McGill Law Journal
Revue de droit de McGill

Portrait of Development Risk as a Young Defence

Marie-Ève Arbour

Volume 59, Number 4, June 2014

Technological Innovation and Civil Responsibility
L'innovation technologique et la responsabilité civile

URI: https://id.erudit.org/iderudit/1026133ar
DOI: https://doi.org/10.7202/1026133ar

See table of contents

Publisher(s)

McGill Law Journal / Revue de droit de McGill

ISSN

0024-9041 (print)
1920-6356 (digital)

Explore this journal

Cite this article

Arbour, M.-È. (2014). Portrait of Development Risk as a Young Defence. *McGill Law Journal / Revue de droit de McGill*, *59*(4), 913–942. https://doi.org/10.7202/1026133ar

Article abstract

Since its (recent) insertion into the vocabulary of jurists, development risk has piqued the curiosity of experts in defective products liability. An investigation into development risk's scope and reach, however, requires a comparative analysis that brings out the issues it raises and the ambiguities it has occasioned. In this light, this article draws support from abundant doctrine, and, perhaps paradoxically, scant jurisprudence on the subject, in an effort to sketch, in broad strokes, a contemporary portrait of development risk.

McGill Law Journal — Revue de droit de McGill

PORTRAIT OF DEVELOPMENT RISK AS A YOUNG DEFENCE

*Marie-Ève Arbour**

Since its (recent) insertion into the vocabulary of jurists, development risk has piqued the curiosity of experts in defective products liability. An investigation into development risk's scope and reach, however, requires a comparative analysis that brings out the issues it raises and the ambiguities it has occasioned. In this light, this article draws support from abundant doctrine, and, perhaps paradoxically, scant jurisprudence on the subject, in an effort to sketch, in broad strokes, a contemporary portrait of development risk.

Depuis son insertion (récente) dans la langue des juristes, le risque de développement suscite la curiosité des experts de la responsabilité du fait des produits défectueux. Pourtant, une reconstruction de sa portée et de son étendue ne semble pouvoir s'effectuer qu'au prix d'une analyse comparative destinée à mettre en relief les enjeux qu'il soulève et les ambiguïtés qu'il fait naître. Dans cette optique, la présente contribution prend appui sur l'abondante doctrine à son sujet, et, peut-être paradoxalement, la rare jurisprudence l'ayant abordé, afin d'esquisser, à grands traits, un portrait contemporain du risque de développement.

* Professor of civil law, Laval University (Québec). I am particularly thankful to Lara Khoury and Etienne Vergès for their outstanding endeavour and to my peer reviewers for their thorough and helpful comments. I would also like to acknowledge the stimulating hospitality I encountered amidst the books and shelves of the Institute of Advanced Legal Studies (University of London) and the European University Institute (Florence). This article builds upon ideas expressed by the author in "Itinéraire du risque de développement à travers des codes et des constitutions" in Benoît Moore, ed, *Mélanges: Jean-Louis Baudouin* (Cowansville, Que: Yvon Blais, 2012) 677 and "Rischi da sviluppo" in Elio Sgreccia & Antonio Tarantino, eds, *Enciclopedia di Bioetica e Scienza giuridica* (Naples: Edizioni Scientifiche Italiane) [in press]. Only in occasion of proofreading was I capable of referring to Richard Goldberg's outstanding monograph *Medicinal Product Liability and Regulation* (Oxford: Hart, 2013) (especially Chapter 8, "The Development Risk Defence and Medicinal Products"). The overall relevancy of this piece is therefore largely underestimated.

Citation: (2014) 59:4 McGill LJ 913 — Référence : (2014) 59 : 4 RD McGill 913

Introduction 915

I. The Territories of the Development Risk Defence 917
A. Supranational Moulds and Pathways 917
B. Of National Clones, Mutants, and Hybrids 924

II. Knowledge or Uncertainty? The Methodology Maze 927
A. The Domain of Knowledge: Existing Data and Accessibility 927
B. The "Whom" Question 929
C. "Enabling", Discovery, and Business Ethics 930
D. Eppur si muove *... (Thou Shall Dissent)* 936

Conclusion 940

Introduction

It is no secret to anyone familiar with tort law that product liability has become an extensive, globally recognized area of private law.[1] The same can be said of the (in)famous development risk defence (DRD),[2] which precludes product liability whenever "the inherent risk of a defective product [is] undiscoverable at the time of supply by a manufacturer."[3] Fuelled by the desire to enhance the "long-term social good"[4], the DRD is said to foster innovation by shielding industries from liability stemming from defective products born of research and development (R&D) in cases where the risk was not discoverable in light of accessible scientific knowledge at the time the product was put onto the market.[5] Conceptually distinct from the state-of-the-art defence[6] (which speaks the language of negligence),[7] the extension of such immunity from liability to producers

---

1 See Mathias Reimann, "Liability for Defective Products at the Beginning of the Twenty-First Century: Emergence of a Worldwide Standard?" (2003) 51:4 Am J Comp L 751; Marie-Eve Arbour, *Fragments de droit québécois et canadien* (Cowansville, Que: Yvon Blais, 2012) at 238.

2 Albeit relevant in the world of common law, this concept does not properly fit in the civilian tradition, where "defences" are unknown and are instead embedded in the dialectic of "fault" and its variations. I nonetheless refer to the DRD as a defence because it is a legal transplant that intervenes *after* a defect has been established, and as such this appears to be the least confusing approach.

3 Richard Goldberg, *Causation and Risk in the Law of Torts: Scientific Evidence and Medicinal Product Liability* (Oxford: Hart, 1999) at 224 [Goldberg, *Causation and Risk*]. See also Richard Goldberg, "The Development Risk Defence and Medicinal Products" in *Medicinal Product Liability and Regulation* (Oxford: Hart, 2013) 168.

4 Jane Stapleton, *Product Liability* (London: Butterworth, 1994) at 225 [Stapleton, *Product Liability*].

5 The EU-style exoneration clause is defined in EC, *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*, [1985] OJ L 210/29, art 7(e) [*PL Directive*].

6 The defence emerged in the US at the dawn of the 1970s. Although the landmark case on this issue was *Beshada v Johns-Manville Products Corp* (447 A (2d) 539, 90 NJ 191 (1982)), a stream of cases had already set the stage for it to be considered by courts. See e.g. *Suter v San Angelo Foundry & Machine*, 406 A (2d) 140, 81 NJ 150 (1979) (observing that "the state of the art refers not only to the common practice and standards in the industry but also to other design alternatives within practical and technological limits at the time of distribution" at 151 [cited to A (2d)]).

7 Although similar in effect, the state-of-the-art defence is linked to the subjective *foreseeability* of risk by the producers, while the DRD revolves around objectively evaluated *knowledge*. As such, the EU-style defence relates more to the type of risk than to the producer's behaviour. See Stapleton, *Product Liability*, *supra* note 4 at 225. The DRD therefore shifts away from the economic dimension embedded within the state-of-the-art defence, as "total lack of experience makes it impossible to foresee such risks and to make estimates regarding the probability of accidents" (Göran Skogh, "Development

amounts to a state in which victims of this type of defective product are, at best, dependent on other legal categories and causes of action in order to obtain compensation (contractual warranty, *vice caché*, negligence, *faute*, *culpa*, dangerous activity, etc.) or, at worst, left to themselves in a situation perhaps reminiscent of the pre-industrial *caveat emptor* paradigm fiercely criticized by PL scholars.[8] Despised and glorified, adopted and rejected, transplanted, transposed, and altered, much has been said—mostly in Europe[9] but also in Quebec[10]—about this immunity from liability that polarizes commentators along a left-right divide.

Risks, Strict Liability, and the Insurability of Industrial Hazards" (1998) 23:87 The Geneva Papers on Risk and Insurance 247 at 248).

8 The economic analysis of law (EAL) has greatly contributed to the idea that personal injury damages must be borne by the enterprises responsible for putting the product on the market. See e.g. Guido Calabresi, "Some Thoughts on Risk Distribution and the Law of Torts" (1961) 70:4 Yale LJ 499 ("[n]ot charging an enterprise with a cost which arises from it leads to an understatement of the true cost of producing its goods; the result is that people purchase more of those goods than they would want if their true cost were reflected in price" at 514).

9 In the civilian world, see Pascal Oudot, *Le risque de développement: Contribution au maintien du droit à réparation* (Dijon: Éditions Universitaires de Dijon, 2005); Michel Cannarsa, *La responsabilité du fait des produits défectueux* (Milan: Giuffrè, 2005); Yvan Markovits, *La directive C.E.E. du 25 juillet sur la responsabilité du fait des produits défectueux* (Paris: Librairie générale de droit et de jurisprudence, 1990) at para 226ff; Jean-Sébastien Borghetti, *La responsabilité du fait des produits* (Paris: Librairie générale de droit et de jurisprudence, 2004) at 397ff; Agnese Querci, "Il rischio da sviluppo: Origini ed evoluzioni nella moderna 'società del rischio'" [Development Risk: Origins and Evolutions in Modern 'Risk Society'] (2012) *Danno e responsabilità* (Special Issue: I 25 anni di *products liability*) 31; Pablo Salvador Coderch & Antoni Rubí Puig, "Riesgos del desarrollo y demarcación judicial de la buena ciencia" [Development Risks and Judicial Delimitation of Good Science] (UC Berkeley: Berkeley Program in Law and Economics, Latin American and Caribbean Law and Economics Association (ALACDE) Annual Papers, 2008). In the common law tradition, see Mark Mildred, "The Development Risks Defence" in Duncan Fairgrieve, ed, *Product Liability in Comparative Perspective* (New York: Cambridge University Press, 2005) 167; Christopher Hodges, "Development Risks: Unanswered Questions" (1998) 61:4 Mod L Rev 560; Simon Whittaker, *Liability for Products: English Law, French Law, and European Harmonization* (Oxford: Oxford University Press, 2005); Stapleton, *Product Liability*, *supra* note 4. In comparative law, see Cees van Dam, *European Tort Law* (Oxford: Oxford University Press, 2006) at art 1410.

