OVERVIEW OF U.S. PRODUCT LIABILITY REGIME

Sara D. Schotland*

I. STANDARD FOR DEMONSTRATING DEFECT

United States product liability law imposes liability on a manufacturer or seller whose product causes injury even though the manufacturer or seller has exercised all due care. Thus, "strict liability" is imposed; negligence need not be shown.

The United States recognizes three types of defect claims and multiple theories are often alleged. First, a manufacturing defect occurs when a manufactured item fails to perform according to the manufacturer's own specifications. Second, a warning defect occurs when a manufacturer fails to adequately warn a consumer of latent risks. Most cases turn on whether the warning adequately communicates risks. "Adequate" warnings must convey the nature and severity of the hazard and provide instructions for safe use. For drugs and other unsafe products, the warning facilitates informed consumer choice. For example, with a warning a consumer can weigh the side effects, allergies, and other concerns before taking medication. Third, a design defect occurs when a product's risks outweigh the benefits of the design. These claims necessarily involve application of a risk to benefit analysis. The availability of feasible, cost efficient, alternative designs that remain consistent with the intended use of the product without causing injury also factor into the analysis.

II. CATEGORIES OF DAMAGES

A variety of compensatory damages as well as punitive damages are available in the U.S. system. Compensatory damages fall into two categories. The first type includes medical expenses and lost wages (both past and future). The second type includes pain and suffering, which remains a very subjective component, and awards can be substantial, especially if the defendant's conduct angers the jury. Therefore, non-economic damages, particularly excessive pain and suffering awards, pose a significant problem for defendants.[1] In addition to the plaintiff's damages, consortium damages may be claimed by a spouse to reflect diminution in marital enjoyment.

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* Cleary, Gottlieb, Steen & Hamilton, Washington, D.C.

1. A few states have enacted tort reform measures, which limit non-economic damages, for example at $250,000. These state measures were enacted in response to high jury awards and escalating insurance costs.

Punitive damages may be awarded if the jury finds the defendant's conduct egregious. Only a showing of gross negligence or wanton malicious conduct justify the award of punitive damages. Factors relevant to awarding punitive damages include: continued marketing of a dangerous product, concealment of evidence, violation of government regulations and disregard of complaints. Punitive damage awards have bankrupted some companies, like Dow Corning, Dalkon Shield, and asbestos manufacturers.

III. REGULATORY COMPLIANCE

Non-compliance with a government regulation results in negligence per se. Conversely, compliance with a government regulation serves as presumptive but not definitive evidence that the product is not defective.

IV. UNIQUE FEATURES OF U.S. PRODUCT LIABILITY LITIGATION CLIMATE

Because of its unique system, litigation remains far more burdensome in the United States than in any other country. Some examples of its distinctive system include:

- the jury system;
- contingent fee compensation to plaintiffs' attorneys;
- litigious society with no penalty for frivolous suits;
- extensive discovery;
- use of party experts (as opposed to more neutral court-appointed experts);
- class actions;
- availability of large pain and suffering awards; and
- availability of punitive damages.

The financial incentive to litigate in the United States is greater than in any other country because the economic reward to the plaintiff and to plaintiff's counsel is potentially substantial, and litigation in the United States will continue to be more expensive than anywhere else in the world. Even if U.S. substantive law were identical to the law in other countries, differences in procedures, financial incentives to litigate, and societal attitude toward compromise make defending a product liability suit in the United States more difficult.

The burdensome nature of discovery contributes to the U.S. reputation. Discovery orders often require a party, and even its subsidiaries outside the United States, to provide documents and other information. This includes affiliates

abroad. In an era where e-mail and facsimile are common vehicles for communication, staff worldwide should be aware of the extensive nature of the U.S. discovery regime and the increasing globalization of litigation. As such, companies should adopt responsible document retention programs.

In the United States., predicting the outcome of a lawsuit remains difficult because of the wide variation among courts and because of the differences in state substantive law. In addition to the traditional claims for manufacturing defect, design defect, and warning defect, plaintiffs have successfully advocated the adoption of novel theories of liability. For example, plaintiffs may allege concert of action or conspiracy and concealment resulting in fraud on the public or on a regulatory agency. Furthermore, in mass tort actions, the universe of plaintiffs has expanded from the traditional personal injury plaintiffs to state attorneys general, insurance companies, and employers seeking recovery of health care costs.

