FOLEY HOAG LLP

Product Liability **Update**

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Foley Hoag LLP publishes this quarterly Update primarily concerning developments in product liability and related law from federal and state courts applicable to Massachusetts, but also featuring selected developments for New York and New Jersey.

MASSACHUSETTS

Massachusetts Federal Court Holds No Personal Jurisdiction Over Out-Of-State Corporation's Contract and Deceptive Practices Claims Against Foreign Corporation Based In Part On Communications With Plaintiff's Employee Working Remotely From Massachusetts, As Employee's Location Was Purely Fortuitous And There Was No Allegation Defendant Intended To Cause Harm In State

In *Collison Communications, Inc. v. Nokia Solutions and Neworks Oy*, No. 19-cv-12251, (D. Mass., Sept. 2, 2020), a Delaware corporation with its principal place of business in New Hampshire sued a Finnish company in the United States District Court for the District of Massachusetts after negotiations regarding integrating plaintiff's technology into defendant's, conducting a proof-of-concept of the technology and defendant's possible acquisition of plaintiff fell apart. Plaintiff's claims included breach of contract, including of the implied covenant of good faith and fair dealing, and violation of Mass. Gen. Law Ch. 93A, the state unfair and deceptive practices statute. Defendant moved to dismiss for lack of personal jurisdiction, arguing plaintiff failed to allege sufficient contacts between defendant and Massachusetts to establish personal jurisdiction under either the Massachusetts long-arm statute, Mass. Gen. Laws ch. 223A, § 3, or the due process clause.

The long-arm statute authorizes jurisdiction as to any cause of action arising from, among other things, "transacting any business" or "causing tortious injury by an act or omission" in Massachusetts, and prior precedent has held the former standard requires "deliberate," as opposed to "fortuitous," contact while the latter requires intent to injure a resident of the forum. Plaintiff argued both clauses were satisfied, as was due process, because some of defendant's negotiations with plaintiff had been with one of its employees who was working remotely from Massachusetts.

Regarding the contract claim, however, the court noted that on the facts alleged defendant had not specifically chosen to work with the remote employee rather than plaintiff's New Hampshire-based employees, nor did the employee's location in any way benefit defendant, so that defendant's Massachusetts contacts were "fortuitous" rather than "deliberate." Similarly, there was no allegation that any false representations to the remote employee were intended to cause injury in the commonwealth, so the long-arm statute did not authorize jurisdiction.

Further, due process would support jurisdiction only if plaintiff's claims directly arose

from or related to defendant's Massachusetts activities, defendant had purposefully availed itself of the privilege of conducting activities in Massachusetts and the exercise of jurisdiction was reasonable. Sufficient relatedness was absent here, as there was no showing that defendant's communications with plaintiff's remote Massachusetts employee were "instrumental either in the formation of the contract or its breach" nor, again, that they were intended to cause harm in the forum. As to purposeful availment, defendant's contacts with Massachusetts were fortuitous, and plaintiff's unilateral action allowing its employee to work remotely in the forum could not justify jurisdiction over defendant.

Lastly, the exercise of jurisdiction would not be reasonable, as Massachusetts did not have an interest in adjudicating a dispute between two foreign companies based solely on a single employee who happened to be working remotely from the commonwealth, and the state was unlikely to be the most effective location for resolving the dispute.

Massachusetts Federal Court Holds Strict Liability-Equivalent Design Defect Claims Involving Prescription Medical Devices Not Automatically Barred By "Comment k" Exception For Unavoidably Unsafe Products, And Exception Must Be Assessed For Particular Device At Issue; Negligent Design Claims Do Not Require Pleading Of Available Safer Alternative Design

In *Taupier v. Davol, Inc.*, 2020 U.S. Dist. LEXIS 174276, 2020 WL 5665565 (D. Mass. Sept. 23, 2020), plaintiff sued a hernia mesh patch manufacturer in the United States District Court for the District of Massachusetts, alleging a patch implanted in him had migrated or deteriorated over time, perforated his large intestine and released bacteria into his body, thus causing prolonged pain and suffering, scarring and economic damages. Plaintiff alleged the mesh used in the patch had a propensity to permit bacteria to enter the body, to shrink up to 50% in size, depolymerize and stress crack after implantation and then flake and eventually degrade. He asserted claims for breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) due to defective design, negligent design, breach of express warranty, breach of the implied warranty of fitness for a particular purpose, negligent failure to warn and strict liability for failure to warn. Defendant moved to dismiss the action in its entirety.

