Nutter uncommon law

PRODUCT LIABILITY
2017 YEAR IN REVIEW

Massachusetts state and federal courts issued a number of important product liability decisions in 2017. The Product Liability practice group at Nutter recently reviewed these cases. Highlighted below are some of the key cases and issues decided in the past year.

UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

Santos-Rodriguez v. Seastar Solutions,
858 F.3d 695 (1st Cir. June 8, 2017)

Significant Holding: District Court properly granted summary judgment on failure to warn claim where the plaintiff failed to show that he—or anyone else—had read the instruction manual of the boat steering system that allegedly caused the plaintiff's injuries. District Court also properly granted summary judgment on design defect claim where the plaintiff's expert failed to point to any defect in the design of the boat's steering system, and the plaintiff's only evidence of defect was the fact that the steering system failed. (Torruella, J.)

Summary: Plaintiff Bernardino Santos-Rodriguez ("Santos") was driving a boat (owned by a third party) in a bay near Guayama, Puerto Rico. The boat was equipped with a hydraulic steering system manufactured by the defendant, Seastar Solutions. The ball-joint at the end of the rod, connecting the steering system to the boat's right motor, broke while the boat was in motion. This caused a loss in steering function, and Santos was ejected from the boat. Santos suffered extensive injuries, which ultimately resulted in paraplegia. Subsequent examination of the boat revealed that rod end failed because of corrosion.

Santos and several of his family members (who were not on the boat at the time of the accident) sued Seastar for failure to warn and design defect. The District Court, after deciding that federal maritime law—rather than Puerto Rico law—applied, granted summary judgment in favor of Seastar. The plaintiffs appealed both the decision to apply federal maritime law and the grant of Seastar's motion for summary judgment. Without addressing whether federal maritime law or the substantive law of Puerto Rico applied, a First Circuit Panel affirmed, holding that plaintiffs' claims did not hold water even under Puerto Rico law.

Causation in failure to warn claims: One of the requirements for alleging failure to warn is that "'the absence of adequate warnings or instructions was the proximate cause of plaintiff's injury.'" *Santos-Rodriguez*, 858 F.3d at 697 (quoting *Cruz-Vargas*, 348 F.3d 271, 276 (1st Cir. 2003)). The First Circuit noted that, on appeal, the plaintiffs summarized evidence showing only that the steering mechanism's manual did not include any warnings about corrosion of the rod end and that the corrosion is what caused the steering mechanism to fail. *Id.* But the First Circuit held that "[u]nless someone read the Manual, no warnings in it could have prevented Santos's injuries." *Id.* at 698. Thus, even if the manual's warnings were inadequate, the plaintiffs could not demonstrate that the inadequacy of the manual was the proximate cause of Santos's injuries.

Expert reports in defective design cases: Although plaintiffs had an expert, his report concluded only that the corrosion of the rod end was the main cause of the failure of the steering system. His report did not state that a defect in the design caused the corrosion or made it particularly susceptible to the corrosion. *Santos-Rodriguez*, 858 F.3d at 698. The First Circuit held that the plaintiffs' only showing regarding defective design was that "something was wrong—the rod end failed" and that that was insufficient to establish defective design. *Id.* The First Circuit therefore affirmed summary judgment in favor of Seastar on the defective design claim.

Importantly, the District Court declined to consider the deposition testimony of the expert that the material of which the rod was made was particularly susceptible to corrosion, holding that it was inadmissible because that opinion was not disclosed in his report. The plaintiffs did not appeal this ruling.

Town of Westport v. Monsanto Company,
877 F.3d 58 (1st Cir. Dec. 8, 2017)

Significant Holding: District Court properly granted summary judgment on breach of the implied warranty of merchantability, where plaintiff failed to show that the health risks of PCBs were known to the defendant during the relevant time period. District Court also properly granted summary judgment on negligent marketing claim, where predicate design defect claim had already been dismissed and plaintiff did not appeal that decision. (Lynch, J.)

