FOLEY HOAG LLP

Product Liability **Update**

August 2016

In This Issue:

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

Massachusetts Superior Court Rejects "Innovator Liability" Failure-to-Warn Claim, Holds Branded Pharmaceutical Manufacturer Owed No Duty to Plaintiff Alleging Injury From Equivalent Generic Drug That Copied Defendant's Labeling But Defendant Did Not Make Or Sell

In *Rafferty v. Merck & Co.*, 2016 Mass. Super. LEXIS 48 (Mass. Super. Ct. May 23, 2016), plaintiff sued his prescribing physician and a pharmaceutical manufacturer for injuries allegedly suffered from use of the drug finasteride, the generic equivalent of a brand name medication manufactured by defendant. Plaintiff brought claims for negligence and violation of Mass. Gen. Laws Ch. 93A (the state's unfair and deceptive practices statute), alleging defendant failed to warn that sexual dysfunction was a potential side effect. Defendant moved to dismiss, arguing Massachusetts does not recognize an "innovator liability" theory that would extend a brand name, *i.e.*, innovator, drug manufacturer's duty to warn beyond users of its product to individuals who use a generic equivalent that copies the manufacturer's labeling.

The court acknowledged that this was an issue of first impression in Massachusetts. The court noted that the federal Food, Drug and Cosmetics Act ("FDCA") established an "onerous and lengthy" process for the approval of a new branded drug by the United States Food & Drug Administration ("FDA"), including approval of its label, while a chemically and biologically equivalent generic drug may be approved through an abbreviated process so long as its label follows that of the branded drug. And under the United States Supreme Court's rulings in *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011) ***(see July 2011 Foley Hoag Product Liability Update)***, and *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2476 (2013) ***(see July 2013 Foley Hoag Product Liability Update)***, failure-to-warn and design defect claims against generic manufacturers are preempted because the FDCA prohibits the manufacturer from departing from the FDA-approved branded drug's design and labeling, leaving the branded manufacturer as the only possible defendant.

Against this background, the court concluded that holding defendant liable as an innovator would be inconsistent with fundamental principles of Massachusetts product liability law, under which a plaintiff must prove that the product he claims caused his injury is traceable to the defendant. Merely issuing instructions about how to use a category of products is too attenuated a relationship to warrant imposing liability. Although defendant generated the information used in the generic drug's warning label, defendant did not affirmatively supply that information to the generic manufacturer, which merely copied the information on its own. In addition, defendant's warning label could be analogized to a non-defective component part, and in Massachusetts manufacturers are not liable for a failure to warn of risks created

solely by the use or misuse of their products with those of another manufacturer.

Further, looking to out-of-state case law, the court held that imposing liability would conflict with general principles of negligence law and public policy. Innovator liability would alter the relationship between brand name and generic drug manufacturers under the FDCA, and the FDA, not the judiciary, was best qualified to balance the policy considerations relevant to possible changes in this relationship. (Indeed, the court noted that that the agency was at that time considering amendments to FDA regulations that would allow a generic drug manufacturer to revise its label to depart from that of the branded manufacturer under certain circumstances). Lastly, negligence liability has historically followed control, and a branded manufacturer neither controls a generic manufacturer's conduct nor profits from its sales. Accordingly, the court granted defendant's motion to dismiss.

First Circuit Affirms Exclusion of Expert Opinion That Benzene Caused Leukemia Due to Failure to Explain Discounting of Conflicting Epidemiologic Studies and Circular Analysis Purporting to Exclude Idiopathic Causation Based on Possibility of Benzene Causation

In *Milward v. Rust-Oleum Corp.*, No. 13-2132, 2016 U.S. App. LEXIS 7470 (1st Cir. April 25, 2016), plaintiffs sued numerous defendants in the United States District Court for the District of Massachusetts for negligence, alleging exposure to defendants' benzene-containing products caused the plaintiff husband's acute promyelocytic leukemia ("APL") ***(see October 2013 Foley Hoag Product Liability Update)***. On the eve of trial, the lone remaining defendant moved to exclude plaintiff's specific causation expert and for summary judgment. The expert had opined that: (i) there is no safe level of benzene exposure; (ii) regardless of plaintiff's dose, certain epidemiologic studies established that an individual's relative risk of developing APL increased when exposed to certain amounts of benzene; (iii) using differential diagnosis, some more common risk factors associated with APL could be ruled out, and since benzene was in general a "potential cause" of APL, she could rule out idiopathic APL, *i.e.*, APL of unknown origin, and thereby rule in benzene as the "only significant potential cause."

