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Products Liability in the European Community: What does it Mean for U.S. Companies?

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In this article, I make two assumptions about the single market unification program in Europe.[1] These assumptions are particularly important in the products liability area. The first assumption is that 1992 represents not a date, but a process. It is a continuum—it began with the signing of the Treaty of Rome[2] over thirty years ago—and it may or may not end at some point in time which, in any event, will not be December 31, 1992. It will be much later than that. That assumption is one that is particularly well evidenced by the experience of the Products Liability Harmonization Directive.[3]

The second assumption is that 1992 represents an opportunity for non-European companies to do business within the European Community that was not available before. It represents an opportunity because it is always easier, all things being equal, to deal with one market than with twelve; to deal with one set of standards than with twelve; and, indeed, to deal with one set of products liability regulations than with twelve.

Let me discuss the history of the products liability harmonization exercise to show how it fits into plans for the harmonization of the European Community. The Products Liability Directive antedates most of the elements of the 1992 program as set forth in the White Paper.[4] Indeed, it antedates Lord Cockfield's White Paper itself. The Products Liability Directive was adopted by the Council in July 1985.[5] It was originally conceived in the early 1970s, before the United Kingdom joined the European

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1. Inspired by the Treaty of Rome, which created the European Economic Community in 1957, the unification program calling for the creation of a barrier-free single market was laid out in detail in the White Paper. Completing the Internal Market, COM (85) 310 final (June 1985). The White Paper's author was Lord Cockfield, then Vice President of the European Commission. The White Paper called for the adoption of approximately 300 pieces of European Community legislation before December 31, 1992.

2. Treaty Establishing the European Economic Community, *reprinted in* TREATIES ESTABLISHING THE EUROPEAN COMMUNITY 207 (1977) [hereinafter Treaty of Rome].

3. *Council Directive of 25 July 1985 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning Liability for Defective Products,* 85/374 O.J. EUR. COMM. (No. L 210) 29 (1985) [hereinafter *Products Liability Directive*].

4. *See supra* note 1.

5. Approval by the Council of Ministers is the final step needed for a directive to be adopted. Thereafter, it must be implemented by legislation in each of the Member States. *See* Treaty of Rome art. 189.

Community, when there were at least certain shared assumptions about the way legal systems worked among the Member states. These assumptions, after the accession of the British and the Irish with their common law systems, became open to some degree of question.

The Products Liability Directive, in its first version, was put forward by the Commission to the Council. It was referred to Parliament which, before the Single European Act,[6] had a much smaller legislative role than it has now. Parliament discussed the proposed text, the Commission experts discussed and revised it, and there was a considerable reaction *against* the proposed directive on the part of industry.

Industry felt that, irrespective of which view of the need for harmonization of products liability rules was followed—that is, whether or not in a unified Europe the law of products liability must be the same in all of the Member States—certain questions still had to be addressed. If the European Community were to harmonize, what would the harmonized rules look like? Does harmonization occur at the least common denominator or at the greatest? Is harmonization to be based on liability with fault or without fault? Should separate regimes for products liability be established in specific sectors of the economy, such as the pharmaceutical sector? These questions were answered by the Commission through its recommendations in favor of *raising* the standard of liability, *eliminating* the need to show fault, and establishing common principles that required all industries to measure up to high standards to which, for example, the Germans have always held pharmaceutical manufacturers.

In the late 1970s and early 1980s, it was commonly felt among industry that the Products Liability Directive was going nowhere. It was confidently predicted that a Conservative government in the United Kingdom could not possibly abandon hundreds of years of legal tradition that links liability to fault.

But in July 1985, Prime Minister Margaret Thatcher's government did precisely what it was not expected to do. It permitted the adoption of the Directive, and broke the link between legal liability and negligence. The Directive establishes liability irrespective not only of fault, but also of the producer's ability to avoid the defect that caused the damage.[7] It is what American or English lawyers call a strict liability system and, on a continuum of such systems, the Directive is at the far stricter end.

Consensus proved to be especially difficult to achieve for only two pro-

6. Before the Single European Act, Parliament's role was purely advisory. *See id.* arts. 137-144. The Single European Act, an amendment to the Treaty of Rome adopted in February 1986, expanded that role considerably. *Id.* arts. 7-12. *See also* The Single European Act, *reprinted in* TREATIES ESTABLISHING THE EUROPEAN COMMUNITY, *supra* note 2, at 1005.

7. Member States may pass legislation on a producer's liability irrespective of the "state-of-the-art" at the time of manufacture. *Products Liability Directive* arts. 7(e), 15(1)(b). It is clear that eventually all Member States will be pushed in this direction by another directive or by repeal of the provision that makes this optional. *Id.* arts. 15(2), 15(3).

visions of the Directive. One concerned whether or not the state-of-the-art defense would protect producers. Would it be a defense for a manufacturer to say that, given the state-of-the-art at the time the item was produced, it was impossible to avoid or even to know about the defect that caused the injury?

