Products Liability: 2013 Year in Review

Massachusetts/U.S. First Circuit

January 2014

Massachusetts state and federal courts issued a number of interesting product liability decisions in 2013. The Product Liability and Toxic Tort Litigation Group at Nutter McClennen & Fish LLP recently reviewed these cases. Highlighted below are some of the key cases and issues decided over the past year.

MASSACHUSETTS SUPREME JUDICIAL COURT

Aleo v. SLB Toys USA, Inc., 466 Mass. 398 (2013)

Significant Holding: The Supreme Judicial Court ("SJC") upheld an $18 million punitive damages award in a case where a woman died after sliding head first down an inflatable pool slide imported and sold by Toys "R" Us. The SJC found that the evidence supported a finding of gross negligence and that the $18 million punitive damages award, which constituted a 7:1 ratio of punitive to compensatory damages, was within the guidelines established by law.

Michael Aleo, widower of Robin Aleo, brought a suit individually and on behalf of his wife's estate, against SLB Toys USA, Inc., Amazon.com Inc., Toys "R" Us, and Amazon.com Kids, Inc., after his wife died from injuries sustained when an inflatable pool slide collapsed while she was sliding down head first. Plaintiff brought claims alleging negligence, breach of implied warranty of merchantability, wrongful death, and violation of the Massachusetts consumer protection statute. The trial court dismissed the statutory claim and SLB Toys and Amazon settled during the trial. The jury found Toys "R" Us liable for negligence, breach of warranty, and wrongful death, awarding compensatory damages in the amount of $2.6 million. The jury also found Toys "R" Us grossly negligent and awarded punitive damages in the amount of $18 million. Toys "R" Us appealed, challenging the exclusion of certain evidence and arguing that the plaintiff should not have been allowed to call the slide "illegal" at trial. It also challenged the sufficiency of the evidence and the constitutionality of the $18 million award of punitive damages. The SJC affirmed the trial court ruling.

The SJC found that the trial court properly excluded Toys "R" Us's expert evidence because the expert based her opinion—that Robin could not have been injured by sliding head first—on tests with different conditions from those of the accident. The SJC also upheld the characterization of the pool slide as "illegal," citing Toys "R" Us's admission that the slide was not tested or certified under a federal safety standard for pool slides.

The jury found that Toys "R" Us failed to comply with the Consumer Products Safety Commission slide standard, 16 C.F.R. § 1207, which requires that slides be able to hold up to 350 pounds and be tested for head-first sliding descents. This supported the negligence and warranty liability findings. At trial, Toys "R" Us argued that the Chinese vendor warranted that the slide conformed to all requirements and pointed to its hiring of a testing company to test the product and issue a certificate of compliance. The certificates failed to mention the slide standard. The Court said that Toys "R" Us did not support its argument about the vendor's warranty with a written agreement and that the evidence of the testing company's role was equivocal. Thus, the evidence also supported the finding of gross negligence.

Regarding punitive damages, the SJC found "a substantial degree of reprehensibility" in Toys "R" Us's conduct. The court considered the nature of the harm (death) and the company's repeated actions (that it imported thousands of Banzai Falls slides into the United States), when

considering the constitutionality of the amount of punitive damages awarded. In affirming the $18 million award of punitive damages, the court explained that the 7:1 ratio of punitive to compensatory damages was within the ratio guidelines established by case law.

Evans v. Lorillard Tobacco Co., 465 Mass. 411 (2013)

Significant Holdings: The SJC refused to adopt the reasonable consumer expectations standard for design defect from comment i to § 402A of the Restatement (Second) of Torts, instead adopting the risk-utility test of the Restatement (Third). The Court upheld the award of compensatory damages, as remitted, but vacated the award of punitive damages remanding it for a new trial. The Court also vacated the trial court's c. 93A findings and conclusions and directed it to reconsider these rulings in light of the SJC's opinion.

