FOLEY HOAG LLP

Product Liability **Update**

In This Issue:

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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

First Circuit Holds Personal Jurisdiction Over Foreign Software Services Provider On Claim Arising Under Federal Law Satisfies Fifth Amendment Due Process' Minimum Contacts Requirement Because Defendant Knowingly Conducted Substantial Business Directly With United States Customers Through Website

In *Plixer Int'l v. Scrutinizer GmbH*, 2018 WL 4357137, 2018 U.S. App. LEXIS 25981 (1st Cir. Sep. 13, 2018), a Maine computer software and hardware company sued a German corporation that offered a global interactive English-language software creation website in the United States District Court for the District of Maine for infringement of plaintiff's registered trademark "Scrutinizer." Plaintiff used its mark in the field of software and hardware analysis, and alleged defendant's use of the term caused confusion, mistake or deception as to the source of its services.

Defendant moved to dismiss for lack of personal jurisdiction, arguing it accepted payment only in euros, its standard contract required all suits to be brought in German courts under German law, it had no office, phone number or agent in the United States, and when the litigation was brought it did not direct any advertising there. The district court noted that because plaintiff's claim arose under federal law, Fed. R. Civ. P. Rule 4(k)(2) authorized jurisdiction over defendant so long as it was "not subject to jurisdiction in any state's courts of general jurisdiction [] and . . . exercising jurisdiction [wa]s consistent with the United States Constitution and laws." The court concluded it could exercise jurisdiction because defendant sold its services to customers directly through its highly interactive website, the website was available throughout the United States and defendant knowingly accepted substantial recurrent business originating from there. The court also certified its order for interlocutory review under 28 U.S.C. § 1292(b), determining that it "involve[d] a controlling question of law . . . and that an immediate appeal from the order may materially advance the ultimate termination of the litigation."

The United States Court of Appeals for the First Circuit permitted defendant to appeal but affirmed. The court first noted that limits on jurisdiction in federal question cases derive from the Fifth Amendment's due process clause, which requires plaintiff to show that defendant had adequate "minimum contacts" with the United States as a whole, rather than specifically with the forum state. Under this standard, defendant's United States contacts must be related to plaintiff's claim,

defendant must by its conduct have purposefully availed itself of the benefits of conducting business in the United States and it must be reasonable for defendant to be haled into court there as a result.

Defendant conceded its website conduct was related to plaintiff's claim. As to purposeful availment, the appellate court noted the United States Supreme Court has not definitively answered whether and to what extent a defendant's online activities constitute contacts with any relevant jurisdiction. Absent such guidance, the court concluded defendant had purposefully availed itself of the benefits of conducting activity in the United States by using its website to engage in sizable and continuing commerce with customers there, as it knew it was serving United States customers and took no steps to limit its website to exclude them. Indeed, defendant's filing of a United States trademark application for the "Scrutinizer" mark after the litigation commenced only confirmed its desire to benefit from the market there. The court rejected defendant's argument it had simply entered its services into the "stream of commerce," which itself carried them into the United States, as defendant's services went only to customers it accepted directly rather than through the activities of an intervening actor who might have brought the services somewhere unexpected.

Finally, as to reasonableness, the court held the United States' interest in adjudicating a dispute regarding domestic trademark law, paired with the domestic plaintiff's interest in obtaining effective relief, outweighed any burden imposed on the foreign defendant by United States litigation.

First Circuit Holds Claims Alleging Prescription Eye Drop Manufacturers' Bottles Dispensed Excessively Large Drops Preempted By FDA Regulations Prohibiting Changes To Dispenser Drop Size Without Prior Agency Approval, Meaning Of Regulations Generally Determined By Regulatory Language And Formal Agency Interpretations Rather Than Individual Agency Actions

In *Gustavsen v. Alcon Laboratories, Inc.,* No. 17-2066, 2018 U.S. App. LEXIS 24221 (1st Cir. Aug. 27, 2018), plaintiffs, on behalf of themselves and a putative class, sued a number of manufacturers of prescription eye drops in the United States District Court for the District of Massachusetts, alleging violation of Mass. Gen. L. ch. 93A (the Massachusetts unfair and deceptive trade practices statute) and similar statutes of sixteen other jurisdictions, along with unjust enrichment under all the states' laws. Defendants' alleged violations consisted of selling their products, as approved by the United States Food and Drug Administration ("FDA"), in bottles that dispensed drops larger than the eye could absorb, thus wasting medication, causing plaintiffs to pay more than needed per delivered dose and posing health risks from drops rolling down the cheek or entering the bloodstream. The district court dismissed plaintiffs' claims, finding them preempted by FDA regulations that prevented defendants from changing their bottles' designs without prior FDA approval.