10 See Nathalie Vézina, "L'exonération fondée sur l'état des connaissances scientifiques et techniques, dite du 'risque de développement': Regard sur un élément perturbateur dans le droit québécois de la responsabilité du fait des produits" in Pierre-Claude Lafond, ed, *Mélanges Claude Masse: En quête de justice et d'équité* (Cowansville, Que: Yvon Blais, 2003) 433. *C.f.* Pierre-Gabriel Jobin & Michelle Cumyn, *La vente*, 3d ed (Cowansville, Que: Yvon Blais, 2007) at 296–300; Claude Masse, "La responsabilité civile (Droit des Obligations III)" in Barreau du Québec & Chambre des notaires du Québec, *La réforme du Code civil*, t 2 (Québec: Les Presses de l'Université Laval, 1993) 241 at 301ff.

Beyond the civil law and common law divide, the exemption clause crystallizes the link between some conceptions of justice and our contemporary economy, as it suggests that too much liability chills innovation. Its features have been extensively documented, to the point that the aim of the present contribution may appear methodologically modest, as it merely seeks to provide a comparative overview of recent developments regarding the DRD, driven by expanding case law on the issue.[11] In which legal systems is the DRD to be found? A classical, horizontal comparative exercise (beyond mainstream EU/USA corresponding endeavours) allows us to map properly the territories it occupies after testifying of its projection, through vertical comparison, at the supranational level (Part I). Despite widespread adoption of the DRD, interpretations vary respecting its elements, including knowledge and its counterpart, uncertainty, which are at the very core of the defence (Part II). A comparative legal analysis provides the ability to highlight methodological and ethical concerns and ambiguity present in the DRD, while raising the delicate practice of melding law and science within the courtroom, which has long stimulated debate among evidence and causation experts.[12] Ultimately, indeed, the DRD's boundaries are set by the judiciary, although "the courtroom is not the place for scientific guesswork, even of the inspired sort," as Justice Posner once warned.[13]

I. The Territories of the Development Risk Defence

As product liability spread to many of the industrial world's legal systems, the DRD, too, marked both national and international levels. Transported by circulating policy reasons and, possibly, path dependencies, the model spread rapidly beginning in the 1960s. Intertwining legal roots make it difficult to determine whether it originated in national laws (Section B) or supranational endeavours (Section A). The following section is, therefore, merely intended to offer greater clarity.

A. Supranational Moulds and Pathways

The 1960s were characterized by the spread of product liability maximodels throughout the industrialized world, including those established

---

[11] See also Geraint Howells, "Product Liability" in Jan M Smits, ed, *Elgar Encyclopedia of Comparative Law* (Cheltenham, UK: Edward Elgar, 2006) 578 at 583.

[12] The defence might be useful in furthering scientific knowledge and testing. See John Murphy & Christian Witting, *Street on Torts*, 13th ed (Oxford: Oxford University Press, 2012) ("self-interest impels manufacturers to disclose all reports of tests on a product as well as the expert opinion made available to them" at 433).

[13] *Rosen v Ciba-Geigy Corp*, 78 F (3d) 316 at 319, 64 USLW 2612 (7th Cir 1996).

in the *Vienna Convention on Civil Liability for Nuclear Damage* (1963);[14] the *European Convention on Products Liability in regard to Personal Injury and Death* (1977), adopted under the auspices of the European Council;[15] and the later, famous European Union *PL Directive*. In light of the general principles of monism and dualism that structure the law of treaties, some models are mandatory, while others are persuasive guidelines that emerge from academic or technocratic experiences (e.g., the *Principles of European Tort Law* (*PETL*)[16] or the Uniform Law Conference of Canada[17]); finally, some are of a hybrid nature, such as the *American Restatement of Torts (Second)*[18] and *(Third)*[19], as they may, through time, penetrate states' legislation or case law. This last model has largely forged a field of law of its own.

In 1965, section 402A, entitled "Special Liability of Seller of Product for Physical Harm to User or Consumer," gave birth to this new field known as product liability. Under this section, any professional vendor who sells a product in a defective condition unreasonably dangerous to its user or consumer is held liable even if he has "exercised all possible care in the preparation and sale of his product."[20] This rule is also applied in civil law jurisdictions, *mutatis mutandis*, through either an extension of the contractual sphere to third parties, special consumer laws, or both

---

14 *Vienna Convention on Civil Liability for Nuclear Damage*, 21 May 1963, 1063 UNTS 265, 2 ILM 727 (entered into force 12 November 1977). See also *Convention on Third Party Liability in the Field of Nuclear Energy of 29th July 1960, as amended by the Additional Protocol of 28th January 1964 and by the Protocol of 16th November 1982*, 29 July 1960, 956 UNTS 251 (entered into force 1 April 1968); *Protocol to Amend the Vienna Convention on Civil Liability for Nuclear Damage*, 29 September 1997, 36 ILM 1454; *Convention on Supplementary Compensation for Nuclear Damage*, 29 September 1997, 36 ILM 1473.

15 *European Convention on Products Liability in regard to Personal Injury and Death*, 27 January 1977, Eur TS 91.

16 See e.g. The European Group on Tort Law, *European Principles on Tort Law* (New York: SpringerWienNewYork, 2005). See generally Miquel Martín Casals, "Una panoramica sui '*Principles on European Tort Law*' (dalla prospettiva spagnola)" [An Overview of *Principles on European Tort Law* (From the Spanish Perspective)] (2005) 70:6 Responsabilità civile e previdenza 1277.

17 See e.g. *Uniform Product Liability Act* adopted by the Uniform Law Conference of Canada, online: Uniform Law Conference of Canada <www.ulcc.ca>. A product is defined as defective "if it falls short of the standard that may reasonably be expected of it in all the circumstances" (*ibid*, s 3(1)).

18 *Restatement (Second) of Torts* § 402(A) (1965) [*Restatement (Second)*].

19 *Restatement (Third) of Torts: Products Liability* (1997) [*Restatement (Third)*]. See also David Owen, "Products Liability Law Restated" (1998) 49:2 SCL Rev 273; Jane Stapleton, "Restatement (Third) of Torts: Products Liability, an Anglo-Australian Perspective" (2000) 39:3 Washburn LJ 363 at 373–74.

20 *Restatement (Second)*, *supra* note 18 at 348.

(whereas common law product liability stems from an extension of the duty of care in tort law, applying *Donoghue v. Stevenson*[21]). The general rule in section 402A was tempered by an exception, which was added to the *Restatement (Second)* as a reporter's comment—comment k—that explicitly addressed dangerous products.[22] This famous comment recognized that the market might include "some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use."[23] American Law Institute reporters were then undoubtedly particularly concerned with drugs and vaccines, as 1965 also marked the infamous thalidomide scandal.[24] After laying the foundation for proper risk-benefit analysis, the comment goes on to state that "[s]uch a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous."[25] In this context, the comment argued that because "there [was] no assurance of safety," economic actors should not be held liable for "unfortunate consequences."[26] The model has been widely adopted in US case law and remains good law in many American states. The economic wind changed from sociodemocratic ideas to neoliberal ones, however, and the time came to update the rule, which had been designed, quite ironically, the same year John F. Kennedy asserted that "[c]onsumers, by definition, include us all."[27] In 1997, a new version, although criticized by some commentators, was proposed by ALI members. Section 2, comment d, of the *Restatement (Third)* provides instead that

> [t]he term "state of the art" has been variously defined to mean that the *product design conforms to industry custom, that it reflects the safest and most advanced technology developed and in commercial use, or that it reflects technology at the cutting edge* of scientific knowledge.[28]

Prima facie, this new rule bears little resemblance to its predecessor. Not only does it apply exclusively to *certain products* (drugs and medical

---

21 *Donoghue v Stevenson*, [1932] AC 562 HL (Scot), [1932] All ER Rep 1 (which removed privity of contract as an obstacle to recovery).

22 *Restatement (Second)*, *supra* note 18 at 353.

23 *Ibid*.

24 Nonetheless, the shift toward strict liability is a more complex confluence of events. See Michael D Green, *Bendectin and Birth Defects: The Challenges of Mass Toxic Substances Litigation* (Philadelphia: University of Pennsylvania Press, 1996) at 8–13.

25 *Restatement (Second)*, *supra* note 18 at 353–54 [emphasis in the original].

26 *Ibid* at 354.

27 John F Kennedy, Address (Special Message to the Congress on Protecting the Consumer Interest, delivered 15 March 1962), online: The American Presidency Project <www.presidency.ucsb.edu/ws/?pid=9108>.

28 *Restatement (Third)*, *supra* note 19 [emphasis added].

devices), it also crystallizes the learned intermediary doctrine[29] while it states that

> [a] prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic *benefits, would not prescribe the drug or medical device for any class of patients*.[30]

Simply stated, neoliberal conceptions of the economy suggest that such a drug shall not be prescribed by any doctor (and should not, to begin with, ever be on the market).

