> Some staunch defenders of products liability willingly concede that the risks of vaccines are better dealt with outside of products liability.<sup>43</sup>

Against this background, the judgment of the ECJ in *Sanofi Pasteur* is undeniably a choice to favour the consumer.<sup>44</sup>

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40 T. BALTHAZAR & S. VAN HECKE, ‘Productenaansprakelijkheid voor gebrekkige geneesmiddelen: de invloed van de informatie in de bijsluiter op de aansprakelijkheid van de geneesmiddelenproducent’, in S. Callens, P. Bogaert, J. Ter Heerdt, F. Gossenlinckx, L. De Bruyckere, G. Straetmans, T. Balthazar, S. Van Hecke & J. Vandeuren (eds), *Het geneesmiddel, juridisch bekeken* (Gent: Mys & Breesch 1998), p (209) at 211.

41 European Commission, *Third Report*, p 11.

42 R. POSNER, *Economic Analysis of Law – Ninth Edition* (New York: Wolters Kluwer Law & Business 2014), p 211, fn. 7.

43 J. GOLDBERG & B. ZIPURSKY, ‘The Easy Case for Products Liability Law: A Response to Professors Polinsky and Shavell’, 123. *Harv. L.R. (Harvard Law Review)* 2010, pp (1932–1933) at 1919.

44 This trend has also been noted by Verdure (C. VERDURE, ‘Arrêt “Boston Scientific Medizintechnik”: l’appréciation du “défaut” dans le cadre de la directive relative aux produits défectueux’, *JDE (Journal de droit européen)* 2015, p (242) at 243.

## 5. Consumer Protection and Full Harmonization

19 This leaves us with a conundrum. In the past, the ECJ has repeatedly emphasized that the EPLD aims at complete harmonization of laws, and that Member States are not allowed to maintain a higher standard of consumer protection that infringes upon this complete harmonization:

‘As regards the [...] argument that that interpretation of the Directive [which exempts suppliers of liability] is liable to lower the level of consumer protection in Denmark, it must be stated that any extension to suppliers of the liability established by the Directive falls within the competence of the Community legislature, for whom it is to amend, if appropriate, the provisions concerned’.<sup>45</sup>

After all the EPLD is a ‘result of complex balancing of different interests, [which include] guaranteeing that competition will not be distorted, facilitating trade within the common market, consumer protection and ensuring sound administration of justice’.<sup>46</sup> The legal basis for the directive is the former Article 100 EEC, now Article 115 TFEU, which is a legal basis to develop the internal market, not to protect the consumer.<sup>47</sup> Did the ECJ just make a U-turn in *Sanofi Pasteur*? Has it become schizophrenic? In this part of the article, I reconstruct the existing case law of the ECJ on products liability in order to clarify that maximal harmonization and consumer protection are not completely at odds with each other under the EPLD.

20 The goal of the EPLD is contested in European scholarship on products liability. Did it aim at levelling the playing field, at consumer protection, or both?<sup>48</sup> In addition, it is often thought that internal market rationales and consumer protection conflict in this part of the law. Scholars have recently maintained that the directive was meant to address the increasing frequency of accidents with pharmaceuticals and food products, but that the legal basis of the directive – internal market – determines its interpretation.<sup>49</sup> Others point out that most Member States already had in place an adequate but doctrinally very diverse array

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45 ECJ 10 January 2006, ECLI:EU:C:2006:6, *Skov Æg v. Bilka Lavprisvarehus A/S and Bilka Lavprisvarehus A/S v. Jette Mikkelsen & Michael Due Nielsen*, curia.europa.eu/juris/documents.jsf?num=C-402/03, para. 44.

