FOLEY HOAG LLP

Product Liability **Update**

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

Massachusetts Supreme Judicial Court Holds Foreign Manufacturer Which Pled Meritorious Personal Jurisdiction Defense in Answer, But Did Not Move to Dismiss, Forfeited Defense By Participating in Merits Discovery for Eighteen Months Before Pressing Defense in Summary Judgment Motion

In *American International Ins. Co. v. Robert Seuffer GMBH & Co. KG*, 468 Mass. 109 (May 14, 2014), a valuable painting was damaged when it fell from the wall where it had been hung with picture hangers manufactured by a German company. The homeowner's insurer sued the manufacturer and the hangers' seller in Massachusetts Superior Court alleging negligence, breach of the implied warranties of merchantability (the Massachusetts near-equivalent of strict liability) and fitness, and violation of Mass. Gen. L. ch. 93A (the Massachusetts unfair and deceptive practices statute). In its answer, the manufacturer pled lack of personal jurisdiction as an affirmative defense and stated that it was "specially appearing and specifically reserving the right to contest this Court's personal jurisdiction over [it]," but did not move to dismiss. The parties then proceeded to take discovery on the merits and, after nearly eighteen months, defendant filed a summary judgment motion based on both the personal jurisdiction defense and the merits. The trial court found that defendant had an "airtight claim that this Court lacks personal jurisdiction," but nevertheless denied the motion finding defendant waived the defense "by delay in bringing [it] forward, coupled with participation in discovery and motions regarding the merits."

Defendant sought interlocutory relief from the order and the Massachusetts Supreme Judicial Court ("SJC") granted direct appellate review. Defendant argued that, read together, the plain language of Massachusetts Rules of Civil Procedure 12(b), regarding motions to dismiss, and 12(h)(1), regarding the "waiver or preservation of certain defenses," permits a party to raise and preserve a personal jurisdiction defense *either* by bringing a motion under Rule 12(b)(2) *or* by asserting it as an affirmative defense in its answer, the latter of which defendant did. Plaintiff argued that while Rule 12 clearly provides that the defense is waived if not raised in either a motion or responsive pleading, the rule does not guarantee the defense's preservation simply by including it in a responsive pleading; in other words, even if a defendant does not *waive* its personal jurisdiction defense if it chooses the pleading route, it may still *forfeit* the defense by not pursuing it in a timely fashion, either because of active participation in litigation of the merits or dilatory conduct.

The SJC affirmed, holding that certain circumstances may justify forfeiture of a personal jurisdiction defense, even if asserted in a responsive pleading, but the inquiry must be

made on a case-by-case basis. The SJC identified several factors relevant to such an inquiry, including: (1) "the amount of time that has elapsed, as well as the changed procedural posture of the case, in the period between the party's initial and subsequent assertion of the defense"; (2) "the extent to which the party engaged in discovery on the merits"; and (3) "whether the party engaged in substantive pretrial motion practice or otherwise actively participated in the litigation." The Court noted that generally a party that elects merely to plead lack of personal jurisdiction "may ensure [the defense's] preservation by moving to dismiss pursuant to Rule 12(b)(2) within a reasonable time, prior to substantially participating in discovery and litigating the merits of the case."

In so holding, the SJC cited a number of Massachusetts Appeals Court and federal court decisions, the latter under a substantially identical federal rule, that endorsed a broader view of forfeiture of some affirmative defenses that can be raised either by pleading or motion. Those decisions asserted that fairness to the other litigants and court dictates that, where a party can seriously contest the court's jurisdiction, it should seek to resolve the matter expeditiously. Otherwise, a party could "keep the defense of lack of personal jurisdiction in its back pocket, even when engaging in conduct signaling that it is submitting to the court's jurisdiction." Requiring early resolution of personal jurisdiction disputes also promotes judicial economy and efficiency, a fundamental goal of the Massachusetts Rules of Civil Procedure and, in particular, Rule 12. Because lack of personal jurisdiction – unlike other affirmative defenses listed in Rule 12(b) – is a potentially dispositive procedural defect, it is "particularly desirable to resolve [that issue] prior to engaging in substantive litigation."

