FOLEY HOAG LLP

Product Liability **Update**

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Foley Hoag LLP publishes this quarterly Update concerning developments in product liability and related law of interest to product manufacturers and sellers.

Massachusetts Supreme Judicial Court Holds Failure-to-Warn Claim Against Drug Manufacturer Not Preempted Because There Was No "Clear Evidence" FDA Would Not Have Approved Plaintiffs' Suggested Warning; Also Holds Non-Physician's Causation Opinion Admissible and $63 Million Compensatory Award Not Excessive

In *Reckis v. Johnson & Johnson*, 471 Mass. 272 (2015), a seven-year-old developed the severe dermatologic disease toxic epidermal necrolysis (TEN) after her parents gave her multiple doses of over-the-counter ibuprofen even after the girl began developing a rash. The child's parents, for themselves and on her behalf, sued the drug's manufacturers in Massachusetts Superior Court for negligence, breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) and violation of Mass. Gen. L. ch. 93A (the Massachusetts unfair and deceptive practices statute), alleging the drug caused the TEN and defendant did not adequately warn consumers that redness, rash or blisters could be signs of a "life-threatening" disease, either with or without specific mention of TEN. A jury awarded the child $50 million and the parents $13 million.

On defendants' appeal, the Massachusetts Supreme Judicial Court ("SJC") granted direct appellate review and affirmed. Regarding defendants' argument that plaintiffs' failure-to-warn claim was preempted by the Federal Food, Drug, and Cosmetic Act, the court noted that under the United States Supreme Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009) (see May 2009 Foley Hoag Product Liability Update), the claim would be preempted only if there was "clear evidence" the United States Food and Drug Administration ("FDA") would not have approved the warnings for which plaintiffs contended. The FDA had previously rejected a citizens' petition requesting that labels for over-the-counter ibuprofen include a warning that redness, rash, or blisters could be a sign of TEN, Stevens-Johnson syndrome or other "life-threatening" diseases. In so doing, the agency specifically noted consumers were unfamiliar with the names of such diseases, but did not specifically address the possibility of referring to "life-threatening" illness in general. Based on this record, and the fact that the rejected warning, including its "life-threatening" language, had been proposed by a citizens group rather than an ibuprofen manufacturer, the SJC held there was clear evidence FDA would have rejected plaintiffs' disease-specific warning but not as to a more general "life-threatening" illness warning. The court also concluded the jury's verdict was likely based on the non-preempted theory, as the jury must have disbelieved the father's testimony that a TEN-specific warning would have caused him not to administer the drug, and in his closing plaintiffs' counsel had explicitly stated plaintiffs did not contend the warning should have mentioned TEN.

The court also rejected defendants' challenge to the opinions of plaintiff's non-physician pharmacologist/toxicologist both that ibuprofen can cause TEN in humans generally and that the doses administered by plaintiffs after their daughter's rash appeared had caused her disease. The court found the expert sufficiently qualified by training and experience to opine to the effects of drugs in humans generally. Moreover, as several witnesses and at least one published study agreed TEN was less severe the sooner drug administration was stopped, this supported, in the court's view, the reverse proposition that the daughter's TEN would never have developed had the drug been stopped at the first sign of a rash.

Finally, the SJC affirmed the compensatory damages awards. Regarding the daughter's award, defendants argued plaintiffs had failed to provide any expert or other evidence of what her future medical expenses and/or lost future earning capacity would be, and the jury had been instructed they could consider these damages categories along with pain and suffering. Since defendant had not requested a verdict form itemizing the damages, however, it was impossible for the court to assess whether the jury had awarded unsupported amounts for the challenged categories, and the court noted that the child had undergone at least twelve surgical procedures, lost all functional vision in at least one eye and approximately half of her lung capacity. For the latter reasons, the court also upheld the parents' award. In both connections the court refused to consider defendants' arguments the awards were significantly out-of-scale compared to all known awards in Massachusetts history.