The *Evans* decision is important in many respects, but from the products liability perspective, the most significant ruling is the Court's refusal to adopt the reasonable consumer expectations standard for design defect in comment i to § 402A of the Restatement (Second) of Torts. Comment i to § 402A recognizes that "[m]any products cannot possibly be made safe for all consumption," and defines an "unreasonably dangerous" product as one that is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." Comment i expressly discusses the application of the consumer expectation test to cigarettes in stating: "Good tobacco is not unreasonably dangerous merely because the effects of smoking may be harmful; but tobacco containing something like marijuana may be unreasonably dangerous."

The Court rejected this standard in favor of the risk-utility test of the Restatement (Third). The Court said: "While consumer expectations may be considered in the risk-utility balancing, the Third Restatement makes it clear that, in sharp contrast with the Second Restatement, consumer expectations do not play a determinative role in determining defectiveness. Third Restatement, supra at § 2 comment g, at 27. The mere fact that a risk presented by a product design is open and obvious, or generally known, and that the product thus satisfies expectations, does not prevent a finding that the design is defective. Id. at 28. Thus, the Third Restatement recognizes the possibility that a product may be made significantly safer through a reasonable alternative design even when consumers, unaware of the alternative design, expect the product to be no safer than it is."

Decedent's son brought a wrongful death action alleging that his mother's death from lung cancer after 40 years of smoking was caused by the negligence of, or breach of warranty by, Lorillard Tobacco Company ("Lorillard"). He alleged that the Newport cigarettes his mother smoked were defective in design because the tobacco smoke emitted by them contained addictive levels of nicotine and carcinogenic levels of tar and because they did not contain a warning before 1966. Plaintiff also alleged that Lorillard had engaged in a campaign to target African-American children by distributing free samples of Newport cigarettes to decedent and other children in the housing project in which they lived for approximately five years prior to 1961. Lorillard argued that Plaintiff's defect claims should fail because Newport was not dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased it; that a warning was not necessary when plaintiff started smoking in 1960 because it was common knowledge that smoking was hazardous; that neither the alleged defect nor the lack of warning was the cause of decedent's harm; that plaintiff's theory would impose categorical liability on all cigarettes which would conflict with Massachusetts and federal law; and that Lorillard had not distributed cigarettes to African-American children.

The jury returned a verdict for Plaintiff, awarding compensatory damages of $71 million, $50 million to compensate for the decedent's six months of pain and suffering and $21 million for the son's loss of his mother's care, comfort, society, etc. The jury also awarded $81 million in punitive damages.

The jury found that Lorillard had breached the implied warranty of merchantability because of a design defect and the lack of a warning before 1966; that Lorillard had been negligent in the design, marketing, or distribution of Newport cigarettes; that it had negligently distributed Newports by giving away free samples to minors; and had failed to fulfill a duty Lorillard voluntarily undertook in 1954 to research the health hazards of smoking and disclose accurate information regarding the results of that research to the smoking public. The trial judge, who had reserved the 93A claim for herself, found a knowing and willful violation of 93A and awarded $2.5 million in attorneys' fees. She did not add additional punitive damages. The trial judge remitted the compensatory damages to $25 million for pain and suffering and $10 million for loss of consortium, but did not reduce the punitive damages.

The SJC upheld the award of compensatory damages, as remitted, but vacated the award of punitive damages. The Court remanded the case for a new trial on punitive damages. The Court also vacated the trial court's 93A findings and conclusions and directed the trial court to reconsider her 93A opinion in light of the SJC's rulings.

Breach of Implied Warranty of Merchantability

The SJC affirmed liability on the basis of the jury's findings that Lorillard breached the implied warranty of merchantability because its Newport cigarettes were defective in design and for lack of a warning.