Summary: Monsanto was the sole manufacturer of PCBs in the United States from 1935 through the late 1970s, when the EPA banned their manufacture and most uses following the passage of the Toxic Substances Control Act of 1976, 15 U.S.C. § 2601 *et seq.* Monsanto produced PCBs for use in both enclosed applications (most commonly transformers and lighting ballasts) and non-enclosed building materials, such as caulks, paints, and sealants. The Town of Westport detected PCBs in its schools in May 2011, including its middle school, which was built in 1969. PCBs were detected in the window glazing, exterior window caulking, and interior door caulking of the middle school building. The town then undertook a multi-million dollar remediation project to remove the PCBs.

The town filed suit against Monsanto and two affiliates, including defendant Pharmacia Corporation, in the United States District Court for, among other things, breach of the implied warranty of merchantability (based on failure to warn) and negligent marketing. The defendant moved for, and the District Court granted, summary judgment in favor of Monsanto. The town appealed, and the First Circuit affirmed the lower court's rulings.

Foreseeability and breach of the implied warranty of merchantability: The First Circuit held that Monsanto did not breach the implied warranty of merchantability because it was not reasonably foreseeable in 1969 that there was a risk that PCBs would volatize from caulk at levels requiring remediation due to their risk to human health. *Monsanto*, 877 F.3d at 65-66. Under Massachusetts law, a plaintiff must establish that a product was defective and unreasonably dangerous for its intended purposes when it was distributed by the supplier, and a supplier can be held liable if it failed to warn end-users of the product's "foreseeable risks" of harm. *Id.* at 65 (citing *Evans v. Lorillard Tobacco Co.*, 465 Mass. 411 (2013)). The town argued that all it needed to demonstrate was that as of 1969, it was foreseeable that there was a risk that PCBs would volatize out of caulk, and that it did not need to further establish that such a process would cause risks to human health. *Id.* The First Circuit disagreed and further noted that the town failed to proffer any scientific studies from 1969 or indeed, at any time before or after, evidencing that PCBs would volatize from caulk at harmful levels, and had failed to show that the defendant was aware of any such risk. *Id.* at 66-67. Lastly, the Court summarily rejected a related breach of warranty claim that the defendant had violated its "post-sale" duty to warn, affirming the District Court's judgment that the Westport Middle School was not an identifiable end-user to whom the defendant could have provided a warning after having sold its products. *Id.* at 67-68.

Negligent marketing: With respect to the town's negligent marketing claim, the First Circuit concluded that, under Massachusetts law, the claim could not be maintained independent of a design defect claim—and in this case, the town had failed to challenge the entry of summary judgment against its design defect claim. *Monsanto*, 877 F. 3d at 68. The Court rejected the town's arguments pointing to dicta in some state court decisions suggesting that absent a design defect, a manufacturer might still be liable if it intentionally targeted children. *Id*.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

Liu v. Boehringer Ingelheim Pharmaceuticals, Inc.,
230 F. Supp. 3d 3 (D. Mass. Jan. 23, 2017)

Significant Holding: District Court denied summary judgment on the plaintiffs' failure to warn claim on the narrow issue of whether prescription drug manufacturer should have warned physician that the drug was especially risky for patients over 80 years old. (Young, J.)

Summary: Dr. Zhensheng Liu was prescribed

***Liu v. Boehringer Ingelheim Pharmaceuticals, Inc.*,**
230 F. Supp. 3d 3 (D. Mass. Jan. 23, 2017)
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Pradaxa (a brand name anticoagulation medication) after he was diagnosed with atrial fibrillation. Dr. Liu was in his eighties at the time he began taking Pradaxa. A year and a half after starting the drug, Dr. Liu fell, sustained a head injury, and experienced continued bleeding. As a result of the continued bleeding, doctors attempted to remove Pradaxa from Dr. Liu's system. Ultimately, Dr. Liu died of cranial bleeding. The personal representatives of Dr. Liu's estate sued Pradaxa's manufacturer for negligent design defect, negligent design and testing, and negligent failure to warn. The defendant-manufacturer filed a motion for summary judgment, which the court granted in part and denied in part.

Negligent and defective design claims: The plaintiffs alleged that Pradaxa was defective in design because there were safer alternative designs, that Pradaxa was not as safe as other drugs in the same class, and that the manufacturer negligently tested and designed the drug. *Liu*, 230 F. Supp. at 6-7. Without much detail, the court held that the plaintiffs had not produced any evidence to support these claims and granted summary judgment in favor of the manufacturer. *Id*.

