Product Liability: 2015 Year in Review

U.S. First Circuit/Massachusetts

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Massachusetts state and federal courts issued a number of important product liability decisions in 2015. The Product Liability and Toxic Tort Litigation Group at Nutter recently reviewed these cases. Highlighted below are some of the key cases and issues decided in the past year.

MASSACHUSETTS SUPREME JUDICIAL COURT

Reckis v. Johnson & Johnson, 471 Mass. 272 (April 17, 2015)

Significant Holding: Interpreting *Wyeth v. Levine* to hold rejection of a Citizen's Petition to change an FDA-approved warning label was not "clear evidence" that the FDA had in fact rejected a warning about potentially life-threatening diseases. (Botsford, J.)

In November 2003, a seven-year-old girl developed toxic epidermal necrolysis (TEN), a severe skin disorder, after her parents gave her several doses of Children's Motrin. The girl's parents, on behalf of themselves and their daughter, sued McNeil-PPC, the drug's manufacturer, and its parent company, Johnson & Johnson, in Massachusetts Superior Court for negligence, breach of implied warranty of merchantability, and violation of Mass. Gen. L. ch. 93A (the Massachusetts consumer protection statute). The plaintiffs alleged that the drug caused the TEN and that the defendants did not adequately warn consumers that redness, rash, or blisters could be signs of a "life-threatening" disease. In 2013, a jury awarded the child $50 million and the parents $13 million in damages, one of the highest personal injury awards in Massachusetts history. The judge ruled in favor of the defendants on the plaintiffs' Chapter 93A claim.

The defendants raised three claims on direct appellate review to the Massachusetts Supreme Judicial Court ("SJC"): that they were entitled to judgment as a matter of law because (1) the plaintiffs' failure to warn claim was preempted by the Food, Drug, and Cosmetic Act (FDCA) and because (2) the plaintiffs failed to prove causation and (3) the damages awarded to the plaintiffs were "grossly excessive" and unsupported by the record. The SJC affirmed.

Of their preemption claim, the defendants argued that the warning the child's parents claimed would have prevented them from administering additional doses of the drug had been expressly rejected by the FDA. The SJC disagreed, stating that the failure to warn claim would only be preempted by the FDCA under *Wyeth v. Levine*, 555 U.S. 555 (2009), if there was "clear evidence" that the FDA would not have approved the warning proposed by the plaintiffs. The defendants argued that the FDA had in fact rejected such a warning, as it had rejected a Citizens' Petition requesting that the label contain a warning stating that that redness, rash, or blisters might be signs of TEN, Stevens-Johnson Syndrome (SJS) or other "potentially life-threatening diseases" "because most consumers are unfamiliar with [the named diseases]." *Reckis*, 471 Mass. at 458. The SJC, however, disagreed, reasoning that this was only "clear evidence" that the FDA would have rejected the disease-specific warning, but not a more general warning related to "potentially life-threatening diseases." The SJC further reasoned that the jury's verdict was likely based on the non-preempted theory of liability (a "life-threatening diseases" warning) because the father also testified that before his daughter's illness, he had never heard of TEN or SJS, the child's mother did not mention TEN or SJS in connection with a warning, and the plaintiffs' counsel stated explicitly in his closing argument that the plaintiffs did not contend that the warning should have named SJS or TEN.

The SJC also rejected the defendants' other arguments, holding that the plaintiffs' expert was qualified to provide an opinion as to causation and that the $63 million verdict was not excessive. In January of this year, the U.S. Supreme Court declined to issue certiorari, effectively ending the case.

UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

In re Celexa and Lexapro Marketing and Sales Practices Litigation, 779 F.3d 34 (1st Cir. Feb. 20, 2015)

Significant Holding: Interpreting *PLIVA, Inc. v. Mensing* to hold impossibility preemption extends to brand name drugs when a proposed label change is not based on new information. (Kayatta, J.)

In a case that is part of the Celexa/Lexapro multidistrict litigation pending in the District of Massachusetts, parents of children who took Lexapro claimed that the defendants deceptively marketed the drug as an effective treatment for adolescent depression despite the fact that clinical trials proved that the drug does not effectively treat depression in adolescents. The plaintiffs asked the court to enjoin the defendants from selling the drug with its current label and force the defendants to seek approval of a new drug label. *Id.* at 38-39. The defendants argued that the plaintiffs' claims were preempted by federal law and that they were barred by California's safe harbor doctrine. The District Court agreed with the defendants, finding the plaintiffs' claims were barred under California's safe harbor doctrine. The plaintiff-parents appealed.

