

INNOVATORS IN THE CROSSFIRE: A POLICY SKETCH FOR UNKNOWABLE RISKS IN EUROPEAN AND UNITED STATES PRODUCT LIABILITY LAW

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I. INTRODUCTION

A product defect results from an unknowable innovation risk¹ when available scientific testing procedures could not have permitted discovery of the defect prior to the product's initial manufacture. Such product defects occur rather commonly in innovative or newly developed products and materials² typically found in the pharmaceutical, medico-technical, nuclear, aviation, and biochemical engineering industries. Legal treatment of product innovation risks has significant economic implications, which this Article addresses. Although strict liability—including liability for innovation risks—has expanded for the last twenty years,³ it now seems to have started to contract on both sides of the Atlantic.⁴

The role of innovation risks in product liability law is currently attracting attention from both lawyers and government administrators. Although currently on the European Union's agenda, the subject of innovation risk has thus far been addressed only tentatively in Council Directive 85/374 of July 25, 1985, concerning the member states'

1. This term excludes losses occurring after the risk has been detected because such losses result from failure to forewarn a user of its consequences, not from the innovation risk itself. James A. Henderson, Jr., *Coping with the Time Dimension in Products Liability*, 69 CAL. L. REV. 919, 922 n.5 (1981). Because these cases do not pose special problems from the perspective of innovation policy, they are excluded from the discussion.

2. The serious effects of asbestos litigation constitute a prominent example. For a summary of the situation in the United States and the possible effects that asbestos may cause for the European law of torts, see Eric R. Bothwell, *The Asbestos Problem and the European Economic Community*, 31 COLUM. J. TRANSNAT'L L. 205 (1993).

3. Even though subsequently overruled by the Illinois legislature, this solution appeared in the Illinois Supreme Court's decision in *Cunningham v. MacNeal Memorial Hosp.*, 266 N.E.2d 897 (Ill. 1970), in which the court extended strict liability to unknowable risks. The court held:

To allow a defense to strict liability on the ground that there is no way, either practical or theoretical, for a defendant to ascertain the existence of impurities in his product would be to emasculate the doctrine and in a very real sense would signal a return to a negligence theory.

Id. at 902. Similar in approach is the harshly criticized New Jersey Supreme Court's decision in *Beshada v. Johns-Manville Prod. Corp.*, 447 A.2d 539 (N.J. 1982). In that case, the court imposed liability upon defendant but did not say "what defendants should have done to avoid harm." *Id.* at 549.

4. As product liability influences production cost, it is likely that liability trends follow the Western world's economic situation. In the 1960s, consumer protection, by means of a strict liability standard, seemed to be affordable. The current economic recession has led many to doubt the wisdom of the earlier solutions.

approximation of regulations of liability for defective products.⁵ Directive 85/374 will likely be revised in the coming months,⁶ and at that time innovator liability will again become a major issue.⁷ The issue is also of interest in the United States.⁸

Before demonstrating some practical dimensions of innovation risks by reference to typical cases, the concept of innovation, as used here, should be narrowed. Because this Article addresses the relationship between innovation and product liability law, it concerns only innovations that are immediately related to the creation and distribution of products. In other words, innovation, as discussed here, stems from invention of a product or modification of a production process. For example, in producing pharmaceuticals, a firm might change its manufacturing process by abandoning traditional methods in favor of genetic engineering technology. This change might result in the development of a new prescription drug or a new kind of application, both of which would be within the scope of this Article.⁹ By contrast, other innovations, such as innovative services and new management techniques, do not lead to the creation and distribution of a new product. Hence, these latter examples of innovations are ordinarily unaffected by product liability laws and are therefore outside the scope of this Article.

5. Council Directive 85/374, 1985 O.J. (L 210) 29. It applies not only within the European Union, but according to the "Treaty between the EEC and the EFTA on the establishment of the European Economic Area, Porto," May 2, 1992, as amended by the Protocol of March 17, 1993, 1993 O.J. (L 109) 2, the Directive is also binding on Austria, Norway, Sweden, and Finland.

6. In November 1982, a symposium on a related topic was held at the N.Y.U. School of Law. At the symposium, the panelists, including some of America's most prominent tort scholars, discussed "The Passage of Time: The Implications for Product Liability." The papers from this conference appear at 58 N.Y.U. L. Rev. 733 (1983).

7. Laurie McCutcheon Mathewson, *Harmonization of Product Liability Laws in the European Community: A Comparative Analysis of the Approaches of the Federal Republic of Germany and the United Kingdom*, 24 LAW & POL'Y INT'L BUS. 1285, 1292 (1993).

8. See Anita Bernstein, *Looking at Europe for the Difference Between Strict and Fault-Based Liability*, 14 J. PROD. LIAB. 207, 214 (1992) ("Looking at changes in European products liability law may deepen the ongoing study of products liability in the United States. American lawyers, scholars, and judges have shown an interest in the directive for several years. The directive is perceived (correctly, I think) as 'American'—a consciously-imported approach that uses products liability litigation as a device to achieve social goals.").