Negligent failure to warn: The plaintiffs claimed that the manufacturer knew of an increased risk of major bleeding for patients over 80 years old and that it failed to include that risk in the drug's warning label. *Id*. at 8. In support of their motion for summary judgment, the defendants made two arguments.

First, the defendants argued that, under the learned intermediary doctrine, it is the responsibility of the doctor to communicate relevant warnings and side-effects to his or patients—not the manufacturer. *Id*. at 8. The plaintiffs argued that the learned intermediary doctrine did not apply to this case because Dr. Liu and one of the plaintiffs had the necessary knowledge and medical training to assess whether Pradaxa would be appropriate for Dr. Liu in light of his age and condition. *Id*. The court rejected the plaintiffs' argument because there was no evidence that either Dr. Liu or the plaintiff played any active role in the decision to use Pradaxa. *Id*.

Second, the defendants argued that the alleged failure to warn was not the proximate cause of Dr. Liu's injury. *Id*. at 9. The court found that the plaintiffs had carried their initial burden of showing that the drug's warnings were inadequate through the affidavits of two physicians (including one of the plaintiffs). *Id*. This showing, the court held, raised a rebuttable presumption that, had the prescribing physician been aware of the inadequacies of the warning, he would not have prescribed Pradaxa. *Id*. But the court held that the defendant rebutted this presumption by pointing to the prescribing physician's deposition, during which he testified that, had he been aware of a clinical study showing that Pradaxa was associated with a higher incidence of major bleeding, he would not have changed his decision to prescribe Pradaxa. *Id*. As the court put it, the prescribing physician, "as a learned intermediary, breaks the chain of proximate causation." *Id*.

The court nevertheless denied the defendants' motion for summary judgment on the negligent failure to warn claim on the issue of whether Pradaxa was especially risky for elderly patients and whether the warning label should have so indicated. *Id*. The court warned that the plaintiffs' case "dangles by a most tenuous thread."

***Meijer, Inc. v. Ranbaxy, Inc.*,**
245 F. Supp. 3d 312 (D. Mass. March 28, 2017)

Significant Holding: District Court certified its denial of the defendants' motion to dismiss—holding that claims for fraud on the FDA arising under federal antitrust and racketeering statutes were not preempted under *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001)—for interlocutory appeal to the First Circuit. (Gorton, J.).

Summary: Purchasers of two generic drugs filed antitrust and racketeering claims against the drugs' manufacturers, under the Sherman Act and Racketeer Influenced and Corrupt Organizations Act. The claims alleged that the drug manufacturers made fraudulent representations to the FDA prior to entering the drugs on the market.

The defendant-drug manufacturers moved to dismiss the claims under the Supreme Court's decision in *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341 (2001), which held that federal law preempted state-law tort claims for fraud on the FDA. The defendants argued that the Court's

***Meijer, Inc. v. Ranbaxy, Inc.*,**
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reasoning in *Buckman* equally applied to federal law claims predicated on fraud on the FDA and, therefore, plaintiffs' claims were preempted by the Federal Drug and Cosmetic Act.

The District Court disagreed. Instead, the court agreed with the plaintiffs' argument that *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014) applied. In *POM Wonderful*, the Supreme Court held that, when two federal statutes complement each other, it would "show disregard for the congressional design to hold that Congress nonetheless intended one federal statute to preclude the operation of the other." *Id*. at 2236. The District Court held that, because the FDCA did not conflict with the Sherman Act or RICO, the plaintiffs' claims could proceed.

The defendants then filed a motion asking the District Court to certify the order denying its motion to dismiss for interlocutory appeal to the Frist Circuit. The court granted the motion.

Preemption of federal law claims predicated on fraud on the FDA is an issue of first impression: A factor that federal district courts must consider in deciding whether to certify an interlocutory order for appeal to the First Circuit is whether "there are grounds for a substantial difference of opinion." *Meijer*, 245 F. Supp. 3d at 315. Although the plaintiffs relied on *Pom Wonderful*, which addressed the intersection of two federal statutes as a matter of statutory interpretation, *Pom Wonderful* made no reference to *Buckman* and did not involve fraud on the FDA. *Id*. Thus, the court held that whether the FDCA precluded claims based on two other federal statute presented a "sufficiently novel" question to warrant certification for interlocutory appeal. *Id*. at 316.