The European Economic Community had earlier adopted the *PL Directive*, which defined product defect based on consumer expectations. It provides that a "product is defective when it *does not provide the safety which a person is entitled to expect*."[31] It draws partly on the American experience, and article 7(e) states that a producer will not be liable if "the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered."[32] Commenting on the *PL Directive* in a European Court of Justice (ECJ) case, Advocate General Tesauro stated that

> the Council opted for a system of strict liability which was no longer absolute, but limited, in deference to a principle of the fair apportionment of risk between the injured person and the producer, the latter having to bear only quantifiable risks, but not development risks which are, by their nature, unquantifiable.[33]

Bolstered by the Thatcherism then in vogue, the DRD had success in Brussels and other world capitals as well as academic endeavours.[34] The

---

29 Concisely, the American-born doctrine states that "manufacturers of prescription drugs have a duty to warn prescribing physicians of the drugs' known dangerous propensities, and the physicians, in turn, using their medical judgment, have a duty to convey the warnings to their patients" (*Kirk v Michael Reese Hospital and Medical Center*, 513 NE 2d 387 at 392, 117 Ill 2d 507 (Sup Ct 1987)). See also *Leesley v West*, 518 NE 2d 758, 165 Ill App 3d 135 (App Ct 1988); *Laws v Johnson*, 799 SW 2d 249 (Tenn App Ct 1990); *Reyes v Wyeth Laboratories*, 498 F 2d 1264 (5th Cir 1974). For a Canadian illustration, see *Buchan v Ortho Pharmaceutical (Canada) Ltd* (1986), 25 DLR (4th) 658, 54 OR (2d) 92 (Ont CA) [*Buchan (CA)* cited to OR]; *Hollis v Dow Corning Corp*, [1995] 4 SCR 634 at paras 28–29, 129 DLR (4th) 609.

30 *Restatement (Third)*, *supra* note 19 at § 6(c) [emphasis added].

31 *PL Directive*, *supra* note 5, art 6.1 [emphasis added].

32 *Ibid*.

33 *Commission v UK*, C-300/95, [1997] ECR I-2651 at I-2658, Tesauro AG.

34 Among them is the Restatement of a single man: see Gert Brüggemeier, *Modernising Civil Liability Law in Europe, China, Brazil and Russia* (Cambridge: Cambridge Uni-

"culturally neutral" language of economic sciences unsurprisingly bloomed and flourished throughout the field of product liability, justifying just about any of the forms it took, be they closer to negligence-based models or risk-distribution anchored rationales.

Although in both the EU and the US harmonization of the DRD remains optional,[35] a fundamental difference exists between the two legal systems: the rule is merely persuasive authority in the latter but becomes truly normative in the former whenever a member state avails itself of the option to adopt the DRD.[36] The EU-style DRD harmonization process requires further explanation. The integration of the DRD in the *PL Directive* was so controversial that the European Council was politically forced in 1985 to leave member states a discretionary margin to either adopt or reject certain features of the directive including the DRD. For example, article 15(1)(b) provides that

> by way of derogation [each member state may] maintain or provide in [its] legislation that the producer shall be liable *even if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of a defect to be discovered*.[37]

This discretionary freedom does not, however, allow member states to alter the wording of the DRD as they see fit, as the degree of harmonization

---

versity Press, 2011) at 86 art 3:204, who proposes the following exclusion cause of liability: "A producer *is particularly not liable* where he can prove that the product's defect, at the point when it was marketed, did not exist or that the defect *was not recognisable* through the current state of science and technology at this point" [emphasis added]. The adverb "particularly" and the adjective "recognisable" reflect the novelty of Brüggemeier's reflection.

35 For a historical account, see Lori M Linger, "The Products Liability Directive: A Mandatory Development Risks Defense" (1991) 14 Fordham Int'l LJ 478.

36 At first sight, the ECJ's interpretation may appear confusing, as total harmonization is the goal of *regulations* rather than *directives*.

37 The compromise is described as follows: "Whereas ... the [DRD] may be felt in certain Member States to restrict unduly the protection of the consumer; whereas it should therefore be possible for a Member State to maintain in its legislation or to provide by new legislation that this exonerating circumstance is not admitted" (*PL Directive*, *supra* note 5 at 30). According to Van den Bergh and Visscher, "[t]he goal to create a level playing field for industry seems to be in contradiction with the essence of international trade itself. *Exploiting differences in legal systems may be objected on distributional grounds, but it is not necessarily in conflict with the goal of allocative efficiency*" (Roger Van den Bergh & Louis Visscher, "The Principles of European Tort Law: The Right Path to Harmonisation?" (2006) 8 German Working Papers in Law and Economics 1 at 4 [emphasis added]).

sought is quite total given the *sui generis*, federal-inspired structure that now characterizes the EU.[38]

The EU learned its lesson after France subordinated the application of the DRD to a post-market duty of safety (*obligation de sécurité*).[39] The ECJ came to the conclusion that the wording of this national measure departed from the harmonized provision in article 7(e).[40] To summarize, the ECJ held[41] that the EU Council unanimity procedure that underlies "market-driven directives"[42] erected upon article 100 of the (former) *Treaty Establishing the European Economic Community*[43] (among them, the *PL Directive*), is incompatible with a bottom-up, minimum approach, because they seek to eliminate legal divergences that "may distort competi-

---

38 For a deeper analysis of the constitutional dimensions of liability rules, see Marie-Eve Arbour, "Sécurité des produits, santé des consommateurs, responsabilités et constitutions: Synergies comparées" (2013) 7:2 McGill JL & Health 169 at 191ff [Arbour, "Sécurité des produits"].

39 "The producer cannot invoke the grounds of exemption from liability [such as the DRD] if ... he has failed to take appropriate measures to avert the harmful consequences thereof" (art 1386–12(2) C civ, modified by *Loi No 2004-1343 du 9 décembre 2004*, JO, 10 December 2004, art 29 [translated by author]).

40 See *Commission v France*, C-52/00, [2002] ECR I-3856 at I-3874.

41 See *ibid* at I-3865–69.

42 The first recital of the *PL Directive* states:

> Whereas approximation of the laws of the Member States concerning the liability of the producer for damage caused by the defectiveness of his products is necessary because *the existing divergences may distort competition and affect the movement of goods within the common market and entail a differing degree of protection* of the consumer against damage caused by a defective product to his health or property (*supra* note 5 [emphasis added]).

As Howells rightly points out, "[p]roduct liability does not directly impose barriers to trade as it makes no specific requirement of products other than they are not defective. Thus the justification must rest upon the distortion of competition ground" (Geraint Howells, "Product Liability: A History of Harmonisation" in Fairgrieve, *supra* note 9, 202 at 203). The rationale laying down the DRD is even more unsatisfactory, as it suggests that "*a fair apportionment of risk between the injured person and the producer* implies that the producer should be able to free himself from liability if he furnishes proof as to the existence of certain exonerating circumstances" (*PL Directive*, *supra* note 5, 7th recital [emphasis added]). I have expressed doubts as to the relevancy of this assumption: "Sur le terrain de l'empirisme ... l'établissement d'un rapport de cause à effet entre la sévérité des normes de responsabilité civile et la vivacité de la recherche et du développement est étayée de preuves contradictoires. Et il n'est pas certain que la tâche qui consiste à établir cette corrélation échoit aux juristes" (Marie-Eve Arbour, "Itinéraire du risque de développement à travers des codes et des constitutions" in Benoît Moore, ed, *Mélanges: Jean-Louis Baudouin* (Cowansville, Que: Yvon Blais, 2012) 677 at 684 [Arbour, "Itinéraire du risque").

43 25 March 1957, Eur TS 1 (Cmd 5179), amended by EC, *Treaty of Lisbon Amending the Treaty on European Union and the Treaty Establishing the European Economic Community*, [2007] OJ C 306/1.

tion and affect the movement of goods within the common market and entail a differing degree of protection of the consumer against damage caused by a defective product to his health or property."[44] Rather, the ECJ concluded that "the margin of discretion available to the Member States in order to make provision for product liability is entirely determined by the Directive itself and must be inferred from its wording, purpose and structure."[45] Hence, it held that the discrepancies in the provisions of French transposition laws were contrary to the spirit of the directive, and although France aimed to increase protection for victims,[46] this nonetheless violated EU law, as establishing a "level playing field"[47] was the rationale underlying the *PL Directive*.[48] Therefore, EU harmonization law holds that inclusion of the DRD in a national legal panorama is optional, but that whenever a member state chooses to do so, adherence to its spirit (and conditions) must be quite total although interpretative flexibility is a tool explicitly recognized by national courts. Disharmony in the law addressing tainted blood, for example,[49] may well be explained by the divergent approaches of the civil and common law to judicial discourse.[50] Nonetheless, the limits of such flexibility remain to be defined.

---

44 *PL Directive*, *supra* note 5 at 29.

45 *Commission v France*, *supra* note 40 at I-3867.

46 See Whittaker, *supra* note 9 at 450ff.

47 The paradigm is widely referred to in product liability scholarship: see e.g. van Dam, *supra* note 9 at art 1505; Van den Bergh & Visscher, *supra* note 37. Nonetheless, the various options left to member states rather seem to impede harmonization: see e.g. Stephen Weatherill, *EU Consumer Law and Policy* (Cheltenham, UK: Edward Elgar, 2005) at 184.

48 *PL Directive*, *supra* note 5, 1st recital.

49 See especially Geraint Howells & Mark Mildred, "Infected Blood: Defect and Discoverability: A First Exposition of the EC Product Liability Directive" (2002) 65:1 Mod L Rev 95; Shanti Williamson, "Compensation for Infected Blood Products: *A and others v National Blood Authority and Another*", online: (2003) 7:5 EJCL 5 <www.ejcl.org>. In France, see e.g. Yvonne Lambert-Faivre, "L'affaire du sang contaminé: Le risque de développement, le principe indemnitaire face à la pluralité d'actions et les limitations de garantis d'assurance responsabilité civile" (1996) D Jur 610. The relevant Italian law is based instead on a provision for dangerous activities (art 2050 *Codice civile*). See generally Umberto Izzo, *La precauzione nella responsabilità civile: Analisi di un concetto sul tema del danno da contagio per via trasfusionale* [Precaution in Civil Liability: Analysis of a Concept on the Theme of Damage from Infection by Transfusion] (Trent: Università degli Studi di Trento, 2007), online: UNITN <eprints.biblio.unitn.it>.

50 This idea was expressed in Geraint Howells, "Consumer Concepts for a European Code?" in Reiner Schulze, ed, *New Features in Contract Law* (Munich: Sellier European Law Publishers, 2007) 119 at 131.