Massachusetts Federal Court Holds Biologics Manufacturer Has No Product Liability or Other Duty Under Various States' Laws to Sell Sufficient Product in FDA-Approved Dose to Meet Market Demand, and Bayh-Dole Act Governing Federally Funded Inventions Creates No Private Right of Action

In *Hochendoner v. Genzyme Corporation*, 2015 U.S. Dist. Lexis 37789 (D. Mass. March 25, 2015), defendant was the sole FDA-approved manufacturer of a biologic agent to treat Fabry disease, a genetic disorder inhibiting the ability of patients' cells to remove fats and leading to early death from conditions such as kidney disease, heart attack and stroke. Between 2009 and 2011, a series of incidents —including alleged viral contamination at defendant's production facility— severely reduced the agent's availability, leading defendant to ration supplies for existing patients at 30% to 50% of the FDA-recommended dose and recommend that new patients not receive the drug.

Patients from 22 states brought a putative class action in the United States District Court for the Western District of Pennsylvania, alleging this caused a less effective treatment, allowing their disease to progress and symptoms to return. Plaintiffs asserted claims under various states' laws for negligence, breach of express and implied warranties, strict liability and violation of state consumer protection and product liability statutes. They also alleged defendant violated the federal Bayh-Dole Act, 35 U.S.C. §§ 200 et seq., through nonuse or unreasonable use of a publicly funded invention. After the case was transferred to the United States District Court for the District of Massachusetts, defendant moved to dismiss on the grounds that (1) as pleaded, plaintiffs' nebulous theories of injury failed to give defendant "fair notice of the plaintiffs' claims and the grounds upon which they rest," as required by Fed. R. Civ. P. 8, and (2) plaintiffs failed to state any claim upon which relief may be granted.

The court first found that plaintiffs satisfied Rule 8's pleading standards for only one of their three alleged injuries—that the lower dosage had a diminished effectiveness that allowed symptoms to return. Their theory of "accelerated deterioration" was too ambiguous to provide fair notice because it failed to differentiate between whether the lower dosage was less effective at preventing the harm caused by the disease or was itself inherently harmful. Plaintiffs' claim that foreign particulates injured them by further diminishing the drug's supply was also inadequate as there was no allegation the particulates themselves caused any direct injury, thus again falling short of fair notice.

In a matter of first impression, the court next analyzed whether the Bayh-Dole Act creates a private right of action for members of the public who use federally-funded inventions and concluded it does not. The court held the statute lacks language that would imply any "intent to confer rights on a particular class of persons" to enforce its provisions and indeed focuses on the rights of the government. Moreover, the statute provides an express remedy—known as the "march-in" right—if the relevant federal agency determines additional licenses to manufacture the invention at issue are necessary

"to alleviate health or safety needs," foreclosing the possibility that Congress intended to create a private right of action.

The court then analyzed plaintiffs' various state law claims, first holding there is no "duty to manufacture sufficient medication to meet market demand" under the common law of torts of any state implicated in the action. The court noted that the two other federal district courts to consider the issue had found no such duty, the claims would work a "radical departure from the law as it exists" and the court should not recognize such a new, expansive duty under common law because "a federal court sitting in diversity cannot be expected to create new doctrines expanding state law." Similarly, no court has ever interpreted a state consumer protection statute "to prohibit insufficient medication production by a patentholder as an unfair trade practice," and to do so would "create an entirely new field of unfair business practices."

Plaintiffs also did not allege a plausible claim for breach of express warranty because defendant did not represent that the lower dosage would be as efficacious as the dose recommended in the packaging and approved by the FDA. Nor was defendant impliedly warranting as a merchant that the limited amount of product supplied would be as powerful as the full amount. Finally, none of plaintiffs' allegations were actionable under the products liability statute of any state at issue, as plaintiffs did not claim that defendant's product was defective in design or manufacture, only that defendant failed to produce a sufficient quantity to meet market demand. Just as with plaintiffs' common law tort claims, the "non-provision of a product" does not fit within the scope of any state product liability statute, and it would be "inappropriate for a federal court sitting in diversity to render an expansion of state laws." For all these reasons, the court dismissed plaintiffs' complaint.