On appeal, the defendants urged the court to affirm on the grounds of either preemption or California's safe harbor doctrine. The First Circuit, stating that "it makes more sense to look first at [the question of preemption] rather than . . . figuring out . . . the question of whether California's safe harbor doctrine would shield [defendants]," affirmed the District Court's dismissal on preemption grounds. *Id.* at 39. In doing so, the First Circuit examined the Supreme Court's decisions in both *Wyeth v. Levine*, 555 U.S. 555 (2009) and *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011). In *Mensing*, the Supreme Court held that state law claims against generic drug manufacturers were preempted because the FDA required that the warning labels of generic drugs be identical to those of their brand-name counterparts. Two years earlier, in *Levine*, the Court held that state law claims against a name-brand manufacturer were *not* preempted, as the manufacturers were permitted to independently modify the language of an approved label under the "Changes Being Effected" ("CBE") process. Relying on both of these decisions, the First Circuit recognized that "[t]he question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Mensing*, 131 S. Ct. at 2579 (citing *Levine*, 555 U.S. at 573). In reconciling the two rulings, the First Circuit stated that the two cases draw a line "between changes that can be independently made using the CBE regulation and changes that require prior FDA approval . . . ." *In re Celexa*, 779 F.3d at 41. In so doing, the First Circuit extended the implied preemption logic of *Mensing*, which dealt with generic drugs, to brand-name drugs.

The First Circuit held that the plaintiffs' claims were preempted because the labels they requested were not based on new information. The FDA had already reviewed the efficacy data that the plaintiffs claimed proved the drug was not as effective as the defendants claimed. Warning label changes made under the CBE procedures require new information. The Court reasoned that because the defendants could not use the CBE procedures to change their warning label, they were barred by federal law from making the changes that the plaintiffs requested. As such, the plaintiffs' claims were preempted.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

Hochendoner et al. v. Genzyme Corp., 95 F.Supp.3d 15 (D. Mass. March 25, 2015)

Significant Holding: Interpreting federal research funding law to confer no private right of action and holding that no duty exists under state law requiring pharmaceutical manufacturers to supply a scarce drug to all eligible patients. (Woodlock, J.)

The defendant, Genzyme, is the sole manufacturer of the only FDA-approved treatment for Fabry disease, a genetic illness that inhibits the abilities of patients' cells to remove fats and leads to early death from complications such as renal disease, heart attack, and stroke. In 2009, various problems at Genzyme's manufacturing facility caused a shortage of the treatment. During the shortage, the defendant adopted a rationing plan under which those who suffered from the disease would be given a dose that was less than the FDA-recommended dose and newly-diagnosed patients would not be prescribed the drug. The plaintiffs (individuals with Fabry disease and their spouses) filed a complaint asserting various state and federal claims, including a claim that the defendants violated the federal Bayh-Dole Act, 35 U.S.C. §§ 200 et seq., through nonuse or unreasonable use of a publicly funded invention. The defendants moved to dismiss.

In a matter of first impression, the court analyzed whether the Bayh-Dole Act confers a private right of action. The Bayh-Dole Act states that "[i]t is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development . . . ." 35 U.S.C. § 200. The Act encourages small businesses and nonprofit organizations to invest in research and development of new inventions by allowing the businesses and nonprofits to retain patent rights to those inventions created with the use of government funds. *Id.* et seq. The Act also purports to "protect the public against nonuse or unreasonable use of inventions." *Id.* at § 200. In interpreting the Act under the standard explained by the U.S. Supreme Court in *Alexander v. Sandoval*, 532 U.S. 275 (2001), the court held that the Bayh-Dole Act contained "many of the characteristics that the *Sandoval* Court identified as indicators that Congress had not created a private right of action." *Hochendoner,* 95 F.Supp.3d at 27. Among these are the lack of the "sort of rights-creating language critical to showing the requisite congressional intent to create new rights" and the method of enforcement included in the Act, a "march-in" right that allows the relevant federal agency to issue additional licenses to manufacture the invention to "alleviate health or safety needs." *Id.* at 27-28; 35 U.S.C. § 203.

In analyzing the plaintiffs' various state law claims, the court held that there is no "duty to manufacture sufficient medication to meet market demand." *Hochendoner,* 95 F. Supp.3d at 30. The court noted that the two federal courts that had looked at the issue had also determined that there is no duty. Moreover, because the relevant highest courts had not indicated that they were willing to expand their state's tort law to include the new proposed duty of care, it was "not appropriate for this court to create the proposed duty as a new component of the common law, especially given that it is such a radical departure from the law as it exists." *Id.* at 31. For similar reasons, the court declined to extend the cited state consumer protection statutes to encompass a claim that "insufficient medication production by a patentholder [is] an unfair trade practice." *Id.*

The court also dismissed the plaintiffs' claims for breach of express warranty because the defendant never represented that the lower dose would be as effective in the treatment of Fabry disease as the FDA-recommended dose. The court also held that the defendant did not create an implied warranty that the reduced dose would be as powerful as the full FDA-recommended dose. Finally, the court held that none of the plaintiffs' allegations survived under the product liability statute of any relevant state, because the plaintiffs did not claim that the defendant's product contained a manufacturing or design defect, only that the defendant failed to produce enough of the product to meet demand. This matter is currently pending appeal in the First Circuit.