B. Of National Clones, Mutants, and Hybrids

In a German case that addressed personal injury caused by an exploding glass bottle (the *Mineralwasserflasche* case),[51] for example, the *Bundesgerichtshof* held that the DRD does not apply to manufacturing defects, as

> [w]hen the EC Directive on product liability was being fashioned it was agreed that the defence under art. 7 (e) should apply not to manufacturing defects, but only to defects of design and construction ... and the only dangers emanating from a product which the German legislator wished to exempt from the scope of the Product Liability Law *were dangers, undetectable even with the exercise of all possible care, arising at the stage of design and construction.*[52]

The court observed that the company's bottle control system was inadequate despite that it may well have been "the best possible machinery."[53] In fact, the court held that increased quality control by visual inspection could contribute to preventing the harm caused by *ausreisser* (isolated defective goods in the production line) and therefore insisted that the defect is specific to the individual product.[54] The judgment ultimately ruled in favour of the plaintiffs, anchoring its conclusion on the general principle of defect-based liability.[55]

Other member states availed themselves of the *PL Directive*'s discretionary window (a compromise clearly designed to satisfy public opinion), thereby depicting dissimilar scenarios in light of the very nature of the in-

---

51 See Bundesgerichtshof (Sixth Civil Senate), 9 May 1995, (1995) NJW 2162, translated by Tony Weir, online: <www.iuscomp.org/gla/judgments/tgcm/z950509.htm> [*Mineralwasserflasche*].

52 *Ibid* at para 1 [emphasis added].

53 *Ibid* at para 2.

54 See *ibid*. The court's reasoning relies upon the technical explanation of the cause of the defect. Be it attributable to a hairline crack, the defence would apply as the risk was undiscoverable; be it a chipped area, conversely, it *was* discoverable and as such would not trigger the defence: see Mildred, *supra* note 9 at 171. However, the court further seems to merge these issues, as it indistinctively concludes that "[t]he evidence shows that the explosion which damaged the plaintiff w*as due either to a chip or to a hairline crack*, both of which are defects under 3 of the Product Liability Law" (*Mineralwasserflasche*, *supra* note 51 at para 2 [emphasis added]).

55 See *ibid*. At the time Justice Burton was deliberating on *A and others v National Blood Authority and another* ([2001] EWHC 446 (QB), [2001] 3 All ER 289 (QBD) [*A and others*]), he was well aware of the German *Mineralwasserflasche* case, and to some degree borrowed the narrow interpretation of the DRD that the *Bundesgerichtshof* had proposed. Using slightly different vocabulary, Justice Burton established a dichotomy between standard and non-standard products in order to distinguish those that are manufactured according to their specifications from others (i.e., "lemons" or defective products) to which the DRD does not apply (see *ibid* at para 36).

volved products. Because of these ad hoc responses to national—sometimes highly localized—consumer product crises (thalidomide, wine, oil, etc.), some products remain outside the DRD's field of application today, including medicines in Germany;[56] foodstuffs in Spain;[57] or, in France, blood products and body parts.[58] The result is an unappealing, compartmentalized structure within liability law, which has shrunk, expanded, twirled, and been eradicated to the rhythm of political and moral sentiments, often oblivious to a principle that should—in my opinion[59]—always guide compensation law: that of equal treatment among victims (*égalité horizontale*). Despite this anti-aesthetic configuration, the model has rapidly spread beyond the EU to many other countries, including Australia,[60] Switzerland,[61] and Japan.[62]

Quebec, on the other hand, has adopted a dual product liability architecture rooted in both the Civil Code of Quebec[63] and the *Consumer Protection Act*.[64] Article 1473 of the 1991 reform of the CCQ mimics the EU's DRD approach:

> The manufacturer, distributor or supplier of a movable property is not liable to reparation for injury caused by a safety defect in the property ... if he proves that, according to the state of knowledge at the time that he manufactured, distributed or supplied the property, *the existence of the defect could not have been known*, and *that he*

---

56 See *Gesetz über den Verkehr mit Arzneimitteln* [Medicinal Products Act (The Drug Law)], BGBl, 12 December 2005, 3394, s 84.

57 See *Real Decreto Legislativo, de 16 de noviembre, 1/2007 por el que se aprueba el texto refundido de la Ley General para la Defensa de los Consumidores y Usuarios y otras leyes complementarias*, BOE 287, 16 November 2007, 49181, art 140(3): "En el caso de medicamentos, alimentos o productos alimentarios destinados al consumo humano, los sujetos responsables ... no podrán invocar la causa de exoneración."

58 Art 1386-12 C civ.

59 I have argued elsewhere that the suppression of a right of action in some legal systems may even be unconstitutional. See Arbour, "Itinéraire du risque", *supra* note 42 at 682.

60 See *Australian Consumer Law*, s 142, being Schedule 2 to the *Competition and Consumer Act 2010* (Cth).

61 See Franz Werro, "La jurisprudence et le droit comparé: La réception des concepts juridiques étrangers" in Publications de l'Institut suisse de droit comparé, ed, *Perméabilité des ordres juridiques* (Zurich: Schulthess, 1992) 165 at 166ff.

62 See *Product Liability Act 1994* (Act No 85 of 1994, Japan), art 4; Hiroyuki Hirano, "La sécurité du consommateur au Japon" in l'Association Henri Capitant des amis de la culture juridique française, ed, *Le consommateur*, t 57 (Brussels, Paris; Bruylant, LB2V, 2007) 407 at 407; Luke Nottage, "Comparing Product Safety and Liability Law in Japan: From Minamata to Mad Cows—and Mitsubishi" in Fairgrieve, *supra* note 9, 334 at 335.

63 LRQ, c C-1991 [CCQ].

64 RSQ, c P-40.1 [CPA].

> *was not neglectful of his duty to provide information when he became aware of the defect.*[65]

Much uncertainty remains regarding the application of the defence,[66] and it is still unclear whether it applies to contractual liability.[67] The defence has clearly not been adopted in section 53 of Quebec's *Consumer Protection Act*, which allows victims to recover based on strict liability, as "[t]he merchant or the manufacturer shall not plead that he was unaware of the defect or lack of instructions."[68]

Finally, some states never seriously considered adopting the DRD (e.g., Finland and Luxembourg); others have been unenthusiastic about judge-made product liability schemes to begin with (such as most Canadian common law provinces,[69] which tend to opt for the state-of-the-art standard that is better suited to the catch-all tort of negligence[70]). Moreover and by reason of a constitutional interference (pre-emption[71]), American victims are prevented altogether from initiating actions based on fail-

---

65 Art 1473 CCQ [emphasis added].

66 See *ABB Inc v Domtar Inc*, 2007 SCC 50, [2007] 3 SCR 461. At least in Quebec, case-law seems to be reluctant to it, but see *Berthiaume c Val Royal Lasalle Ltée*, [1992] RJQ 76, JE 92-71. For a similar observation in France, see Borghetti, *supra* note 9 at 555–60.

67 See Vézina, *supra* note 10 at 453–54.

68 CPA, *supra* note 69, s 53, para 3. See Marie-Eve Arbour, "Garantie de qualité: Droit de la consommation" in Pierre-Claude Lafond & Gérald Goldstein, eds, *Contrats nommés I* (Montreal: LexisNexis, 2001) fasc 8. Similarly, the new *Civil Code of the People's Republic of China*, Book VIII: Law of Delict/Act on Liability Law (2009), is silent on the matter: see Brüggemeier, *supra* note 34 at 190.

69 See Denis W Boivin, "Strict Products Liability Revisited" (1995) 33:3 Osgoode Hall LJ 487; *Andersen v St Jude Medical Inc*, [2002] OTC 53, 111 ACWS (3d) 234 (Ont Sup Ct): "There is good reason to leave to the legislatures the decision on whether to impose strict liability on manufacturers, and whether that should be done in all industries" (Dambrot J at para 38).

70 See e.g. *Privest Properties Ltd v Foundation Co of Canada Ltd*, 128 DLR (4th) 577, 11 BCLR (3d) 1.

71 See e.g. *Cipollone v Liggett Group*, 505 US 504, 112 S Ct 2608 (1992); *Medtronic v Lohr*, 518 US 470 at 485, 116 S Ct 2240 (1996); *Geier v American Honda Motor Co*, 529 US 861, 120 S Ct 1913 (2000); *Altria Group, Inc v Good*, 555 US 70, 129 S Ct 538 (2008); *Riegel v Medtronic*, 552 US 312, 128 S Ct 999 (2008). See also Robert RM Verchick & Nina Mendelson, "Preemption and Theories of Federalism" in William W Buzbee, ed, *Preemption Choice: The Theory, Law, and Reality of Federalism's Core Question* (New York: Cambridge University Press, 2009) 13 at 15–19; Catherine M Sharkey, "Federalism in Action: FDA Regulatory Preemption in Pharmaceutical Cases in State Versus Federal Courts" (2007) 15:3 JL & Pol'y 1013; Peter H Schuck, "FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot" (2008) 13:1 Roger Williams U L Rev 73. For an account of the subject in French, see Arbour, "Sécurité des produits", *supra* note 38 at 178ff.

ure to warn (information defect) when it comes to certain products (e.g., medical devices and tobacco products).[72]

II. Knowledge or Uncertainty? The Methodology Maze

As already mentioned, the premise underlying the DRD is surprisingly simple. Overly broad liability chills innovation, threatens to make certain products entirely unavailable, and increases insurance premiums. To avoid these negative effects, the DRD aims to strike an acceptable compromise. It reintroduces the "knowledge variable" that is usually excluded by strict product liability schemes, which focus on *product defects*, evoking common law dialectics between foreseeable and unforeseeable, avoidable and unavoidable. Accordingly, producers of defective goods are legally excused if insufficient scientific knowledge was available at the time the product was commercialized. Recent product liability scholarship has distilled a two-prong DRD test out of the knowledge element and the discovery variables, which gives rise to a *sui generis*, EU-style product liability regime, distinct from the American approach.[73] Although helpful, this framework raises four difficult questions that will undoubtedly require judicial clarifications. First (Subsection A), how accessible must the knowledge be? Second (Subsection B), who must it be available to, and what criteria should be used to evaluate it? Third (Subsection C), how should the ethical questions be addressed that arise whenever producers of goods generate knowledge regarding the very products they put on the market? Finally (Subsection D), how should novel or marginal scientific opinions be evaluated?