Massachusetts Superior Court Holds Manufacturing Defect Claims Against Medical Device Manufacturer For Violations of Generally Applicable Requirements Under Food, Drug and Cosmetic Act Imposed Requirements Parallel to Federal Law and Hence Not Preempted

In *Dwyer v. Boston Scientific Corp.*, 2015 Mass. Super. LEXIS 56 (Mass. Super. Ct. Mar. 31, 2015), a man implanted with a cardiac resynchronization therapy defibrillator died from head trauma sustained after he lost consciousness and fell when the device malfunctioned. The device was later explanted and returned to the manufacturer for testing, which confirmed the wiring within its transformer had failed. Decedent's wife sued the manufacturer in Massachusetts Superior Court for negligence and breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) alleging her husband's death had been caused by a manufacturing defect resulting from defendant's violation of various Current Good Manufacturing Practices regulations (CGMPs) applicable to all medical devices. Among other things, plaintiff alleged defendant failed to "establish and maintain procedures to ensure that all purchased product[,]" here the wires and/or wire insulation within the transformer windings, "conformed to specified requirements," to "inspect[], test[], or otherwise verif[y] as conforming to requirements" all purchased products and to "identify by suitable means the acceptance status of [finished] product, to indicate the conformance or nonconformance of product with acceptance criteria."

Defendant moved to dismiss, principally on the ground that plaintiff's claims were expressly preempted by the 1976 Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA"). Under the statute, as interpreted by the United States Supreme Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008) (see April 2008 Foley Hoag Product Liability Update), state common law claims challenging the safety or effectiveness of a device are preempted if (1) federal law has established requirements applicable to the device at issue and (2) compliance with state common law would impose requirements that are "different from, or in addition to" the federal ones.

The court first noted that in a case such as *Riegel*, where the device had received a pre-market approval ("PMA") from the FDA imposing requirements based on safety and effectiveness that were specific to devices at issue, the first prong of *Riegel*

was readily satisfied. Courts have split, however, on whether claims based on violation of the generally applicable CGMPs satisfy this test. Noting the absence of Massachusetts authority on the issue, the court agreed with the reasoning of the United States Court of Appeals for the Seventh Circuit that there is no "sound legal basis . . . to distinguish between general requirements [such as the CGMPs] and 'concrete, device-specific' requirements [such as those related to the PMA process] given that [the MDA] uses the phrase 'any requirement.' And federal law is clear: for manufacturers of Class III medical devices, the . . . [CGMPs] adopted by the FDA . . . are legally binding requirements under [the FDCA]."

Regarding the second prong, the court held that to survive preemption, "a state law cause of action must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA." Plaintiff satisfied the first requirement by alleging defendant violated specific CGMPs which gave rise to the defect causing her injury. Moreover, the same allegations, even in the absence of the CGMPs, would also give rise to a right to recover under Massachusetts law, which imposes a duty of reasonable care on manufacturers and recognizes a breach of warranty where a product is defective and unreasonably dangerous as a result of a manufacturing defect. Accordingly, plaintiff's state law claims paralleled federal requirements and were not preempted.

Massachusetts Federal Court Holds Foreign Manufacturer Subject to Personal Jurisdiction Because It Regularly Sent Employees to Massachusetts and Exercised Control Over U.S. Subsidiary with Extensive Massachusetts Contacts, Including Sale of Product Causing Plaintiff's Injury

In *Lewis v. Dimeo Constr. Co.*, 2015 U.S. Dist. LEXIS 68280 (D. Mass. May 27, 2015), a construction worker at a Massachusetts jobsite was injured when a powder-actuated tool malfunctioned. The worker and his wife sued the manufacturer in Massachusetts Superior Court for negligence and breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability), alleging the tool was defectively designed and unreasonably dangerous. Defendant, a Liechtenstein-based corporation, subsequently removed the case to the United States District Court for the District of Massachusetts on the basis of diversity jurisdiction and then moved to dismiss for lack of personal jurisdiction.

Defendant did not do business, manufacture or sell products, employ workers, pay taxes or own an office or other property in Massachusetts. Rather, defendant sold its products to a wholly-owned subsidiary in Oklahoma, which offered the products for sale throughout the United States, including in Massachusetts where it sold to five authorized distributors and operated two customer service and repair centers. Additionally, defendant itself regularly sent employees to the state for business purposes (177 trips in the eight years preceding the accident), including forty-three trips to test product prototypes or conduct market research, nine to conduct product training and twenty-seven to meet with the subsidiary's management or provide support to sales staff regarding new product introductions.