This case is now pending before the First Circuit.

***Gustavesen v. Alcon Laboratories, Inc.*,**
---F.Supp.3d ---, 2017 WL 4374384
(D. Mass. Sept. 29, 2017)

Significant Holding: Altering the size or shape of an eye drop dispenser would be a "major change" to the container and would require FDA re-approval. Thus, federal law preempted plaintiffs' claims that the design of the container violates state consumer protection laws because it dispenses drops larger than the human eye can absorb. (Wolf, J.)

Summary: This is a putative class action in which the plaintiffs allege that manufacturers of prescription eye drops violated state consumer protection laws by intentionally designing eye droppers to dispense more liquid than a human eye can absorb. Excess liquid is wasted by rolling down users' cheeks or draining through their tear ducts. The defendants allegedly designed the droppers this way to cause consumers to buy eye drops more frequently than necessary, which would drive up profits.

The defendants moved to dismiss on a number of grounds, including that the doctrine of impossibility preemption barred the plaintiffs' claims because the Food Drug and Cosmetic Act and FDA regulations prohibit the defendants from changing the dropper design without FDA re-approval. The court agreed that impossibility preemption applied, granted the motion to dismiss on that basis, and did not address the other arguments.

Impossibility preemption: The contours of impossibility preemption are set forth in three recent Supreme Court cases. In *Wyeth v. Levine*, the Court held that state law claims related to allegedly insufficient warnings on a prescription drug label were not preempted by FDA regulations allowing the manufacturer to strengthen warnings without pre-approval. 555 U.S. 555 (2009). In *Pliva, Inc. v. Mensing*, state laws requiring generic drug manufacturers to strengthen label warnings were preempted by FDA regulations requiring a generic's label to match the corresponding brand-name drug's label. 564 U.S. 604 (2011). And in *Mutual Pharmaceutical Co. v. Bartlett*, a state law requiring a generic manufacturer to make a drug safer by altering its composition or label was preempted by FDA regulations requiring a generic to have the same composition, dosage form, strength, and labeling as the corresponding brand-name drug. 570 U.S. 472 (2013).

Based on this Supreme Court trilogy, the *Gustavesen* court held that the plaintiffs' claims that state laws required the defendants to use droppers that dispense less liquid would be preempted by federal law. Specifically, the FDA has three categories of changes to previously approved

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drugs: major, moderate, and minor changes. Minor and moderate changes do not require FDA approval, so a state law requiring such changes would not be preempted. But the FDA must approve major changes before they are implemented and brought to market. Thus, a state law requiring a major change would be preempted.

FDA guidance provides that "'[c]hanges in the size and/or shape of a container for a sterile drug product' are major changes requiring preapproval." *Gustavesen*, 2017 WL 4374384 at *8 (quoting Guidance for Industry Changes to an Approved NDA or ANDA (2004)). The court held that changes to the dropper tip, which dictates the amount of liquid dispensed, would be major changes because they would entail changing the size and/or shape of the container. As a result, the defendants could not change the dropper design without the FDA's approval, making it impossible to comply with federal law and state consumer protection statutes.

The court further rejected the plaintiffs' argument that the defendant manufacturers should have submitted a differently-designed product for FDA approval in the first instance. Relying on the rationale in a Sixth Circuit case dealing with a similar issue, the court found that the plaintiffs' position was akin to the argument that a manufacturer could have stopped selling the product, which would have allowed it to comply with both federal and state law. *Gustavesen*, 2017 WL 4374384 at *10 (citing *Yates v. Ortho-McNeil-Jansen Pharm., Inc.*, 808 F.3d 281 (6th Cir. 2015)). But in *Bartlett*, the Supreme Court rejected just that argument. Accordingly, the *Gustavesen* court held that defendants "could not have marketed droppers that complied with state consumer protection and unjust enrichment laws in the manner plaintiffs advocate without the FDA's prior approval. It is irrelevant that the defendants could have designed an entirely different product before they sought approval, which may never have been granted." *Id*. at *11.

Informal agency action does not take precedence over official agency guidance: The plaintiffs argued that the FDA does not require preapproval of all container closure systems. They pointed to three occasions where the FDA permitted manufacturers to change containers or closures without preapproval.