A. The Domain of Knowledge: Existing Data and Accessibility

Although still scarce, recent comparative case law analysis has shed light on a possibility to avoid liability rooted in "scientific and technical" knowledge, and, by implication, the producer's capacity to avoid risks. Knowledge entails two conditions: that relevant data indeed exists, and that it be accessible to the producer. The least worrying concern is *accessibility*, which may now be moot due to the proliferation of online databases and search engines (e.g., open access services, Google Scholar, etc.) and the hegemony of the English language within academia and the scientific community. Accessibility refers to the potential to identify the results of technical and R&D studies. By 1997, a well-known ECJ case[74] had

---

[72] See *ibid*.

[73] See Lucas Bergkamp & Rod Hunter, "Product Liability Litigation in the US and Europe: Diverging Procedure and Damage Awards" (1996) 3 MJECL 399.

[74] See *Commission v UK*, *supra* note 33.

already provided valuable insight as to the reach of the DRD. The ECJ's case, coupled with Advocate General Tesauro's opinion, began to establish the parameters of the *knowledge* element embedded in the DRD.[75] Indeed, the former had set the table for establishing the parameters of the *knowledge* element of the DRD with the predictable, academic "Manchurian hypothesis": Does a tiny publication in the Mandarin language constitute accessible knowledge? Probably not. Is "knowledge" coterminous with peer-reviewed articles written in English? Probably not. Scientific and technical knowledge remains, reasonably enough, a factual question that is left to courts' discretion.

Existing data refers to scientific information surrounding a given risk, founded on sources such as trials or experiments whose results are exposed and discussed in scholarly publications. A wide interpretation of the text of article 7(e) suggests that producers ought to know every scientific result, in every relevant technical or scientific field, that could enable them to discover the defect. This heavy informational burden has been criticized by invoking a hypothetical "lucky" plaintiff who "turn[s] up information from a totally unexpected field"[76] which precludes the defendant from availing himself of the DRD.

At least in Germany, the impossibility of improving a product due to lack of scientific knowledge is no defence to liability when, though unavoidable, a risk is *known* to the producer. This conclusion was reached by the *Bundesgerichtshof* in a seminal German case[77] that held that the explosion of a glass bottle containing mineral water does not fall within the scope of the development risk exemption, as such risk *is* known to producers. The court seemingly shifted its focus away from the defect toward the risk of harm itself. Although there were no technical means available to prevent the (rare) occurrence of this risk, the court stuck to a narrow interpretation of the knowledge element and discarded the arguments the defendant had put forward to exclude himself from liability. These thoughts echoed in London when Justice Burton, apparently seduced by the Germanic argument, held in the context of contaminated blood litigation that

> [i]t would, in my judgment, be inconsistent with the purpose of the directive if a producer, in the case of a known risk, continues to supply products simply because, and despite the fact that, he is unable

---

75 See *ibid* at I-2659. See also *A and others*, *supra* note 55 at paras 47–49.

76 Christopher Newdick, "Risk, Uncertainty and 'Knowledge' in the Development Risk Defence" (1991) 20 Anglo-Am L Rev 309 at 310.

77 *Mineralwasserflasche*, *supra* note 51. More recently, see OLG Munich, 11 January 2011, (2011) Az 5 U 3158/10 (available on openJur). In a similar context in Belgium, see Civ Namur, 5e Ch, *Riboux v SA Schweppes Belgium* (21 November 1996).

> to identify in which if any of his products that defect will occur or recur.[78]

Seemingly, the boundaries of the DRD are interpreted narrowly, thereby confining the scope of an exoneration clause that seems at odds with the risk distribution rationale that underlies product liability.

B. The "Whom" Question

Another of the most critical issues was articulated by Newdick: "[T]o whom ought that information be available before it may be described as 'discoverable'?"[79] Is knowledge to be evaluated in light of subjective or objective criteria? The "whose knowledge?" question was at the core of *Commission v UK*.[80] In their transplant of the *PL Directive*, English legislators adopted a formulation of the supranational instrument that rejected key features of the DRD. In their place, the UK substituted an assessment of scientific knowledge from the standpoint of "a producer of products of the same description as the product in question"[81] (i.e., the producer's perspective). The UK provision uses the language of negligence: reference to classes of producers suggests reasonableness, objective standards, and other porous terms well known to common lawyers.[82] Despite this clear disparity in the wording of the provisions, the ECJ came to the conclusion that the action introduced by the Commission was premature, given that UK courts might still interpret the *PL Directive*'s section 7(e) national clone in conformity with EU law. According to Attorney General Tesauro, however, this knowledge standard is "not concerned with the practices and safety standards in use in the industrial sector in which the producer is operating."[83]

As a result of the above-mentioned criterion, knowledge needs to be apprehended in light of a twin notion: that of discoverability, which in turn leads to the labyrinth of causation.[84]

---

78 *A and others*, *supra* note 55 at para 74.

79 Newdick, *supra* note 76 at 310.

80 *Commission v UK*, *supra* note 33.

81 *Consumer Protection Act 1987* (UK), c 43, s 4(1)(e).

82 See Mildred, *supra* note 9 at 168.

83 *Commission v UK*, *supra* note 33 at I-2658.

84 Although highly relevant, much of the debate surrounding causation will be left aside here. For a thorough analysis, see Goldberg, *Causation and Risk*, *supra* note 3; Richard Goldberg, ed, *Perspectives on Causation* (Portland, Or: Hart, 2011); Lara Khoury, "Causation and Health in Medical, Environmental and Product Liability" (2007) 25:1 Windsor YB Access Just 135. See also Christophe Quézel-Ambrunaz, *Essai sur la causalité*

C. "Enabling", Discovery, and Business Ethics

Discoverability purports to establish the elusive link between knowledge and proof of a defect—the trail of breadcrumbs—allowing an inference that an improper R&D process caused the defect. While knowledge may be described as a bundle of objective information, discoverability refers to a manufacturer's intellectual capacity to assemble the pieces of the puzzle to "enable the existence of the defect to be discovered."[85] The key word is likely the verb "enable"—meaning permit[86]—which, despite lending itself to varying interpretations, clearly introduces a subjective element into the evaluation of the DRD. The question becomes whether, aside from dissenting or isolated opinions (discussed below), the knowledge available was such as to allow, scientifically speaking, the producer to discover the defect. Did he have the benefit of the interdisciplinary knowledge of a scientific, technical team[87] or rather consciously handpick from available information in a teleological fashion? In this context, evaluation of a producer's behaviour may discover a partial merging of the DRD and the state-of-the-art defence.

Evaluation of the safety of everyday products usually calls for knowledge of technical standards (e.g., ISO, CEN, DIN). Assessing products with significant R&D cycles often entails the difficult task of combining two or more data sources. Airplanes may today be faster, safer, and ever more comfortable due to advances in metal alloys, physics, thermal radiation, electronic devices, meteorological science, etc. Would all this knowledge preclude the DRD, say, in the context of the Air France flight 447 accident over Brazil? Was Airbus capable of anticipating the risk of data distortion due to the presence of ice crystals in its airspeed measurement device, despite the fact that "[t]he obstruction of the Pitot probes by ice crystals during cruise was a phenomenon that was *known but misunderstood* by the aviation community at the time of the accident"?[88] In the case of experimental products—excepting GMOs, drugs, and medical devices—there might be little, contradicting, or no knowledge at all. Of-

---

en droit de la responsabilité civile (Paris: Dalloz, 2010); other contributions in the instant volume.

85 *PL Directive*, *supra* note 5, art 7(e).

86 See *A and others*, *supra* note 55 at paras 51, 183.

87 See Oudot, *supra* note 9 at 40.

88 See Bureau d'Enquêtes et d'Analyses pour la sécurité de l'aviation civile (BEA), *Final Report on the accident on 1st June 2009 to the Airbus A330-203 registered F-GZCP operated by Air France flight AF 447 Rio de Janeiro–Paris* (July 2012), online: <http://www.bea.aero/docspa/2009/f-cp090601.en/pdf/f-cp090601.en.pdf> at 199 [emphasis added]. The causes of this tragedy were, however, even more complex, as human error also contributed.

ten, producers *generate their own knowledge* through the R&D they directly carry on or sponsor. They might know that a particular molecule cures a pathology, but remain unaware of its effects when combined with another. In such cases, does the "enabling" factor refer to the methodological capacity of the producer to gather sufficient knowledge (and if so, to what extent?), or is discoverability to be ascertained through existing knowledge stemming, say, from clinical trials? There is evidence of the discoverability loop in the thalidomide story, as the trials conducted on animals had failed to prove the drug's toxicity. Rats did not metabolize the drug, and it was assumed the same would be true for humans, but this was ultimately true of many tests in which extrapolation of animal to human response is impossible.[89] In such circumstances the producer did not have knowledge, and thus, the DRD appears to apply, leaving victims without compensation. An alternative approach is to suggest that the producer was in fact able to discover the defect, had it combined the result of these trials (knowledge) with proper human clinical trials (discoverability).

