LITIGATION

A BRAVE NEW WORLD: THE DAWN OF HYPER-COMPLEX LITIGATION- HOW THE INFLUX OF IMPORTED PRODUCTS, THE RISE OF CROSS-BORDER AND MULTINATIONAL LITIGATION, AND DIMINISHED INJURY REQUIREMENTS MEAN BIG PRODUCTS LIABILITY HEADACHES FOR MANUFACTURERS IN THE YEARS TO COME

*By Laura C. Fey and Harley V. Ratliff**

A Brave New World

In the world of products liability, complex litigation has most often taken the form of the mass tort: multiple lawsuits arising out of a common incident (or a series of common incidents), litigated across various state and federal court jurisdictions. The classic example, of course, is asbestos, which slogs on even today. Yet, as we near the end of the first decade of the 21st century, complex products litigation is becoming, for lack of a better description, *more complex.*

A legal treatise once defined complex litigation in the same manner that U.S. Supreme Court Justice Potter Stewart famously regarded obscenity: You know it when you see it.[1] For product manufacturers, the writing is on the wall. The simultaneous convergence and dispersal of mass tort products litigation across various countries, continents and jurisdictions is taking place. Stated more simply, big-ticket products litigation is on the move.

On one hand, products imported from abroad – most notably from China – have increasingly brought with them unexpected legal entanglements (including criminal prosecution), unwanted media exposure, and unending crisis management headaches for American companies. On the other hand, the plaintiffs' bar has demonstrated its intent to export domestic products litigation to foreign jurisdictions – primarily Canada – to

---

* *Ms. Fey is a partner at Shook Hardy & Bacon LLP. She represents corporate clients in a variety of litigation matters, including class actions and multi-district litigation, in state and federal courts throughout the country. Clients rely on Ms. Fey, a trial attorney formerly with the Department of Justice, to develop and implement proactive strategies for favorably resolving complex litigation issues. Mr. Ratliff is an associate at Shook, Hardy & Bacon LLP. His practice focuses primarily on the defense of products liability claims, including the coordination and development of resolution strategies for international personal injury and insurance claims. The authors would like to thank Kelly Foos for her assistance in preparing this article.*

1. *See* Jay Tidmarsh & Roger H. Transgrud, Complex Litigation: Problems in Advanced Civil Procedure 1 (Foundation Press, 2002); *see also Jacobellis v. Ohio*, 378 U.S. 184 (1964); *see also* Black's Law Dictionary (8th ed. West 2004).

maximize leverage, recycle domestic efforts, and intensify strain on corporate defendants. More globally, many countries are moving, albeit some faster than others, toward a more American-style approach to mass-tort or aggregate litigation. In other, more extreme cases, foreign governments are pursuing manufacturers and their employees directly for civil and criminal liability arising out of the sale, use and testing of their products.

The result for corporate defendants is a burgeoning litigation trade imbalance. The impact it will have on how such actions are planned, managed and litigated will be significant. Complex products litigation no longer begins and ends in local state and federal courts. From the initial document collection to the ultimate resolution, the traditional model for defending these actions is becoming obsolete.

Managing the defense of hyper-complex litigation means now, more than ever, being able to successfully coordinate not only state and federal personal injury actions, but also criminal, regulatory, governmental, and international efforts in a way that is efficient, economical and – most importantly – effective.

Importing Products; Importing Litigation

For years, complex products litigation has been the unfortunate province of a few, targeted industries. Many of these industry participants (*e.g.*, pharmaceutical and medical device manufacturers, tobacco companies, and makers of chemical-based products) have, in turn, developed sophisticated in-house legal departments that grasp the breadth and pervasiveness – not to mention the international creep – associated with such litigation.

The Import Influx

Complex products litigation has, however, recently forayed into new territory: the imported consumer product. Many of these products – *e.g.*, pet foods, toothpastes, toy trucks, etc. – are traditionally innocuous and not typically associated with mass tort litigation.

Our country's reliance on imported products, particularly those from China, has increased dramatically in the past decade. In 1996, for example, agricultural and seafood imports from China totaled approximately $453 million. Ten years later, the total value was more than $4 billion.[2] The dependence on Chinese manufacturing and production has brought with it a demonstrated risk for increased products liability litigation domestically.

---

2. *See* Marilyn Geewax, *Bush Creates Panel To Ensure Safety of Imported Food and Products*, Cox News Service (July 19, 2007).

The litany of recent issues with imported products is, by now, well-known: pet food tainted with melamine;[3] toothpastes mixed with a solvent found in anti-freeze; seafood contaminated with unapproved antimicrobial agents; and children's toys with allegedly dangerous levels of lead surface paint, to name a few. Extensive litigation has since followed.