Negligence

The Court set aside the jury's findings with regard to negligence. The jury found negligence in the design, marketing, or distribution of Newport cigarettes; negligence in failing to warn decedent of the health hazards and addictive properties of Newport cigarettes at any time prior to 1970; and negligence in Lorillard's distribution of free samples of Newport cigarettes to minors. The jury was not asked to find causation as to each theory of negligence, but instead was asked whether "any negligence" of Lorillard was "a substantial factor in causing . . . [decedent's] lung cancer." The SJC explained that because it did not know on which theory or theories the jury found causation, the jury's findings of liability for negligence would be upheld only if the jury was correctly and adequately instructed on each theory of negligence. The Court concluded that the jury was incorrectly instructed as to negligent design and inadequately instructed as to negligent marketing, and vacated the jury's finding of liability for wrongful death based on the theory of negligence.

Breach of a Voluntarily Assumed Duty

In 1954, Lorillard joined other major cigarette manufacturers in placing in major newspapers a full-page, one-day advertisement, entitled "A Frank Statement to Cigarette Smokers." At trial, the plaintiff alleged, and the jury found, that by joining in the 1954 "Frank Statement," Lorillard voluntarily undertook a duty to research the health hazards of smoking and to disclose accurate information regarding the results of the research to the general public, including the decedent. The SJC, however, concluded that by joining the "Frank Statement," Lorillard did not voluntarily undertake a legal duty it otherwise did not have to research the health risks of smoking and disclose to the public the results of that research. Thus, the SJC reversed the jury's finding on this claim.

Punitive Damages

Because the SJC vacated the findings of negligent liability and reversed the finding of breach of a voluntarily undertaken duty, it also vacated the jury's findings that Lorillard was grossly negligent and that Lorillard acted in a manner that was malicious, willful, wanton, or reckless. Because it vacated the jury's award of punitive damages for wrongful death, the Court did not reach the issue of whether pre-judgment interest applies to punitive damages.

The *Evans* opinion is lengthy, occupying 58 pages in the Massachusetts Reports. The Court's discussion focuses on the product liability theories of negligent design and breach of implied warranty, yet it also contains discussion and rulings on a number of errors by the trial judge from jury selection, through evidentiary rulings, to the misapplication of offensive collateral estoppel in her c. 93A opinion.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

Chasse v. Stryker Corp, et al., No. 12-11694 (D. Mass. March 20, 2013)

Significant Holding: A complaint alleging violations of Current Good Manufacturing Practice requirements for a medical device established by federal regulations sufficiently pleads a parallel claim in order to avoid preemption if violation of the requirements is alleged to have caused plaintiff's injury.

Plaintiffs filed a complaint against defendants for the negligent manufacture and distribution of the Trident hip replacement system. The complaint alleged that the FDA had inspected defendants' manufacturing facility and, at the conclusion of the inspection, notified defendants of numerous violations of federal regulations in their manufacturing and inspection processes for the Trident hip. The complaint also alleged that a few months later, the FDA issued a warning to Defendants that the Trident hip system was "adulterated" because the methods used in, or the facilities or controls used for, the system's manufacture, packaging, storage, or installation, were not in conformity with the Current Good Manufacturing Practice ("CGMP") requirements of 21 C.F.R. part 820.

Defendants moved for summary judgment on the basis of preemption. The court stated that the key question was whether the complaint properly pleaded a "parallel" claim in order to avoid preemption under *Riegel*. Defendants argued that CGMPs are not "device-specific" and are therefore "too general to constitute binding federal requirements." The court denied defendants' motion, while noting that some district courts have concluded that the CGMPs are too general to serve as a basis for a parallel claim. Ultimately, the court pointed to two Circuit Courts of Appeals opinions that addressed the same issue and ultimately rejected efforts to dismiss substantially similar claims. In doing so, the court held that CGMPs are legally binding requirements that can serve as the basis of parallel claims when they are alleged to have caused a plaintiff's specific injury.