Perhaps of most interest to practitioners, as it involved an issue of first impression, the court declined to dismiss plaintiff's implied warranty of merchantability design defect claim. The court held the complaint's allegations of the mesh's propensities were sufficient, "albeit barely," to state a warranty-based design defect claim. The court then rejected defendant's argument that such claims involving prescription medical devices were barred by comment k to Restatement (Second) of Torts § 402(a). Section 402(a), which Massachusetts looks to in interpreting implied warranty-based product liability claims, recognizes strict liability for products that are defective and unreasonably dangerous, but comment k notes that "[t]here are some products which . . . are quite incapable of being made safe for their intended and ordinary use," this is "especially common in the field of drugs," and such a product, provided it is "properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous." In the absence of any Massachusetts state or federal appellate authority, and with other jurisdictions split on the issue, the court predicted that the Massachusetts Supreme Judicial Court ("SJC") would not categorically apply comment k to bar strict liability-equivalent design defect claims against all prescription medical devices and would instead analyze whether the particular device was unavoidably unsafe, which precluded dismissal here.

The court also denied dismissal of the negligent design claim, having already determined the allegations about the mesh's properties were sufficient to state a design defect claim based on the materials used and that plaintiff's injury allegations were sufficient to support an inference the mesh was a proximate cause of his harm. The court rejected defendant's argument that plaintiff was required to allege the availability of a safer alternative design that could be implemented without undue cost, citing an opinion of the United States Court of Appeals for the First Circuit that interpreted a seminal SJC opinion as suggesting Massachusetts law may not impose such a requirement.

The court dismissed all of plaintiff's remaining claims. His claim for breach of express warranty failed because he did not allege any specific affirmation of fact or promise, or any description, sample or model, to which the mesh failed

to conform. The claim for breach of an implied warranty of fitness for a particular purpose failed because plaintiff did not allege the patch was used for anything other than its ordinary purpose. His negligent failure-to-warn claim failed because his conclusory allegations that he was not informed of the risks of the mesh, and that its warnings and instructions were incorrect, inadequate and incomplete, did not identify any particular warnings or instructions defendant should have provided to plaintiff's physician but did not. And his strict liability failure-to-warn claim failed because Massachusetts does not recognize strict liability as such but rather assesses liability under the implied warranties of the Uniform Commercial Code, particularly the implied warranty of merchantability, and to the extent plaintiff was asserting a failure-to-warn claim under the latter doctrine it overlapped completely with his negligent failure-to-warn claim and failed for the same reasons.

Massachusetts Federal Court Applies Local Statute Of Limitations To Permit Claims Against Resident Medical Device Manufacturer, As State Has Significant Interest In Holding Resident Accountable And Louisiana Does Not Have More Significant Relationship To Claims Even Though Plaintiffs Resided And Device Was Implanted There; Plaintiffs Adequately Pled Design Defect, Failure-To-Warn And Express Warranty Claims Where They Alleged Safer Alternative Designs And That Defendant Represented Device Was Safe When It Was Not

In *Holbrook v. Boston Scientific Corp.*, No. 20-10671-WGY (D. Mass., Sept. 16, 2020), a woman and her husband sued a Massachusetts-based pelvic mesh manufacturer in the United States District Court for the District of Massachusetts alleging design defect, failure to warn and breach of express warranty after mesh implanted in the wife to treat stress urinary incontinence allegedly eroded, caused various symptoms and had to be removed, causing her to suffer continued incontinence and pain. Plaintiffs were Louisiana residents and the mesh had been both implanted and removed there. Defendant moved to dismiss the complaint as both untimely under Louisiana's one-year statute of prescription, the civil law equivalent of a statute of limitations, and inadequate under the Louisiana Product Liability Act ("LPLA"). The court granted the motion without prejudice to plaintiffs' moving to file an amended complaint, plaintiffs then filed such a motion and defendant opposed it, arguing the amendment would be futile as the claims remained time-barred and legally insufficient.