For example, of the twelve products liability multidistrict litigations (MDLs) created in 2007 by the Judicial Panel on Multidistrict Litigation, the body responsible for making federal consolidation determinations, three were directly related to products manufactured in China: MDL-1850: *In re Pet Food Prods. Liab. Litig.*, MDL-1897: *In re Mattel, Inc. Toy Lead Paint Prods. Liab. Litig.*, and MDL-1893: *In re RC2 Corp. Toy Lead Paint Prods. Liab. Litig.* All three consolidated actions were created just months following the initial product recalls.[4] On October 15, 2008, Menu Foods Inc. announced that the MDL Court overseeing the pet-food litigation had certified the settlement class and given final approval to a comprehensive settlement agreement.[5] The $24 million settlement will be funded by Menu Foods and at least nine other named defendants, including Nestle Purina Petcare Co., Petco Animal Supplies Inc. and Chemnutra Inc.

Perhaps more troubling for corporate defendants is the fact that criminal proceedings have been filed in the wake of these imported product recalls.

On February 6, 2008, the Federal Food & Drug Administration's (FDA) Office of Criminal Investigations "announced that two Chinese na-

---

3. The use of melamine in various Chinese-made food products has proven not limited to pet food. Numerous products continue to be recalled in the United States and Canada because of the presence or suspected presence of melamine. In China, the use of melamine in baby formula allegedly resulted in the death of at least four infants. More than 54,000 babies were reportedly sickened by the allegedly tainted formula. *See* Linda Nguyen, *Chocolate Coins Sold in Costco, Dollar Stores Contain Melamine: CFIA*, Canwest News Service (Oct. 8, 2008); *see also Anita Chang, Report: China's Animal Feed Tainted with Melamine*, Associated Press (Oct. 30, 2008).

4. *See Transfer Order*, MDL-1850: *In re Pet Food Prods. Liability Litig.* (June 19, 2007 JPML) (transferring thirteen initial actions related to allegedly contaminated pet food in the District of New Jersey); *Transfer Order, In re Mattel, Inc. Toy Lead Paint Prods. Liability Litig.*, MDL No. 1897 (transferring the eleven initial actions arising out of Mattel, Inc.'s recall of toys with allegedly elevated levels of lead paint to the Central District of California). *Transfer Order, In re RC2 Corp. Toy Lead Paint Prods. Liability Litig.*, MDL No. 1893 (transferring the fourteen initial actions arising out of the recall of certain toys by RC2 Corp. and Learning Curve Brands, Inc. due to allegedly elevated levels of lead in surface paints). A fourth MDL involving Chinese-related products recently has been transferred. *See Transfer Order, In re Heparin Prods. Liab. Litig.*, MDL No. 1953.

5. *See* October 22, 2008 Press Release, *available at* www.petfoodsettlement.com. A statewide settlement in Hawaii also attained preliminary approval on May 19, 2008 from the Circuit Court of the First Circuit. The $240,000 settlement, arising from the case *Lum v. Menu Foods, Inc.* (Civil No. 07-1-0849-05) is split in half, between paying claims and payments to Hawaiian humane societies. The class consists of Hawaii residents who purchased in Hawaii between November 8, 2006 and March 7, 2007 Menu Foods pet food that was recalled between March 16, 2007 and the present.

tionals and the businesses they operate, along with a U.S. company," ChemNutra, "and its president and chief executive officer had been indicted in separate but related cases."[6] The defendants have been charged with "delivering adulterated food that contained melamine, a substance which may render the food injurious to health, into interstate commerce" and "introduction of a misbranded food into interstate commerce."[7] If convicted, the defendants face up to seven years in federal prison and fines potentially totaling millions of dollars.[8]

Likewise, criminal charges have been filed in California state court against four executives and two companies in the aftermath of the imported toothpaste recall.[9] On March 7, 2008, charges were brought against Los Angeles based-importers Vernon Sales, Inc. and Selective Imports Corp. for importing from China ninety thousand tubes of toothpaste allegedly contaminated with diethylene glycol, a solvent that has been associated with kidney and liver disease.[10] The companies' four top executives have been charged with a combined sixteen counts of receiving, selling and delivering adulterated drugs and products.[11] Each of the sixteen counts "carries a maximum penalty of one year in jail and a $1,000 fine."[12]

No End in Sight

The odds seem unlikely that the recent rash of imported product advisories and recalls, and the subsequent related litigation, both civil and criminal, is a short-term occurrence.

First, and as noted above, more and more products are imported into the United States. The number of imported consumer products has doubled in the past decade.[13] Over the past two years, two-thirds of all consumer recalls were related to imported goods. And nearly two-thirds of those goods came from China.[14] As long as there is an economic incentive to manufacture and/or import foreign products, the likelihood

---

6. *See FDA Investigation Leads to Several Indictments for Importing Contaminated Ingredients Used in Pet Food,* Food and Drug Administration Documents and Publications, Feb. 6, 2008.

7. *Id.*

8. *See Complaint, United States of America v. Sally Miller,* No 08-23 (W.D. Mo., Feb. 6, 2008).

9. *See* Louise Story & Geraldine Fabrikant, *4 Executives Are Charged Over Tainted Toothpaste,* N.Y. TIMES, Mar. 7, 2008, at C3.

10. *Id.* Although no deaths were reported in the United States, government officials in Panama concluded that at least 115 people died after ingesting a Chinese-made cold medicine also containing deithylene glycol. *See id.*

11. *Id.*

12. *See* Tiffany Hsu, *L.A. files charges on China imports,* L.A. TIMES, Mar. 7, 2008, at C3.