The district court excluded the expert's opinion under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 597 (1993) (holding proponent of expert testimony must show it to be relevant, reliable and helpful to the fact-finder). and thus granted summary judgment. The court noted that in deposition testimony the expert disavowed any intention or ability to analyze epidemiologic studies that appeared to conflict with her hypothesis that there was no safe level of benzene exposure, and without such analysis it was not possible to determine if her methodology was reliable. In addition, the expert's ruling in of benzene as a *potential* cause to rule out idiopathic origin and hence opine that benzene was the *actual* cause was impermissibly circular.

On appeal, the United States Court of Appeals for the First Circuit affirmed. Regarding the epidemiologic studies, plaintiff argued that studies showing an increased risk of APL above a certain level of exposure and other studies detecting no increased risk at such levels did not actually conflict because the latter studies did not affirmatively conclude there was no relationship between benzene and APL. Plaintiff also argued the expert did not disavow any willingness to consider the other studies, and her opinion was in any event reliable because it was based on reliable epidemiologic evidence.

The appellate court rejected these arguments. The court noted that reliance on studies showing no evidence of increased risk would necessarily lead to a different opinion than reliance on studies that showed such risk. Because the expert's opinion was based on the scientific literature, for her opinion to be reliable she needed to explain why she had relied on some studies but not others. At deposition, however, she had clearly testified she could not opine as to which studies could be relied upon and which should be discounted.

As for the expert's differential diagnosis, the court agreed her reasoning was circular. Plaintiff's only argument in this respect was essentially to assert that differential diagnosis is a reliable methodology, which defendant had not disputed. Here, however, the expert provided no scientifically reliable method to rule out idiopathic APL, particularly given the frequency of idiopathic cases. The court further held the expert had no reliable method even to rule in benzene as a potential cause of plaintiff's disease because this conclusion was based

on the same unreliable methodology by which the expert concluded there was no safe level of benzene exposure without considering the other studies.

Massachusetts Federal District Court Holds Defendant Not Subject to Personal Jurisdiction On Out-of-State Plaintiffs' Claims as Defendant Was Not At Home in State, Appointment Of Agent For Service Did Not Consent to General Jurisdiction There And Plaintiffs' Claims Had No Nexus to Defendant's In-State Activities

In *Simmons v. GlaxoSmithKline LLC* (In re Zofran (Ondansetron) Prods. Liab. Litig.), No. 1:15-md-2657-FDS, 2016 U.S. Dist. LEXIS, 59296, four plaintiffs filed suit in Missouri state court against a pharmaceutical manufacturer alleging it failed to warn that its morning sickness drug could cause birth defects. Defendant removed the case to the United States District Court for the Eastern District of Missouri and the Judicial Panel for Multidistrict Litigation transferred the case to the District of Massachusetts. Defendant then moved to dismiss the claims of the three non-Missouri plaintiffs for lack of personal jurisdiction, arguing defendant was not "at home" in Missouri and had not consented to general jurisdiction there, nor was there any nexus between the claims and defendant's Missouri-based activities so as to support specific jurisdiction. Plaintiff cross-moved for remand to Missouri state court, arguing there was not complete diversity of citizenship between the parties and hence no subject matter jurisdiction in federal court.

Citing reasons of judicial economy, the court first considered defendant's motion to dismiss and noted that in a multidistrict litigation the transferee court has personal jurisdiction over a defendant only if the transferor court had such jurisdiction. Under the United States Supreme Court's decision in *Daimler AG v. Bauman*, 134 S. Ct. 746, 761 (2014) ***(see April 2014 Foley Hoag Product Liability Update)***, a corporation is subject to general jurisdiction only where it is essentially "at home," which except in "exceptional circumstances" is its state of incorporation or principal place of business. Here Delaware was defendant's state of incorporation and headquarters, and plaintiff's allegations that defendant regularly marketed and sold its drug in Missouri were not exceptional circumstances under *Daimler*.

The court also rejected plaintiff's contention that defendant's appointment of a registered agent for service of process in Missouri impliedly consented to general jurisdiction there. The court noted that the Missouri statute requiring foreign corporations to designate an agent for service contained no language concerning personal jurisdiction, and plaintiff's argument was inconsistent with *Daimler* as it would subject a corporation to general jurisdiction in every state in which it had a registered agent.