46 ECJ 25 April 2002, curia.europa.eu/juris/documents.jsf?num=C-52/00, para. 29.

47 S. WHITTAKER, in *The Development of Product Liability*, pp (24–28) at 1.

48 Verhoeven suggests it aims at both: D. VERHOEVEN, *Productveiligheid en Productaansprakelijkheid*, p 32.

49 P. MACHNIKOWSKI, ‘Conclusions’, in P. Machnikowski (ed.), *European Product Liability – An Analysis of the State of the Art in the Era of New Technologies* (Cambridge: Intersentia 2016), pp (680–681) at 669; see also D. FAIRGRIEVE et al., in *European Product Liability – An Analysis of the State of the Art in the Era of New Technologies*, p (17) at 26.

of liability provisions to deal with accidents caused by defective products. The goal of the directive was not to install such a regime – that would have been superfluous – but to get rid of this diversity.<sup>50</sup> Still others seem to take it for granted that the EPLD has to be interpreted as aiming at increased consumer protection,<sup>51</sup> while at the same time conceding that it is maximally harmonizing.<sup>52</sup>

21 This confusion is not unjustified. Substantively, the directive propagates strict liability. What else could be the point to strict products liability and the corollary reduction of the burden of proof than protecting victims of product-related accidents? As a legal instrument, however, the directive aims at levelling the playing field. Several parts of the directive suggest that the main motivation behind the legislative action of the Union was to foster free movement of goods by imposing a uniform liability regime. Arguments can be found in the legal basis of the directive (Art. 100 EEC), its preamble,<sup>53</sup> and the directive itself. The ‘consumer’ is not mentioned once in the directive’s substantive provisions, that always mention the more neutral ‘injured person’.<sup>54</sup> Moreover, as it stands, the ECJ has emphasized on several occasions that the directive is maximally harmonizing within its scope, and has sanctioned quite a few Member States that endeavoured to increase consumer protection by infringing upon that maximally harmonizing character.<sup>55</sup> In every instance it enforces full harmonization, the ECJ effectively limits the rights of

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- 50 M. KRUTHOF, ‘Wie is aansprakelijk voor schade veroorzaakt door onveilige producten? De toepassing van de artikelen 1382, 1384, lid 1 en 1645 BW herbekeken in het licht van het – door het Hof van Justitie sterk beperkte – aanvullend karakter voorzien in artikel 13 Wet Productaansprakelijkheid’, in I. Claeys & R. Steennot (eds.), *XLe Postuniversitaire Cyclus Willy Delva 2013-14 – Aansprakelijkheid, kwaliteit en veiligheid van producten, diensten en bouwwerken* (Mechelen: Kluwer 2015), p (143) at 211.
- 51 H. MICKLITZ, in *European Consumer Law*, p (239) at 243: ‘in an internal market the compensatory interests of the consumer arising from the damage incurred by defective products cannot be left to the free interplay of market forces’.
- 52 H. MICKLITZ, in *European Consumer Law*, p (239) at 267. See also D. VERHOEVEN, *Productveiligheid en Productaansprakelijkheid*, pp 250-256.
- 53 More in particular the 1st recital (‘distortion of competition’ and ‘differing degree of protection of the consumer’ are reasons for the harmonization), 10th recital (‘uniform period of limitation’), 16th recital (a stand-still period is deemed appropriate in case a Member State wants to abolish the development risk defence), 17th recital (cap on liability has to be high enough with a view to ‘the correct functioning of the common market’), 18th recital (possible ‘greater harmonization’ in the future).
- 54 Although consumer protection its mentioned in Art. 15, para. 3 EPLD and 16, para. 2 EPLD.
- 55 ECJ 25 April 2002, curia.europa.eu/juris/documents.jsf?num=C-183/00; ECJ 25 April 2002, curia.europa.eu/juris/documents.jsf?num=C-52/00; ECJ 25 April 2002, curia.europa.eu/juris/documents.jsf?num=C-154/00; ECJ 10 January 2006, curia.europa.eu/juris/documents.jsf?num=C-402/03; ECJ 9 February 2006, curia.europa.eu/juris/documents.jsf?num=C-127/04; ECJ 5 July 2007, curia.europa.eu/juris/documents.jsf?num=C-327/05; ECJ 2 December 2009, curia.europa.eu/juris/documents.jsf?num=C-358/08.

consumers in those countries – which it willingly concedes.<sup>56</sup> This case law explains the ensuing debate on the goal of the directive.