13. *See* Melanie Trottman, *When Recall Isn't Total: Surge in Imports Challenges Voluntary System,* WALL ST. J. (July 15, 2008).

14. Geewax, *supra* note 2; *see also* Trottman, *supra* note 13.

of exposure to unpredictable downstream products liability litigation will persist.[15]

Consider, for example, the case of imported food. The United States imports approximately $65 billion in food goods annually.[16] Between 2002 and 2007, the amount of food items imported from China increased by more than one hundred forty percent.[17] As one scholar suggested, the result of the increasingly complex supply chain may be "regular food-borne outbreaks."[18]

Take the case of Chinese shrimp. More than one hundred fifty million pounds of Chinese shrimp were imported into the United States during the past year.[19] The U.S. Department of Agriculture (USDA) has reported that as much as ten percent of this shrimp contains Salmonella.[20] The FDA, meanwhile, is able to inspect less than one percent of the imported foods the agency is expected to monitor.[21] Where there are perceived gaps in the system, lawsuits tend to follow – regardless of whether actual injuries exist. Moreover, while potentially dangerous pathogens associated with food-borne illnesses are evolving, techniques in detecting these microbial agents are improving.[22] The result is more and better documented outbreaks of food-borne illnesses. In March 2008 at least eight domestic produce distributors voluntarily recalled cantaloupe imported from Honduras following reports of more than sixty Salmonella-related illnesses in the United States and Canada.[23] It was the second such recall in as many months.[24] Both incidents were publicized extensively on plaintiffs' firm web sites.

Second, traditional regulatory defenses and safe harbor provisions for certain imported products may prove less effective than in other types

---

15. The issue with imported products is not limited to China. As former FDA Director of Import Operations and Policy told The *New York Times* last summer: "The reality is, this is not a single-country issue at all . . . [w]hat we are experiencing is a massive globalization." *See* Andrew Martin and Griff Palmer, *China Not Sole Source of Dubious Food*, N.Y. TIMES, July 12, 2007, at C1.

16. Goody L. Solomon, *Watching for Iffy Imports: Skimpy U.S. Inspection Resources Are Raising Concerns*, WASH. POST, Jun. 20, 2007, at F7.

17. *See* Toni Johnson, *China's Troubled Food and Drug Trade*, COUNCIL ON FOREIGN RELATIONS, Oct. 17, 2008.

18. *See* Dan Thanh Dang & Larry Carson, *Food Recalls Likely To Be More Common; Foodstuffs' Increasingly Global Origins, Multiple Agencies Bar Thorough Checks*, BALTIMORE SUN, Nov. 6, 2007, at 1D.

19. *See* Frank Ahrens, *FDA Halts Imports of Some Chinese Seafood*, WASH. POST, Jun. 29, 2007, at D1.

20. *See* Diedtra Henderson, *Chicken from China? Questionable Farming Practices Fuel Skepticism of US Plan to Import Poultry*, BOSTON GLOBE, May 9, 2007, at F1.

21. Alexei Barrionuevo, *Food Imports Often Escape Scrutiny*, N.Y. TIMES, May 1, 2007.

22. *See* Kenneth M. Odza, *Foodborne Illness and Practical Protections*, THE COOPERATIVE GROCER, Jan.-Feb. 2008.

23. *See FDA Warns Not to Eat Cantaloupe from Honduran Grower*, Mar. 22, 2008. *See also* Sara Stefanini, *Recalls of Tainted Cantaloupe Continue to Rise*, PRODUCTS LIAB. L. 360, Mar. 31, 2008.

24. *Id.*

of products litigation. For example, makers of pharmaceutical and medical devices have, for years, rightfully cloaked themselves with the protection of regulatory oversight and approval when confronted with products liability claims. Indeed, the U.S. Supreme Court recently affirmed this position in *Riegel v. Medtronic, Inc.*, barring all common-law claims challenging the safety and effectiveness of medical devices that had received FDA pre-market approval.[25] Although legislative efforts are underway,[26] the perception has been created that imported consumer goods lack the kind of comprehensive regulatory oversight often associated with products approved by, say, the FDA. With *Riegel* (and potentially *Wyeth v. Levine*[27]) – likely cutting a sizable chunk out of their portfolio of once-profitable work, industrious plaintiffs' attorneys will no doubt be looking to invest in potential litigation that they perceive to be less likely to be strangled by federal law.

Third, plaintiffs' attorneys have increasingly eschewed the need for clients with identifiable injuries, relying instead on so-called no-injury claims such as emotional distress, medical monitoring and consumer protection violations (*i.e.*, monetary losses associated with the purchase price of the product). In these instances – at least for the plaintiffs' attorneys involved – the mere act of recalling the product *is the injury*. Stated differently, under this expansive approach every consumer who purchases a recalled product becomes a *de facto* plaintiff waiting to be enrolled in the next mass action. The lead paint toy lawsuits are illustrative. Questions remain as to whether the level of lead found in these toys' surface paint, along with the likely potential exposure pathways, can cause the type of cognitive injuries – either presently or in the future – associated with lead exposure. Yet, the lack of clear causation evidence has not stopped the

---

25. *See Riegel v. Medtronic Inc.*, 128 S. Ct. 999 (2008).