Massachusetts Federal Court Holds Manufacturer of Investigational Drug and Medical Device Responsible for Clinical Trial Investigator's Allegedly Inadequate Informed Consent Form; Plaintiff's Design and Manufacturing Defect Claims Failed Due to Lack of Specific Factual Allegations in Complaint

In *Zeman v. Williams*, 2014 U.S. Dist. LEXIS 91501 (D. Mass. July 7, 2014), plaintiff participated in a clinical trial designed to investigate the treatment of Young-Onset Parkinson's Disease by delivering an investigational gene therapy agent through an investigational brain infusion delivery system. Although the study protocol required the gene therapy to be delivered to both sides of plaintiff's brain, the clinical trial investigator allegedly erroneously delivered it only to one side, thereby causing serious harm. Plaintiff filed suit in the United States District Court for the District of Massachusetts against multiple defendants, including the investigator for medical malpractice and failure to obtain an adequate informed consent to the clinical trial, asserting that the consent form he gave plaintiff failed to warn, among other things, of the possibility and risks of improper placement of the therapeutic agent and that the therapy was experimental. Plaintiff also sued the alleged manufacturer of both the gene therapy agent and brain delivery system, and sponsor of the clinical trial, alleging it participated in drafting and approving the consent form, and was negligent in doing so, and that the brain infusion device was negligently designed and manufactured. The manufacturer/sponsor moved to dismiss, arguing (1) it owed no duty to plaintiff with respect to the consent form's content, and (2) plaintiff's negligent design and manufacturing claims were preempted by federal law and in any event lacked sufficient non-conclusory allegations to state a claim.

With respect to plaintiff's informed consent claim, the court first observed that federal clinical trial regulations imposed a duty on the investigator, *i.e.*, the physician administering the trial, to obtain a patient's informed consent to participation in the trial, but made the sponsor responsible both for selecting qualified investigators and "providing them with the information they need to conduct the investigation properly." The court thus concluded that although under the regulations the sponsor's obligation to provide necessary information was owed to the investigator, in at least one sense it was also owed to the patient, as the sponsor must provide the investigator sufficient information for him or her to obtain the patient's informed consent. Drawing a parallel to the learned intermediary doctrine – under which a pharmaceutical company is liable to the patient if it has not given an adequate warning to the treating physician – the court held that a clinical trial sponsor may be liable "[i]f the investigator fails to inform a subject about some substantial risk because the sponsor has failed adequately to inform the investigator about the risk." The court then concluded that the complaint adequately pled a claim because it alleged the sponsor approved the informed consent form and "knew or should have known that the form did not adequately and reasonably present the alternatives to and risks and potential consequences of the trial."

Regarding the claim for negligent design and manufacture, plaintiff alleged the device was manufactured in violation of the Federal Food, Drug and Cosmetic Act ("FDCA") and regulations thereunder, but did not specify which FDCA provisions or regulations were violated or how. Similarly, the allegations that defendant negligently designed and/or manufactured the device were not supported by any specific facts. Accordingly, the court held plaintiff's design and manufacturing defect claims lacked sufficient non-conclusory factual allegations to demonstrate a plausible entitlement to relief as required by the United States Supreme Court in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). For this reason, the court did not need to reach defendant's argument that the design defect claim was preempted by the FDCA, but noted that the absence of specific allegations made it impossible to tell whether plaintiff's claims merely paralleled federal law requirements so as not to be preempted, or impermissibly went beyond them.

The court's ruling regarding plaintiff's informed consent claim against the manufacturer/sponsor appears to have been without precedent in Massachusetts, and is at least questionable. The court itself acknowledged that neither the federal clinical trial regulations nor Massachusetts appellate authority authorized a cause of action by a patient against a sponsor for warnings given by the physician investigator; in fact, the Massachusetts courts have only imposed on physicians, not third parties, a duty to provide adequate information to obtain an informed consent from the patient because only the physician is touching or otherwise invading the patient's body by conducting the treatment. Moreover, the duty to warn the physician that is imposed on a drug or medical device manufacturer by Massachusetts product liability law typically arises because the manufacturer is a seller or lessor of its product, while the clinical trial sponsor here provided the products for free in order to investigate their safety and efficacy.