Genereux v. Hardric Laboratories, Inc., Nos. 04-12137, 10-11652, 2013 WL 3157520 (D. Mass. June 23, 2013)

Significant Holding: Evidence that a plaintiff has been exposed to above-ordinary levels of a hazardous substance, without more, is insufficient to maintain a cause of action for medical monitoring. Rather, under Massachusetts law, a plaintiff must provide proof of "subcellular," physiological change in order to maintain a cause of action for medical monitoring.

Plaintiffs, current and former employees of defense contractor Raytheon Company ("Raytheon"), brought actions seeking medical monitoring for themselves and their families for beryllium-related diseases. Plaintiffs alleged that Raytheon handled beryllium negligently at its Waltham facility, exposing employee plaintiffs and, indirectly, members of their households to elevated levels of beryllium. As a result, plaintiffs' exposure to beryllium increased their risk of beryllium-related diseases, particularly Chronic Beryllium Disease. Defendant Raytheon moved for summary judgment, alleging "a specific infirmity of Plaintiffs' claim" and contending that plaintiffs' own expert testified that he could not state, with reasonable medical certainty, that any plaintiff had suffered subcellular change.

The United States District Court for the District of Massachusetts, applying Massachusetts state law, granted summary judgment, explaining that the SJC in *Donovan v. Philip Morris USA, Inc.*, 455 Mass. 215 (2009) ("*Donovan I*"), required proof of "subcellular," or physiological, change for plaintiffs to maintain a cause of action for medical monitoring. Here, plaintiffs failed to provide evidence of subcellular change, a necessary element of the claims plaintiffs asserted. Accordingly, the case presented no genuine dispute of material facts, and Raytheon was entitled to judgment as a matter of law.

In upholding the requirement that plaintiffs prove the existence of subcellular change, the court explained that this element ties the modern doctrine of medical monitoring to traditional tort law. In addition, the

subcellular change element served as a check on the ability of plaintiffs seeking medical monitoring to prevail merely on the basis of increased harm. In reaching its decision to grant summary judgment, the court noted that, standing alone, the increased risk of subcellular change is insufficient to prove plaintiffs' claims for medical monitoring.

Connell v. BRK Brands, Inc., No. 10-12101, 2013 WL 3989649 (D. Mass. Aug. 1, 2013)

Significant Holding: Where a plaintiff seeks to assert non-mutual collateral estoppel to apply an out-of-state judgment to a claim brought under Massachusetts law, the plaintiff fails to establish the first prong of collateral estoppel—identity of issues—if he does not establish that the applicable law of the foreign state is identical to that of Massachusetts.

In 1998, a woman died in a fire caused by a lit cigarette left in her bed. At the time of the fire, the woman's mobile home contained two smoke detectors manufactured by defendant BRK Brands, Inc. ("BRK"), one outside of each bedroom. There were no smoke detectors in the bedrooms or in the kitchen. Industry standards at the time of the fire specified that smoke detectors should be installed inside the bedrooms, as well as in the kitchen. The woman's estate sued BRK, alleging that the smoke detectors were defectively designed and that BRK had failed to properly warn of the potential delay in the sounding of the smoke alarm in the case of a smoldering fire. BRK moved for summary judgment, and plaintiff sought to apply offensive collateral estoppel as to the issue of defectiveness. Although the court denied the motion for summary judgment as to the design defect and warranty claims, it refused to apply collateral estoppel.

Offensive Collateral Estoppel

Plaintiff sought to invoke non-mutual collateral estoppel as to the design defect claim, citing to a case where a federal jury in New York entered a verdict finding that the design of the BRK smoke detector was defective and that BRK was negligent in its failure to use ordinary care in the design, testing, marketing, and sale of the smoke detector. The court refused to apply collateral estoppel because the Plaintiff failed to satisfy the first prong of the collateral estoppel test; establishing identity of issues. The court stated that the Plaintiff's argument was "fundamentally flawed" because the earlier decision had been decided under New York law and Plaintiff failed to make any assertion that the applicable Massachusetts law is the same as the New York law that applied in the earlier case. The court also noted that there were several verdicts from other jurisdictions in which the jury determined that the smoke alarm was not defectively designed and that BRK was not negligent.