26. On August 14, 2008, President George W. Bush signed into law the Consumer Product Safety Improvement Act of 2008 (CPSIA). The CPSIA is considered the most comprehensive overhaul of the consumer product safety laws since the creation of the Consumer Product Safety Commission (CPSC) in 1973. The CPSIA – spurred largely by the rash of imported consumer product recalls – provides the CPSC with greater funding, increased staff, and the authority to impose significantly higher penalties. In addition, the CPSIA broadly restrains the CPSC's preemption authority and adopts new whistleblower protections. The CPSIA is expected to be a boon for plaintiffs' attorneys. As David Arkush, Director of Public Citizen's Congress Watch Division, stated: "This is a huge victory for consumers over big business." *See* Victor E. Schwartz, Cary Silverman & Christopher E. Appel, *Consumer Product Safety Reform Could Mean a Boon for Safety or a Boondoggle For Plaintiffs' Lawyers: It's Up to the CPSC, State AGs, the Court, and You*, 36:43 PROD. SAFETY & LIAB. REP. (BNA) 1106 (Nov. 3, 2008).

27. *See Wyeth v. Levine*, – S.Ct. – , 75 USLW 3500, 76 USLW 3018 (U.S. Vt. Jan. 18, 2008) (No. 06-1249). Before the Court in *Levine* is the issue of whether state-law tort claims are pre-empted to the extent they would impose liability for a drug manufacturer's use of labeling that the FDA approved after being informed of the relevant risk. If so, state-law claims that challenge such labeling would be impliedly pre-empted. A decision is expected in 2009.

extensive filing of medical monitoring class actions and the formation of two multidistrict litigations.

Fourth, the incredible diversity of products manufactured abroad means no company or industry is necessarily immune from potential import-related products litigation – even the most highly-regulated.[28]

Finally, the ability of American consumers to redress claims against exclusively foreign companies remains to a degree limited, meaning that domestic or multinational entities will likely continue to shoulder the bulk of defending liability in such cases in U.S. courts. Although China and other countries have products liability laws, it is unlikely that American consumers will attempt to actually pursue their claims abroad.[29] Conversely, while attempts to litigate against potentially liable foreign entities in U.S. courts are being made (*e.g., In re Menu Food Pet Food Prods. Liab. Litig.*), such lawsuits raise issues of choice-of-law, venue, forum non conveniens and enforcement of judgments, making exclusively overseas targets markedly less attractive to plaintiffs' attorneys.

In the end, mass tort litigation is often triggered by the one bad headline, and imported product recalls have been front-and-center in the U.S. media for more than a year. With many of these situations involving perceived vulnerable classes (children, pets, etc.), the ongoing heightened media scrutiny with regard to consumer products – and the litigation that inevitably follows – should be expected to continue.

Beyond Our Borders: Litigation Abroad

While products imported from abroad are spawning mass tort litigation domestically, a new and equally troubling aspect of products litigation is creating complexity outside U.S. borders. For many years, the threat of international class or aggregate product litigation seemed like thunder in the distance – more a ghost story attorneys told their clients than a tangible business threat.

The likelihood, however, that companies will now have to litigate outside the United States, particularly cross-border, what were once thought to be traditionally domestic products liability cases is stronger than ever. The export of American products litigation has begun. Understanding this recent legal diaspora, and the challenges it poses to product manufacturers, is fundamental to the new management of modern mass tort litigation.

The Canadian Double-Down

At a 2008 products liability symposium, a well-regarded New York City plaintiffs' attorney stood before a room of lawyers and in-house

28. Most recently, for example, the pharmaceutical industry has seen a series of lawsuits stemming from products manufactured, if only in part, overseas.

29. *See* Article 41 of the PRC Product Quality Law; *see also* Article 106 of the General Principal Civil Law.

counsel. The topic of his presentation was, in part, to forecast the next direction of mass tort litigation. His message to those listening was clear.

"Canada is next."

For many companies, defending products liability litigation in Canada is very much *now*. Although law reforms taking place in Europe (and discussed below) may be ominous, class action litigation in Canada – often designed to mimic a particular domestic mass tort counterpart – represents the most immediate products liability challenge for corporate defendants outside the United States.

Canada's experience with class action proceedings is fairly nascent. In the early 1990s, Ontario became the first Canadian province to introduce formal class proceedings.[30] Fast-forward fifteen years and, with the passing of its Class Proceedings Act, Nova Scotia became the most recent Canadian province to enact comprehensive class legislation.[31] In fact, Prince Edward Island remains the only Canadian province without some type of similar legislation.

While class action law in Canada has matured rapidly, plaintiffs' attorneys in the United States have found obtaining (or maintaining upon appeal) class certification involving personal injury actions in federal court increasingly difficult. The hurdle of overcoming individual issues of reliance and specific causation has often proved too high to justify certifying these types of classes. In addition, the Class Action Fairness Act (CAFA) has made it easier for defendants to remove such cases from state court to federal court. Too often rebuked at home, many plaintiffs' attorneys are now looking north of the border not only for class-wide relief, but to maximize their domestic efforts as well, attempting, in essence, to broker two potential windfalls for the cost of litigating little more than one.