The court began by reciting the three-part test for determining whether exercise of specific jurisdiction over a foreign defendant is proper: (1) the litigation must result from alleged injuries that arise out of or relate to defendant's in-forum activities ("relatedness"); (2) defendant must have purposefully availed itself of the privilege of conducting activities within the forum, thus invoking the benefits and protections of its laws ("purposeful availment"); and (3) it must be reasonable to require defendant to defend a suit there (the "gestalt factors"). Here, defendant's contacts with Massachusetts related to plaintiff's injury because defendant introduced the product that injured him into the market and ensured a Massachusetts distribution network for the product by training its subsidiary's Massachusetts employees and testing product prototypes in the state. Regarding purposeful availment, defendant exercised complete control over its subsidiary which sold products there, thus distinguishing cases finding a lack of purposeful availment where a foreign manufacturer was merely aware of its subsidiary's distribution network in the forum. Moreover, defendant's own direct contacts with Massachusetts—regularly sending its employees there for business purposes—sufficed to establish purposeful availment. Finally, consideration of the five gestalt factors did not, on balance, suggest the exercise of jurisdiction would be unreasonable. The court found it would not be inconvenient for defendant to litigate in Massachusetts in light of defendant's extensive travel there for other reasons, the

state has an interest in adjudicating disputes involving injuries caused by products entering the state and litigating the case there might avoid piecemeal litigation, the need for English-to-German translation in Liechtenstein litigation and the need to transport evidence and witnesses there. The court therefore denied the motion to dismiss.

Massachusetts Federal Court Holds No Personal Jurisdiction Over Foreign Corporation Despite Contractual Relationship and E-Mails with Massachusetts Plaintiff Where Contract Was Not Executed in Massachusetts, Performed There or Governed By Its Laws

In *Copia Communications, LLC v. AMResorts, L.P., et al.*, C.A. No. 14-13056 (D. Mass. Feb. 5, 2015), defendant, a Jamaican corporation that owned two hotels in Jamaica, contracted with plaintiff, a Massachusetts-based internet service provider, to provide such services at defendant's hotels. Defendant was not registered to do business in Massachusetts, and had no employees, property or offices there. While the contract required defendant to send formal notices to plaintiff in Massachusetts, and the parties' contract negotiations included some emails sent by defendant to plaintiff's officers there, all in-person meetings took place in Jamaica and the contract was ultimately signed there. Plaintiff's services were also performed entirely in Jamaica, although plaintiff shipped or brought certain equipment from Massachusetts and defendant sent its payments there.

In 2014, defendant purported to terminate the contract in advance of an automatic renewal. Claiming the termination was untimely so that the contract had in fact renewed, plaintiff sued defendant and another entity (the latter having no apparent relationship to the dispute) in the United States District Court for the District of Massachusetts for, among other things, breach of contract, breach of the implied covenant of good faith and fair dealing and violation of Mass. Gen. L. ch. 93A (the Massachusetts unfair and deceptive practices statute). Defendant then moved to dismiss for lack of personal jurisdiction.

As there was no contention defendant was subject to jurisdiction in Massachusetts generally, but rather only for claims arising out of the contract, the court applied the standard governing specific jurisdiction. First, the court held plaintiff's claims did not actually arise out of any of defendant's activities in the forum. Among other things, the contract was not executed in Massachusetts, contemplated performance only in Jamaica and created no ongoing connection to Massachusetts: "the relatedness requirement is not met merely because a plaintiff's cause of action arose out of the general relationship between the parties; rather, the action must directly arise out of the specific contacts between the defendant and the forum state." Second, defendant did not purposely avail itself of the privilege of conducting business in Massachusetts, as the contract was governed by Jamaican law and did not necessarily require any performance in or shipments of equipment from Massachusetts. The court thus distinguished recent precedent in the United States Court of Appeals for the First Circuit—*C.W. Downer & Co. v. Bioriginal Food & Science Corp.*, 771 F.3d 59 (1st Cir. 2014) (see April 2015 Foley Hoag Product Liability Update)—on the ground that it involved a contract that was actually formed in Massachusetts and contemplated plaintiff would perform extensive services there: "[m]erely making payment in Massachusetts and providing for contractual notice to an address [there] . . . hardly constitutes purposeful availment." Finally, the exercise of jurisdiction in Massachusetts would be unreasonable, as the state had little interest in adjudicating a dispute over conduct occurring almost exclusively in Jamaica under a contract governed by its law. The court thus granted the motion to dismiss.

