Product-Liability Risk Exposure in the U.S. and Europe

Similar But Still Separate and Distinct

By Benjamin L. Guendling

Most major companies increasingly foster business relationships and conduct commercial transactions across national borders and create new opportunities in many sectors. Businesses worldwide are becoming more interconnected to serve customers' needs and requirements in a global marketplace. For European companies manufacturing or selling products in the U.S., however, such an international "footprint" comes with additional risk: in industries such as oil and gas, consumer, medical devices, and aerospace, they face an increased risk of product-liability litigation in the U.S.

Recent lawsuits brought against companies, such as BP in the wake of the devastating oil spill in the Gulf of Mexico and medical and auto manufacturers as a result of major recalls, underline the potential product-liability risk to which affiliates of European companies domiciled within the U.S. are directly exposed.

Additionally, the United States Supreme Court has issued opinions in cases in which European manufacturers have been sued in U.S. courts for products that are made abroad but sold in the U.S. These cases illustrate the risk of non-U.S. companies being sued in U.S. courts.

On a positive note, as a result of tort-reform efforts, state legislatures and the United States Supreme Court have advanced certain restrictions and limitations similar to those in Europe, intended to limit overreaching and unreasonably high jury verdicts, particularly regarding punitive damages.

However, U.S. product-liability law and litigation are still separate and distinct from what we see in European legal systems and can be characterized by biased state court judges and local juries potentially favoring the local plaintiff; treacherous and increasingly expensive discovery and disclosure requirements (including ever-increasing rights to e-discovery); remaining risks of punitive damages; mass tort litigation and class actions; and comparatively high costs for legal counsel, experts, and insurance.

Some similarities to the risk exposure in Europe

To file a (strict) product-liability claim, jurisdictions worldwide more or less require the injured person to prove (1) the actual damage; (2) the defective nature of the product, i.e., it is unsafe or unreasonably dangerous; and (3) the causal relationship between damage and defect.[1]

European and U.S. courts use similar rationales to decide what is commercially reasonable to ensure product safety. On a case-by-case basis, both courts balance safety and commercial criteria: pricing, legal and regulatory safety standards, scientific and technical state of the art, or insurance costs. But whether you apply the more subjective—in the EU, prevailing—consumer expectation test or the U.S. typical risk-utility balancing test, a product need not be absolutely safe, but it must be affordable.

Furthermore, noncompliance with mandatory legal or regulatory safety standards is handled similarly in the U.S. and in Europe. If a product does not comply with the mandatory safety standards applicable at the time of sale (such as NHTSA[2] or FDA[3] regulations), courts might *presume* that there is a (design) defect.

On the other hand, even if the seller/manufacturer can show that the product complied with regulatory standards at the time of sale, potential product liability is not necessarily removed. Rather, the applicable regulatory safety standards might be considered a *minimum* for potential product-liability claims only, and do not always preempt these claims. Compliance with such safety standards often merely creates a presumption that the product was reasonably safe, but the plaintiff can overcome this presumption by showing that higher, objective scientific standards existed at the time of sale which the seller/manufacturer should have considered in designing the product to be reasonably safe.[4]

Finally, similar defenses to limit product-liability exposure are available in most jurisdictions around the world. For example, valid defenses exist if the seller or manufacturer can prove that (1) the defect appeared *after* the product was put into circulation (provided there was no post-sale failure to warn or to instruct the user/consumer); (2) the product was designed according to the state of the art; or the defect is due *solely* to compliance of the product with mandatory regulations issued by the governmental authorities; or (3) in case of an alleged liability of the component manufacturer, the defect in the component was caused during the manufacture of the final product without any fault of the supplier (e.g., if the supplier was not involved in the design of the products and manufactured and supplied the component "build to print").

Finally, in most jurisdictions a claim would be rejected or reduced in case of comparative fault, known risks that have been assumed, alteration, or abuse of the allegedly defective product.

Separate and additional risk exposure in the U.S.

In comparing European and U.S. product-liability law, the European Commission concluded the following at the turn of the twenty-first century:

> The truth is that, although the European and American legislations are very close in terms of principles, this is not the case with their practical application. Practical application of the European legislation does not appear to have the same results and consequences for those concerned as in the United States.[5]

It further concluded that:

> [T]he trial by juries, the "no win, no fee" principle, the awarding of high punitive damages, the possibility of class actions are elements that encourage victims to go to court. This is claimed to create a climate of unpredictability of the outcome for producers.[6]