BRK's Motion for Summary Judgment

As to the design defect/breach of warranty claims, BRK argued that the smoke detectors had not been properly located; at least one had sounded; there was no evidence as to the extent of the fire, smoke, heat, or gases produced by the fire; and that there was no evidence as to the woman's movements or actions relating to the fire. Although the court stated that BRK made "a compelling argument that . . . the evidence on the issues of defect and causation is so lacking that summary judgment is warranted," the Court could not "find as a matter of law that no reasonable jury could find for the Plaintiff" as to the design defect/breach of warranty claims. The court nonetheless cautioned the plaintiff that "the links that jurors will have to make in order to find in her favor . . . are, at best tenuous." The court entered summary judgment for BRK on the failure to warn claims based on evidence that the smoke detectors contained instructions advising that smoke detectors should be placed in each bedroom and that the instruction manual contained an express warning about smoking in bed.

Milward v. Acuity Specialty Prods. Group, No. 07-11944, 2013 WL 4812425 (D. Mass. Sept. 6, 2013)

Significant Holding: Expert testimony regarding causation is inadmissible where the expert employs a "differential diagnosis" analysis to determine the cause of disease where the overwhelming majority of cases are idiopathic in origin.

Plaintiff Brian Milward and his wife sued several makers of products containing benzene, alleging that the chemical

caused him to develop a rare type of acute myeloid leukemia known as acute promyelocytic leukemia ("APL"). Milward spent approximately 30 years as a pipefitter and refrigerator technician. During that time, Milward was allegedly exposed to benzene in paint manufactured by Rust-Oleum Corp., the only remaining defendant in the case. James Stewart, an industrial hygienist, testified on behalf of plaintiffs regarding the extent of Milward's exposure to Rust-Oleum paint. Plaintiffs then offered the testimony of Dr. Sheila Butler, who testified that in light of the extent of Milward's exposure, there was a "reasonable medical probability that there is a direct causal association between Mr. Milward's APL and his excessive occupational exposure to benzene containing substances." Rust-Oleum Corp. moved for summary judgment on the grounds that plaintiffs lacked the reliable expert testimony necessary to prove that benzene exposure caused Milward's APL. The court granted the motion.

Admissibility of Expert Opinion Regarding Exposure

The court held that Stewart's testimony as to the amount of time Milward was exposed to benzene was reliable. Stewart based his estimate on the testimony of Milward's former co-worker, who reported that 90% of the paint he used was Rust-Oleum brand, and that "[e]verybody uses the same products in the industry." Although Rust-Oleum disputed the amount of time that the co-worker actually worked with Milward, the court determined that "resolving this dispute about the factual underpinnings of Stewart's opinion is the province of the jury." Rust-Oleum also complained that Stewart did not properly discount Milward's exposure in light of the decrease in the amount of benzene in Rust-Oleum's paint from 1993-2004. However, the court found that the estimated exposure levels were so low during this period that the proposed adjustment would not have changed the cumulative exposure estimate. The court reasoned that "[t]o the extent there was any error, it goes to Stewart's general credibility in the eyes of the jury and not the admissibility of his testimony."

Admissibility of Expert Opinion Regarding Causation

The court rejected Dr. Butler's opinion regarding specific causation as inadmissible, characterizing her expert report as "relatively devoid of substantive content." Dr. Butler engaged in a differential diagnosis analysis in order to rule out other possible causes of Milward's APL. Although differential diagnosis is a "useful and accepted means of assessing causation," the court found that this particular analysis was not reliable in a case involving APL because 70 to 80 percent of cases are idiopathic in origin. According to the court, in situations where "a disease has a discrete set of causes, eliminating some number of them raises the probability that the remaining option or options were the cause-in-fact of the disease." Where the majority of cases are idiopathic to begin with, however, "eliminating a few possible causes leaves not only fewer possible causes but also a high probability that a cause cannot be identified." The court also rejected Dr. Butler's opinion because she did not and could not quantify a threshold exposure level for benzene, and was unqualified to opine on the relative risk of causation based on benzene exposure. Butler had testified at her deposition that she was "not an epidemiologist" and did not intend to weigh different epidemiological studies.