22 Be that as it may, the EPLD only maximally harmonizes products liability within its scope. This scope can be determined by reading together several judgments of the ECJ. I will not go into great detail here. Other authors have conducted this analysis at greater length elsewhere.<sup>57</sup> Based on their analysis, it seems fair to assume that the directive regulates claims for compensation of death, personal injury or damage to consumer goods as defined by Article 9 EPLD, caused by defects as defined by Article 6 EPLD in products as defined by Article 2 EPLD. Liable under the EPLD are the participants in the chain of production and marketing, under the conditions of Article 3 EPLD.

For our purposes the case *Moteurs Leroy Somer* is key. A generator in a hospital caught fire because of a defective alternator. The maintenance company compensated the hospital and subsequently brought a claim against *Moteurs Leroy Somer*, the alternator's manufacturer. No other damage occurred than damage to professional goods, but the cause of action the plaintiffs invoked was similar to that of the EPLD because it was enough to prove damage, defect and causation. Was this compatible with the maximally harmonizing character of the directive? The ECJ reasoned that 'it is apparent both from the wording and from the structure of Directive 85/374, and in particular from Article 1, Article 9 and the ninth recital in the preamble [...], that compensation for damage to an item of property intended for professional use and employed for that purpose is not one of the matters regulated by that directive'.<sup>58</sup>

In other words, the directive does not regulate all possible accidents with defective products, but only accidents that lead to death, personal injury or damage to consumer goods. It is only concerned with private interests, which I refer to as interests of consumers.<sup>59</sup>

23 Once we know that the directive focuses on the relationship between producers and consumers, the next question that comes to mind is how the interests of consumers and producers are weighed against each other within this predetermined

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56 ECJ 25 April 2002, curia.europa.eu/juris/documents.jsf?num=C-183/00: 'the rights conferred under the legislation of a Member State on the victims of damage caused by a defective product under a general system of liability having the same basis as that put in place by the Directive may be limited or restricted as a result of the Directive's transposition into the domestic law of that State'.

57 See D. FAIRGRIEVE et al., in *European Product Liability – An Analysis of the State of the Art in the Era of New Technologies*, pp 331-339 at 17; M. KRUTHOF, in *XLe Postuniversitaire Cyclus Willy Delva 2013-14 – Aansprakelijkheid, kwaliteit en veiligheid van producten, diensten en bouwwerken*, pp 143-224.

58 ECJ 4 June 2009, curia.europa.eu/juris/documents.jsf?num=C-285/08, para. 27.

59 See fn. 4.

scope. The preamble suggests that many of the provisions of the EPLD are designed to benefit the consumer. Internal market goals are mentioned in the first recital, but in the second recital it immediately follows that ‘liability without fault’ is ‘the *sole means* of adequately solving the *problem*, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production [emphasis added]’. Of course, the term ‘fairness’ is only begging the question, but in the following recitals we clearly see that more often than not what benefits the consumer is considered ‘fair’.<sup>60</sup>

Also pointing in this direction is the prohibition of exoneration clauses in the relationship between producer and consumer (Art. 12 EPLD) – and only in this relationship. The relevance of such provisions is generally quite limited in a tort context, because plaintiff and defendant typically only get in touch with each other after the accident. In products liability a prohibition of exoneration clauses is of greater importance because the opportunities of plaintiff and defendant to enter into a transaction before an accident are more extensive. This is why Article 12 EPLD can be interpreted as a clear decision against the market.<sup>61</sup> Even if both parties were in the – be it rare – position to freely agree upon a more efficient allocation of the risks related to the product, they are not allowed to. In the realm of products liability law, the European legislature has willed that the producer compensate the consumer, even if this goes against both parties’ *ex ante* interests.