In other words, what are the effects of *traces* or partial knowledge on the discoverability variable? Barker et al. ask the right question:

> [W]hat if there is *some* evidence that the product may have been defective *but the causal connection has not been established according to the usual scientific methods* used to determine whether use of a product can cause a particular side effect (and hence be defective as not being as safe as persons generally are entitled to expect)?[90]

They add: "Can the [DRD] apply to a supply of the drug at the time the potential risk was discovered but before it had been established whether the risk was a real risk? It appears that it can."[91] Until now, case law has remained focused on knowledge, neglecting discoverability. Nonetheless, a Dutch case handed down in the sensitive context of contaminated blood concluded that the DRD applied in the following context.[92] The plaintiff contracted HIV during the famous window period in which detection is impossible (that is, the period between the moment of infection and the

---

89 See Carl F Cranor, *Toxic Torts: Science, Law, and the Possibility of Justice* (New York: Cambridge University Press, 2006) at 10.

90 Kit Barker et al, *The Law of Torts in Australia*, 5th ed (South Melbourne: Oxford University Press, 2012) at 654–55 [first emphasis in original, second emphasis added]. The authors provide a further example: "Initial testing on a drug, say, may reveal that it is possible that it could cause certain side effects but further testing is required to establish whether it does so" (*ibid* at 655).

91 *Ibid* at 655.

92 RB Amsterdam, 3 February 1999, *Scholten v The Foundation Sanquin of Blood Supply* (1999) NJ 1999 621. See also Goldberg, *Medicinal Product Liability and Regulation*, *supra* note 3 at 22–23.

actual development of HIV detectable antibodies); so that the risk, hence, was unavoidable. The court of first instance held that the blood supplier had acted in light of technological and scientific knowledge at the time of the transfusion. Was the defect discoverable with the help of proper research and development (and funding)? The court never really asked that question, as it rather relied on the consumer expectation test: "the general public is entitled to expect that blood products in the Netherlands have been 100% HIV-free for some time."[93] Moving away from the prevailing objective criteria that the landmark case *A and others* had advocated, the Dutch case, precisely through the door left open by the discoverability element, seems to reintroduce the possibility of American-inspired interpretations.

Discoverability gains further force when the producer is capable of setting its *own* development risk boundaries through corporate strategies. Bureaucracies do not repeat R&D already carried out in laboratories and universities. Once invited to release a market authorization, for example, national regulators (e.g., Health Canada) and supranational agencies (e.g., European Medicines Agency, the Food and Drug Administration) evaluate the methodology that underlies scientific knowledge. Technocrats analyze the exactitude of scientific correlations between variables to assess the risks and potential benefits. However, the formulation of hypotheses and even the very selection of appropriate variables, through protocols, are among the prerogatives of the researchers, who will decide—whenever economically feasible[94]—*what* will be studied[95] in order to meet the regulators' requirements. Ironically enough, it may not be in a producer's best interest to know too much—including pharmacogenomic effects[96]—as too much knowledge could lead to the exclusion of the DRD, and, consequently, expose producers to liability. A group of Australian au-

---

93 Daily Wuyts, "The Product Liability Directive: More Than Two Decades of Defective Products in Europe" (2014) 5:1 Journal of European Tort Law 1 at 9.

94 See Goldberg, *Causation and Risk*, *supra* note 3 at 230.

95 The producer is not alone in this task, as ethics committees and international standards exist to "help" carry out the research ethically. Nonetheless, the standards ("best practices") and approval processes have more to do with the research materials and subjects than the parameters. See e.g. US, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research (The Belmont Report)* (18 April 1979), now embedded in *Basic HHS Policy for Protection of Human Research Subjects*, 45 CFR §§ 46.101–46.124 (1991).

96 For an explanation of pharmacogenomics, see Richard Weinshilboum, "Inheritance and Drug Response" (2003) 348:6 New Eng J Med 529 (explaining that "[a]s our knowledge of genetic variations in proteins involved in the uptake, distribution, metabolism, and action of various drugs improves, our ability to test for that variation and, as a result, to select the best drug at the optimal dose for each patient should also increase" at 536).

thors accordingly note this "incentive for a defendant not to conduct the necessary further testing to establish the causal connection, although the failure to do so may well amount to common law negligence."[97]

Commenting on the UK blood contamination case *A and others*,[98] another author formulated similar comments, emphasizing that

> [o]ne issue which was left unclear by Burton J's judgment *is whether the conduct of the producer,* particularly in relation to efforts to discover the relative safety of a product by comparing it with another, *is to be taken into account when assessing the discoverability of the defect*.[99]

Although this would have properly addressed the discoverability issue, scrutinizing safety testing amounts to reintroducing fault into the product liability dialectic, and would certainly expand the length and complexity of trials, which strict liability sought, in the wake of the 1970s, precisely to circumvent.

A single example will suffice to illustrate these difficulties. In the recent 222-page Canadian common law negligence case *Andersen v. St. Jude Medical*,[100] the safety of heart valves coated with Silzone was the object of a class action after some patients suffered thromboembolic complications. Designed and manufactured by the defendant, the medical device had been authorized for distribution and sale in Canada in 1997.[101] After being regularly implanted in patients beginning in September 1997, a voluntary recall of the valves was issued on 21 January 2000. A clinical trial carried on while the device was on the market—under the name AVERT[102]—had brought to light "a small, but statistically significant in-

---

97 Barker et al, *supra* note 90 at 655, n 121. Conversely, Australian courts have held the defendant liable although there were no means to test for the defect at time of the sale. See e.g. *Ryan v Great Lakes Council*, [1999] FCA 177, 102 LGERA 123, aff'd [2000] FCA 1099, 177 ALR 18. See also Claudia Newman-Martin, "Manufacturers' Liability for Undiscoverable Design Flaws in Prescription Drugs: A Merck-Y Area of the Law" (2011) 19 Torts Law Journal 26.

98 See *A and others*, *supra* note 55.

99 Leigh-Ann Mulcahy, "Civil Law Liability" in Peter Feldschreiber, ed, *The Law and Regulation of Medicines* (New York: Oxford University Press, 2008) 181 at 201 [emphasis added].

100 *Andersen v St Jude Medical*, 2012 ONSC 3660 (available on QL), Lax J [*Andersen*].

101 It was only approved by the FDA in March 1998.

102 "AVERT was a randomized control trial (RCT) sponsored and funded by St. Jude and is an acronym for Artificial Valve Endocarditis Reduction Trial. Its purpose was to study whether Silzone was clinically effective in reducing prosthetic valve endocarditis, but its protocol included the collection of data on adverse events that are complications of valve surgery. The protocol specified that the study would take four years to complete" (*Andersen*, *supra* note 100 at para 26).

crease in explants due to a medical complication known as paravalvular leak (PVL)."[103] The AVERT study, hence, ended prematurely in 1999. As 36,000 devices had already been sold, national regulators took varying action to manage the risk.[104]

The decision captured the spirit of many—if not all—actions involving defective products:

> While it would be naïve to think that the company was unconcerned about profits or protecting its intellectual property, no valve manufacturer would be in business very long if it neglected patient safety and marketed products that didn't work.[105]

The crux of the case materializes in the key issue surrounding the allegation of a design defect, which the court summarizes by asking whether "a Silzone coating on a mechanical heart valve [put] patients at a *materially increased risk* of experiencing one or more ... complications."[106] The court answered this question negatively, holding that

> the plaintiffs did not establish that the defendants failed to exercise a reasonable degree of care in the pre-market design and testing or in the post-market surveillance of Silzone-coated products that would be expected of a reasonable and prudent prosthetic heart valve manufacturer in similar circumstances.[107]

More specifically, the plaintiffs had argued that although the defendant St. Jude complied with the FDA's *Draft Heart Valve Guidance*, ISO 5840[108] and ISO 10993[109] standards,[110] more testing should nonetheless

---

[103] *Ibid* at para 1. "Silzone is a proprietary term for a coating comprising layers of titanium, palladium and an outer layer of metallic silver. This was applied to the polyester (Dacron) sewing cuff that surgeons use to attach a prosthetic heart valve to heart tissue" (*ibid* at para 2).

[104] By way of an advice notice, the United Kingdom Medical Devices Agency (MDA) warned physicians about these safety concerns; regulators in Australia and New Zealand immediately withdrew market approval, while Health Canada and the FDA, though informed by the Data Safety Monitoring Board (DSMB) of the risk uncovered in the AVERT clinical trial, took no action.

[105] *Andersen*, *supra* note 100 at para 73. The court added that "[e]vidence that a business is motivated by profit cannot, without more, be treated as evidence that it fell below the standard of care. At most, the evidence demonstrates that St. Jude behaved as would be expected of a commercially-motivated party" (*ibid* at para 74).

[106] *Ibid* at para 5 [emphasis in original].

[107] *Ibid* at para 6.

[108] See International Organization for Standardization, *ISO 5840: Cardiovascular implants—Cardiac valve prostheses*, 4th ed (Geneva: ISO, 2005). The abstract states that ISO 5840

> outlines an approach for qualifying the design and manufacture of a heart valve substitute through risk management. The selection of appropriate qualification tests and methods are derived from the risk assessment. The

have been done following pre-clinical (*in vitro*) and animal trials,[111] thereby contesting the American-style risk utility assessment[112] advocated by the defendant.[113]

St. Jude appears to have sought regulatory approval of its Silzone-coated valve despite gaps in knowledge about its clinical effectiveness:[114] cautionary labelling reflected the strategic step-by-step approach taken by the defendant. The plaintiff believed the coated valve offered no greater benefit than another one already marketed by the same defendant. On this issue, the court held that the risk utility test does not require defendants to assess

> whether the benefits of the Silzone valve outweighed the benefits of the conventional valve relative to their risks. Rather, it was required to consider *whether the potential benefits associated with the addition of Silzone outweighed the potential risks of Silzone*.[115]

Methodologically, the court confined the analysis to the device itself, shifting away from the American idea suggesting that product comparison and

---

> tests may include those to assess the physical, chemical, biological and mechanical properties of heart valve substitutes and of their materials and components [in addition to] those for pre-clinical *in vivo* evaluation and clinical evaluation of the finished heart valve substitute.

109 See International Organization for Standardization, *ISO 10993: Biological evaluation of medical devices*, parts 1–20 & Supp (Geneva: ISO, [nd]) (sets standards in order to assess the biocompatibility of a medical device at the preclinical stage).