The court rejected this argument. The plaintiffs did not cite any law indicating that an agency action, rather than the agency's official position, is relevant to interpreting a regulation. And instead, the Supreme Court has declined to follow an agency's practice rather than the agency's official standards. Further, the evidence the plaintiffs provided of occasions where the FDA purportedly permitted changes to containers was not convincing. Some of the plaintiffs' exhibits did not actually contradict the FDA's preapproval requirement, nor did they demonstrate that the FDA did not require preapproval in those cases. And other exhibits merely provided evidence of the FDA having failed to strictly follow its own guidance. The FDA failing to follow its own guidance did not cause the court to doubt the meaning of that guidance, which requires preapproval for changes to the size and/or shape of a container.

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The plaintiffs appealed this opinion, and the case is pending before the First Circuit. *See Gustavesen v. Alcon Laboratories, Inc.*, No. 17-2066 (1st Cir.).

In re: Zofran (Ondansetron) Products Liability Litigation, 261 F. Supp. 3d 62 (D. Mass. Aug. 4, 2017)

Significant Holding: A brand-name drug manufacturer is not liable for injuries caused by a generic drug where there are alleged misrepresentations or omissions on the drug's label. (Saylor, J.)

Summary: This is a multidistrict litigation involving injuries allegedly due to Zofran. The FDA approved Zofran to combat nausea and vomiting for patients undergoing chemo therapy or radiation or for patients who recently had surgery.

The plaintiffs alleged that GlaxoSmithKline ("GSK"), Zofran's manufacturer, pursued an off-label marketing campaign for Zofran to treat pregnancy-related nausea and vomiting. Zofran's prescribing information contained a section on pregnancy, which stated that studies using pregnant rats and rabbits showed no evidence of impaired fertility or birth defects, but that there were no well-controlled studies with pregnant women. The section

concluded with the following warning: "Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed." *In re: Zofran (Ondansetron) Products Liability Litigation*, 261 F.Supp.3d at 66. But animal studies conducted for GSK had allegedly shown "clinical signs of toxicity, intrauterine fetal deaths, stillbirths, congenital heart defects, craniofacial defects, impairment of ossification (incomplete bone growth), and other malformations in fetuses exposed to Zofran during gestation." *Id*.

Parents and guardians of children born with birth defects brought these cases, alleging that GSK is liable for birth defects caused by the birth mothers' ingestion of either Zofran or its generic equivalent. The plaintiffs had two theories of liability with respect to the generic version: (1) GSK made misrepresentations and omissions in Zofran's label resulting in injuries due to the ingestion of the generic version that would not have been prescribed absent the misrepresentations and omissions; and (2) GSK intended to create a market for the use of Zofran to treat pregnancy-related nausea and vomiting, and GSK knew generic manufacturers would be required to use Zofran's label. The defendants moved to dismiss the claims related to women who took the generic drug. The court granted the motion, and dismissed those claims.

Innovator liability: The majority of courts to consider innovator liability—whether a brand-name drug manufacturer is liable for harm caused by a generic equivalent—have rejected it. That conclusion is based on the bedrock principle that a manufacturer is not liable for harm caused by a different company's product. A few courts, though, have taken the opposite view and extended liability for harm caused by generic drugs to brand-name manufacturers.

The plaintiffs here brought claims under six states' laws: Georgia, Indiana, Kentucky, Massachusetts, New York, and Oklahoma. None of the highest courts of those states have squarely addressed the issue of innovator liability. Thus, the court assessed the plaintiffs' theories of liability using relevant cases from lower courts and federal courts in those states.

The court concluded that each of the states would likely adopt the majority position and decline to hold brand-name manufacturers liable for injuries caused by generic equivalents. In particular, with respect to Massachusetts, the court analyzed two Massachusetts Superior Court cases directly addressing the issue of innovator liability. *See Rafferty v. Merck & Co.*, No. 2013-04459, 2016 WL 3064255 (Mass. Super. Ct. May 23, 2016) [*Rafferty* was included in **Nutter's 2016 Year In Review**]; *Kelly v. Wyeth*, No. 200303314B, 2005 WL 4056740 (Mass. Super. Ct. May 6, 2005). In both cases, the Superior Court declined to adopt the doctrine.