9. Under § 29(3) of the German Pharmaceuticals Act of 1976, Gesetz zur Neuordnung des Arzneimittelrechts § 29(3), 1976 Bundesgesetzblatt [BGBl] I 2445 (F.R.G.), German law requires a re-approval by the German *Bundesgesundheitsamt* (the FDA's equivalent prior to the distribution of a newly developed drug).

Cases of innovation risk share a common feature: the lag time between the introduction of a defective product into the stream of commerce and when scientific knowledge has advanced far enough to allow detection of the defect. The course of asbestos litigation illustrates this common feature.¹⁰ The time lag between first commercial use and discovery of a product defect also figured in DES (diethylstilbestrol), a synthetic estrogen prescribed to pregnant women to prevent miscarriages and later found to be a cause of vaginal and cervical cancer in those women's daughters;¹¹ and in a full-blood transfusion infected by a serum hepatitis virus undetectable at the moment of transfusion.¹² Less well known is the case of a supposedly harmless prescription diuretic that allegedly caused a small bowel lesion requiring surgical correction.¹³ Apart from these products, which have actually been subjects of litigation, several realistic hypotheticals might be imagined. Physical harm could result from microwave ovens, wireless electronic devices, genetically engineered food, or food preserved by means of nuclear radiation. Any product potentially harmful to human beings could present an innovation risk.

For each new product, an innovation risk poses a conceptual problem, requiring a balance between interests of consumers and producers. The risk may also be conceptualized in terms of striking an appropriate balance between the goals of scientific innovation and the social goals inherent in liability cases.¹⁴

II. INNOVATORS' LIABILITY—THE LAW IN EUROPE TODAY

The EU's product liability directive¹⁵ imposes a uniform strict liability standard on all member states. However, for political reasons the directive contains certain "escape clauses," which authorize member states to derogate from specified provisions of the directive.¹⁶ Arising from the development risk defense, one such clause lets each member

10. Among more recent decisions, the most prominent is *Anderson v. Owens-Corning Fiberglas Corp.*, 266 Cal. Rptr. 204 (Cal. Ct. App. 1990).

11. *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988).

12. *Cunningham v. MacNeal Memorial Hosp.*, 266 N.E.2d 897 (Ill. 1970).

13. *O'Hare v. Merck & Co.*, 381 F.2d 286 (8th Cir. 1967).

14. Richard E. Byrne, *Strict Liability and the Scientifically Unknowable Risk*, 57 MARQ. L. REV. 660 (1974).

15. See *supra* note 5.

16. Council Directive 85/374, *supra* note 5, art. 15(1)(b).

state independently decide whether a manufacturer can deny a consumer's claim for damages by claiming that: (1) it had no knowledge of the product defect (lack of knowledge); and (2) it had no way of discovering the defect prior to marketing the product because the relevant state of the art had not encompassed such knowledge (lack of discoverability).¹⁷ As to this escape clause, member states have made different decisions.¹⁸

Optional escape clauses like the one mentioned above tend to dilute the intended approximation of the member states' laws. Such clauses also allow consumers to forum-shop. To address these difficulties, the member states have agreed on periodic revisions of the directive and its administration. Although the first of these revisions was due in 1993, it has yet to be completed.¹⁹ When enacted, the revision agenda will likely grant member states an option to derogate from the directive's strict liability standard for innovation risks. If the revision does not provide an escape clause, it would impose a significant legal change on most of Europe, because only a few countries have enacted laws that provide limited coverage for selected innovation risks.²⁰

17. For applicable yardsticks of "knowledge" or "knowledgeability," see Christopher Newdick, *Risk, Uncertainty and "Knowledge" in the Development Risk Defence*, 20 *ANGLO-AM. L. REV.* 309 (1991).

18. Among the EU member states, only Spain and Luxemburg have opted out of the development risk defense. The products liability laws and regulations of Belgium, Denmark, France, Germany, Ireland, Italy, the Netherlands, Portugal, Greece, and the U.K. recognize the development risk defense. The British extension of the defense's scope has led the EU commission to file an infringement proceeding against the U.K. before the European Court of Justice under Art 169 of the Treaty of Rome. See Commission, Ninth Annual Report to the European Parliament on Commission Monitoring of the Application of Community Law—1991, [1992] *O.J. (C 250)* 17. For speculation on the impact of this diversified practice on U.S. manufacturers' business activity in Europe, see Patrick Thieffry et al., *Strict Product Liability in the EEC: Implementation, Practice and Impact on U.S. Manufacturers of Directive 85/374*, 25 *TORT & INS. L.J.* 65 (1989).

19. Council Directive 85/374, *supra* note 5, arts. 9, 21. In anticipation of this revision, a report is presently being prepared, see 14 *PRODUCTS LIABILITY INT'L* 189 (1993).

