Published by *Product Liability Law360* on April 8, 2014. Also ran in *Appellate* and *Life Sciences Law360.*

Drug Design Defect Claims Post-Bartlett

-- By Anand Agneshwar and Anna K. Thompson, Arnold & Porter LLP

Law360, New York (April 08, 2014, 6:40 PM ET) -- In June 2013, the U.S. Supreme Court in Mutual Pharmaceutical Co. v. Bartlett[1] held that "state law design defect claims that turn on the adequacy of a drug's warnings are preempted by federal law."[2] Tucked away in a footnote, however, the Supreme Court noted that its holding does "not address state design defect claims that parallel the federal misbranding statute."[3]

Plaintiffs have seized on this footnote, arguing that design defect claims are not preempted if the prescription drug was misbranded under federal law. This "parallel misbranding" argument should not succeed. The Supreme Court did not expressly carve out an exception to the preemption holding in Bartlett and, just two years prior, had rejected similar arguments in a failure-to-warn case. The Sixth Circuit is currently addressing this issue,[4] and we will likely see a decision later this year.

Preemption Background

To assess the strength of plaintiffs' parallel misbranding arguments, we must first understand the Supreme Court's recent preemption decisions in Mensing and Bartlett. In 2011, the Supreme Court in PLIVA Inc. v. Mensing,[5] held that federal law requires generic labeling to be the same as the brand-name drug, and thus prevents generic manufacturers "from independently changing their labels."[6] It is, the high court concluded, impossible to comply with both state and federal requirements.

Last year, the Supreme Court in Bartlett considered whether the same Mensing preemption analysis applies to design defect claims. The plaintiff in Bartlett took generic Sulindac and developed a rare skin disorder.[7] She brought a design defect claim against the generic manufacturer, arguing that a generic manufacturer can comply with both state and federal law by refraining from selling the drug.[8]

In a 5-4 decision, the Supreme Court rejected the "stop-selling" theory and extended Mensing to preempt state law design defect claims involving generic drugs which "turn on the adequacy of the drug's warning."[9] In a footnote, the high court commented:

We do not address state design defect claims that parallel the federal misbranding statute. The misbranding statute requires a manufacturer to pull even an FDA-approved drug from the market when it is "dangerous to health" even if "used in the dosage or manner, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof." The parties and the [g]overnment appear to agree that a drug is misbranded under federal law only when liability is based on new and scientifically significant information that was not before the FDA.[10]

Bartlett's Aftermath

In the nine months after the Bartlett decision, plaintiffs have continued to bring design defect claims against generic manufacturers.[11] Courts largely have rejected these efforts, finding "Bartlett [to be] directly applicable."[12] But, plaintiffs have now developed a "parallel misbranding" cause of action premised on the Supreme Court's footnote in Bartlett.[13]

How Did the Footnote Come About?

In Bartlett, the U.S. Food and Drug Administration argued in an amicus brief that Mensing's preemption analysis applied only to claims that turn on the adequacy of the drug labeling. The FDA distinguished these from "pure" design defect claims, which the FDA argued are preempted unless they "parallel the FDCA's drug 'misbranding' prohibition."

The FDA continued: "[A] manufacturer has a federal duty not to market a drug if, inter alia, it is 'dangerous to health' when used as provided in the labeling. A state-law duty not to market the drug in the same circumstances would not conflict with federal law if it appropriately accounted for [the] FDA's role under the FDCA."[14] The Bartlett majority responded to the FDA's brief in a footnote, noting that its holding does not "address state design defect claims that parallel the federal misbranding statute."[15]

To circumvent Bartlett preemption, then, some plaintiffs have advanced a "parallel misbranding" theory. In Gardley-Starks, for example, the plaintiff moved to reconsider her dismissal because the court must "first determine the requirements imposed by state law to see whether such duties are parallel or conflict with federal law requirements."[16] The district court disagreed and applied Bartlett.[17]

But in Hassett v. Dafoe, a Pennsylvania state court citing the Bartlett footnote concluded that "state negligence claims based upon the misbranding of drugs under the federal statute or failure to conform the generic label to the updated [reference listed drug], a form of misbranding, are not foreclosed by Mensing."[18]