Massachusetts Federal Court Finds Cigarette Distributors Not Fraudulently Joined to Defeat Diversity Jurisdiction in Wrongful Death Action Where There Was No Evidence Plaintiff Would Not Pursue Claims Against Them and There Was Viable Breach of Warranty Claim For Sale of Allegedly Defective Product

In *Flavin v. Lorillard Tobacco Company, et al.*, 2015 U.S. Dist. LEXIS 73728 (D. Mass. June 8, 2015), decedent died of lung cancer allegedly caused by smoking cigarettes manufactured and distributed by defendants. Decedent's wife brought suit in Massachusetts Superior Court alleging the cigarettes were defectively designed and asserting

claims for negligence, breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability), violation of Mass. Gen. L. ch. 93A (the Massachusetts unfair and deceptive practices statute) and wrongful death. After defendants removed the case to federal court, plaintiff sought remand to state court, arguing the federal court lacked diversity jurisdiction because she and the defendant distributors were all Massachusetts citizens. Defendants conceded the distributors were incorporated and had their principal place of business in Massachusetts, but argued they were sham defendants named solely to defeat diversity.

The court first noted that joinder is fraudulent if there is clear and convincing evidence "either that there has been outright fraud committed in the Plaintiff's pleadings, or that there is no possibility, based on the pleadings, that the Plaintiff can state a cause of action against the non-diverse defendant in state court." Joinder of a defendant is not fraudulent if plaintiff has even a *possibility* of stating a valid cause of action; she need not demonstrate a likelihood of success. Defendants argued joinder was fraudulent under either theory, as plaintiff was unlikely actually to litigate the claims against the distributors and her claim against them was not legally sufficient because she failed to identify a connection between the alleged harm and their conduct. The court, however, disagreed on both counts. There was no evidence counsel did not exhibit good faith in naming the distributors as defendants, and because Massachusetts law holds a distributor strictly liable for a breach of the implied warranty of merchantability even when acting merely as a conduit for the injurious product, plaintiff alleged a sufficient connection between her husband's death and the distributors. Accordingly, the court granted plaintiff's motion to remand.

Massachusetts Federal Court In Multi-District Litigation Holds Corporate Officer Lacking Personal Involvement with Products at Issue Was Fraudulently Joined and Thus Did Not Defeat Diversity Jurisdiction, and Massachusetts Statute of Limitations With "Discovery Rule" Does Not Apply to Plaintiffs Who Sued in Mississippi But Later Declared Massachusetts Their "Home Forum"

In *In Re: Fresenius Granuflo/Naturalyte Dialysate Products Liability Action*, 2015 U.S. Dist. LEXIS 25, 39 (D. Mass. Jan. 2, 2015), plaintiffs or their decedents allegedly suffered cardiac arrest from excessive blood bicarbonate levels caused by dialysis products designed and manufactured by the defendant Massachusetts-headquartered corporation and its affiliates. Plaintiffs brought numerous suits around the country against the corporations and two officers and directors, alleging the products were defectively designed and carried inadequate warnings. The Judicial Panel on Multidistrict Litigation created a multidistrict litigation ("MDL") for pretrial management of all federal cases in the United States District Court for the District of Massachusetts. That court then addressed motions by California plaintiffs whose cases defendants had removed from California state courts on the basis of diversity of citizenship (the "California cases") to remand the cases to state court, and by defendants in 127 suits involving persons who had received the products in Mississippi (the "Mississippi cases") to dismiss based on the Mississippi statute of limitations.