V. CLASS ACTIONS AND OTHER MASS TORT CONSOLIDATION DEVICES

When a court finds a large number of plaintiffs too numerous to join, but shares common issues, a court can certify a class action. Class actions prove a particular disadvantage to defendants because class membership is not mandatory (compulsory); plaintiffs with serious cases may pursue their own separate suits. Another disadvantage for defendants results from the potential that a single nationwide finding of liability will occur. However, evidence suggests a trend disfavoring national class certification in mass personal injury litigation, including all medical device and drug cases.

For example, the court denied class certification in the litigation involving folbatrol, blood concentrate (HIV), tampons, artificial hip cases, Dalkon Shield, artificial heart valves, tetracycline, L-Tryptophan, and DES. Lack of commonality in plaintiffs' claims and differences in state substantive law account, in part, for these denials of nationwide class certification. Factors evidencing a lack of commonality include differences in:

- brands relevant to design defects;
- warranties, which included different individual warnings by physicians depending on the nature of the illness;
- causation;
- severity of illness, current and pre-existing medical condition;
- doses and exposure duration and conditions;
- age and lifestyle; and
- the type of harm (i.e., differences in injuries, economic loss, and emotional distress).

Other mass tort management tools include statewide consolidation of similar cases for state cases and nationwide consolidation of similar cases via the multidistrict litigation (MDL) procedure for federal cases. MDL procedure achieves cost reductions in discovery response, and consolidates pretrial discovery by avoiding inconsistent pretrial rulings, and reduces duplicative discovery.

VI. AN EXAMPLE "CASE HISTORY" OF PRODUCT LIABILITY LITIGATION

The L-Tryptophan litigation involved over 2000 claims by individuals alleging that this nutritional supplement caused eosinophilia myalgia syndrome (EMS), a new condition. The severity of EMS varied; the most serious effects included severe incapacitation, some paraplegia, and approximately forty deaths. Upon learning about the reports of EMS, the principal manufacturer of L-Tryptophan stopped selling the product and cooperated fully with a FDA recall.

Defense attorneys for the principal manufacturer designed a program to coordinate pre-trial discovery through MDL to avoid duplicative discovery demands. They successfully opposed class certification by arguing that reliance on MDL achieved the same case management benefits as a class action; this protected the defendant from a single nationwide determination of liability.

This company also adopted a policy of settling timely claims upon evidence of product ingestion and EMS symptoms. Over 2000 claims settled under this national settlement program; many involved alternative dispute resolution mechanisms, such as non-binding mediation and binding arbitration trials.

Jury trials were necessary in only a few cases when, despite using alternative dispute resolution, plaintiffs' demands remained unreasonable. In total, there were only three jury trials, one of which ended in a defense verdict. Despite a vigorous effort by the plaintiffs for punitive damages on the basis that the defendant produced a "bioengineered nutritional supplement." the juries for the other two trials only awarded compensatory damages Unlike most mass tort defendants, this company emerged from litigation in good financial condition; it has resumed payment of dividends and profitable operations.

VII. DEFENSES OF SPECIAL RELEVANCE TO NON-U.S. CORPORATIONS

A. Forum Non Conveniens Dismissal

Attracted by the high damages awards available in U.S. courts, Latin American and other foreign plaintiffs increasingly sue in U.S. courts, even when their injuries occur abroad and when they have never been to the United States.

Del Monte Fresh Produce obtained dismissal of several suits filed by non-U.S. plaintiffs due to forum non conveniens. Plaintiffs from Costa Rica and Guatemala, among others, alleged reproductive injuries from exposure to the nematacide DBCP.[2]

In evaluating forum non conveniens motions, courts typically consider the following factors: 1) adequacy of remedies abroad; 2) private interest; and 3) public interest. In general, federal courts are more receptive to forum non conveniens arguments than are state courts. Because of their tradition of showing hospitality to non-U.S. citizens, plaintiffs file in state courts more often.