Most centrally, however, while the court purported to recognize a possible claim based on the sponsor's warnings to the *investigator*, it actually permitted the claim to proceed based solely on the contents of the consent form provided by the investigator to the *patient*, as the complaint contained no allegations regarding what the sponsor allegedly failed to tell the investigator, or that the investigator did not otherwise know that information. Indeed, the information plaintiff complained was omitted from the consent form either would have been obvious to any reasonable investigator (*e.g.*, that he might perform the procedure erroneously, with harmful consequences), or was in fact given (*e.g.*, the consent form, attached to the complaint, described both "human gene transfer" generally, and "[t]he study agent" specifically, as "experimental").

Massachusetts Federal Court Rejects Claim for Negligent "Failure to Discontinue Marketing" Against Prescription Drug Manufacturer as Inconsistent with Massachusetts Law's Recognition That Such Drugs Are Beneficial But Unavoidably Unsafe and Hence Not Unreasonably Dangerous

In *Tersigni v. Wyeth-Ayerst Pharmaceuticals, Inc.*, 2013 U.S. Dist. LEXIS 174762 (D. Mass. June 25, 2014), plaintiff was diagnosed with primary pulmonary hypertension ("PPH"), a fatal heart valve disease, which his treating physician attributed to use of the combination anti-obesity medication popularly known as "Fen-Phen." Plaintiff sued the drug's manufacturer in the United States District Court for the District of Massachusetts asserting claims for breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability), negligence and fraud based on the manufacturer's failure adequately to warn his physician of the drug's risks, including PPH. Although the court denied defendant's motion for complete or partial summary judgment, finding a triable issue regarding whether the physician would have prescribed the drug if given additional warnings (**see January 2014 Foley Hoag Product Liability Update**), defendant renewed the latter part of its motion on the eve of trial, arguing that at least plaintiff's warranty and fraud claims should be dismissed as duplicative of his negligent failure-to-warn claim.

Plaintiff conceded the case was "essentially a negligence action," so that all other claims should be dismissed, but argued his negligence claims should not be limited to failure to warn but should also include a theory of negligent "failure to discontinue marketing" because the drug's risks allegedly exceeded its benefits. The court rejected this theory, however, holding it was inconsistent with Massachusetts case law adopting comment k of the Restatement (Second) of Torts, § 402A (1965). That comment, involving "unavoidably unsafe products," notes that "[t]here are some products which, in

the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use," and cites drugs, and especially prescription drugs, as examples. For this reason, therefore, the law recognizes that "[s]uch a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous."

Although plaintiff relied heavily on a recent decision of the Pennsylvania Supreme Court recognizing a theory similar to the one he advanced, the court noted that as a federal court sitting in diversity jurisdiction it was bound to interpret Massachusetts law in accordance with the current opinions of the state's highest tribunal, which had "consistently hewed to the letter of comment k." The court also rejected plaintiff's argument that his proposed claim would not be inconsistent with comment k because, unlike the examples referred to in comment k itself, Fen-Phen was ultimately withdrawn from the market and subject to a ban by the United States Food and Drug Administration ("FDA"), which was definitive proof the drug's risks did outweigh its benefits. The court commented that these facts only supported its rejection of plaintiff's theory, as allowing it to proceed would usurp the FDA's role as the preeminent agency regulating the prescription drug market.

First Circuit Holds Beryllium Plaintiffs Could Not Establish Claim for Medical Monitoring Under Existing Massachusetts Law Due to Lack of Proof of Subcellular Injury, and Contention Law Should Not Require Such Proof Was Waived By Counsel in Discussions Framing Summary Judgment Issues