20. Examples of such national regulations are the German Atomic Energy Act as revised on July 15, 1985, Atomgesetz, 1985 *BGBI I* 1565, the Pharmaceuticals Act, 1976 *BGBI I* 2445, Act on Genetic Technologies as revised on December 16, 1993, Gentechnikgesetz, 1993 *BGBI I* 2066, Act on Environmental Liability of December 10, 1990, Gesetz über die Umwelthaftung, 1990 *BGBI I* 2634.

III. BASIC CONCEPTS OF TORT LIABILITY

Before addressing the question of a reasonable liability standard for innovation risks, it would be useful to distinguish risk-interiorizing liability models from those in which risks are exteriorized.²¹ Interiorizing a loss entails its allocation somewhere within the tortfeasor-victim relationship. By contrast, a loss-exteriorization model transfers the loss beyond the tortfeasor-victim relationship onto a third party. Even though the concept of loss-exteriorization has its partisans,²² it is not particularly common and therefore will not be covered here.²³

A. *The Casus Rule*

A risk-interiorizing liability model as such has not yet been transformed into a liability rule. Though the model requires damage allocation within the tortfeasor-victim relationship, it does not indicate whether the tortfeasor or the victim finally must bear it. This issue is resolved by another distributive mechanism, the actual liability rule. The simplest liability rule is the ancient "Casus rule,"²⁴ which allocates unintentional losses where they initially have fallen.

B. *Strict Liability*

The Casus rule's opposite is the straightforward rule of strict tort liability.²⁵ Liability attaches if all of these three conditions are met: act,

21. These terms may seem a bit curious. The use of the more common terms internalization and externalization, however, did not seem advisable here, because these terms carry special meanings in an economic analysis context.

22. For Germany, see Karl Sieg, *Haftungersetzung durch Versicherungsschutz [Replacement of Liability by Insurance Coverage]*, 113 ZEITSCHRIFT FÜR HANDELSRECHT (ZHR) 95, 102 (1949).

23. Only New Zealand and the Canadian province of Saskatchewan seem to use a loss-externalization model. See Richard S. Miller, *The Future of New Zealand's Accident Compensation Scheme*, 11 U. HAW. L. REV. 1 (1989); Richard S. Miller, *An Analysis and Critique of the 1992 Changes to New Zealand's Accident Compensation Scheme*, 52 MD. L. REV. 1070 (1993); CRAIG BROWN & ELIZABETH CUMMINS SETO, *NO-FAULT AUTOMOBILE INSURANCE IN CANADA* (1988).

24. The Latin word *casus* means *chance* or *accident* and is referred to in many ancient Roman rules of law, e.g. *casus a nullo praestantur*, Dig. 50.17.23 (Ulpian).

25. Practical difficulties occur however in judging whether there is a causative link between a given action and its alleged result. After all the issue of causation is perceived to be one of the most difficult in all of the world's developed tort law systems.

damage, and causation between the two.²⁶ A rule of strict liability does not require establishment of the tortfeasor's fault.²⁷ Absolute liability is an aggravated version of strict liability, but there is little consensus on what it means.²⁸

C. Negligence

Midway between the Casus rule and strict liability²⁹ lie a variety of fault-based liability concepts that dominate most Western tort regimes. These concepts are addressed under the rubric of negligence. Negligence allows the transfer of a loss away from the victim, if (and only if) the tortfeasor can be charged with the violation of a duty of care.

IV. THE DILEMMA OF INNOVATORS' LIABILITY—INNOVATION POLICY AND CONSUMER PROTECTION IN CONFLICT

In the present context, negligence concepts do not take us far enough toward analyzing innovation risks. Because these risks by definition are unforeseeable and unavoidable, there cannot be a duty of care to avoid them and thus no violation of that duty.³⁰ Under these circumstances the introduction of a negligence standard seems to

26. For the products liability context, see *Greenman v. Yuba Power Prod., Inc.*, 377 P.2d 897 (Cal. 1962).

27. Thus it is indeed undeniable, as some authors point out, that from a strictly logical standpoint the state of the art defense can not be reconciled with the concept of a truly 'strict' liability. See Marshall S. Shapo, *Comparing Products Liability: Concepts in European and American Law*, 26 CORNELL INT'L L.J. 279 (1993); John Vargo, *Strict Liability for Products: An Achievable Goal*, 24 IND. L. REV. 1197, 1236 (1991).

28. Under the key word "strict liability," *BALLENTINE'S LAW DICTIONARY* 1225 (3d ed. 1969) points to the definition it gives for "absolute liability." *BLACK'S LAW DICTIONARY* 1422 (6th ed. 1990), provides identical definitions.

29. For the European and American view of the distinction between strict and fault based liability, see Bernstein, *supra* note 8.