In assessing futility, the court applied the same standard as on a motion to dismiss for failure to state a claim, *i.e.* whether plaintiffs pled "enough facts to state a claim to relief that is plausible on its face." Regarding timeliness, the court noted that while Louisiana's statute of prescription would bar the claim, Massachusetts' three-year statute of limitations would not. Under Massachusetts choice-of-law rules, the court would apply its local statute permitting the claim unless "maintenance of the claim would serve no substantial interest of the forum" and "the claim would be barred under the statute of limitations of a state having a more significant relationship to the parties and the occurrence." Here, Massachusetts had a significant interest in holding a resident defendant accountable for conduct that took place in the commonwealth, which plaintiffs alleged both the design of the mesh and development of its labeling had. Further, while Louisiana also had an interest in applying its law to the claims, that interest was not so dominant that it warranted displacing Massachusetts' limitations statute.

As for the adequacy of plaintiffs' claims under the LPLA, the statute required plaintiffs to prove they were injured by a characteristic of a defendant's product that is "unreasonably dangerous in its construction (manufacture), design, warning, or [breach of] express warranty." While plaintiffs' design defect claims alleged a mesh made of biological rather than synthetic material or inserted through the abdomen rather than transvaginally would have posed less risk, defendants argued they failed to allege how the benefits of a safer design would outweigh the burden of implementing it. The court noted, however, that without discovery and expert consultation it is typically "almost impossible" to plead the specifics of an alternative design, in light of which plaintiffs' allegations were sufficient.

The court also found plaintiffs' failure-to-warn claim viable, as the amended complaint alleged defendant underreported to the United States Food and Drug Administration ("FDA") information about the mesh's propensity to fail, including through erosion, and specified multiple warnings defendants should have provided plaintiffs' doctor, such as about the potential need for corrective or revision surgery. Although some case law has held a failure to warn not a causal factor

where the medical community had been aware of a product's complications for years, plaintiffs argued the data about the risks of pelvic mesh for stress urinary incontinence were not as developed as other uses for which FDA and other organizations had issued clear warnings. Under these allegations, plaintiffs' doctor plausibly was not inherently on "high alert" about the product.

Lastly, with respect to express warranty, the court found that plaintiffs' allegations that defendant represented its mesh was safe to treat stress urinary incontinence, but that the mesh did not conform to those representations and in fact posed various risks, were sufficient.

Massachusetts Superior Court Holds Plaintiff Denied Kidney Transplant Due To Possibility Of Latent Infection From Defendant's Medical Device, And Thus Subjected To Painful and Expensive Dialysis, Sufficiently Stated Claim For Actual Physical Injury Rather Than Mere Speculative Or Potential Harm

In *Barnes v. Lahey Clinic Hospital, Inc.*, No. 1981-CV-03791 (Middlesex Cnty. Sup. Ct., August 24, 2020), plaintiff sued the manufacturer of a blood temperature regulator used in his open heart surgery in Massachusetts Superior Court, alleging the device was defective in that non-tuberculous mycobacteria ("NTM") could accumulate in its water tank and then spread through the air to infect patients. After his heart surgery plaintiff, who also suffered from kidney disease, allegedly went into kidney failure, needed a transplant and had a suitable donor identified, but his doctors determined the procedure was too risky because of his possible NTM infection; even though plaintiff tested negative for NTM, an infection could take years to manifest. Plaintiff was thus treated instead with dialysis, from which he alleged numerous complications, including infections as well as additional surgeries and hospitalizations, that would not have occurred but for defendant's device.

Defendant moved to dismiss on the ground that plaintiff had not sufficiently pled any physical harm, since he had not actually developed an infection from defendant's device, and cited case law precluding recovery for a mere potential future injury. The court, however, disagreed, concluding that based on his allegations plaintiff's physical harm was not merely speculative or potential but rather actual, as he alleged "the deprivation of needed, available medical treatment" which forced him "to undergo a painful and expensive alternative." Accordingly, the court denied defendant's motion.