On plaintiffs' appeal, the United States Court of Appeals for the First Circuit affirmed. Defendants first challenged subject matter jurisdiction, arguing plaintiffs had not pleaded sufficient factual matter to plausibly demonstrate actual injury, a necessary requirement for standing. Defendants noted pharmaceutical pricing is highly discretionary and asserted plaintiffs' assumption that bottles dispensing smaller drops would carry a lower price was purely speculative. The court, however, found plaintiffs' allegations about published studies and statements from defendants' executives made consumer savings from smaller drops plausible, hence plaintiffs' alleged economic harm and increased health risks represented sufficiently particularized, concrete and imminent harm to support standing.

As to preemption, the court noted the parties agreed plaintiffs' claims would be preempted if under federal law

defendants could not unilaterally change their bottle designs to comply with the state law underlying plaintiffs' claims. Accordingly, the critical question was whether plaintiffs' proposed design changes would constitute a "minor" or "moderate change" under the relevant FDA regulations, neither of which would require prior agency approval to implement, or a "major change," which would.

After analyzing the regulatory language, the FDA's explanatory Federal Register preamble on promulgating the regulations and formal agency guidance documents, the court held that changing the dispenser design as suggested would be a "major change" under 21 C.F.R. § 314.70(b), as it would change "a drug product container closure system that controls the drug product delivered to a patient." Although plaintiffs cited various instances—some of which the district court had refused to consider—in which FDA had allegedly permitted similar changes by individual manufacturers of specific products without prior approval, the court expressed skepticism that "sporadic agency action in individual cases is capable of reflecting the fair and considered judgment of the agency on a matter of regulatory interpretation," and held such evidence insufficient to override the actual regulatory text and formal agency interpretations. Members of **Foley Hoag's Product Liability and Complex Tort Practice Group** submitted an amicus curiae brief on behalf of the Product Liability Advisory Council in support of defendants regarding the preemption and regulatory interpretation issues.

Massachusetts Federal Court Holds Defendants' Compliance With Applicable Safety Regulations Does Not Defeat Negligence Claim As Matter Of Law, Where Negligence Claim Survives Implied Warranty Of Merchantability Claim Must Survive As Well

In *Preferred Mut. Ins. Co. v. Barros Co.,* No. 15-13414, 2018 U.S. Dist. LEXIS 140764 (D. Mass. Aug. 20, 2018), falling snow and ice allegedly severed a gas pipe connecting a propane tank and emergency generator for a residence, leading to an explosion that destroyed the home. The homeowners' insurer as subrogee sued the generator manufacturer and the installer of the generator and piping in the United States District Court for the District of Massachusetts, alleging negligence by the installer in failing adequately to protect the gas line and generator from falling snow, negligence by the manufacturer in failing to warn of the need to protect the generator and line, breach of the implied warranty of merchantability (Massachusetts' near-equivalent of strict liability) against the manufacturer for a manufacturing defect, and breach of contract for failing to install the generator in a workmanlike manner. Defendants moved for summary judgment on all counts, arguing, among other things, that defendants met or exceeded all applicable regulations during installation, and plaintiff failed to identify any manufacturing defect or enforceable contract.

The court first noted it was undisputed that the piping installer had used more supports for the piping than required by the applicable regulations, and city inspectors had approved both the piping and tank installations. Nonetheless, the court held, while "compliance with a statute or regulation is prima facie evidence of due care, it is not conclusive." Accordingly, plaintiffs' experts' opinions that the piping could have been better protected by placing it elsewhere on the property, burying it underground or better supporting it created issues of material fact and rendered summary judgment inappropriate.

Having denied summary judgment on the negligence claims, the court then held it was compelled to do the same for the implied warranty of merchantability claim. Under established Massachusetts law, "[a] defendant cannot be found to have been negligent [in a product liability case], without having breached the warranty of merchantability," since if the two standards differ in any case the strict liability near-equivalent standard requires more of a product seller than does the negligence standard. Accordingly, the court could not dismiss the warranty claim while letting the negligence claim survive. Finally, the court dismissed plaintiffs' breach of contract claim because the only possible contract was the manufacturer's express warranty, which had expired over a year prior to the explosion.