30. This is why, even though the existence of the state of the art defense within the action in strict liability is not consistent with that concept, it is also not correct to say that that defense introduces an element of negligence. To that effect, however, Vargo, *supra* note 27, writes: "This generally accepted two-part definition of state of the art—technological and economic feasibility—is, in essence, the equivalent of the risk-utility standard of negligence." *Id.* at 1236. As long as "ought implies can," a duty of care cannot have been violated. Everything else would amount to a duty to know about the unknowable. *Id.*; see also Alan Calnan, *Perpetuating Negligence Principles in Strict Products Liability: The Use of State of the Art Concepts in Design Cases*, 36 SYRACUSE L. REV. 797 (1985); Kathleen D. Wilkinson, *Admissibility of State of the Art Defense—Manufacturer's Expertise May No Longer Be Allowed in the Courtroom*, PA. B. ASS'N Q., Oct. 1985, at 205.

represent a covert implementation of the Casus rule. Thus, we could reasonably formulate the issue as follows: Which one of the two remaining models, the Casus rule or strict liability, better addresses problems associated with innovators' liability?

The answer to this question depends on the standard for evaluating rules of law. These evaluation standards vary. First, there is the classical question of justice, which follows such ancient concepts as *iustitia distributiva* and *iustitia commutativa*, of right and wrong, of good and evil. Despite their age, these criteria have retained their validity. It is still a most relevant issue whether the public perceives a rule as fair, equitable, and thus acceptable. Like many other basic considerations, the notion of fairness is not easily put into practice. Even though most people have a sense of right and wrong, this sense is imprecise. It therefore seems helpful to add some practical considerations to this very general view of things and to inquire about the efficiency of a rule of law. On this view, the question must be asked whether a rule promotes the efficient allocation of scarce resources.³¹

A. *The Cybernetics of Liability Law*

This question is answered by the economic analysis of law that is based on the premise that legal rules influence human behavior by pricing certain activities.³² That is, an individual who wishes to engage in an activity must decide whether he wants to pay the price for the activity or to avoid the activity and thus the expense.

1. Basic Economics of Tort Liability

A premise of this economic view of tort liability is that a tortfeasor must have an incentive to minimize the potentially harmful effects of his actions. Under the Casus rule, this incentive does not exist. The actor who has caused an unintended harm never has to contribute to indemnification: *casus sentit dominus*. This changes under a fault-based system of liability in which duties of care have to be met. To fulfill these

31. Paul Burrows, *Idealised Negligence, Strict Liability and Deterrence*, 2 INT'L REV. L. & ECON. 165 (1982). Burrows justly stresses that, understood in this limiting sense, the economic analysis of law is suited to provide valuable assistance for legal decision-making. For an example of the occasionally rather populist criticism of economic analysis, see Vargo, *supra* note 27, who reaches different conclusions.

32. See generally RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* (4th ed. 1992).

duties a potential tortfeasor will try to prevent harm as long as such prevention is cheaper than compensating the victims. Even though this is a sensible approach, it is not satisfactory because an activity's damage-potential is determined (1) by how dangerous that particular activity's performance is and (2) by how many individuals perform it.³³ Both the inherent risk of an activity and the intensity of its performance are determined by the competitive long-range marginal cost, including the cost for damage control and victim compensation for one unit of activity.

This is how the cybernetics of liability law works: the stricter the liability regime, the higher the liability risk, the higher the cost for a unit of activity, the higher its price.³⁴ In cases of unlimited demand-elasticity, any increase in the liability standard increases liability risk, driving up costs and decreasing demand. This decreased demand in turn leads to a reduced activity level and thus to a reduction of overall damage. In short, stricter liability results in less output and thus less damage. Unfortunately, this hypothesis is not especially helpful because it does not indicate whether and how much positive effect has been lost along the way. The only decisive figure therefore is a comprehensive comparison between all positive and negative effects stemming from an activity, in other words, its so-called welfare balance. This welfare balance is the only tool to accurately measure the effects of liability rules.

In the area of liability law, the welfare balance shows that the concept of strict liability is superior to other forms of liability regulation because it best internalizes costs resulting from an activity.³⁵ Theoretically, this internalization will automatically lead to a 'correct' price for any given activity, i.e. a price that best mirrors its welfare balance. This price should be high enough to reduce performance of the

33. As this concept may sound somewhat abstract, here is an example: Chopping firewood is a dangerous activity. In order to cut back on the number of individuals who are sustaining injuries while performing this activity, warnings might be issued to wear protective gear and to apply due care. It is likely that such warnings would lead to a certain reduction of the total amount of injury stemming from the chopping of firewood. Experience shows, however, that warnings only work to a certain point. In order to further reduce the total amount of injury sustained by the population of firewood choppers, the number of individuals engaging in the activity would have to be reduced. If only half of all former woodchoppers continued to chop firewood, this would cut the total amount of injury that woodchopping causes annually by half. Both, the amount of risk that is involved in the performance of a certain activity and the number of individuals who perform it determine the total amount of injury that will result from that activity over a certain amount of time.

34. POSNER, *supra* note 32, at 163.

35. *Id.* at 175.

activity to the point where it can no longer be replaced by a cheaper alternative, i.e. by an alternative with a more favorable welfare balance. This price should also be low enough to allow the activity to be conducted if there is no alternative activity and consumers are able and willing to spend the money.