NEW YORK/NEW JERSEY SUPPLEMENT

New Jersey Supreme Court Holds Product Liability Act Providing Exclusive Remedy For Manufacturing, Design And Warning Defects Does Not Preclude Consumer Fraud Act Claims For Deceptive, Fraudulent, Misleading Or Other Unconscionable Practices In Sale Of Product, As Such Conduct Is Not Covered By Product Liability Act

In *Sun Chem. Corp. v. Fike Corp.*, 243 N.J. 319 (2020), an ink manufacturer sued the manufacturer of an explosion isolation and suppression system in the United States District Court for the District of New Jersey, alleging plaintiff installed the system in its dust collection system and, on its first day of operation, the suppression system failed audibly to alert plaintiff's employees to a dust fire that then led to an explosion, causing several injuries as well as damage to plaintiff's facility. Plaintiff alleged defendant had falsely represented that its system would prevent explosions, had an audible alarm, complied with industry standards and had never failed, and asserted a single count under the New Jersey Consumer Fraud Act, N.J. Stat. §§ 56:8-1 et seq. ("CFA"). Plaintiff sought recovery for damage to its facility, workers compensation payments and work hours lost due to the employee injuries and the cost of the suppression system itself.

Defendant moved for summary judgment, arguing plaintiff's claim was governed solely by the New Jersey Product Liability Act, N.J. Stat. §§ 2A:58C-1 et seq. ("PLA"), so that a CFA claim was not permitted, and the district court agreed. After plaintiff appealed to the United States Court of Appeals for the Third Circuit, it certified to the Supreme Court of New Jersey a series of questions that the court reformulated as essentially one: whether a CFA claim can be based, in part or exclusively, on product-related harm that might also give rise to claims under the PLA.

The CFA was enacted in 1960, declares any "unconscionable commercial practice, deception, fraud, false pretense, false promise [or] misrepresentation . . . in connection with the sale or advertisement of any merchandise" to be unlawful, creates a right to recover any resulting "ascertainable loss of moneys or property" and requires that the damages be trebled and attorneys' fees awarded. Under the court's prior precedent, the CFA applies to conduct that is more specifically regulated by another statute unless there is a "direct and unavoidable conflict" between the two, in which case only the more specific statute applies.

The PLA was adopted decades later in 1987 to clarify "certain matters" but not "codify all issues relating to product liability." Under the statute, a "[p]roduct liability action" is "any" claim "for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty," and "harm" is defined as "physical damage to property, other than to the product itself," or "personal physical illness, injury or death," including pain and suffering, emotional harm and loss of consortium or services. A product manufacturer or seller can be liable in a product liability action "only" if plaintiff proves the product was "not reasonably fit, suitable or safe for its intended purpose" due to a manufacturing defect, design defect or failure to provide adequate warnings.

Plaintiff argued the PLA did not apply because plaintiff's requested damages were primarily economic, and allegedly stemmed from deceptive conduct rather than a product defect, while defendant responded that plaintiff did claim for property damage, should not be able to avoid the PLA by pleading only economic losses and many of those losses stemmed from employee injuries. Ultimately, the court held it is "the underlying theory of liability," not "[t]he nature of the plaintiff's damages," that determines whether the CFA or PLA applies. In so ruling, the court did not discuss the PLA provisions that it governed "any" claim for "personal . . . injury" or "damage to property" allegedly "caused by a product, irrespective of the theory underlying the claim," except express warranty claims.

Based on other provisions of the CFA and PLA, the court concluded that the two statutes covered different conduct relating to products and thus were not in "direct and unavoidable conflict," as the CFA regulated deception or unconscionable conduct in connection with product sales while the PLA governed design, manufacturing or warning defects. In addition, CFA amendments adopted after the PLA made unlawful the sale of children's products that were the subject of government or manufacturer recalls, or government safety warnings, providing further evidence the CFA could govern at least some product-related claims.

Accordingly, although "claims premised upon a product's manufacturing, warning, or design defect . . . must be brought under the PLA," and "CFA claims for the same conduct are precluded," "nothing about the PLA prohibits a claimant from seeking relief under the CFA for deceptive, fraudulent, misleading, and other unconscionable commercial practices in the sale of the product."

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