Massachusetts Federal Court Holds Plaintiff's Treating Physicians' Expert Testimony Insufficient To Create Triable Issue That Prescription Drug Caused Plaintiff's Conditions Where Testimony Only Stated Conditions Were Possible Effects Of Drug And Did Not Address Plaintiff's Use Of Other Drugs With Same Effects

In *Jackson v. Johnson & Johnson and Janssen Pharmaceuticals, Inc.,* No. 15-13983, 2018 U.S. Dist. LEXIS 150594 (D. Mass. Sept. 5, 2018), plaintiff sued a pharmaceutical manufacturer and its parent company in the United States District Court for the District of Massachusetts alleging he developed obesity, diabetes and gynecomastia from defendants' antipsychotic medication, and asserted a variety of claims, including negligence and strict products liability for defective manufacture, design, and failure to warn, as well as breach of an express warranty regarding the drug's performance. Following discovery, defendants moved for summary judgment on all counts, arguing plaintiff had not produced evidence to meet his burden of both general medical causation, *i.e.*, that the drug could cause the alleged conditions, and specific medical causation, *i.e.*, that it did cause them in plaintiff.

The court first noted that each of plaintiff's claims required proving that defendants' antipsychotic medication had actually caused his harm, and expert testimony was required to prove such medical causation. After numerous extensions of his disclosure deadline, plaintiff had ultimately disclosed three experts, all of whom were his treating physicians.

The court then pointed out numerous deficiencies in plaintiff's expert disclosures, which were largely incomplete or ambiguous as to the experts' expected causation testimony and rendered it insufficient to create a triable issue on causation. For starters, the experts' statements that plaintiff was treated for his conditions said nothing about what actually caused them. In addition, assertions that plaintiff's conditions were possible side effects of defendants' medication could not, without more, support a finding that the medication actually caused plaintiff to develop the conditions. Indeed, expert opinion regarding specific causation was especially important where, as here, plaintiff was also taking other medications with the same potential side effects. For all these reasons, the court granted defendants' summary judgment motion.

NEW YORK/NEW JERSEY SUPPLEMENT

New Jersey Supreme Court Holds (1) New Jersey Law Applies To Pharmaceutical Failure-To-Warn Claims By Multistate Plaintiffs As Manufacturing And Labeling Occurred In-State, (2) New Jersey Product Liability Act Presumption Of Adequacy Of FDA-Approved Warnings May Be Overridden By Clear And Convincing Evidence Manufacturer Had Newly Acquired Information Of Causal Association With Adverse Effect But Failed To Update Warnings Under FDA Regulations, (3) Presumption Not Overcome By Single Company Document Referring To Causation Rather Than Association

In *In re Accutane Litigation,* 2018 N.J. Lexis 1187 (N.J. Oct. 3, 2018), 532 plaintiffs from forty-five jurisdictions sued a pharmaceutical company for failure to warn of the risks of its prescription acne drug, asserting it caused plaintiffs to contract inflammatory bowel disease ("IBD"). The cases were consolidated in Multicounty Litigation in New Jersey Superior Court in Atlantic County.

In 2015, the trial court concluded New Jersey law governed all claims and granted summary judgment for defendant because under N.J.S.A §2a:58C-4, part of the New Jersey Products Liability Act ("NJPLA"), if a drug's warnings have been approved by the United States Food and Drug Administration ("FDA") "a rebuttable presumption shall arise that the warning or instruction is adequate." The Appellate Division of the Superior Court reversed in part, holding each case had to be decided under the law of the jurisdiction in which plaintiff was prescribed and took the drug.

After the New Jersey Supreme Court granted certification, it reversed and dismissed all claims. The court first agreed with the trial court that New Jersey law applied because that state had the most significant relationship to the case, as the conduct giving rise to the injury—the manufacture and labeling of the drug—had occurred in New Jersey.

As for the adequacy of defendant's warnings, even though the NJPA creates a rebuttable presumption of adequacy for an FDA-approved warning, such a warning can grow stale based on years of clinical experience with

the drug. Accordingly, the court held the presumption could be overcome by clear and convincing evidence that a manufacturer knew or should have known, based on newly acquired information, of a causal association between the drug and a clinically significant hazard, but failed to update the label according to the FDA's "Changes Being Effected" ("CBE") regulations, 21 C.F.R. §§ 201.57(c), 314.70(c). The court asserted this newly articulated ground for overcoming the presumption was a natural extension of two of the court's previous decisions, which permitted overcoming the presumption by proving defendant (1) deliberately concealed or failed to disclose knowledge of harmful effects acquired after the drug came on the market, or (2) made an economically driven decision to delay amending the warning despite an FDA opinion that such a revision was appropriate.