110 The Ontario court stated that "[t]he plaintiffs led no evidence at trial of Canada-specific industry standards and they acknowledge that the FDA's Guidance document and ISO standards are relevant in determining whether St. Jude met industry standards" (*Andersen*, *supra* note 100 at para 103).

111 *Ibid* at para 58.

112 This "requires a balancing or weighing of foreseeable risk against the foreseeable utility of the product based on information available to the manufacturer at the time of distribution of the product and without the benefit of hindsight" (*ibid* at para 61). The Court relies on *Rentway Canada Ltd v Laidlaw Transport Ltd*, 49 CCLT 150 at paras 43–46, 16 MVR (2d) 86 (Ont SC (H Ct J)), aff'd 45 ACWS (3d) 373 (available on QL) (Ont CA); *Ragoonanan Estate v Imperial Tobacco Canada Ltd*, (2000) 51 OR (3d) 603 at paras 103–04, 4 CCLT (3d) 132 (Ont Sup Ct (Civ Div)).

113 The court stated that they disagreed on

> (i) the degree of certainty the defendants were required to have about the benefits of Silzone before distributing the product, (ii) the reasonableness of the product development process including the testing undertaken and the manner in which the testing results were interpreted and, (iii) the role and impact of industry and regulatory standards and practices and regulatory approval (*Andersen*, *supra* note 100 at para 60).

114 See *ibid* at para 94.

115 *Ibid* at para 95 [emphasis added].

safer alternatives be at the heart of asserting defectiveness. Accordingly, in the eyes of the court "the conventional valve *did not meet the same need as the Silzone valve* because it did not address the risk of [prosthetic valve endocarditis]."[116] Through these lenses, the coated valve brought about distinct risks, and different benefits, as "PVE was a known risk with the conventional valve that the Silzone valve had the potential to address."[117] The case was therefore dismissed.

In the UK, scholarship suggests that "industry *practice* is less relevant than industry *capability*, or the potential for greater safety, in judging whether a 'state of the art' defence is made out."[118] Albeit stringent, the hybrid nature of such a position appears more satisfactory, as some objectiveness in the criteria allows judges to leave aside dubious corporate choices designed to avoid specific risk testing.[119] From a conceptual point of view, though, asserting the centrality of such a paradigm may well amount to merging, as was already mentioned, the DRD with the distinct state-of-the-art defence and vocabulary.

D. Eppur si muove *... (Thou Shall Dissent)*

This raises a final question, as R&D is largely advanced by initially marginal scientific voices: Were Galileo and Copernicus aware of the close intimacy between dissent and heresy? What are the "weight" and relevance of dissent and isolated scientific opinions? In his submission to the ECJ in *Commission v. UK*, Attorney General Tesauro rightly pointed out that "*the progress of scientific culture does not develop linearly* in so far as new studies and new discoveries may initially be criticized and regarded as unreliable by most of the scientific community, yet"—he added—"subsequently after the passage of time undergo *an opposite process of 'beatification' whereby they are virtually unanimously endorsed*."[120] He then tackled the issue directly: "[W]here there is a risk that is not certain

---

116 *Ibid* at para 96 [emphasis added].

117 *Ibid* at para 95.

118 Simon Deakin, Angus Johnston & Basil Markesinis, *Markesinis and Deakin's Tort Law*, 6th ed (New York: Oxford University Press, 2008) at 739 [emphasis in original].

119 Say, for example, that a drug manufacturer knows the effect of A (molecule) + B (pathology-1) + C (posology) on human health, but suspects that A (molecule) + B (pathology-2) + C (posology) might produce significant side effects, so the drug manufacturer does not proceed with drug testing for pathology-2, fearing disastrous scientific and commercial results. How would a similar situation be handled by the DRD?

120 *Commission v UK*, *supra* note 33 at I-2659 [emphasis added].

and will be agreed to exist by all only *ex post*, [may] the producer ... still rely on the [DRD]"?[121] In answer to his own query,[122] he stated that

> the state of scientific knowledge cannot be identified with the views expressed by the majority of learned opinion, *but with the most advanced level of research which has been carried out at a given time.*[123]

The scientific community recently provided an interesting example, by investigating whether eating genetically modified maize causes health problems in laboratory rats. The answer suggested in a scholarly article published in *Food and Chemical Toxicology* by G.-E. Séralini et al. is that it does, as their research results

> demonstrate that lower levels of complete agricultural glyphosate herbicide formulations, at concentrations well below officially set safety limits, *induce severe hormone-dependent mammary, hepatic and kidney disturbances*. Similarly, disruption of biosynthetic pathways that may result from overexpression of the EPSPS transgene in the GM NK603 maize *can give rise to comparable pathologies that may be linked to abnormal or unbalanced phenolic acids metabolites, or related compounds.*[124]

In sum, "the significant biochemical disturbances and physiological failures documented in this work confirm the pathological effects of these GMO and R treatments in both sexes, with different amplitudes."[125] Many scientists fiercely opposed these results, arguing that the type of rats used in the study was predisposed to tumours, and that the statistical evidence presented was inconclusive.[126] These methodological gaps therefore allegedly contaminated the experiment and gave rise to results that—despite being subjected to appropriate peer review—were not scientifically sound.[127] Is Séralini's article credible? When a reliable answer cannot be

---

[121] *Ibid.*

[122] The relevance of the "isolated opinion" seems to be unclear. See Goldberg, *Causation and Risk*, *supra* note 3 at 225.

[123] *Commission v UK*, *supra* note 33 at I-2659 [emphasis added].

[124] Gilles-Eric Séralini et al, "Long Term Toxicity of a Roundup Herbicide and a Roundup-Tolerant Genetically Modified Maize" (2012) 50 Food and Chemical Toxicology 4221 at 4230 [emphasis added].

[125] *Ibid.*

[126] See e.g. Alexander Y Panchin, Letter to the Editor, "Toxicity of roundup-tolerant genetically modified maize is not supported by statistical tests" (2013) 53 Food and Chemical Toxicology 475. Critics abound; these are but random examples found in a foray into "pure" science databases.

[127] Séralini's study was later removed from Food and Chemical Toxicology's pages. Indeed, the editors held that

> [u]ltimately, *the results presented (while not incorrect) are inconclusive, and therefore do not reach the threshold of publication for Food and Chemical Toxicology. The*

found within the scientific community, it is even more elusive to legal experts, who are intellectually ill equipped to second-guess scientists' methodological choices and tactics. In such matters, speculation is always at best tentative and at worst empty rhetoric.

From a legal standpoint, then, what can possibly be done in the face of such scientific polemics? Coderch and Puig anticipated the problem triggered by "uncertain science" that may nonetheless influence the amount and quality of knowledge[128] for the purpose of making findings on a balance of probabilities.[129] Quite predictably, the debate leads to the junk science–good science dialectic, which underlies the landmark American case of *Daubert*,[130] as the criteria embedded in the DRD invite analysis of the scientific evidence presented by expert witnesses (whether appointed by the court or hired by the parties).[131] In a different context, the Australian decision in *Peterson v. Merck Sharp & Dohme*[132] was a pharmaceutical consumer class action involving the drug Vioxx. The court held in that case that the drug's side effects were not sufficiently known to the producer so as to constitute *scientific knowledge*. The drug had been approved around 1999 by regulators but was withdrawn from the market in the fall of 2004 after a study revealed that its side effects included doubling the risk of adverse cardiovascular events.[133] A year later, the federal appeals

---

peer review process is not perfect, but it does work. The journal is committed to getting the peer-review process right, and at times, expediency might be sacrificed for being as thorough as possible (Elsevier, Press Release, "Elsevier Announces Article Retraction from Journal Food and Chemical Toxicology" (28 November 2013) online: Elsevier <www.elsevier.com> [emphasis added]).

128 See Coderch & Puig, *supra* note 9 at 23–27.

129 In this regard, scientific philosophical schools of thought (Popper, Kuhn, Galileo, etc.) may not be of the utmost relevance to lawyers. Newdick (*supra* note 76) and Coderch & Puig (*supra* note 9) have summarized these debates.

130 *Daubert v Merrell Dow Pharmaceuticals*, 509 US 579, 113 S Ct 2786 (1993). The criteria adopted by the US Supreme Court were echoed in Ottawa. See e.g. *R v J–LJ*, [2000] 2 SCR 600 at para 32, 192 DLR (4th) 416; *R v Trochym*, 2007 SCC 6 at para 36, [2007] 1 SCR 239. Similar issues have been raised in an environmental context. See *Spieser v Canada (PG)*, 2012 QCCS 2801 at paras 20–21 (available on CanLII).

131 See Jean-Louis Baudouin & Patrice Deslauriers, *La responsabilité civile, Volume II: Responsabilité professionnelle*, 7th ed (Cowansville, Que: Yvon Blais, 2007). Baudouin and Deslauriers suggest that theoretical disparity might lead to confusion between legal causality and scientific causality: "Devant une seule théorie proposée par le demandeur, et plusieurs soulevées par la défense, la jurisprudence, bien souvent, estime que le premier ne s'est pas adéquatement déchargé du fardeau probatoire qui est le sien" (*ibid* at para 2-107).

132 *Merck Sharp & Dohme v Peterson*, [2011] FCAFC 128 at paras 206–08, 196 FCR 145 [*Merck Sharp*].