In *Genereux v. Raytheon Company*, 2014 U.S. App. LEXIS 10718 (1st Cir. June 10, 2014), current and former employees of a defense manufacturer, and members of their families, sued in the United States District Court for the District of Massachusetts alleging defendant's negligent handling of beryllium at its plant exposed them to elevated levels of the substance and thus increased their risk of various diseases, particularly chronic beryllium disease ("CBD"). As none of the plaintiffs exhibited any actual CBD symptoms, they sought a program of medical monitoring for the disease rather than damages. The court initially dismissed the claim for failure to allege actual injury, but reinstated it after the Massachusetts Supreme Judicial Court ("SJC") held in *Donovan v. Philip Morris USA, Inc.*, 914 N.E.2d 891 (Mass. 2009) (*"Donovan"*) (**see April 2010 Foley Hoag Product Liability Update**), that a suit "for medical monitoring, based on . . . subclinical effects . . . state[s] a cognizable claim," and that one of the elements of this claim was that plaintiff suffered "subcellular changes that substantially increased the risk of serious disease, illness, or injury." The court said it would "leave for another day consideration of cases that involve exposure to levels of chemicals or radiation known to cause cancer, for which immediate medical monitoring may be medically necessary although no symptoms or subclinical changes have occurred."

Shortly after plaintiffs' claims were reinstated, defendant moved for summary judgment on the ground plaintiffs could not prove they had suffered subcellular harm. Plaintiffs' expert opined that plaintiffs were at a significantly increased risk of developing beryllium-related diseases, including associated subcellular changes, but admitted he could not state with any degree of medical certainty that any plaintiff had in fact already suffered such changes. Accordingly, the court granted summary judgment (**see July 2013 Foley Hoag Product Liability Update**).

On appeal to the United States Court of Appeals for the First Circuit, plaintiffs argued the district court erred in finding their evidence of subcellular harm insufficient, and that in any event under the facts of plaintiffs' case Massachusetts law would not require a showing of such harm to succeed on a claim for medical monitoring. With respect to plaintiffs' first argument, the appellate court held, for substantially the same reasons articulated by the district court, that plaintiffs' expert's testimony fell short of proving actual subcellular injury as defined in *Donovan*.

Regarding plaintiffs' alternative argument – essentially asking the First Circuit to decide the issue that *Donovan* "left for another day" – the court held it had been waived. At a status conference before the district court framing the issues to be decided on summary judgment, plaintiffs' counsel had agreed on numerous occasions that "the question that the SJC left for another day" was not being pressed by plaintiffs, as they allegedly *had* suffered subcellular harm. Although plaintiffs argued they had preserved the issue by raising it both in their amended complaint and opposition to defendant's summary judgment motion, the court found that even if the issue had been adequately raised (which was not at all clear), plaintiffs' counsel's representations at the status conference regarding

the nature of the summary judgment issues had followed, and thus overridden, any position taken in these documents. In short, having made a strategic decision to pursue a legal theory explicitly recognized in *Donovan*, plaintiffs could not then "disavow their earlier decision and attempt to change horses midstream in hopes of finding a swifter steed."

Massachusetts Federal Court Grants Summary Judgment Against Plaintiff's Claim that Allegedly Defective Drill Caused Fire Where Plaintiff Could Not Identify Drill Model and Proffered No Admissible Expert Evidence of Defect or Causation

In *Williams v. Techtronic Industries North America, Inc.*, 2014 U.S. Dist. LEXIS 84940 (D. Mass. June 23, 2014), plaintiff's barn and farm equipment were destroyed when a fire started approximately 30-45 minutes after plaintiff left the barn with the battery charger for a handheld drill manufactured by defendant plugged in. A variety of other electrical items were in the barn – including electric heaters, fluorescent lights, overhead lights, electrical outlets, a well pump, an air compressor, a band saw that was also plugged in, a bench grinder, a drill press, a welder and a fuse box – as were eight tons of fertilizer, gasoline and diesel fuel. A Massachusetts state police fire and explosion inspector investigated and concluded that only the drill charger and air compressor could possibly have energized the fire, and it likely started in the area of the barn where the drill charger, and not the compressor, was located, but there was insufficient evidence to determine the fire's actual cause. Plaintiff's insurer then conducted its own investigation, including by examining the remains of the drill and charger, and concluded there was no evidence either had caused the fire but there were numerous other potential causes. The insurer then destroyed the evidence it had collected, including the drill and charger.