Regarding specific jurisdiction, that exists when there is a demonstrable nexus between a plaintiff's claims and defendant's forum-based activity, but the complaint failed to allege any nexus whatsoever between the non-Missouri plaintiffs' claims and defendant's in-state conduct. Given the lack of either general or specific jurisdiction, the court therefore granted defendant's motion to dismiss those claims. In addition, as there was complete diversity of citizenship between the remaining parties, the court denied plaintiff's motion to remand for lack of subject matter jurisdiction.

Massachusetts Federal Court Holds *Res Ipsa Loquitur* Permits Inference of Manufacturing Defect in Cardiac Guide Wire Based on Lack of Evidence of Negligent Handling and Physicians' Testimony Spontaneous Breakage Was Rare; Off-Label Use No Bar To Claim Where Use Was Foreseeable And Not Shown To Impose Greater Stress Than On-Label Use

In *Fertik v. Stevenson*, No. 12-10795-PBS, 2016 U.S. Dist. LEXIS 63539 (D. Mass. May 13, 2016), plaintiff sued two physicians and the manufacturer of a cardiac guide wire in the United States District Court for the District of Massachusetts alleging plaintiff was injured when, unbeknownst to either physician, the guide wire broke inside plaintiff's body during surgery. Plaintiff alleged the manufacturer negligently manufactured the wire and that was the exclusive reason it failed. The manufacturer moved for summary judgment, arguing plaintiff failed to produce reliable evidence of negligent manufacture and the doctrine of *res ipsa loquitur* did not permit an inference of negligence because the manufacturer did

not have exclusive control over the wire, there was always a risk of breakage even without any physician or manufacturer negligence and the physicians' use of the wire was "off-label," *i.e.*, for a purpose not included in its United States Food and Drug Administration-approved labeling.

The court first noted that, under Massachusetts law, *res ipsa loquitur* permits an inference of negligence where the specific cause of an accident cannot be shown if the instrumentality causing the accident was in the sole and exclusive control of the defendant and the accident is of a type that would not ordinarily happen without the defendant's negligence. Showing defendant's exclusive control does not require plaintiff to exclude all other possible causes of the accident so long as the evidence is sufficient to permit a jury reasonably to find conclude defendant's negligence was more likely than not the cause. Here the evidence of exclusivity was sufficient because the manufacturer had produced no evidence the wire was mishandled between the time it left the manufacturer's control and the time the physicians removed it from its packaging, the parties agreed the physicians had not negligently handled the wire and the physicians testified it appeared undamaged when they removed it from its packaging. In addition, the physicians' testimony that they had collectively performed more than 18,000 similar procedures and a guide wire had broken fewer than six times was sufficient evidence for a jury to conclude the wire broke because of a manufacturing defect.

The court also rejected the manufacturer's contention that *res ipsa loquitur* could not apply because the physicians had employed the guide wire for an off-label use. The court held there was no controlling authority that immunized a manufacturer from a defect claim based on an off-label use that was foreseeable. Here plaintiff produced evidence that surgeons at a prominent teaching hospital had used the wire in the same manner thousands of times, while the manufacturer produced no evidence either that these uses were unforeseeable or that they imposed stresses on the wire that were greater than those of "on-label" procedures.

In light of its ruling that that *res ipsa loquitur* would permit an inference of negligence, the court decided it need not address the manufacturer's argument that plaintiff's expert's opinion regarding how the guide wire broke was inadmissible under *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 597 (1993) (holding proponent of expert testimony must show it to be relevant, reliable and helpful to the fact-finder to be admissible), and denied the manufacturer's summary judgment motion.