133 The door was wide open for the defence, although, according to commentators, "this conclusion is surprising as it had earlier been held *that the drug was defective because*

division, known as the Full Court, rejected the imposition of a duty to warn on the defendant Merck toward the plaintiff of risks of heart disease, as scientific and technical knowledge was inconclusive.[134] Indeed, the result of one study made available in March 2000 named VIGOR was held insufficient to establish scientific knowledge, hence allowing recourse to the DRD, in force in section 142 of the *Australian Consumer Law*.[135]

Can this debate on the place of dissenting science be further nourished by scholarship in international trade law? The temptation is great, as minority opinions have caught the attention of WTO arbitrators in their interpretation of the *Sanitary and Phytosanitary (SPS) Agreement*,[136] and specifically determining the quality of scientific *expertise* underlying SPS measures adopted or maintained by member states. Article 2(1) of the *SPS Agreement* provides that such measures may be undertaken if "necessary for the protection of human, animal or plant life or health." All such SPS measures must be "*based on scientific principles* and [shall not be] maintained without *sufficient scientific evidence*."[137] In interpreting this provision, the WTO appellate body has mentioned that risk assessment is not bound by any "monolithic conclusion" of majoritarian scientific opinion, as these may hide the uncertainty within the community.[138] Nonetheless, SPS measures still must meet the "sufficiency" criterion[139] by demonstrating "the existence of a sufficient or adequate relationship

---

no warnings had been given that the drug *may cause the side effect*" (Barker et al, *supra* note 90 at 655 [emphasis added]). If knowledge was lacking, how could the producer have disclosed the unknown risks to consumers through proper warnings? Liability, though, had instead been found on the basis of contractual warranty, as the court of first instance had held that Vioxx was not reasonably fit for its purpose and was not of merchantable quality as it did not meet consumers' expectations that arthritic pain medication should not double the risk of heart attack. Insights might also be gleaned, *mutatis mutandis*, from the duty to warn, as the underlying problem is similar: where a producer acquires knowledge of a risk of harm to consumers, that producer must take action to inform consumers of the risk (by modifying the product, recalling it, or withdrawing it from the market). Though this obligation may not always be statutory, it undoubtedly influences the distinction between negligence and strict liability.

134 *Merck Sharp*, *supra* note 132 at paras 206–08, special leave to appeal to HCA on the causation issue refused, [2012] HCATrans 105 (11 May 2012).

135 *Supra* note 60.

136 *Agreement on the Application of Sanitary and Phytosanitary Measures*, 15 April 1994, 1867 UNTS 493, art 2(2) [*SPS Agreement*].

137 *Ibid* [emphasis added].

138 *EC Measures Concerning Meat and Meat Products (Hormones): Report of the Appellate Body*, WTO Doc WT/DS26/AB/R; WT/DS48/AB/R (1998) at para 194, online: WTO <www.docs.wto.org>.

139 Panels are not to substitute their own opinion for that of competent national authorities. Their task is rather to examine the compliance of the risk assessment carried out by a member with the requirements of the SPS Agreement (see *ibid* at para 117).

between two elements, *in casu*, between the SPS measure and the scientific evidence."[140]

The wording of the DRD probably opens the door to similar questions that flow from the definition of "scientific and technical knowledge" contained at article 7(e) of the *PL Directive*. A last, intriguing question will be left unexplored: To what extent does "science" include the humanities, epidemiology, or metaphysics?

Conclusion

The effects of the DRD on product liability are twofold. First, it predictably sends victims back to the labyrinth of fault-based liability (or other relevant causes of action) and invites them to search out other defendants. Focusing on different elements of the DRD may result in a more or less subjective analysis. Insisting that efforts could have been made by an industry to discover a defect, to carry on further research, etc., saddles plaintiffs with a burden that the directive seemingly sought to lift. As Howells and Mildred suggest, this situation is explained by the political compromise that was reached in the *PL Directive*. Even if it comes at the cost of further fractioning the interior market, flexibility as to the strictness of liability may well be available to member states willing to exercise their discretion. In this regard, strict liability and fault-based liability advocates will each long persist within the world of product liability, accompanied by "third-way"[141] proponents of hybrid solutions.

Second, the policy reasons underlying the exoneration clause have always been economic in nature: too much liability is said to chill innovation. However, little tangible proof of the correlation has been presented in empirical research. Ironically enough, although this aspect of the DRD merits further study, its proponents have never really been bothered by the lack of evidence surrounding the argument's foundation in the alleged "chilling effect". Indeed, one study conducted at the European Commission's request remains utterly prudent in establishing such a cause-effect relationship.[142] A qualitative analysis was also carried out by the Fondazione Rosselli to illustrate the impact of the DRD on product liability. Published in 2004, the study cautiously concluded that

---

[140] *Japan—Measures Affecting Agricultural Products: Report of the Appellate Body*, WTO Doc WT/DS76/AB/R (1999) at para 73, online: WTO <www.docs.wto.org>.

[141] See e.g. art 2050 *Codice civile* (which encompasses liability for dangerous activities).

[142] See John Meltzer, Rod Freeman & Siobhan Thomas, *Product Liability in the European Union: A Report for the European Commission* (Lovells: London, 2003), online: European Commission <ec.europa.eu>.

> it can be said that the [DRD] has had the merit of providing industry with a clear-cut reference for evaluating product safety. At the same time, *there is no evidence that the absence of the [DRD] in specific countries and/or industries have significantly hindered innovation*.[143]

Indeed, participating companies[144] expressed the sentiment that if the DRD were to disappear, they would simply invest in more comprehensive insurance coverage or would deploy additional efforts to better assess the safety of their products.[145] There is a clear contradiction between this indifference toward the DRD on the part of economic actors and alarmism about its demise.[146] The shallowness of the rationale of chilling innovation probably explains the polarized positions found in contemporary scholarship and case law.

However, antibodies are present in most states' veins that may allow them to ward off the DRD by allowing plaintiffs to institute their action on other grounds.[147] Somewhat by default, negligence, *faute*, and all of

---

[143] Alessandra Alaimo et al, *Analysis of the Economic Impact of the Development Risk Clause as provided by Directive 85/374/EEC on Liability for Defective Products* (Turin: Fondazione Rosselli, 2004) at 40–41, online: European Commission <ec.europa.eu> [emphasis added]. Another study released in 2003 showed that 94 per cent of a sample of manufacturers responded negatively to the question, "Do any disparities in product liability risks as between Member States discourage the marketing of products?" See Meltzer, Freeman & Thomas, *supra* note 142 at 27, fig 6. On these reports, see Duncan Fairgrieve & Geraint Howells, "Rethinking Product Liability: A Missing Element in the European Commission's Third Review of the European Product Liability Directive" (2007) 7:6 Mod L Rev 962.

[144] 291 questionnaires were distributed to economic operators, and 75 telephone interviews were conducted.

[145] See Alaimo et al, *supra* note 143 at 46, fig 3.

[146] The main weakness of the report seems to have been in identifying a priori the variable under study—here, the DRD—without formulating an open question that would have allowed it to properly isolate a variety of factors that ultimately determine whether corporations will choose to engage in a particular commercial field or to settle in a given country. Such a question would have clarified the overall importance given to the DRD in light, *inter alia*, of what are likely more relevant variables, such as the cost of labour, tax issues, regulatory compliance, etc. By contrast, pinpointing a specific variable at the outset may grant it de facto overimportance. This flaw might explain why some respondents became interested in the DRD *while* participating in the study.

[147] This choice is allowed by article 13 of the *PL Directive*, *supra* note 5. *C.f. María Victoria González Sánchez v Medicina Asturiana SA*, C-183/00, [2002] ECR I-3905 (and similar cases). See also Marie-Eve Arbour, "Corte di giustizia e protezione delle tradizioni giuridiche nell'interpretazione della Direttiva CEE/374/85" [Court of Justice and the Protection of Legal Traditions in the Interpretation of Directive CEE/374/85] (2003) 4 *Danno e responsabilità* 375. Surprisingly, the commission held that "[t]he coexistence of different product liability rules ... *is considered positive because the range of rules allows consumer protection to be improved*" (EC, Commission, *Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Fourth report on the application of Council Directive 85/374/EEC of 25 July 1985*

their variations have historically formed the basis of personal injury law, but have long been considered inadequate bases on which to ground compensation for damage caused by innovative products.[148] Nonetheless, it is to be anticipated that the costs and the uncertainty associated with such actions will render them decreasingly effective, as proof of negligence requires scientific evidence that is often outside the reach of plaintiffs. Pharmaceutical litigation, for example, revolves around a two-part strategy, which consists of proving a failure in product safety evaluation before the products' introduction into the market and establishing a further failure to warn health professionals (in case of prescription drugs) or consumers (for over-the-counter medicines) of a risk. Proof of causation can also turn cases into fora for scientific debate,[149] as the waltz of variables endlessly shifts according to new hypotheses, theorems, deductions, and assumptions. Such an endeavour requires expert examination of the methodology and protocols underlying clinical trials and often involves a level of complexity that materializes in extended hearings.

Ultimately the benefit of the DRD lies not so much in its actual results for producers, but rather in the enrichment of judicial discourse through the use of comparative legal approaches that increase the circulation of ideas and solutions available within courtrooms.[150]

---

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 (Brussels: EC, 2011) at 4 [emphasis added]). Furthermore, this issue raises the problem of determining the respective boundaries of contract and tort. See Franz Werro & Vernon Valentine Palmer, eds, *The Boundaries of Strict Liability in European Tort Law* (Durham: Carolina Academic Press, 2004).

148 *Contra* James Gordley, *Foundations of Private Law: Property, Tort, Contract, Unjust Enrichment* (Oxford: Oxford University Press, 2006) at 159–81.

149 Its centrality is reflected by the choice of some courts to address it first. See *Buchan v Ortho Pharmaceutical (Canada) Ltd* (1984), 8 DLR (4th) 373 at 376–77, 46 OR (2d) 113 (Ont H Ct J), aff'd *Buchan (CA)*, *supra* note 29.

150 Justice Burton professed,

> I would of course pay particular attention to any European decisions, not because they are binding upon me, but because not only does respect have to be paid, on the usual principles of comity, to reasoned decisions of competent foreign courts considering the same or similar issues, whatever the nature of the legislation, but particularly so where Community courts are applying the directive (*A and others*, *supra* note 55 at para 44).