No remedy for injuries caused by generic drugs: This case implicates the issues in *Pliva, Inc. v. Mensing*, 564 U.S. 604 (2011): a generic manufacturer must use the same drug composition and label as were approved for the brand-name version, and a plaintiff cannot recover against a generic manufacturer on a state law claim based on the generic manufacturer's failure to provide different warnings. The court in *In re: Zofran* acknowledged that a person harmed by a generic drug generally cannot sue either the generic or the brand-name manufacturer. The court explained, though, that a tort system must balance fairness and the appropriate allocation of risk. It is not clear that it would be fair or wise to impose 100% of the liability on brand-name manufacturers who many control only a small percent of the market. And, as the court noted, adopting the doctrine of innovator liability could have a negative impact on the development of new drugs.

* * *

In an earlier opinion in this case, the court held that Federal Rule of Procedure 9(b)'s particularity requirements for pleading fraud apply to complaints filed in multidistrict litigations as they apply to any other action. See *In re: Zofran (Ondansetron) Products Liability Litigation*, No. 1:15-md-2657-FDS, 2017 WL 1458193 (D. Mass. Apr. 24, 2017). As the court explained, "it is not appropriate to plead fraud claims in general terms, in the hope that discovery will reveal greater particularity as to the actual misrepresentations." *Id*. at *5.

MASSACHUSETTS APPEALS COURT

Pantazis v. Mack Trucks, Inc.,
92 Mass. App. Ct. 477 (Nov. 27, 2017)

Significant Holding: Court affirmed summary judgment in favor of manufacturers of component parts used to assemble a dump truck, concluding that manufacturers of parts that are not themselves defective have no duty to warn assemblers or end users of the risks of the system the parts were used to create. (Milkey, J.)

Summary: Mack Trucks manufactured "incomplete vehicles" that have only a chassis, cab, and engine. Components and equipment are added to these incomplete vehicles to create many types of trucks, including dump trucks, flatbed trucks, and fire trucks. The plaintiff's late husband purchased a Mack Truck incomplete vehicle in 1987 and had it transformed into a dump truck. Certain components of the mechanism that tilts the body of the truck were exposed—which created considerable risk to someone working under the truck—even though the tilt system could have been installed with guards. Mack Trucks included warnings in its manual about the dangers of equipment installed as part of the tilt system. The manufacturer of the tilt system component included general warnings in its manual about the dangers of exposed, unguarded equipment. It also distributed warning stickers to be affixed to the truck with information for preventing "possible injury or death," including how to avoid getting caught or entangled in the machinery. In 2009, the plaintiff's husband was found dead under the truck, and his clothes were caught in the tilt system.

His wife brought a wrongful death action against Mack Trucks and the company that now owns the assets of the entity that manufactured a component of the tilt system. The plaintiff did not allege that the incomplete vehicle or the tilt system component were defective. Instead, she claimed that both manufacturers had a duty to warn installers and end users of the risks of an unguarded tilt system because such future use was foreseeable. In the alternative, she argued that even if component manufacturers do not have such a duty, in this case they voluntarily assumed a duty to warn because they provided certain warnings about such use.

The trial court entered summary judgment in favor of both defendants. The Appeals Court affirmed, holding that component manufacturers do not have a duty to warn of the risks of a system in which the components are used, and the manufacturers here did not assume that duty by issuing some warnings.

Component parts doctrine: The Appeals Court followed the Massachusetts Supreme Judicial Court's use of the component parts doctrine from *Mitchell v. Sky Climber, Inc.*, 396 Mass. 629 (1986). In *Mitchell*, the Court held that a component part manufacturer has no duty to warn "of a possible risk created solely by an act of another that would not be associated with a foreseeable use or misuse of the manufacturer's own product." *Id.* at 632. In applying the component parts doctrine from *Mitchell*, the Appeals Court here concluded that the assembly of the exposed tilt system by downstream actors (not the defendants) gave rise to the potential dangers. And because the defendants manufactured components that were not defective, they did not have a duty to warn installers or end users of the risks of the unguarded tilt system.