In the present case, however, plaintiffs failed to demonstrate any of the three bases for overcoming the presumption. Plaintiffs' principal argument was that the drug labeling should have used the word "cause," instead of "has been associated with," to describe the relationship between the drug and IBD. The court rejected the argument, noting a physician would understand the term "associated" to include the possibility of causation. Further, although one of defendant's internal documents stated the drug had been found to be causally associated with IBD, this document, culled from voluminous discovery, failed to establish that the company had actually made such a determination, engaged in deliberate concealment of knowledge of causation, or otherwise knew or should have known that the term "associated" was inadequate.

New Jersey Supreme Court Incorporates Four *Daubert* Factors For Assessing Admissibility Of Expert's Opinion But Declines To Formally Adopt *Daubert* Standard, Holds Court Did Not Abuse Discretion In Excluding Expert Causation Opinion That Relied On Case Reports And Small Unpublished Studies To Contradict Conclusions Of Multiple Large Published Epidemiological Studies

In *In re Accutane Litig.*, 234 N.J. 340 (2018), a mass tort Multicounty Litigation consolidated in the New Jersey Superior Court in Atlantic County, over two thousand users of the defendants' prescription acne drug alleged it caused them to develop Crohn's disease. During the decade-plus of litigation, a series of epidemiologic studies have been published, all concluding the drug is not causally associated with Crohn's. In 2015, the trial court precluded plaintiffs' experts from testifying that the studies were flawed and the drug can cause Crohn's disease, but the Appellate Division of the Superior Court reversed (*see October 2017 Foley Hoag Product Liability Update*).

After granting certification, the New Jersey Supreme Court reversed and restored the trial court's preclusion order. The court first re-affirmed that a trial court's decision to admit or exclude scientific expert testimony in civil cases is reviewed under the abuse of discretion standard. While a 2017 New Jersey Supreme Court opinion suggested that an appellate court need not be so deferential on admissibility of expert scientific evidence, that authority "carr[ied] weight" in criminal matters but was "not appropriate in the context of a civil mass tort case."

The court then held the trial court had not abused its discretion in excluding plaintiffs' expert testimony. Under New Jersey law, the court's gatekeeper role is to determine the soundness of an expert's methodology, including ensuring it involves data and information reasonably relied on by experts in the field. Here, the trial court's decision was based on the experts' "stray[ing] from their own claimed methodology in order to reach their conclusions," and accorded with "decisions of many other courts that experts cannot selectively choose lower forms of evidence in the face of a large body of uniform epidemiological evidence." The trial court properly identified multiple concerns with plaintiffs' experts' methodology, including that they had:

(1) disregarded eight of the nine published epidemiological studies and relied instead on case reports and animal studies that are much lower in the causation evidence hierarchy; (2) purported to rely on one epidemiological study despite disagreeing with its ultimate conclusion; and (3) relied on small unpublished studies to support their opinions despite opining that the much larger published studies they disregarded were too small to be probative.

Finally, the court took the opportunity to clarify New Jersey law regarding the trial court's gatekeeping function for expert testimony and consider whether to formally adopt the standard established in *Daubert v. Merrill Dow Pharm.*, 509 U.S. 579 (1993), under which the proponent of expert testimony must establish its reliability by reference to four objective factors listed in the decision or otherwise. The court concluded that the four factors listed in *Daubert*—whether the expert's theory can be or has been tested, has been subjected to peer review and publication, has a known or potential error rate and enjoys general acceptance in the relevant scientific community—"are aimed at achieving the same examination for peer acceptance of a methodology (but not the outcome reached from that methodology)" as required under New Jersey law. The court thus accepted the *Daubert* factors as a "helpful—but not necessary or definitive—guide for our courts to consider when performing their gatekeeper role concerning the admission of expert testimony."

Despite adopting the *Daubert* factors and acknowledging "little distinction between *Daubert's* principles regarding expert testimony and our own," the court declined to formally "declar[e] [New Jersey] a '*Daubert* jurisdiction.'" Among other things, the court noted that New Jersey applies the pre-*Daubert* "general acceptance test" of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), in criminal matters. The court also expressed concern about sweeping the voluminous and sometimes inconsistent *Daubert* jurisprudence of other jurisdictions into New Jersey law by a wholesale adoption of *Daubert*. Accordingly, the court elected not to "adopt a 'standard' that we cannot fully discern in its application at this time."

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