Regarding the California cases, plaintiffs argued the defendant Massachusetts-based corporation, its CEO and the defendant officer of an affiliate were actually California citizens, thus defeating diversity. The court first concluded the corporation was indeed a Massachusetts citizen at the times the respective actions were filed. Although it had previously had its headquarters in California, it had moved them—including CEO, legal and accounting functions as well as some manufacturing activity—to Massachusetts before the suits, and even its remaining California manufacturing was directed from Massachusetts. Accordingly, Massachusetts was the corporate "nerve center" and principal place of business under United States Supreme Court precedent. Nor was the corporation judicially estopped by assertions in prior lawsuits that its principal place of business was California, as those assertions either were made before the Supreme Court clarified the citizenship standard or had been specifically corrected by defendant in prior litigation.

As for the individual defendants, the CEO was a Massachusetts or Nevada resident at the relevant times, despite his ownership of real and personal property in California and wife's residency there, as he actually resided in homes and also held driver's licenses and voter registrations in the former states. While the other individual defendant was indisputably a California citizen, he had been fraudulently joined in the suit to defeat jurisdiction, as he was an officer of one of the Massachusetts corporation's foreign subsidiaries, had no direct power to affect the operating activities of the U.S. defendants and plaintiffs did not adequately plead his personal involvement or "participatory connection" with the injury-producing products. Finding there was "no possibility that Plaintiffs can state a cause of action" against the officer, the court dismissed him from the cases and denied the motion to remand.

Regarding the Mississippi cases, the MDL court had adopted a case management order ("CMO") that, among other things, allowed plaintiffs to file cases directly in the MDL court and required all plaintiffs, regardless of place of filing, to designate a state as their "home forum." Defendants argued Mississippi law applied to all the Mississippi cases because it was the place of injury and the suits had not been commenced within three years of injury or death as required by the statute of limitations. Plaintiffs responded that, at least as to cases in which plaintiff had designated Massachusetts as his "home forum," the Massachusetts limitations statute should apply and, since the state's "discovery rule" only required suit within three years of when plaintiff knew or should have known the factual basis for his claim, the resulting fact-intensive inquiry necessitated denying the motion to dismiss.

The court first recognized federal courts were required to apply the choice-of-law rules of the forum state, but the issue was complicated by the CMO's provisions. For actions where the states of filing and "home" designation coincided, that was plainly the forum. For cases filed directly in the MDL, plaintiff's "home" designation governed because it was the best evidence of where he would have sued but for the CMO, which indeed defined the home forum as "the place where the complaint will be deemed to have originated." For cases plaintiffs originally filed in Mississippi but later gave a Massachusetts "home" designation, however, the actual place of filing controlled. The court rejected plaintiffs' argument the CMO effectively permitted them to amend their complaints and change the underlying forum from Mississippi to Massachusetts by their "home" designation, as the Supreme Court has held courts should be reluctant to grant a change of venue if the requesting party would also thereby achieve a change in applicable law. Applying the respective choice-of-law principles of Massachusetts and Mississippi, the court concluded each would apply its own limitations statute, the former because of the state's substantial interest in permitting plaintiffs' claims and the latter because it viewed limitations issues as procedural and thus governed by forum law. The court left the parties to file further dispositive motions in individual cases in light of its ruling.

First Circuit Affirms Summary Judgment Against Claim Fire Truck Was Defectively Designed Due to Lack of Redundant Hose Restraints Where Plaintiff Offered No Expert Testimony Regarding Reasonableness of Design or Causation

In *King v. Pierce Manufacturing, Inc.*, 2015 U.S. App. LEXIS 7366 (1st Cir. May 4, 2015), a woman was fatally injured in 2010 when, while walking down the street, she was struck by the nozzle of a hose that had come loose from a passing fire truck. The truck was built by defendant in 2002 to the specifications of the local fire department, which included hose compartments with covers to secure the hoses but not redundant hose restraints offered by defendant to provide extra security within the covers.

The administrator of decedent's estate sued the truck manufacturer in Massachusetts state court, and defendant removed the case to the United States District Court for the District of Massachusetts on the basis of diversity jurisdiction. Plaintiff asserted claims for negligence, breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) and wrongful death, alleging the truck was defectively designed because it was not equipped with a redundant hose restraint that would have prevented the hose from coming loose. Defendant offered the expert testimony of a mechanical engineer who had inspected the truck and opined it was not defective or unreasonably dangerous, and the accident was caused by the fire department's failure properly to stow the hose in the hose compartments. Plaintiff offered no expert testimony in rebuttal, arguing instead that "common sense is all that is required to determine whether the fire truck should have had [redundant] hose restraints." The district court granted summary judgment

for the manufacturer due to plaintiff's failure to offer any expert testimony regarding the alleged defectiveness of the truck's design or causation. The court further held that plaintiff's case "also founder[ed] on the issues of foreseeability and intervening cause." (See October 2014 Foley Hoag Product Liability Update).