Because Plaintiffs could not establish that it was more likely than not that Milward's exposure to benzene was a cause-in-fact of his APL, the court entered summary judgment for Rust-Oleum.

Calisi v. Abbott Laboratories, No. 11-10671 (D. Mass. Sept. 27, 2013)

Significant Holdings: (1) Drug manufacturer did not voluntarily assume a duty to warn patient directly of risks associated with drug simply through TV advertisements, a website, and an educational video viewed by patient where patient admitted that she never paid attention to the warnings on the TV ads, there was no evidence that patient visited the website, and the educational video contained a 12-sentence message regarding the drug's risks and encouraging patients to discuss the risks with their own physicians. (2) Expert testimony is insufficient to support the contention that the drug label failed to sufficiently warn physicians of the risks associated with the drug where expert has no reasonable basis for his opinion.

Plaintiff, a rheumatoid arthritis patient who allegedly developed lymphoma as a result of using the drug Humira, filed suit against the defendant drug manufacturer, alleging that defendant failed to warn plaintiff and her treating physician about the alleged risks of developing lymphoma from taking Humira. The defendant moved for summary judgment and sought to exclude testimony of plaintiff's warnings expert (among others). The court granted the motion.

Learned Intermediary Doctrine

Plaintiff argued that defendant, through its TV advertisements, website, and an educational video, voluntarily assumed a duty to warn her directly of the risks of developing lymphoma, thereby vitiating the learned intermediary doctrine. The court disagreed, pointing to the fact that the plaintiff admitted she "never paid attention" to the warnings in the TV ads, and that there was no evidence that she had ever used the website. As for the educational video, the court noted that it contained a 12-sentence message at the end regarding the risks associated with the drugs and encouraging patients to discuss the risks with their doctors. The court concluded that even assuming that the video was a direct communication between the defendant and the plaintiff, the "totality of . . . communications with the patient and the patient's reasonable understanding based on those communications" does not support a conclusion that the defendant voluntarily assumed a duty to directly warn the plaintiff.

Plaintiff's Warning Expert

Plaintiff offered the testimony of Michael Hamrell, Ph.D., a regulatory affairs expert with degrees in biochemistry and pharmacology, to support her contention that the drug label failed to sufficiently alert physicians to the alleged lymphoma risk associated with the drug. The court excluded Hamrell, who was not a medical doctor, stating that he did not have a reasonable basis for his opinion because he did not have the proper understanding as to what information a physician needs in order to prescribe a specific drug. The court also found that Hamrell was unable to show that his opinion was the product of reliable experience, principles, or methods. He offered no methodology to assess the effect of the label on a physician, and "took no steps to determine if the label is misleading, confusing, or downplayed any relevant risk." Hamrell also testified that he knew of no literature, studies, or data that supported his opinion. Because the plaintiff needed to provide expert testimony in order to demonstrate that the warning failed to reasonably warn physicians of the alleged risk of lymphoma associated with use of the drug, the court granted summary judgment in defendant's favor.

Nutter's Products Liability: 2013 Year in Review is a publication of the Product Liability and Toxic Tort Litigation Group of Nutter McClennen & Fish LLP in Boston. The bulletin was prepared by Shagha Tousi, Katy O. Meszaros, and Hilary S. Blackwood. For further information or if we can be of assistance, please contact your Nutter products liability lawyer or the chairperson of the Product Liability and Toxic Tort Litigation Group:

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