The Appeals Court also found that the defendants had not assumed a duty to warn based on having provided some warnings. The warnings the defendants provided did not suggest that it would be safe to be under the truck while the tilt system was engaged. And the Restatement of Torts specifically uses the example of a chassis that can be turned into any type of truck to underscore that the chassis manufacturer does not have a duty to warn of the risks of particular potential adaptions made by downstream actors. *See* Restatement (Third) of Torts: Products Liability § 5, comment d.

MASSACHUSETTS SUPERIOR COURT

Clairmont v. Amer Sports Winter & Outdoor Co., 34 Mass. L. Rptr. 449 (Mass. Super. Ct. Oct. 30, 2017)

Significant Holding: Applied longstanding precedent that expert testimony is generally necessary to establish design defect and the availability of a reasonable alternative design to avoid summary judgment on negligence, defective design, and breach of warranty claims all based on a theory of defective design. The court also granted summary judgment in favor of the manufacturer on a failure to warn claim where the plaintiff had failed to introduce any evidence that the product posed a reasonably foreseeable risk to consumers. (Ricciuti, J.)

Summary: Defendant Amer Sports manufactured Solomon Gore-tex Contragrip ankle high hiking boots. The boots featured a "speed lacing" design, which included a J-shaped hole through which the boots' laces passed. Plaintiff Francis Clairmont was wearing the boots during a shopping trip to the Derby Street Shoppes in Hingham, Massachusetts, when the lace of her left boot caught on the J-shaped hook of her right boot. Clairmont's legs became tangled and she fell forward, injuring herself.

Clairmont sued Amer Sports for negligence, defective design, breach of warranty, and failure to warn. When Amer Sports filed for summary judgment, the primary issue was whether the plaintiffs were required to present expert testimony on whether the design of the speed laces was defective and whether there was a reasonable alternative design. The Superior Court, noting that whether the plaintiff's case required expert testimony was a question of law that it could resolve, held that expert testimony was required and granted Amer Sports' motion for summary judgment primarily on that basis.

Requirement of expert testimony in defective design claims: To establish a claim for defective design in Massachusetts, a plaintiff must show that the manufacturer "'failed to exercise reasonable care to eliminate avoidable or foreseeable dangers to the user of the product.'" *Clairmont*, at *2 (quoting *Morrell v. Precise Engineering, Inc.*, 36 Mass. App. Ct. 935, 936 (1994) (Rule 1:28 opinion)). Further, in claims alleging negligence in the defective design of the product (including claims of breach of the implied warranty of merchantability premised on defective design), the plaintiff must prove the existence of a reasonable alternative design that would have reduced the risk of injury, without undue cost or interference with the performance of the product. *Id.* (quoting *Evans v. Lorillard Tobacco Co.*, 465 Mass. 411, 443-44 (2013)).

The plaintiff presented no expert testimony on whether the boots' speed-lace design was defective or whether there was a reasonable alternative design, and argued that they did not need expert testimony to support their claim. The Superior Court disagreed, noting that "Massachusetts courts have routinely held that expert testimony in design defect cases is required." *Id.* (and cases cited). The court noted that it is only in rare cases, where the alleged design defect is so simple or obvious that the jurors do not need technical assistance, that expert testimony is not required. *Id.* Because this case would have required the jury to consider, among other things, the biomechanics of a person walking in the boots, the Superior Court held that expert testimony was required to support the plaintiff's negligence, defective design, and breach of warranty claims. Because the plaintiff presented no expert testimony, the Superior Court granted summary judgment in favor of Amer Sports on those claims.

Evidence of foreseeability in failure to warn claims: A manufacturer has a duty to warn only against "a foreseeable use of its product involving a hazard not apparent to the user." *Id.* at *3 (citing *Fegan v. Lynn Ladder Co.*, Inc., 3 Mass. App. Ct. 60, 63-64 (1975)). The Superior Court held that the plaintiff did not present any evidence that the speed laces posed a foreseeable risk, or a risk that could have been discovered through additional testing of the boots, and granted summary judgment for Amer Sports on the failure to warn count.

PRODUCT LIABILITY DEFENSE

TOP RANKED PRACTICE

For decades, product liability defense has been one of the cornerstones of Nutter's highly successful litigation practice. Some of the leading companies in the world have turned to Nutter to defend hundreds of cases involving allegedly defective drugs, medical devices, automotive products, and industrial materials. Because of the similar complexities involved in toxic tort litigation, those same clients and other market leaders have chosen us to defend them in cases involving damages from alleged toxic exposures.