2. Information as a Governing Element

In a free market economy, individual choices depend on the "right" price. Only if the price of a good reflects all costs incurred in the course of production, including financing its risk potential, should the consumption of this good fall within an economically acceptable level. If the price of the good includes only part of the production costs, that price will be too low. Such "understatement" will lead to an increase in consumption, just as an overstatement will lead to a decrease of consumption. In other words, if a price is inflated because it includes costs that do not really exist, for example, because a nonexistent risk potential has to be financed, this price inflation reduces consumption of the good below the level of maximum efficiency. In such a case, the incidence of an activity would be reduced even where its performance would lead to welfare gains instead of losses. The foregoing explanation highlights the significance of accurate pricing, which is most likely when there is solid information about all of a good's price-sensitive parameters. Inaccurate information on these parameters leads to distortions in prices.

B. *Distortions of Costs Caused by Lack of Information*

In both Europe and the United States, liability risks and the cost involved in their coverage are two major factors that must be evaluated and integrated into the calculation of price for a particular activity.³⁶ The less accurate the risk assessment, the less accurate the calculability of an activity's cost, the more inaccurate the resulting price. What consequences do these distortions produce for innovators' liability?

36. W. Kip Viscusi & Michael J. Moore, *An Industrial Profile of the Links between Product Liability and Innovation*, in *THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION* 81 (Peter W. Huber & Robert E. Litan eds., 1991).

1. The Markets for Liability Insurance

Liability insurance rests upon two principles³⁷: (1) solidarity, according to which all insureds promise one another mutual coverage, and (2) risk quantifiability on a statistical basis. For innovation risks, the second principle is problematic because insurance companies calculate future risks on the basis of past experience.³⁸ For example, an insurer collects data on the average damage resulting from defective anesthesia devices, and he also knows about the probability of such damage. On the basis of average damage and incidence of damage, insurance companies calculate their premiums. For innovation risks, however, this approach does not work, because for innovations, reference data are unavailable. This lack of information makes the insurer insecure, causing it to react in a defensive, though understandable, fashion. To shield itself from incalculable risks, such an insurer will rate any unknown risk as a bad risk and charge a "worst case premium," i.e. a premium that contains a disproportionately high safety margin. Sometimes an insurer will even refuse to provide coverage at all.³⁹ As a consequence, the innovator of a new product is unlikely to find adequate insurance coverage at reasonable cost.⁴⁰

2. The Capital Markets

The same mechanism is at work in the financial markets where almost every inventor has to find the financial resources to manufacture and market his innovation. Lenders judge their borrowers' credit rating by using, among other factors, the assets versus liability ratio and the availability of collateral. If sufficient assets and potential collateral are unavailable, the prospect for extraordinary returns will occasionally satisfy the lender. These prospects, however, depend on the market and on the cost structure under which the borrower operates. Liability risks or—more accurately—their perception by other parties can result in costs. The higher a lender rates this risk, the more precautions it will take

37. Sean F. Mooney, *The Liability Crisis*, 32 VILL. L. REV. 1235 (1987).

38. C. Robert Morris, Jr., *Enterprise Liability and the Actuarial Process—The Insignificance of Foresight*, 70 YALE L.J. 554, 574 (1961).

39. That is why John W. Wade regards the argument that losses could be spread among all users of a product as not convincing in the present context. See John W. Wade, *On the Effect in Product Liability of Knowledge Unavailable Prior to Marketing*, 58 N.Y.U. L. REV. 734, 755 (1983).

40. *Accord* RESTATEMENT (THIRD) OF TORTS, § 101 cmt. b (Council Draft No. 1, 1993).

against losing money. For good reasons, most banks are risk averse. In uncompetitive markets, conservative risk assessments usually translate directly into increased returns. In other words, banks can make money by underrating their customers' credit. The extra margin that they charge in addition to regular interest adds to the bank's profit margin. If a borrower is adjudged liable and then goes bankrupt, the lender would lose part of its loan; but could pay for the loss with insurance it had bought for the extra interest. If an innovation proved to be safe and the borrower repaid the loan, the extra interest represents additional profit.

In this situation, financially weak innovators⁴¹ may find themselves at the mercy of banks and insurance companies that tend to overstate the liability risk involved in an innovation and, as a result, tend to overcharge for their services. Such overstatement usually results from lack of technical knowledge. This setting, where other people make money on an innovator, and the innovator is left with all of his invention's economic risk, deters rather than encourages innovation.⁴²

In short, because of the mechanisms at work in both the insurance and the banking industry, the financing of innovative activity is a particularly difficult endeavor. Risks tend to be exaggerated and borrowers tend to be overcharged for financing.⁴³ Instead of being advanced, innovative activity is impeded.⁴⁴

C. *Problems of Innovation Policy*

If an increased liability standard drives up prices for new products and discourages innovators from innovative activity, this threatens

41. UWE TRÄGER, DIE WIRTSCHAFTSPOLITISCHE BEDEUTUNG DES EUROPÄISCHEN PATENTSYSTEMS IM URTEIL KLEINERER UND MITTLERER UNTERNEHMEN IN AUSGEWÄHLTEN LÄNDERN [The Economic Significance of the European Patent System according to the Judgement of Small and Medium Size Companies in Selected Countries] Tab. 4.1/2(1) (1994).