On appeal to the United States Court of Appeals for the First Circuit, plaintiff challenged the district court's determination that his claims required presentation of expert testimony, arguing that jurors could find, based on lay knowledge, that the absence of hose restraints in a fire truck constituted a design defect that exposed pedestrians to an unreasonable risk of injury. The court of appeals affirmed, holding expert testimony regarding a product's defectiveness is required in complex product liability cases in order to mitigate against jury "conjecture and surmise" regarding the cause of the injuries and the relevant standard of care. Here, the jurors would obviously be familiar with the sight of a fire truck on city streets, but their lay knowledge would not extend to the design of the vehicle's hose bed and the relative propriety of different types of hose restraints. Unlike in cases involving defects so obvious as not to require expert testimony, jurors here could not be expected to conclude whether a hose stored in a bed equipped with crosslay covers but not redundant hose restraints would be likely to come loose in a manner that threatens pedestrian safety. Moreover, where the manufacturer offered various hose-restraint options but the fire department chose not to order them, an average juror would not know who bore responsibility for ensuring that trucks were equipped with adequate restraints.

First Circuit Holds Statute of Limitations Bars Asbestos Claims Against Defendants Protected by Bankruptcy Plan Where Claims Not Asserted within 30 Days After Plan's Effective Date, When Automatic Stay Expired, and Plan Did Not Extend or Toll Limitations Period

In *Barraford v. T&N Ltd*., 2015 U.S. App. LEXIS 2129 (1st Cir. Feb. 11, 2015), plaintiff's husband died of mesothelioma in 2002 after having been regularly exposed to asbestos from defendants' construction product in the 1960s and 1970s. She sued approximately thirty asbestos product manufacturers in Massachusetts Superior Court but not defendants who, along with their parent corporation, had filed for protection under Chapter 11 of the United States Bankruptcy Code and were protected from suit by the statute's automatic stay. Plaintiff did not file a claim in the bankruptcy proceeding or seek relief from the stay to join defendants in her lawsuit. Defendants' bankruptcy reorganization plan, which became effective in 2007, discharged them of all liabilities other than for pending and future asbestos claims—which liabilities were expressly limited to available insurance and preserved only until it was exhausted—and assigned such claims to be pursued by a trust created pursuant to a "channeling injunction" under section 524(g) of the Bankruptcy Code.

In 2011, the trust, as plaintiff's assignee, sued defendants in Massachusetts Superior Court, asserting claims for wrongful death, negligence and breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability), among others, and alleging that exposure to defendants' product caused decedent's mesothelioma. Defendants removed the action to the United States District Court for the District of Massachusetts, which dismissed the suit based on the statute of limitations (see April 2014 Foley Hoag Product Liability Update). The court ruled that under the Bankruptcy Code, the automatic stay had expired upon confirmation of defendants' reorganization plan, and the trust then had thirty days to bring suit, which it failed to do.

On appeal, the United States Court of Appeals for the First Circuit affirmed. The trust argued the intent of the plan was to modify and extend the automatic stay, and hence any applicable limitations periods, to preserve all asbestos claims until defendants' available insurance was exhausted, after which time the trust would have 30 days to sue. Thus, the trust argued, the stay was still in effect to preclude expiration of the statute of limitations, but not to bar the trust from asserting claims. The First Circuit disagreed, holding "the Plan unambiguously terminated the automatic stay without limitation or qualification and contains no provision that even remotely provides for any further tolling of the limitations period beyond that granted by the Bankruptcy Code." The absence of such language for claims by the trust was particularly striking because the plan did expressly toll limitations periods for claims *against* the trust. Moreover, the plan specifically preserved defendants' (and their insurers') right to assert "any" defenses to reduce or eliminate their liability.

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