Plaintiff sued the drill's manufacturer and seller in the United States District Court for the District of Massachusetts asserting claims of negligence and breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) arising from the drill's allegedly defective design. At deposition, plaintiff testified he did not know the model of the drill, charger or battery he had used, and there was no other admissible evidence identifying those products. Defendants then moved for summary judgment arguing plaintiff had not come forward with sufficient evidence of (1) product identification, (2) defect and/or (3) causation. The court granted the motion on each of these grounds.

The court first held that, because a product liability plaintiff must demonstrate that the manufacturer or seller was the source of the product at issue to succeed on his or her claims, plaintiff's inability to provide admissible evidence identifying the drill and charger mandated summary judgment. In addition, summary judgment was required because there was no evidence, much less expert evidence, that the drill was negligently or defectively designed, as plaintiff's only disclosed expert had not produced a report by the court-ordered deadline or even as of the time of defendants' motion. The court rejected plaintiff's argument for more time based on the fact that a key deposition of one of the manufacturer's employees, who was expected to testify concerning a different but similar drill, had not yet taken place, holding, "It cannot be the case that [plaintiff]'s bald assertion that an unknown opinion based on a deposition that has not yet occurred, that will focus on the recall of another product is sufficient to defeat summary judgment."

Finally, summary judgment was required because plaintiff presented no admissible evidence that defendants' drill caused the fire. Plaintiff relied solely on burn patterns near the drill's location in the barn and the proffered testimony of the fire inspector. Even assuming the inspector qualified as an expert and that plaintiff complied with his expert disclosure obligations under Fed. R. Civ. P. 26, however, the inspector's testimony would be insufficient to establish causation because his conclusion was at most that the drill battery *possibly* caused the fire, while Massachusetts law requires expert testimony that an alleged design defect was more likely than not the actual cause of the injury.

Massachusetts Federal Court Holds Plaintiff's Injuries from Being Struck by Police Cruiser Responding to False Fire Alarm Not Proximately Caused by Allegedly Negligent Conduct of, Among Others, Manufacturer and Seller of Product that Caused False Alarm

In *Litowsky v. Asco Power Technologies, L.P.*, 2014 U.S. Dist. LEXIS 33479 (D. Mass. March 14, 2014), a pressure transducer in a fire pump controller that was part of a sprinkler system at a Massachusetts elementary school malfunctioned and caused a false fire alarm. Plaintiff was walking on a road approximately two

and a half miles from the school when he was struck by a police cruiser responding to the alarm, causing severe injuries. Plaintiff sued the school district and the manufacturer, seller and installers of the allegedly defective transducer, as well as the contractor who annually tested it, in the United States District Court for the District of Massachusetts. As to the manufacturer, plaintiff asserted claims for negligence and breach of the implied warranty of merchantability (the Massachusetts near-equivalent of strict liability) arising out of the transducer's allegedly defective design. All defendants except the manufacturer moved to dismiss the complaint arguing its allegations were insufficient to demonstrate either the existence of a duty to plaintiff or that defendants' actions were a proximate cause of his injuries. After the court granted the motions on the latter ground, the manufacturer moved for judgment on the pleadings on essentially the same grounds, and the court also allowed that motion.

In its brief opinion allowing the non-manufacturer defendants' motions, the court noted that "although causation is generally left to a jury to decide, it may be determined as a question of law where there is no set of facts that could support a conclusion that the plaintiff's injuries were within the scope of liability." Here, plaintiff could not prove his injury was a reasonably foreseeable result of defendants' conduct, a requirement for proximate causation. The court acknowledged authority in other jurisdictions permitting a plaintiff to proceed to trial on facts similar to those of this case, but stated that Massachusetts law was clear that a defendant may not be held liable "for all possible injury, no matter how remote or farfetched." In particular, the court relied on a recent decision of the Massachusetts Supreme Judicial Court affirming the dismissal on proximate causation grounds of a claim by a police officer injured while rushing to the scene of an emergency, observing that here the link between defendants' conduct and plaintiff's injury was even more attenuated. Accordingly, "if the limits of proximate cause are to be expanded to the degree suggested by Plaintiff, the decision to do this will have to come from the Court of Appeals."

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