The relative advantages for plaintiffs to litigating class actions in Canada – relative to other non-domestic jurisdictions – are well known. With the exception of Quebec, there is no real language barrier and travel is relatively convenient. The legal system, while different from the United States', is still grounded in the common law. Pre-trial efforts in the United States (*i.e.*, discovery, pleadings, expert witness development, etc.) can be recycled for purposes of Canadian litigation, reducing potential costs. Due to supply chain similarities and the availability of nearly identical legal theories, copycat pleadings can be easily mutated to fit the Canadian legal system. Often, plaintiffs' attorneys appointed to MDL leadership positions (i.e., plaintiff steering committee, plaintiff leadership committee, lead liaison counsel, etc.) coordinate or lead from behind the scenes these parallel Canadian class proceedings; bringing with

30. Todd J. Burke, *Canadian Class Actions and Federal Judgments: Recognition of Foreign Class Actions in Canada*, 17 BUS. L. TODAY 49 (Sept./Oct. 2007) *available at* http://www.abanet.org/buslaw/blt/2007-09-10/burke.shtml.

31. The act will not technically come into effect until it is "proclaimed."

them their knowledge of the litigation and understanding of the key factual issues.

The threshold for certifying these new products liability class actions in Canada is proving considerably lower than in the United States, making the filing (or multiple filings in multiple provinces) of parallel class proceedings in Canada a seemingly worthwhile adventure for both Canadian and U.S. plaintiffs' attorneys.

Take, for example, the recent litigation involving Medtronic, the Minnesota-based maker of implantable medical devices. On December 6, 2007, just months after a $400 million MDL settlement that covered products claims related to the company's defibrillators,[32] the Ontario Superior Court, in *Peter v. Medtronic*, certified a class of patients implanted with certain of the company's same defibrillators.[33] Once again, the reliance on diminished injury requirements was notable. The court, in certifying the class, was not troubled by the fact that class members could not prove a present physical injury or a "foreseeable and recognizable psychiatric illness" as a result of the alleged product defect.[34] Rather, the court noted vaguely that these plaintiffs still "may be able to prove damages."[35]

This is not an isolated case, but rather is representative of the numerous class action proceedings presently being litigated in Canada and serving as the legal doppelganger to their American counterparts. And rulings such as the one in *Peter v. Medtronic* will likely serve to only further cement the increasingly symbiotic relationship between domestic and cross-border Canadian products litigation.

The Coming Wave: International Products Litigation

While litigation is charging ahead in Canada, "access to justice" movements – the concept that individuals should be allowed to redress consumer claims in court – have steadily gained steam in Europe and abroad during the past decade. What the long-term implications of this movement mean for corporate defendants remains unclear. What is known, however, is that international products litigation is becoming very much part of the modern mass tort rubric.

Three areas of interest are worth briefly addressing.

---

32. *In re Medtronic, Inc. Implantable Defibrillator Products Liability Litig.*, No. 05-MDL-1726 (D. Minn.).

33. *See Peter v. Medtronic, Inc.*, No. 05-CV-295910CP, slip op. (Ontario Sup. Ct. Justice Dec. 6, 2007).

34. *Id.* at 14.

35. *Id.* Less than five months after the decision in *Peter v. Medtronic*, the same Ontario court certified a class consisting of nearly two thousand recipients of defibrillators made by a different manufacturer. *See* Carissa Wyant, *Guidant Suit Granted Class Action Status in Canada*, MINNEAPOLIS/ST. PAUL BUS. J., Apr. 11, 2008. Another class action is pending in Toronto against a third maker of heart devices. *See* Joe Schneider, *St. Jude Sued in Canada over Failures of Riata Defibrillators*, BLOOMBERG.COM, Apr. 1, 2008, http://www.bloomberg.com/apps/news?sid=a9oGFMBjmeT4&pid=20601082.

First, significant legislative developments in Europe are making the ability to redress product claims more readily available through aggregate or class-style litigation. The most notable recent development occurred on December 21, 2007, when "the Italian Parliament passed a law that significantly expanded the scope of representative actions permissible in Italian courts."[36] Although the new law, which is scheduled to take effect on January 1, 2009,[37] still does not allow for individual plaintiffs to bring such suits, it does potentially allow any consumer association to file a representative action and request damages on behalf of consumers for alleged tort liability, unfair trade practices or anti-competitive behavior, provided such unlawful acts damage the rights of a plurality of consumers and users.

The new law also includes traditional "opt-in" provisions and certification phases – concepts no doubt familiar to U.S. class action practitioners. Although the country still employs the "loser pays" rule, Italy does allow for contingency fee arrangements, and legal aid is available to litigants.[38] And Italy is not alone in moving forward with legislation designed to empower consumer litigants.