42. That is why the more innovative a product the more uncertain its chances for development and marketing. See CARL-CHRISTIAN VON WEIZSÄCKER, INNOVATION UND BESCHÄFTIGUNG [INNOVATION AND EMPLOYMENT] 15 (1988).

43. Without being overly unfair, it might even be said that—at least in Europe—banks and insurance companies would be the prime beneficiaries of an increased standard of innovators' liability. After all, it is they who will be able to collect higher interest payments and insurance premiums.

44. This insight, occasionally referred to as "market deterrence" is not new. See GUIDO CALABRESI, THE COSTS OF ACCIDENTS: A LEGAL AND ECONOMIC ANALYSIS 27 (1970); JEFFREY O'CONNELL, ENDING INSULT TO INJURY: NO-FAULT INSURANCE FOR PRODUCTS AND SERVICES 76-80 (1975).

reduction of an economy's innovative momentum, i.e., of one of the most important assets that any modern economy can have in the global marketplace.⁴⁵

No matter how one evaluates the mechanism by which today's law tries to provide incentives for innovative activity,⁴⁶ the support for the goal of innovation has remained unanimous. More than desirable, innovative activity is indispensable to the survival of any modern industrial and post-industrial society. This holds particularly true for Western economies that cannot draw upon many natural resources but instead depend on the success of their technology-intensive refining industries.⁴⁷ In principle, innovative activity deserves encouragement⁴⁸ or, at least, sufficient space to breathe.⁴⁹ The devastating effects of discouraging innovation, even outside the technical sector, can be seen in the formerly communist and now struggling countries of South-eastern Europe. In contrast, the national economies of Pacific basin countries show the positive effects of innovation.

From the above remarks, what practical lessons can be drawn for the appropriate standard of innovators' liability? If an economy's ability to generate and implement innovations is indeed decisive for its survival, logic requires protection of innovators. Innovators should bear burdens only if other equally important interests cannot be protected in any other

45. See generally JOSEPH A. SCHUMPETER, *THE THEORY OF ECONOMIC DEVELOPMENT: AN INQUIRY INTO PROFITS, CAPITAL, CREDIT, INTEREST, AND THE BUSINESS CYCLE* (Redvers Opie trans., 1934).

46. In the face of the plethora of problems in the field of the law of competition, many are critical of the present system of innovation promotion. See, e.g., FRITZ MACHLUP, *AN ECONOMIC REVIEW OF THE PATENT SYSTEM* (1958); EDITH T. PENROSE, *THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM* (1951).

47. Even countries with a large supply of natural resources, such as Russia, cannot do without technology and thus need innovation in order to realize the economic value they possess. A lack of technology leads to waste and environmental problems.

48. For a study that the EEC-Commission conducted in the mid-eighties, see A. PIATIER, *BARRIERS TO INNOVATION [LES OBSTACLES À L'INNOVATION DANS LES PAYS DE LA COMMUNAUTÉ EUROPÉENNE]* (1984); 1 *THE REPORT OF THE PRESIDENT'S COMMISSION ON INDUSTRIAL COMPETITIVENESS, GLOBAL COMPETITION: THE NEW REALITY* 51 (1985); 2 *id.* at 59.

49. Here it should be noted that the decision to promote innovative activity as such does not in any way determine the shape of the promotion mechanism. Apart from the model that is being practiced today, there are numerous other possibilities, e.g., granting tax privileges to venture capital funds or, as practiced before, the temporary reduction of liability standards for highly innovative industries. See Edmund W. Kitch, *Vaccines and Product Liability—A Case of Contagious Litigation*, *REGULATION*, May-June 1985, at 11, 12; Edmund W. Kitch, *Suffer the Little Children*, *WALL ST. J.*, Mar. 25, 1986, at 30.

way. Consumer protection is probably not such an interest. Though an individual's physical integrity must be valued highly, this valuation must still be subject to scrutiny with regard to its efficiency. Even an individual's interest in its physical integrity must be scrutinized that way because occasionally it turns out that what is labeled as the consumers' collective interest in fact is not more than that of a particular victim.

In some progressive European circles, this is often depicted as a competition between the consumer's interest in reducing potentially harmful innovations and the industry's interest in the promotion of such innovations. The portrayal of these interests, as always in conflict, oversimplifies the issue, for many inventions both serve consumers' immediate interests and protect them from likely risks. This is true of most innovations in pharmaceutical and medical technology. Recognition that innovation mostly is to the consumers' benefit can be seen in the example of many European countries when victims of vaccination risks are compensated by governments, not manufacturers.⁵⁰ A rationale for this governmental burden is that an activity furthering the public's benefit should be carried out, even if a small number of individuals will foreseeably suffer harm. In other words, no one would seriously advocate a reduction of vaccination risks to zero by forbidding vaccinations.