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60 Provisions said to be in favour of the consumer: the 4th and 5th recital claim that the protection of the consumer requires that it can hold many actors jointly and severally liable. The 6th recital surmises that a safety-centred consumer expectations test is the best way to ‘protect the physical well-being and property of the consumer’. The 8th recital urges that consumer protection requires that the fact that the damage is caused by a defect and a third person not reduce the liability of the producer. In the 9th recital it is said that the definition of damage is based on the requirement to protect the consumer; compensation of non-material damage is not regulated, but explicitly mentioned as not excluded by the directive. The 10th recital even mentions the uniform period of limitation as being in the interest of consumers. In recital 12, the same motivation is said to justify the prohibition of exoneration clauses – but only in relation to the injured person (so not among professionals). The 16th recital explains that the development risk defence can be excluded if a Member State wants to offer more protection to the consumer. The 17th recital maintains that every cap on liability has to be sufficiently high in order to ensure ‘adequate protection of the consumer’. **In favour of the producer:** exclusion of liability in case of ‘misuse of the product not reasonable under the circumstances’ (6th recital); exonerating circumstances as implied in the same ‘fair apportionment of risks’ (7th recital) (however, I believe it is fair to say that these exceptions only confirm the rule); contributory or comparative negligence of the consumers as another ground for exemption (8th recital); the deductible/threshold of 500 EUR (9th recital); the period of limitation (10th and 11th recital).

61 See for arguments G. CALABRESI, *The Costs of Accidents* (New Haven: Yale University Press 1970), pp 52 and 136.

24 The same choice in favour of the consumer can be perceived at several occasions in the case law of the ECJ as well. As long as some interpretation of the directive does not transgress the borders set by the maximally harmonizing directive, the ECJ generally takes a consumer friendly stance. *Sanofi Pasteur* is a good example, taking into account the historical importance of the debate on the burden of proof in products liability law. Moreover, in paragraph 31 of the judgment, the Court seems to suggest that liability of the producer is the goal of the directive. In *Boston Scientific Medizintechnik*, the ECJ applies the consumer expectations test in a somewhat ambivalent fashion. It has been noted by others before that the Court first refers to the reasonable expectations of the public at large in paragraph 37, and then goes on to say that ‘safety requirements for those devices which *such patients* are entitled to expect are particularly high [emphasis added]’ in paragraph 39.<sup>62</sup> The latter test is also applied in *Sanofi Pasteur* (para. 41). This is inconsistent, but telling. One of the problems with the consumer expectations test is to determine whose expectations matter exactly.<sup>63</sup> A professional user might have more realistic expectations concerning the product’s safety than an uninformed bystander. The Court in *Boston Scientific Medizintechnik* benchmarks the safety level against the particular expectations of the patients. This automatically warrants a higher safety level than if the expectations of members of the general public not yet struck by a heart deficiency had been taken into account. In *Veedvald*<sup>64</sup> and *Declan O’Byrne*,<sup>65</sup> the Court has ruled that the grounds for exemption in Article 7 EPLD have to be interpreted strictly because the principle is that the producer should be held liable once a defect has caused the plaintiff’s damage.

The willingness of the ECJ to protect the consumer is even noticeable in cases about harmonization – as long as it falls outside of the scope of the EPLD. As discussed above, the Court in *Novo Nordisk Pharma* gladly approves of measures that reduce the information asymmetry between consumer and producer in cases involving pharmaceuticals. In *CHU Besançon*,<sup>66</sup> the ECJ allows liability schemes in which a service provider that uses a defective product without having manufactured it is held liable under conditions similar to those of the EPLD. The Court even adds that ‘since any no-fault liability on the part of service providers is thus, at the very most, additional to producer liability as deriving from Directive 85/374, it can [...] contribute to enhancing consumer protection’ (para. 35).

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62 L. BERGKAMP, *EJRR* 2015, p (309) at 311.