Similar, although more restrictive, class action legislation has been passed in Denmark and Finland.[39] In Germany, the traditional bar on contingency fee arrangements has been repealed. In many countries, a violation of the country's consumer code is itself the injury claimed, regardless of whether a showing of actual harm or reliance can be made – further demonstrating the increasing viability of no-injury claims not only in the United States, but also abroad. And with product recalls up by more than fifty percent in Europe, the litigation landscape abroad is more and more mirroring our own. Indeed, in one recent survey nearly half of all business leaders questioned believed that American-style litigation was increasingly taking hold in Europe.[40]

Second, one-off product litigation in jurisdictions that are geographically remote and perhaps unfamiliar both in terms of legal systems and cultural intricacies, continue to emerge. In these jurisdictions, traditional products liability claims can morph into quasi-criminal proceedings, pulling in not only the manufacturing entity, but also the employees charged with making decisions on the company's behalf.

---

36. *See* Shook, Hardy & Bacon Class Action & Complex Litigation Alert, *Italian Parliament Passes New Representative Action Law*, Jan. 8, 2008 (available upon request).

37. There remains speculation that the law may still be stripped of some of its more pro-consumer provisions before enactment.

38. See "Bersani Decree"(Title 1 of Law 4 August 2006 nr. 248) *available at* ec.europa.eu/comm/competition/sectors/professional_services/conferences/20061230/lirosi.pdf.

39. For a comprehensive summary of recent international litigation developments, *see* Mark A. Behrens, Gregory L. Fowler & Silvia Kim, *Global Litigation Trends - Class Actions, Contingency Fees, and Punitive Damages: Moving Toward the American Civil Law Model?*, 17 MICH. ST. J. INT'L LAW (forthcoming).

40. *See Litigious U.S. Ways Strangling Global Growth*, NEWSMAX.COM, May 29, 2008.

In Nigeria, for example, multiple suits are presently being prosecuted by a variety of local governmental entities against foreign manufacturers relating to the sale, use and/or testing of their products in Nigeria. In June 2007, the Nigerian government began prosecuting civil and criminal proceedings (in Nigeria) against an international pharmaceutical company, seeking more than $7 billion in damages and arresting company officials, including the company's former medical director.[41] One plaintiff, the Nigerian State of Kano, has since demanded nearly $2 billion to settle the litigation.[42] In November 2007, the Nigerian government also filed suit against a number of tobacco manufacturers, requesting more than $42 billion in damages related to under-age smoking.[43]

The litigation in Nigeria is not without a rather troubling link to mass tort litigation in the United States. In both instances, the Nigerian government is represented by attorney Babatunde Irukera, who recently merged his eighteen-lawyer, Lagos, Nigeria-based firm with Simmons-Cooper, the Madison County, Illinois, plaintiffs' firm best known for its asbestos work.[44] The global courtroom is, without question, getting smaller. Depending on the outcome, the lawsuits in Nigeria may very well serve as an unfortunate bellwether for other countries and political regimes seeking financial and political capital from multinational product manufacturers.

Finally, practical management concerns related to domestic litigation, but involving foreign participants in foreign jurisdictions, have increasingly become an issue in complex products litigation. Although perhaps overlooked, individual personal injury lawsuits similar to those in the United States are often filed in international jurisdictions in the aftermath of a domestic mass-tort action. These cases typically persist after settlement of domestic claims, calling into question just how "global" these resolutions really are. In December 2007, for example, Mark Lanier, the well-known Vioxx plaintiffs' attorney, threatened (whether legitimate or not) that there could be as many as several thousand Vioxx cases filed in Germany, Israel and the United Kingdom.[45]

---

41. *See Nigeria files new Pfizer claims*, BBC NEWS, July 20, 2007; *Pfizer Employees in Nigeria Court Over Fatal Drug Trials; Case to Resume March*, THOMPSON FINANCIAL, Feb. 4, 2008.

42. *See Pfizer seeks settlement over drugs trial: Nigerian official*, YAHOO!NEWS, Apr. 28, 2008, http://news.yahoo.com/s/afp/20080428/wl_africa_afp/nigeriauscompanydrugspfizer.; *see also* Erin Fuchs, *Nigeria Case Settlement in Sight for Pfizer*, HEALTH LAW 360 (Oct. 27, 2008).

43. *See* Christine Caulfield, *Nigerian State Drops $23B Tobacco Suit*, PRODUCTS LIAB. L. 360, Feb. 25, 2008.

44. Richard Lloyd, *Into Africa: SimmonsCooper's Novel International Expansion*, AM. LAWYER 24 (Mar. 2008). SimmonsCooper is not the only U.S. plaintiffs' firm to make a run at an international presence. In 2007, the well-known and highly lucrative plaintiffs' firm of Cohen, Milstein, Sellers & Toll opened an office in London. *See* Jonathan D. Glater, *To the Trenches: The Tort War is Raging On*, N.Y. TIMES (June 22, 2007).

45. Julie Kay, *Vioxx Pact Isn't The End – It's The Beginning: Merck Faces Slew of U.S., Foreign Suits*, NAT'L L.J. 1 (Dec. 3, 2007).

Coordinating the defense of these cases in-line with worldwide corporate objectives – rather than in an *ad hoc*, country-by-country manner – is another piece of the new complex puzzle.