Fast Facts

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More recent studies show that the European Commission's conclusions of more than a decade ago are still valid. Primarily in the pharmaceutical and automotive industries, we still see multimillion dollar verdicts or judgments (and innumerable private settlements) in the U.S., while similar cases handled by the professional judges in Europe are either rejected or result in more limited damages being awarded or judge-guided settlements. This is also true in industries such as tobacco, asbestos, medical devices, food, cosmetics, toys, machinery, and aviation. Sometimes it is hard to precisely define the exact risk exposure because many cases are settled by a confidential agreement. Still unclear, however, is to what extent preemption law might limit such risk exposure in the near future. The trend seems to be that the regulatory authorities put more effort and resources in the evolution of regulatory requirements; consequently, strict regulatory compliance might significantly lower the exposure to product-liability claims related to compliant products.[7]

One major difference between European and U.S. product-liability law still seems to be the types and amount of available damages.[8] Although the United States Supreme Court and product-liability statutes on the state level have tended to reduce certain damages to reasonable numbers,[9] differences with European jurisdictions like Germany remain significant. The majority opinion in Germany and other continental European jurisdictions still is that punishment is primarily reserved to criminal law; civil damages are generally not meant to punish—they merely compensate for suffered damages. However, because of restrictions on punitive damages in the U.S., German courts recently have been less reluctant to serve U.S. court decisions awarding punitive damages to defendants domiciled in Germany.[10]

Moreover, a positive example of U.S. tort reform[11] is presented in the Michigan Products Liability Act, which stipulates:

> In an action for product liability, the total amount of damages for noneconomic loss shall not exceed $280,000.00, unless the defect in the product caused either the person's death or permanent loss of a vital bodily function, in which case the total amount of damages for noneconomic loss shall not exceed $500,000.00.[12]

On the other side of the ledger, U.S. plaintiff attorneys, now facing such limitations regarding punitive damages, have proven to be creative in finding new ways to claim seven-digit damages by focusing on less restricted compensatory damages, such as damages for pain and suffering, or finding a way to sue the plaintiff in a less regulated state.

In contrast, German courts have more recently tended to grant damages for pain and suffering. However, in such matters, the awarded amounts are comparatively low. In medical malpractice cases, U.S. juries still grant millions of dollars in damages; a German plaintiff suffering similar injuries can sometimes recover less than a thousand euros for pain and suffering.[13]

Furthermore, in a widely publicized case involving hospital beds, the German Federal Court of Justice[14] recently rejected the award of major recall costs in a product-liability claim.[15] Although, in general, such costs might be recovered in a negligence claim, the German courts confirmed their traditional approach of limiting damages to compensation for actually incurred costs and reasonable amounts. Therefore, it is no surprise that the 85 million euros cap for product-liability claims involving death or bodily injury in Section 10(1) of the German Product Liability Act rarely seems to be discussed by a German court.

In addition to the potential for higher damages awards in the U.S. compared to Europe, studies show that costs for product-liability insurance in some sectors cause Europe's exports to the U.S. to be between two and ten times more expensive than exports to other countries.[16]

It is also interesting that U.S. product-liability litigation focuses on *design* defects. In contrast, in Europe, many product-liability cases still involve *manufacturing* defects.[17] This distinction should be considered by European businesses assessing their potential risk exposure when putting products into the U.S. commerce stream, especially in circumstances in which they are engaged as a supplier to support the development of cutting-edge products. To the extent that U.S.-based customers or those distributing the products in the U.S. ask to manufacture such products based on the customer's design, it is essential to seek contractual provisions requiring the *customer* to protect the European contract manufacturer or component supplier against any third-party claims based on design defects and have adequate liability insurance in place.

A final consideration is the United States Supreme Court's ongoing struggle to define predictable and transparent standards for personal jurisdiction of foreign manufacturers selling their products in the U.S. Plaintiffs' attorneys continue to try to sue European manufacturers in the much more "promising" U.S. courts. However, the Supreme Court has shown a tendency to construe the "minimum contacts" requirement in a restrictive way and therefore has denied personal jurisdiction in cases in which products are placed into the U.S. stream of commerce indirectly and in small numbers through a nonaffiliated independent distributor.[18]

New rulings continue the trend toward restricting personal jurisdiction over a foreign manufacturer: the Court has clarified that a nonresident defendant is present in the U.S. and the general jurisdiction requirements are only met if its own direct connections (as opposed to the connections of its in-state U.S. affiliate) are so continuous and systematic as to render it "essentially at home" there.[19] Although these recent decisions have been interpreted as "pro-business,"[20] some

dissenting opinions imply a clear warning, and the specific facts of these cases should not lead to false conclusions—any foreign manufacturer selling defective products to the U.S. in higher quantities still may be subject to personal jurisdiction in the U.S. state where such products are actually sold. Any international manufacturer of safety- and health-related products that are sold in significant numbers in the U.S. is well advised to consult and work with a U.S. legal counsel from "cradle to grave" for any such product.

Conclusion

The trend toward globalization has turned our world into one vast commercial marketplace. However, applicable legal standards for product-related liabilities have not followed suit; some similarities exist, but meaningful differences remain between Europe and the U.S.