The second impediment that needed to be resolved to complete agreement in the Council, was whether there should be an absolute limit, a cap, on the potential liability of a producer for a single industrial accident. In the spirit of the new Europe, of the Single European Act, and of what was to become the 1992 exercise, the Council of Ministers finally agreed to leave those two matters open for the Member States to decide. Therefore, in the Directive, Member States may or may not choose to permit the state-of-the-art defense to be used against a products liability action.[8] They may or may not choose to impose a cap on aggregate liability.[9] There are restrictions on the ways that either may be done.[10]

After the Council resolved the problem areas and adopted the Directive, the Member States were given three years to adopt implementing legislation.[11]

A directive under the Treaty of Rome is binding as to the result to be achieved,[12] but Member States may implement the directive by their own domestic, legislative, or regulatory means. Implementation should have been carried out by July 1988. More than three years since the Directive's enactment now have passed. In what may be an object lesson concerning the real difficulties in achieving some of the more grandiose 1992 objectives, precisely *one* Member State, Greece, has adopted the Directive.[13] The other eleven countries are currently being taken before the European Court of Justice for having failed to implement the Directive adequately.[14] Greece is an exception because it took the Directive verbatim and adopted it as a domestic law.

That is the current status of the new rules. Although the Directive has not been implemented yet, it will be. It sets out the products liability regime that all companies doing business in Europe will have to contend

8. *Id.* art. 7(e).

9. *Id.* art. 16(1). The limit may not be lower than 70 million ECU ($100 million) for damage "caused by identical items with the same defect." Neither "identical" nor "same" is defined.

10. A Member State excluding the state-of-the-art defense must notify the Commission and must hold the measure "in abeyance" for nine months to allow the Commission to propose a new directive on the point. *Id.* art. 15(2). After ten years, both issues will be revisited with an eye toward achievement of the Directive's consumer protection objectives.

11. *Id.* art. 19(1).

12. Treaty of Rome art. 191.

13. *See* European Comm. Press Release 100(88) 877 (Dec. 22, 1988) (announcing the commencement of the legal actions and indicating the Commission's satisfaction with the Greek implementation).

14. Nine Member States—Belgium, Denmark, Germany, Spain, France, Ireland, Luxembourg, the Netherlands, and Portugal—have not implemented the Directive through national laws. The other two Member States—Italy and the U.K.—have adopted legislation, but the Commission does not consider it satisfactory. *See id.*

with, starting not in 1992, but the minute that implementation is accomplished in each of the Member States. That could be next week, and it almost certainly will be before 1992.

What are the new products liability rules all about? Those persons who are used to reading statutes and other legal materials in the continental code system, are used to the notion that complex conceptual and jurisprudential ideas are often expressed in simple, if broad and abstract, language. The French law of negligence in the Napoleonic Code is set forth in three or four sentences.[15] This is the format of the Products Liability Directive. Its essense is this simple proposition: the producer shall be liable for damage caused by a defect in its product.

Conceptually, that proposition is not radically different from the one used in the United States. But in translating that concept into practice, the Directive provides that to succeed in a products liability action, a plaintiff must show only three things: that there was a defect, that the plaintiff suffered an injury, and that the defect caused the injury.[16] That is all a plaintiff must show to win a damages award. It is obviously a simple thing for a plaintiff to do in many cases. The Directive then shifts the burden of proof to the defendant to show affirmatively a lack of liability.[17] The only defenses permitted to a manufacturer are such traverses as: the product was not made by it; when the product left the factory, it was not defective or, if it was defective, that was because of something someone else did (such as combining it with another product); or the plaintiff was contributorily negligent or reckless when using the product.[18] If those defenses do not obtain, liability is the starting point in the analysis. That is a radical departure from the system of negligence law as is found in the United States.

Since the beginning of the exercise of harmonizing directives in various areas, European Community institutions have been careful to avoid extraterritorial reach whenever possible. They have tried to structure their legislative initiatives so as to bind only persons and entities in Europe, even if in practice they have avowedly extraterritorial effect. To deal with the problem of foreign producers who sell products in the Community, and who may not be available for service of process in Europe, liability is imposed not only on a producer, but on the European Community importer of a product made outside the Community.[19] If neither the producer nor the importer can be found, the Directive assigns responsibility to any company or individual whose trademark or distinguishing mark appears on the product, whether or not that company or individual actu-

15. CODE NAPOLEON art. 1382 ff.
16. *Products Liability Directive* art. 4.
17. *Id.* art. 7.
18. *Id.* arts. 7, 8.
19. *Id.* art. 3(2).

ally had anything to do with its manufacture or distribution.[20] A licensor, for example, may end up bearing the producer's liability.