Sensitive treatment of innovation promotion is also demanded by contemporary policy on protection of intellectual property. Policy makers bent on reshaping national liability rules on innovation risks must keep in mind international regulation of intellectual property. Otherwise lawmakers risk taking back with one hand (i.e., via tort law) what the law has granted with the other (i.e., via intellectual property law).

Returning to the question at the beginning of Part IV, imposing strict liability upon innovators is likely to increase the financial burden upon innovators. This burden is disproportionate to risks that innovators actually create; not every innovation risk is an asbestos disaster. The economic calculus that normally gives strict liability an edge over less strict forms of liability does not work here. The specter of another

50. The German "Law for the Control of Contagious Diseases of July 18, 1961" as revised on December 18, 1979, *Bundesseuchengesetz*, 1979 BGBI I 2262.

asbestos tragedy further complicates the marketing of innovations, already an activity underestimated in its difficulty by the public.⁵¹

In liability regulation systems based upon damage-interiorization, innovation risks could be handled adequately only on the basis of the Casus rule. In other words, for innovation risks, the currently prevailing "product-oriented" approach⁵² to strict liability that only asks if there is a defect⁵³ would have to be given up and be replaced by the Casus rule. This would leave victims of innovations risks without any compensation.

V. TORT LAW—AN EASY WAY OUT?

Although the above analysis has suggested a liability rule for innovation risks, this answer is unacceptable. Even in Europe, where a victim is compensated by the community for damages⁵⁴ and where the

51. How difficult it can be to market an invention, even if it is based on a truly brilliant idea, is best illustrated by the case of Chester Carlson, the inventor of xerography. Between 1940 and 1944 Carlson made 18 attempts to find a commercial backer for his invention. IBM alone turned him down three times. Then he authorized the Battelle Memorial Institute to be his licensing agent. After no success was in sight, he finally assigned the patent to Battelle. Battelle made another 36 attempts before in 1946 the Haloid Company of Rochester, N.Y. (later Xerox) offered its assistance in the commercialization of Xerography. See *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195 (2d Cir. 1981).

52. See *Feldman v. Lederle Lab.*, 479 A.2d 374, 385 (N.J. 1984) ("The emphasis of the strict liability doctrine is upon the safety of the product, rather than the reasonableness of the manufacturer's conduct. It is a *product-oriented* approach to responsibility." (emphasis added)).

53. See, e.g., *Johnson v. Raybestos-Manhattan, Inc.*, 740 P.2d 548 (Haw. 1987); *In re Hawaii Fed. Asbestos Cases*, 699 F. Supp. 233 (D. Haw. 1988); *Cunningham v. MacNeal Memorial Hosp.*, 266 N.E.2d 897 (Ill. 1970); *Nave v. Rainbo Tire Serv., Inc.*, 462 N.E.2d 620 (Ill. Ct. App. 1984); *Gelsumino v. E. W. Bliss Co.*, 295 N.E.2d 110 (Ill. Ct. App. 1973); *Halphen v. Johns-Manville Sales Corp.*, 788 F.2d 274 (5th Cir. 1986); *Oakes v. Geigy Agric. Chem.*, 77 Cal. Rptr. 709 (Ct. App. 1969).

54. Most European countries, e.g. France, Germany, Italy or Great Britain, have established very elaborate and rather complicated systems of social security. In Germany, most social security benefits can be claimed on the basis of the Code of Social Laws (Sozialgesetzbuch [SGB—Parts I—X]). The SGB requires (almost) every employee to enroll in the heavily regulated health insurance scheme (gesetzliche Krankenversicherung) which provides (almost) full coverage for all medical expenses. Also, a so-called accident insurance (gesetzliche Unfallversicherung), comparable to the American workers' compensation schemes, is required by federal law. Health insurance, the general pension fund (gesetzliche Rentenversicherung) and the unemployment insurance (Arbeitslosenversicherung) are financed by employers and employees. The contributions are calculated as a percentage of the monthly gross income. Apart from these insurance schemes there is also a system for social welfare (Sozialhilfe). It provides for a basic level of support and is grounded on the Federal Statute on Social Assistance of May 24, 1983, Bundessozialhilfegesetz [BSHG], 1983 BGBI I 613. Benefits include support to the cost of the everyday life (usually

effects of the Casus rule would not be gravely felt, the Casus rule is not a realistic option. Regardless of any considerations of innovation policy, the Casus rule itself does not meet the moral standards of the world's leading industrial nations. An appropriate solution must balance the social interest in high volume of innovative activity against an advanced level of consumer protection. Such a solution cannot be achieved by means of a damage-interiorizing approach. Instead, it might be provided by a liability system that allows exteriorization of innovation risks.