First Circuit Affirms Dismissal of Claims Against Biologics Manufacturer For Lack of Standing Where Plaintiffs Failed to Allege Particularized and Concrete Harm From Defendant's Alleged Failure to Sell Sufficient Product in FDA-Approved Dose to Meet Market Demand

In *Hochendoner v. Genzyme Corp.*, 2016 U.S. App. LEXIS 9438 (May 23, 2016), plaintiffs filed two putative class actions, subsequently consolidated, in the United States District Court for the District of Massachusetts, asserting claims under various states' laws for negligence, breach of express and implied warranties, strict liability and violation of state consumer protection and product liability statutes for alleged harms caused by supply interruptions of a biologic drug manufactured by defendant. They also alleged defendant violated the federal Bayh-Dole Act, 35 U.S.C. §§ 200 et seq., through nonuse or unreasonable use of a publicly funded invention. The district court dismissed plaintiff's claims because (1) plaintiff's theories of "accelerated deterioration" caused by defendant's inability to produce sufficient quantities of its drug and foreign particulate contamination were too ambiguous to provide fair notice under the pleading requirements of Fed. R. Civ. P. 8; (2) the Bayh-Dole Act does not create a private right of action for members of the public who use federally-funded inventions; and (3) there is no "duty to manufacture sufficient medication to meet market demand" under the common law of torts of any state implicated by plaintiff's claims ***(see July 2015 Foley Hoag Product Liability Update)***.

On plaintiffs' appeal regarding the "accelerated deterioration" claims only, the United States Court of Appeals for the First Circuit affirmed as to all plaintiffs except one, but on different grounds. Plaintiffs argued their complaints did provide adequate notice of their claims or, alternatively, the district court should have allowed them to amend the complaints. The appellate court, however, noted that plaintiffs bore the burden of demonstrating standing, an essential element of a case or controversy and hence federal court jurisdiction, by plausibly showing harm that is "concrete" and "particularized." Although plaintiffs were required to allege such harms specifically for each claim, the complaint contained only "scattered descriptions of generalized harms," which were generally insufficient. With respect to a single plaintiff, however, who allegedly had suffered an allergic reaction when he returned to a full dose of the drug, the complaint was sufficient because it asserted a particularized harm potentially attributable to defendant.

Regarding plaintiffs' argument they should have been permitted to amend their complaints, the court held such arguments waived because plaintiffs never sought to amend in the district court. Accordingly, the court ordered that the plaintiffs' accelerated deterioration claims—and contaminant claims, even though not raised by the appeal—should be dismissed, but only without prejudice, as it would be improper to dismiss with prejudice where plaintiffs' lack of standing had deprived the district court of jurisdiction.

First Circuit Holds Jurisdictional Transfer Statute Permits Transfer To Proper Court To Cure Lack of Either Personal or Subject Matter Jurisdiction

In *Fed. Home Loan Bank of Bos. v. Moody's Corp.*, 821 F.3d 102, 105 (1st Cir. 2016), plaintiffs sued in the United States District Court for the District of Massachusetts for fraud, negligent misrepresentation and violation of Massachusetts Gen. L. Ch. 93A (the state unfair and deceptive practices statute), alleging defendant had published false ratings for certain securities. The district court granted defendant's motion to dismiss for lack of personal jurisdiction and denied plaintiff's request instead to transfer the case to New York, where defendant was headquartered, holding the court had no power to do so under 28 U.S.C. § 1631's provision that a court finding a "want of jurisdiction" shall transfer the action to a proper court if that is "in the interest of justice." The district court held the statute only permitted transfer when the original court lacked subject matter, but not personal, jurisdiction ***(see January 2015 Foley Hoag Product Liability Update)***.

On plaintiff's appeal, the United States Court of Appeals for the First Circuit reversed. The court first determined it had subject matter jurisdiction because plaintiff's federal charter's "sue-and-be-sued" clause caused the bank's claims to arise under federal law. The court then held that § 1631 applied to both subject matter and personal jurisdiction, and a trial court must consider whether transfer could cure a lack of either. The statute used only the unqualified term "jurisdiction," unambiguous language that trumped defendant's arguments based on legislative history and legal treatises. In addition, other courts of appeals were, by and large, in accord with this conclusion. Accordingly, the court remanded so the district court could determine whether it was in the interest of justice to transfer the action to cure the lack of personal jurisdiction.

This Update was prepared by Foley Hoag's Product Liability and Complex Tort Practice Group, which includes the following members:

David R. Geiger
Chair and Editor

Matthew C. Baltay

Jonathan M. Ettinger

Barbara S. Hamelburg

Michael B. Keating

Matthew E. Miller

Peter A. Sullivan

Colin J. Zick

Daniel J. Procaccini
Associate Co-Editor

Shrutih V. Tewarie
Associate Co-Editor

Richard G. Baldwin

Christopher Cifrino

Daniel McFadden

Creighton K. Page

Daniel J. Procaccini

Alice (Chang) Yu

FOLEY HOAG LLP