1. Adequacy of the non-U.S. forum

A threshold determination involves assessing the adequacy of the non-U.S. forum, whereby courts typically rely on affidavits from competing foreign legal experts about the strengths and weaknesses of remedies abroad. The fact that a non-U.S. forum bases its system on civil law does not impose strict liability, and does not have generous damages awards does not mean that the foreign plaintiffs have no adequate legal remedy in their own courts. As such, U.S. courts generally find that foreign legal systems provide adequate alternative forums.

In an extraordinary effort to demonstrate that non-U.S. courts are inadequate, attorneys representing Latin American plaintiffs have lobbied for legislation purporting to divest their courts of jurisdiction. In two cases, one involving DBCP and another involving Ecuadorian shrimp farmers,[3] the plaintiffs attempted to use legislation passed in their home countries to portray the non-U.S. forum as inadequate. The U.S. courts rejected this maneuver by plaintiffs and dismissed both cases. In the Ecuadorian shrimp case, for example, the trial court noted that after having been dismissed on forum non conveniens, the plaintiffs lobbied the Ecuadorian legislature to obtain a law divesting their home courts of jurisdiction.

2. Private interest factors

The private interest factors include: (1) location of key documents; (2) location of key witnesses; and (3) location of key records. If these key items of evidence are located abroad, forum non conveniens dismissal is more likely.

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2. Delgado v. Shell Oil Co., 231 F.3d 165, 169 (5th Cir. 2000). Other defendants in the suit included DBCP manufacturers and banana growers.

3. Re Ecuadorian Shrimp Litigation, No. 94-10139 (Fla. Broward County Ct. 1994).

3. Public interest factors

The public interest factors include: 1) the burden on the local U.S. courts; 2) the difficulty of applying foreign law; and 3) the need for translation of foreign language documents and testimony.

B. Personal Jurisdiction

Lack of personal jurisdiction exists as a viable defense for defendants who have no, or virtually no, contacts with the forum. Whether a foreign corporation (one incorporated outside the jurisdiction in which it is being sued) is subject to the jurisdiction of the forum involves compliance with the U.S. Constitution and the law of the forum state. U.S. constitutional Due Process criteria require "minimum contacts" with the forum, such that the maintenance of the suit does not offend "traditional notions of fair play and substantial justice," in order to subject a foreign defendant to the forum's jurisdiction.[4]

In practice, the "minimum contacts" requirement is interpreted quite broadly, and sometimes very little contact is required to subject a foreign corporation to the jurisdiction of a U.S. court, especially in mass disaster cases. Even without an office or business address in the forum, sales, contracts, transactions, or isolated visits to a jurisdiction may suffice. One factor may include whether defending a suit in the United States involves a substantial burden on a foreign.

1. Specific jurisdiction

All states have long-arm statutes, which permit its courts to assert "specific jurisdiction" over a defendant for claims that arise out of the defendant's forum-oriented activities.

2. General jurisdiction

Under the concept of "general jurisdiction," a state may also exercise personal jurisdiction over a defendant for claims that do not arise out of the defendant's forum activities if the defendant engages in "systematic" and "continuous" conduct in the forum, thereby making it reasonable to treat the defendant as if it were a local resident for jurisdictional purposes.

4. Int'l Shoe Co. v. Washington, 326 U.S. 310, 316 (1945).

3. Alter ego

As a general matter, a separately incorporated local subsidiary of a foreign corporation will not have its local presence attributed to its foreign parent corporation for jurisdictional purposes. This holds so long as it preserves a proper degree of independence and does not, by conduct such as commingling assets with its parent or failing to observe corporate formalities, permit the corporate veil between itself and its parent to be disregarded. However, if the plaintiff can show that the local subsidiary serves as an agent or a mere department of its parent, it may be characterized as the jurisdictional equivalent of the foreign corporation so as to subject the foreign parent to the forum court's jurisdiction. Moreover, when a local office is not separately incorporated, but is merely a branch of a foreign corporation, its presence in the United States will generally be treated as that of the corporation itself for purposes of personal jurisdiction.