OUR TEAM

The Nutter product liability defense team includes two members of the American College of Trial Lawyers, two Fellows of the Litigation Counsel of America, product liability defense attorneys who are named in the peer-reviewed "Best Lawyers in America," and attorneys who are named as "Super Lawyers" in Massachusetts. The practice has been recognized by *U.S. News & World Report* and *Chambers USA.*

OUR COMMITMENT TO BUILDING A CULTURE AND ATMOSPHERE OF LEGAL EXCELLENCE HAS LED TO TOP INDUSTRY ACCOLADES INCLUDING:

Best Lawyers BEST LAW FIRMS U.S.News & World Report 2017

Nutter earned a "Tier 1" ranking in Boston in the *U.S. News & World Report* "Best Law Firms" edition for Product Liability Defense.

LAW 2013 GO-TO TOP 500 FIRM

Nutter has been named a "Go-To" law firm in Torts Litigation by Johnson & Johnson.

RANKED IN USA CHAMBERS AND PARTNERS 2017 LEADING FIRM

Nutter's Litigation: General Commercial—Massachusetts practice has been recognized by *Chambers USA.*

INDUSTRY EXPERTISE

Nutter lawyers are frequently sought after by the media for their insights on cutting-edge developments in the products liability industry, including 3D printing, medical devices, food and beverage litigation, automotive liability, and other topics.

Nutter's products liability lawyers were recently featured in *Bloomberg BNA, Corporate Counsel, Medical Design & Outsourcing, DRI's The Voice, Huffington Post, Inside Counsel, Medical Device and Diagnostic Industry (MD+DI), The Gourmet Retailer, Additive Manufacturing Today, Food Manufacturing Magazine, Massachusetts Lawyers Weekly,* MCLE's *Massachusetts Courtroom Advocacy,* and the ABA's *Products Liability Litigation Newsletter.*

A member of the firm also co-authored the "Product Liability" 2016 chapter supplement in the Massachusetts Superior Court Civil Practice Jury Instructions and currently serves as chair of the Massachusetts Supreme Judicial Court's Standing Advisory Committee on the Rules of Civil and Appellate Procedure.

REPRESENTATIVE EXPERIENCE

Nutter's Product Liability practice group has a proven track record of successfully resolving complex cases. We have:

- Defended mass torts in a variety of contexts such as: medical devices, including artificial spinal discs, artificial metal-on-metal hips, artificial knees, cardiac devices, surgical instruments, bone cement, surgical sutures, spinal fusion plates, tissue morcellators, and latex gloves; pharmaceuticals, including antibiotics, anti-inflammatory drugs, and birth control patches; and consumer products, including facial cleansers and baby powder.
- Represented clients in various roles, including as trial counsel, national counsel, leading expert teams, and local counsel.

A LEADER IN PROFESSIONAL ORGANIZATIONS

Nutter is highly active in numerous organizations, strengthening its industry knowledge and cultivating relationships with key members of the business community. Recent highlights include:

- Presented at ACI's Drug and Medical Device Litigation Conference, DRI's Drug and Medical Device Seminar, the Boston Bar Association, and a Bloomberg BNA webinar
- Addressed U.S. litigation at a program in Zurich, Switzerland
- Selected as a Fellow of the American College of Trial Lawyers
- Participated in conferences addressing motor vehicle product liability litigation, the food and beverage sector, and current issues in pharmaceutical, medical device, and biotech litigation
- Sponsored DRI's Drug and Medical Device Conference, ACI's Drug and Medical Device Litigation Conference, and the Advanced Medical Technology Association (AdvaMed) Conference

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ABOUT NUTTER

Nutter is a Boston-based law firm that provides legal counsel to industry-leading companies, early stage entrepreneurs, institutions, foundations, and families, across the country and around the world. The firm's lawyers are known for their client-centric approach and extensive experience in business and finance, intellectual property, litigation, real estate and land use, labor and employment, tax, and trusts and estates. Founded in 1879, Nutter is dedicated to helping companies prosper in today's fast-paced business environment.