To foster sustainable growth in the U.S. marketplace, all of the following should be carefully considered in advance to mitigate the potential impact of U.S. product-related liability risks:

- The corporate setup, operation, and oversight of U.S. subsidiaries in a manner to avoid "piercing the corporate veil" of the parent company in Europe
- The product's design
- Design-validation testing
- Supplier agreements related to the product's components
- Manufacturing and quality controls
- Product instructions, e.g., for use and for installation
- Advertising claims
- Distribution networks and related distribution agreements
- Product-liability and recall insurance coverage ■

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ENDNOTES

1. Unless there is a particular product liability act on the state level, most U.S. courts would apply the Restatement (Third) of Torts: Product Liability. The equivalent in Germany is the Federal Product Liability Act (Gesetzueber die Haftung fuer fehlerhafte Produkte), which is based on the EU Directive 85/374/EEC. This article focuses on strict liability and does not cover and compare rules governing the sale of goods, such as differences in warranty claims according to Article 2 of the Uniform Commercial Code (UCC) vs. the German Civil Code (see §433 to §479 of the Buergerliches Gesetzbuch (BGB)).
2. National Highway Traffic Safety Administration <http://www.nhtsa.gov/> (accessed May 5, 2016).
3. US Food and Drug Administration <http://www.fda.gov/> (accessed May 5, 2016).
4. The complex issue of preemption is in flux and cannot be covered in this article. For additional references, see endnote 20.
5. Commission of the European Communities, *Liability for defective products* (July 28, 1999), 396 final, p 13.
6. Commission of the European Communities, *Liability for defective products* (January 31, 2001), 893 final, p 9.
7. See the list on recent product-liability cases related to the drugs and automotive industry by Wittner & Wheeler, *A Look Through Tinted Glass: What Does the Future Hold for Preemption in Motor Vehicle Litigation?*, 39 PSLR 515 (May 16, 2011).
8. See Wagener & Dawson, *Risk Factors for the Away Team in US Litigation*, ACC Docket (December 2010), p 34.
9. *State Farm Mut Auto Ins Co v Campbell*, 538 US 408; 123 S Ct 1513; 155 L Ed 2d 585 (2003); *BMW of North America, Inc v Gore*, 517 US 559; 116 S Ct 1589; 134 L Ed 2d 809 (1996).
10. See German Constitutional Court (Bundesverfassungsgericht) decision, 2 BvR 2805/12; BeckRS 2013, 45947 (January 9, 2013).
11. As a justification for a reform of the US tort system, the US Senate stated that "the US tort system is by far the world's most costly tort system." A study conducted by the insurance industry—the Tillinghast study—estimated the current overall annual cost of the US tort system at a staggering $117 billion. US Senate Report No. 105-32 (June 19, 1997), p 3.
12. MCLA 600.2946a(1).
13. A recent example has been the "*Bio-Tattoos*" case decided by the Oberlandesgericht Karlsruhe: The plaintiff was promised that the "bio" tattoo will disappear at latest after seven years. Since the tattoo remained in the skin, the court granted minor compensatory damages for pain and suffering. See OLG Karlsruhe, NJW-RR 2009, p 743.
14. The Bundesgerichtshof, the highest appellate court in civil litigation matters.
15. Pflegebettenurteil, BGH, NJW 2009, p 1,080.
16. See Fondazione Rosselli, *Analysis of the Economic Impact of the Development Risk Clause as provided by Directive 85/374/EEC on Liability for Defective Products: Final Report* (July 10, 2014), pp 73–74; European Commission, *Report on the Application of Directive 85/374 on Liability for Defective Products, COM* (2000) 893 final, p 9.
17. On the basis of the data collected in response to the 1999 Green Paper (Commission of the European Communities, *Liability for defective products* (July 28, 1999), 396 final), published in the second report on the EC-Directive, approximately 60 to 70 percent of settled claims are based on manufacturing defects and 1 to 11 percent concern design defects. See European Commission, *Report on the Application of Directive 85/374 on Liability for Defective Products*, COM (2000) 893 final, p 12.
18. *J McIntyre Machinery, Ltd v Nicastro*, 564 US 873; 131 S Ct 2780; 180 L Ed 2d 2780 (2011); for the applicable standards, see also *Goodyear Dunlop Tires Operations v Brown*, 564 US 915; 131 S Ct 2846; 180 L Ed 2d 796 (2011).
19. *Daimler AG v Bauman*, 571 US ___; 134 S Ct 746; 187 L Ed 2d 624 (2014); see also *Walden v Fiore*, 571 US ___; 134 S Ct 1115; 188 L Ed 2d 12 (2014).
20. See Moellenberg & DeJulius, *Driving Preemption Forward After* Williamson v Mazda, 39 PSLR 811 (July 25, 2011), pp 1–6.