PREPARING FOR THE HYPER-COMPLEX

As mass tort litigation moves more readily across borders – both into and out of the United States – it is, undoubtedly, getting more complex. The real questions are: What is the import of all of this? How can companies prevent (or, at least, put themselves in the best possible position to defend) increasingly complex litigation and protect their brands? And what should companies expect when today's complex products litigation arrives when it is least expected?

The Best Litigation Is No Litigation

The first piece of advice is, of course, always the easiest to give and the most difficult to accomplish: Avoid the litigation before it begins.

No two companies, regardless of industry or product, are similarly situated. And when it comes to litigation prevention and protecting brand reputation, each company must assess its own operations, supply chains and products in terms of potential liability risk. Fundamentally, preventing big-ticket litigation (and, indeed, litigation at all levels) requires an ongoing, individualized analysis. Despite the increasing risk and cost profile presented by today's complex products litigation, a surprising number of companies do not invest in proactive litigation prevention strategies. Indeed, one recent study found that forty-three percent of European and Asian companies had not adopted formal risk-management policies or procedures; yet the directors of these same companies were spending "an average of 13 percent of their time discussing litigation and expect that amount to increase over the next three years."[46] The unfortunate trade-off in not investing time and money in preventing litigation is often more time and money spent in *litigation*.

Preventing litigation does not begin and end with the in-house legal department. Rather, it requires an integrated approach to system-wide business practices.

This starts with a company's employees, whose records and testimony ultimately become the critical component of any future litigation. Employees should understand potential litigation risks and how those risks can best be avoided in the normal course of their day-to-day duties – without sacrificing efficiency or productivity. Companies should take the time to ensure that their employees know and comply with applicable corporate governance standards; understand and follow good records creation and management practices; and recognize how their actions can affect the company's risk exposure. Audits should be conducted on a regular

46. NEWSMAX, *supra* note 40.

basis to make sure that these practices are up-to-date and are being followed.

Another preventative measure is for companies to analyze the workings of their increasingly complex supply chains, and to ensure that proper protections are in place throughout the supply chain. The recent imported product litigation has, if anything, cast an uncomfortable spotlight on the failure of many companies to grasp the vast network of supply tributaries involved in the manufacture of their products. These gaps have increased risk exposure and mired these companies in litigation that is disruptive, expensive and potentially undermines long-standing brand reputation.

Take, for example, the Menu Foods' pet food recall, which is expected to cost the company in total an estimated $54 million (if not more). Lost revenues may linger long after the litigation concludes as pet owners scratch the company's products permanently from their shopping lists. Likewise for the toy companies involved in the lead paint recalls. Toy sales for these companies flattened during the critical 2007 holiday season and investors took note. Mattel and RC2 Corp.'s stocks dropped twenty and thirty percent, respectively, during the same time period.[47] For these companies, the resulting litigation is but one part of a very expensive product problem.

How a product gets to market is a simple question, but for many companies, it is one without an easy answer. Moreover, although many companies have strong quality assurance programs in place – both here and abroad – such programs may not be enough to protect them from downstream products litigation in the United States. Companies now must not only watchdog their own facilities, but also must affirmatively address suppliers' responsibilities with respect to safety and quality, and insulate themselves from potentially harmful actions of their various third-party suppliers.[48] Doing so means conducting risk assessments down the supply chain; analyzing and (if necessary) revising supplier agreements to properly address issues such as safety documentation and product quality; addressing supplier responsibilities (including responsiveness with respect to recalls, traceability, and crisis management); and reviewing applicable insurance coverage. Further, agreements should be reached with players in the supply chain as to how the burden of any litigation costs and any potential judgments will be shared. Companies should know who their suppliers are – and who their suppliers' suppliers are – and ensure that the proper protections are in place at every link

---

47. *See* Justin Grant, *Recalls haunt toy companies in "Blue Christmas,"* REUTERS, Dec. 21, 2007.

48. The oversight task is not made easier by the myriad of potential suppliers that can be involved in bringing a product to market, particularly when those suppliers are located abroad. For example, it is estimated that of the approximately one million food processors in China, at least seventy percent are food workshops with fewer than ten workers. Johnson, *supra* note 17.

along the ever-expanding chain. Failure to do so is at the heart of much of today's mass tort litigation.

Consumer products companies also should put into place recall and crisis management plans that *effectively* address how to best get the company's messages to the public. The selected members of the crisis management team should meet on a routine basis so that they know each other well before any crisis hits. The days of "no comment" are long gone. Companies must be prepared to take control of their message early, effectively, and in a manner that lets their consumers and the public know they are being forthcoming and are taking the issue seriously. Responding to a product crisis on an *ad hoc* basis inevitably results in critical decisions that are later regretted. Similar planning should go into ensuring that product labeling, warnings, and marketing messages are accurate and do not omit critical information.

Finally, companies should stay on top of emerging issues important to the company's industry, including litigation, legislation and regulation.[49] Companies should actively engage in the legislative and regulatory process with respect to proposed legislation and regulation they believe is likely to assist or hinder them in their business operations.