VI. PROPOSAL

What could be the contours and characteristics of such a system? Its prime goal must be to assure adequate victim compensation without unduly burdening innovators. This requirement rules out full compensation for the victim. However, such a regulation could provide for a victim's reasonable living conditions and, as far as medically possible, for restoration of his physical integrity. Damages for pain and suffering, as well as punitive damages, would have to be excluded.⁵⁵ Attorneys' fees would have to be capped in order to reduce litigation costs.⁵⁶

Who should pay the compensation? As both producer (as under a regime of strict liability) and injured consumer (as under the Casus rule) cannot be held liable, a capital fund would have to be established. This would lead to the further question of how it would be funded. Basically, there are two possibilities: A taxpayer-funded approach would provide the broadest possible basis of compensation and could be justified on the basis that promotion of innovative activity concerns the general public and thus the public should compensate the victims. Though this solution

around DM 600,- per person), assistance (up to 100%) to the cost of (modest) housing, and membership in the health insurance scheme.

55. For the amounts of damage awards, see MARK A. PETERSON & GEORGE L. PRIEST, *THE CIVIL JURY: TRENDS IN TRIALS AND VERDICTS, COOK COUNTY, ILLINOIS, 1960-1979*, at 3 (1982). For a wealth of statistical data, see MARK A. PETERSON, *CIVIL JURIES IN THE 1980S: TRENDS IN JURY TRIALS AND VERDICTS IN CALIFORNIA AND COOK COUNTY, ILLINOIS* (1987).

56. Attorneys in Continental Europe are not allowed to collect contingency fees and the prevailing party has to be reimbursed for his costs. This increases the litigation risk and to a large degree eliminates frivolous personal injury suits and the practice of "orange-mailing" (this expression refers to the practice of settlements in the Agent Orange litigation). For an analysis of the ratio between litigation expense payments and net compensation in asbestos cases, where only 39% of the total costs incurred in the course of a court proceeding reach the injured victim, see JAMES S. KAKALIK ET AL., *VARIATION IN ASBESTOS LITIGATION COMPENSATION AND EXPENSES* (1984).

is plausible, it would be unworkable, particularly in the United States. That leaves only a "partial" solution comparable to the Workers' Compensation schemes⁵⁷ found in various American states as well as in most European countries. The parallel between innovation risks and the risks that Workers' Compensation covers is evident. Both risks are largely beyond the individual's control, and their creation lies in the public interest.⁵⁸

Thus, the financial burden of the compensation fund might justifiably fall upon all producers, with a possible discount for those who could prove innovative activity, e.g. by having obtained at least one patent within a certain time-span. Less innovative producers then bear more of the burden than more innovative ones. Regulation of coverage for individual consumers could be modeled upon coverage for work-related accidents.

VII. SUMMARY

There are at least two reasons for not including innovation risks from the scope of the European Product Liability Directive, as well as from American strict tort liability. First, such inclusion "would arguably violate a manufacturer's right to be judged by a normative behavior standard to which it is reasonably possible for a manufacturer to conform."⁵⁹ Second, inclusion of such risks would provide a "disincentive to be inventive"⁶⁰ because, for reasons inherent in the banking and insurance industries, innovators would bear a financial burden disproportionate to the risks that they create. Nevertheless, to distribute innovation risks fairly and not to unduly burden injured consumers, a regulatory scheme should be devised to permit victims to continue their lives under reasonable circumstances. This goal might be achieved through externalization of damages to a fund supported by noninnovative producers. Such a fund might resolve the conflict of values between consumer protection and innovation policy.

57. See, e.g., The North Carolina Workers' Compensation Act, N.C. GEN. STAT. § 97 (1985).

58. The setup of a public compensation scheme, of course, is very complex. Therefore, the very sketchy ideas that have been presented here are designed only as an incentive for further discussion.

59. RESTATEMENT (THIRD) OF TORTS, *supra* note 40, at 12.

60. Charles B. Burr, II, *Disincentive to be Inventive* (or, the Little Red Hen fable with a modern twist), 70 A.B.A. J., May 1984, at 93.

the 1990s, the number of people in the UK who are aged 65 and over has increased from 10.5 million to 13.5 million (19.5% of the population).

There is a growing awareness of the need to address the needs of older people, and the Government has set out a strategy for the 21st century in the White Paper on *Ageing Better: The Government's Strategy for Older People* (Department of Health 1999). This sets out a vision of a society in which older people are able to live well, and to contribute to their communities.

The White Paper also sets out a number of key objectives for the Government, including: to ensure that older people are able to live well; to ensure that older people are able to contribute to their communities; to ensure that older people are able to live independently; and to ensure that older people are able to live in their own homes.

The White Paper also sets out a number of key actions for the Government, including: to improve the quality of life of older people; to improve the health of older people; to improve the social and economic conditions of older people; and to improve the services available to older people.

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