63 C. HODGES, *Product Liability*, p 96.

64 ECJ 10 May 2001, curia.europa.eu/juris/documents.jsf?num=C-203-99.

65 ECJ 9 February 2006, curia.europa.eu/juris/documents.jsf?num=C-127/04.

66 ECJ 21 December 2011, curia.europa.eu/juris/documents.jsf?num=C-495/10.



25 Of course, the image drawn above is not all-inclusive. In the cases about harmonization the Court has held, for instance, that the rights of victims in Spain may be restricted as a result of the transposition of the EPLD.<sup>67</sup> Moreover, the ECJ prohibits not imposing the € 500 threshold/deductible for damage to consumer goods,<sup>68</sup> prohibits the liability of the supplier beyond the cases provided in Article 3 EPLD,<sup>69</sup> and prohibits more stringent conditions for exemption than those Article 7 EPLD provides<sup>70</sup> – in all these cases enforcing provisions of the EPLD that prejudice the interests of the consumer. In *Aventis Pasteur v. O’Byrne*<sup>71</sup> the Court has considered that the limitation period is fair towards the producer because ‘that liability represents, for the producer, a greater burden than under a traditional system of liability, [and that the limitation period is meant] not to restrict technical progress and to maintain the possibility of insuring against risks connected with that specific liability’ (para. 42).<sup>72</sup>

## 6. Conclusion

26 This teaches us an important lesson. The question whether the directive aims at consumer protection can be answered at different levels of abstraction. On the one hand one could ask whether the directive as a whole is meant as a consumer protection device. The answer to this first question is negative or mixed at most. In line with the legal basis of the directive (former Art. 100 EEC, current Art. 115 TFEU), the ECJ has always pressed the point that the EPLD, taken as a whole, is fully harmonizing within its scope – even to the detriment of consumers. Within this perimeter set by the ECJ, however, the directive undeniably counts as a consumer protection device. This is manifested in the overall equilibrium struck by the directive and in the way the ECJ interprets the directive within the boundaries of the full harmonization – or rules about what falls outside the directive’s scope.

The subcategory of consumers that is protected by the directive and the case law of the ECJ are the consumer-victims. It is almost inevitable that increased

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67 ECJ 25 April 2002, curia.europa.eu/juris/documents.jsf?num=C-183/00.

68 ECJ 25 April 2002, curia.europa.eu/juris/documents.jsf?num=C-52/00; ECJ 25 April 2002, curia.europa.eu/juris/documents.jsf?num=C-154/00.

69 ECJ 25 April 2002, curia.europa.eu/juris/documents.jsf?num=C-52/00; ECJ 10 January 2006, curia.europa.eu/juris/documents.jsf?num=C-402/03; ECJ 14 March 2006, curia.europa.eu/juris/documents.jsf?num=C-177/04; ECJ 5 July 2007 curia.europa.eu/juris/documents.jsf?num=C-327/05.

70 ECJ 25 April 2002, curia.europa.eu/juris/documents.jsf?num=C-52/00.

71 ECJ 2 December 2009, curia.europa.eu/juris/documents.jsf?num=C-358/08.

72 This case does not end as badly for O’Byrne as this quote might suggest. Beginning from para. 50 of the judgment, the ECJ offers some guidance to the national courts to avoid the conclusion that the limitation has been reached and to grant compensation to O’Byrne after all.

liability of manufacturers following the decrease in the burden of proof will lead to higher prices.<sup>73</sup> In other words, the trend in the case law of the ECJ benefits consumer-victims at the detriment of consumers as a class that suffer from increased prices. This is a reasonable policy decision and is undeniably where the case law of the ECJ is heading. Whether it is justified, remains to be seen.

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73 The risk of inefficient price increase is one of the critiques of products liability, as formulated in A. POLINSKY & S. SHAVELL, 'The Uneasy Case for Product Liability', 123. *Harv. L. R.* 2010, p (1437) at 1472.