Bracing for the Onslaught

As our former secretary of defense Donald Rumsfeld so astutely (and infamously) pointed out, there will always be "unknown unknowns" that are, to some degree, impossible to prepare for. Thus, the reality remains that even the most robust due diligence (with respect to design, quality assurance, manufacturing, etc.) may not shield a company from being pulled into a world of increasingly complex products litigation. For many companies, defending themselves in this type of litigation is a new – and eye-opening – experience.

Companies unfamiliar with modern mass tort procedure can vastly underestimate the time, expense and planning required to effectively defend and ultimately resolve these types of litigations. For example, companies may make an unrealistic internal assessment as to potential case volume. A company might have ten reported events associated with its product and thus (understandably) expect ten cases to be filed, if that.

But with less concern for finding clients with actual injuries, plaintiffs' attorneys increasingly fill their inventory with litigant chaff. Indeed,

---

49. One important emerging issue affecting many industries is climate change. In light of the increasing focus on the impact corporations have on the environment, corporations should consider better incorporating citizenship and sustainability into their core business strategy. Companies that address these challenges not only are being responsible citizens, they can actually improve their competitive position through innovation. Companies that are ahead of the game when new regulations are put into place can save money and resources by improving their operations. Moreover, these same companies improve their corporate standing with consumers and may actual achieve greater market share by producing "green" products that are desirable to consumers.

the relationship between *actual injuries* and total case volume within a particular litigation has become a grotesquerie of our tort system. In addition, the twenty-four-hour news cycle and the advent of the Internet have made it easier for plaintiffs' attorneys to more efficiently seek out large numbers of clients. Within several weeks of one recent imported product recall, a Google™ search for attorneys involved in the potential litigation registered more than half-of-a-million hits.

By signing up online, former customers are transformed with the push of a button into future plaintiffs, often without understanding the implications of their actions. All of this results in the number of cases ballooning well beyond what anyone, other than the plaintiffs' attorney, would consider remotely reasonable. Ten cases quickly become one hundred, five hundred or one thousand cases over the course of several months. Most of these end up in multidistrict litigation, which, for better or for worse (and the jury is still very much out), has emerged as the predominate model for litigating mass torts in federal court.

Additionally, many companies – who thankfully are not on the regular roll call of mass tort defendants – are simply unaware of how vast the landscape is in which today's complex products litigation occurs. Although litigation may begin as a mass of personal injury actions, it often splinters into a host of different, albeit factually-related lawsuits. This may include all, or some combination of the following: States' attorney general actions, Department of Justice investigations, regulatory or administrative actions (FDA, SEC, CPSC, etc.), deceptive trade practices class actions, securities/investor suits, insurance/reinsurance recovery, third-party/secondary-payor claims, *Qui Tam* proceedings, and local criminal prosecution of the company or its employees.[50]

Think of it as a litigation pinwheel. Each of the above actions start as connected to the initial products litigation. But as the wind blows stronger, these derivative actions break free, taking on a life of their own and often lasting long after the initial products litigation has been resolved.

A coordinated approach to defending all aspects of the litigation is critical to the successful and efficient resolution of every suit. Consider the already onerous issue of paper and electronic discovery. As litigation becomes more complex, companies, and their outside counsel, must have the resources and know-how to successfully manage these global-scale

---

50. For example, in the aftermath of a California meat packing company's recall of more than 140 million pounds of beef – the largest meat recall in U.S. history – local prosecutors filed felony and misdemeanor charges against the slaughterhouse manager and an assistant. *See* David Brown, *USDA Orders Largest Meat Recall in US History*, WASH. POST, Feb 18, 2008, at A1. *See* Victoria Kim, *Charges of Meat Plant Cruelty Filed*, L.A. TIMES, Feb. 16, 2008, at B1; www.meatingplace.com, Feb. 18, 2008. For more information on important developments in law, legislation, regulations and science impacting food and beverage companies, please contact Laura Fey to subscribe to Shook, Hardy & Bacon's weekly Food & Beverage Litigation Update.

document issues, including collection, review and production, in a consistent fashion.

As a final point, the importance of the earliest cases, including individual plaintiff's cases, can be overlooked. The positions taken in those cases, as well as the testimony given and discovery responses provided, can haunt the company in future cases. Further, a significant adverse verdict and/or a large settlement in an early case will enhance the probability that many other cases will follow. Plaintiffs' lawyers are often well coordinated and communicate on a worldwide basis. It is essential that the company get the defense of these kinds of cases right the first time.

Conclusion

By most estimates, the idea of globalization as an economic principle did not take hold until the mid 1990's. More than a decade later, the concept is making its imprint on American litigation. For corporate defendants, this has resulted in an undesirable import/export dilemma. More and more, products arrive from overseas bringing with them unexpected litigation. At the same time, domestic litigation is heading outside of U.S. courtrooms as plaintiffs' attorneys look to expand the litigation playing field. Complex products litigation is taking more time and consuming more resources than ever. Further, it is having a significant impact on brand reputation and stock value. Companies must now, more than ever, be prepared to address the realities of these new litigation dynamics.