Still, one might think that there is the advantage of certainty in any harmonization. Europeans have decided for public policy reasons that it is appropriate to assign risks in this way, that consumers should be able to recover damages even if they cannot prove that anyone was at fault in the manufacturing or design process. Whether one shares this view or not, it might be felt that at least it confers the benefit of certainty.

I think, however, that the Directive fails to provide that advantage. Despite its summary approach to the overriding principles of liability, the Directive is far from a model of clarity. Key terms such as "causation," for example, are not defined. American litigators know that days and weeks are spent in courtrooms arguing about causation. Yet "causation" is not defined in the Directive.

"Defect" is not defined in the Directive in a useful way. It is said that a product is defective when it does not "provide the safety which a person is entitled to expect," "taking all circumstances into account" including (and one presumes this is an illustrative list, not an exhaustive one):

- the presentation of the product,
- the use to which it could reasonably be expected that the product would be put, and
- the time when the product was put into circulation.[21]

These terms defy solid, rigorous definition. Clearly, they are going to be the subject of extensive litigation. The intent to avoid uncertainty and litigation through the use of language like this is, I would predict, going to bring about precisely the opposite result.

What does it mean to say that a producer can "reasonably expect" that a product will be put to a certain use and not to other uses? How much knowledge does a manufacturer have to have about the abuse or misuse of its pharmaceutical product before it must "reasonably expect" that someone will abuse or misuse the product in that way? What does it mean to say that there is a measure of safety that a citizen has an entitlement to expect? How much safety is that? When the "presentation" of the product is considered, to what extent is a warning label sufficient as part of the product's packaging to put someone on notice that it should not be used, for example, before driving a motor vehicle? Or that it should not be used by someone with certain medical conditions? Reliance on such terms as "presentation" is an invitation to difficulties. Those difficulties, in my opinion, have not yet been addressed by the European Community.

How can producers avoid manufacturing a defective product under the new system? The Directive gives no guidance. The Directive is not set out

20. *Id.* art. 3(3).
21. *Id.* art. 6(1).

the way an American or English statute is, expressing or at least implying instructions for producers as to how they can avoid liability. It does not lay down a standard of care for manufacturers. They do not know, for example, whether a warning label will be enough to exclude or reduce liability or, if so, what kind of warning label is required. While "the presentation of the product" may help to reduce liability or deny the existence of a defect, article 12 obscurely says, "The liability of the producer deriving from this directive may *not* be limited or excluded by *a provision* limiting his liability or exempting him from liability."[22] "A provision": what is that? A provision of a contract? A provision in a warning label? A provision of law?

How will the Directive work as a practical matter? In most hospitals, medicines are dispensed without a patient knowing from which vial a particular injection came or, therefore, which company manufactured it. An injured plaintiff will file a lawsuit and it will be the responsibility of the producer/defendant to show that the substance that injured the plaintiff was made by another company.

There is a further danger. If a regime of strict liability is adopted in Europe, where many American products are in free circulation, then one can easily foresee the following. An injured European, who would normally have come to New York, for example, to file a products liability case to take advantage of a jury, liberal verdicts, etc., may still come to New York, but no longer to make use of New York law. The plaintiff will come to New York and argue that under normal choice of law principles, European law governs the injury, that is, strict liability. The plaintiff will win the case on the merits. A New York jury will not be told that there is a cap on damages in national legislation implementing the European Directive,[23] because limitations on damages are contrary to the public policy of New York, as has many times been enunciated by the New York Court of Appeals.[24] There is the possibility of great mischief here: the expansion of the liability net without the limitation on exposure that makes risks insurable.

Does this mean that after the Directive is implemented the European Community will become "American" in its approach to products liability? Possibly, but I think not. Generally, juries will not determine liability in Europe. There are also no contingency fees, so plaintiffs' lawyers have no financial stake in products liability litigation. Finally, the standard for measuring damages in all of the Member States has always been, and will continue to be, far stricter than it is in the United States.

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22. *Id.* art. 12 (emphasis added).

23. That is, national legislation implementing art. 16(1). *See supra* note 9 and accompanying text.

24. *See, e.g.*, Kilberg v. Northwest Airlines, Inc., 9 N.Y.2d 34, 172 N.E.2d 546, 211 N.Y.S.2d 133 (N.Y. 1961).

How should American companies react? Americans must first educate themselves about the European Community system. They must monitor and follow carefully the details of implementation in the Member States. It is necessary to deal more intimately than has been the case in the past with European insurance companies. The open-endedness of potential liability under the new Directive is something that few companies—except perhaps those that print their own money—can risk going alone.