Rosbeck v. Corin Group, PLC, 2015 WL 6472249 (D. Mass. Oct. 27, 2015)

Significant Holding: A cause of action can exist under Massachusetts state law against a hospital for distribution of an allegedly defective medical device, thus preventing removal to federal court. (Sorokin, J.)

The plaintiffs, husband and wife, filed suit in Massachusetts Superior Court alleging the husband suffered injuries following his hip resurfacing surgery. The plaintiffs sued the implant manufacturers for negligence, breach of warranty, and consumer fraud, as well as the non-diverse hospital at which the surgery was performed for breach of

warranty. The manufacturers removed the case to federal court. The plaintiffs moved to remand. In response, the manufacturing defendants argued that the plaintiffs had fraudulently joined the hospital to defeat diversity.

Under First Circuit law, the party claiming fraudulent joinder must prove that "there is no *reasonable possibility* that the state's highest court would find that the complaint states a cause of action upon which relief may be granted against the non-diverse defendant." *Id.* at *2 (emphasis added) (quoting *Universal Truck & Equipment Company, Inc v. Southworth-Milton, Inc.*, 765 F.3d 103, 108 (1st Cir. 2014)). The manufacturing defendants provided three reasons why they met that burden. Among these was that Massachusetts does not recognize a claim for breach of warranty against a hospital for supplying a medical device to a patient as part of his treatment. The manufacturing defendants also stated that there was a "uniformity of jurisprudence" against holding hospitals strictly liable for breach of warranty. *Id.* at *4. The District Court stated that there was no definitive Massachusetts case law on the question and that a review of the jurisprudence revealed that the "uniformity" claimed by the manufacturing defendants "does not exist." *Id.* While the District Court agreed that an "overwhelming majority of jurisdictions refused to apply strict liability principles to claims against hospitals and physicians involving the distribution of allegedly dangerous drugs or medications . . . . [t]his sentiment was not quite unanimous." *Id.* (internal citations omitted). Citing a 1984 Alabama Supreme Court case in which a hospital was held liable as a seller of goods for breaching an implied warranty, the District Court stated that there was a split in authorities. The court held that in light of the split, the manufacturing defendants "face[d] an uphill battle in proving fraudulent joinder." *Id.* at *5.

The court also cited the fact that the manufacturing defendants could point to no Massachusetts case law or statutory law suggesting a policy of favoring hospitals that would foreclose or foreshadow a rejection of the plaintiffs' claim. For these reasons, the court ultimately held that the manufacturing defendants could not demonstrate that the plaintiffs had no "reasonable possibility of success against [the hospital]," *Id.* at *6-7, and the case was remanded.

MASSACHUSETTS SUPERIOR COURT

Dwyer v. Boston Scientific Corp., 2015 WL 3384894 (Mass. Sup. Ct. April 2, 2015)

Significant Holding: Interpreting *Riegel v. Medtronic* to hold allegations that defendant violated general, non-specific Current Good Manufacturing Practices in manufacturing a PMA-approved medical device were sufficient "parallel claims" to avoid federal preemption. (Miller, J.)

The plaintiff, the wife of a man who died after receiving an allegedly defective defibrillator device, sued the device manufacturer for a variety of claims sounding in product liability. The defendant manufacturer sought dismissal of all claims, arguing that they were preempted by federal law, or that, in the alternative, they failed to state a claim upon which relief could be granted. The court denied the motion to dismiss.

The plaintiff's claims alleged that the device at issue—which had been approved for use by the FDA pursuant to the rigorous Pre-Market Approval ("PMA") process—was defective because it failed to meet product specifications in violation of various Current Good Manufacturing Practices ("CGMPs") set forth in the FDA regulations. CGMPs "govern the methods used in, and the facilities and controls used for, the design manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." 21 C.F.R. § 820.1(a)(1). They are generally applicable federal requirements and differ from the concrete, device-specific requirements typically related to the PMA process.

In response, the defendant argued that, given the fact that a PMA device was at issue, the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA") preempted such claims, as they "impose[d] state law requirements that differ[ed] from or add[ed] to the requirements" imposed by federal law. *Dwyer*, 2015 WL 3384894 at *4. The court ruled against defendant, adopting the Seventh Circuit's reasoning in *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010) and finding "no 'sound legal basis . . . to distinguish between

general requirements [such as the CGMPs] and 'concrete, device-specific requirements [such as those related to the PMA process]' given that [the MDA] uses the phrase 'any requirement.'" *Dwyer*, 2015 WL 3384894 at *5 (quoting *Bausch*, 630 F.3d at 555, quoting 21 U.S.C. § 360k(a)). Such claims, the court concluded, paralleled, rather than added to, the federal requirements, and therefore were not preempted by federal law.

Nutter's Product Liability: 2015 Year in Review is a publication of the Product Liability and Toxic Tort Litigation Group of Nutter McClennen & Fish LLP in Boston. The bulletin was prepared by Rebecca H. Gallup and Katy O. Meszaros. For further information or if we can be of assistance, please contact your Nutter product liability lawyer or the chairperson of the Product Liability and Toxic Tort Litigation Group:

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