In re Darvocet Appeal

The Sixth Circuit, in a consolidated appeal in the Darvocet (propoxyphene) multidistrict litigation, will be one of the first appellate courts to directly address the parallel misbranding theory. In 1978, a public health group filed a citizen petition raising concerns about health risks with propoxyphene,[19] and eventually the FDA asked two advisory committees to look at the issues raised.[20] Although the advisory committees recommended that the drug be withdrawn from the market,[21] the FDA in July 2009 determined that withdrawal was not warranted.[22] It did, however, require a black box warning and directed the reference listed drug holder to conduct a clinical trial.[23] More than a year later, after the initial results of the trial were released, the FDA concluded that the drug's risks outweighed the benefits and requested that propoxyphene be withdrawn.[24]

On these facts, the amended Darvocet complaints alleged that the defendants misbranded the drug.[25] The plaintiffs argued that the design defect claims survive because "federal law neither required the [g]eneric [d]efendants to sell propoxyphene nor prohibited them from withdrawing their products from the market."[26] The multidistrict litigation court disagreed and dismissed the claims as preempted under Mensing and Bartlett.

Likelihood of Success of the Parallel Misbranding Theory

The plaintiffs in the Darvocet appeal now argue that their design defect claims survive under Bartlett because the Supreme Court created an exception for misbranded products if federal law itself requires the drug to be pulled from the market.[27] The plaintiffs alleged that after the FDA approved propoxyphene, "new scientifically significant information emerged that prohibited the sale of propoxyphene [and] state-law causes of action that seek to impose liability for injuries ... are not preempted."[28] There are, however, several shortcomings to plaintiffs' argument.

First, there is no real difference between a design defect misbranding argument and a failure-to-warn misbranding claim. A generic manufacturer can unilaterally change neither the composition of the drug nor the drug labeling. The FDA argued in Mensing and in Bartlett that neither of these causes of action are preempted under the parallel misbranding theory if the plaintiff shows that the generic company had information that the FDA had not previously considered.[29]

But in Mensing, the Supreme Court created no exception for such a theory in failure-to-warn claims; there is no reason to create one now for design defect claims.[30] The high court's footnote in Bartlett therefore cannot be read to create an "exception" to preemption.[31] Rather, the Supreme Court was simply responding to the FDA's amicus brief to say, "We do not address [whether] state design defect claims that parallel the federal misbranding statute [are preempted]."[32]

Second, even assuming such an exception exists, a plaintiff can avoid preemption on the parallel misbranding theory only if the state law claim is based on "new and scientifically significant information that was not before the FDA."[33] To succeed on a design defect claim under this theory, then, a plaintiff needs to: (1) allege a state cause of action for misbranding, (2) identify the "new and scientifically significant information that was not before the FDA," and (3) prove that the FDA would have found the drug to be misbranded in light of this new information.

A plaintiff can satisfy these requirements, if at all, only in the narrowest of factual circumstances. For example, in Mensing, the Supreme Court noted that "as a practical matter, genuinely new information about drugs in long-use (as generic drugs typically are) appears infrequently."[34] Creating an exception to preemption, moreover, would create an evidentiary morass, as the parties would be invited to speculate on how the FDA would have acted in hypothetical situations.

Finally, in Lashley v. Pfizer Inc., the Fifth Circuit recently concluded that "parallel" claims argument is a concept applied to express — and not conflict or implied — preemption. The Supreme Court has never adopted the theory in the generic prescription drug context, and accordingly, the Fifth Circuit held: "[W]e do not agree with [plaintiffs] that some of their state law claims against generic manufacturers are parallel to federal law claims, and thus not preempted. ... [The cases plaintiffs cite] concern express preemption ... [but] the inquiry is not whether there is a 'parallel' claim where one looks for absence of conflict with the statute; the inquiry is whether the state law claim is impliedly preempted."[35]

Conclusion

In conjunction with Mensing, the Supreme Court's recent decision in Bartlett effectively forecloses state law product liability claims against generic manufacturers. But, as counsel for plaintiffs in the Darvocet appeal himself acknowledged in the days immediately following Bartlett, "Footnote 4 may just be a red herring. ... But the [c]ourt acknowledged that there might

not be preemption of state design defect claims where you have new, scientifically valid info that the drug was not safe. It certainly provides an avenue for plaintiffs to pursue these claims."[36]

Plaintiffs have not abandoned all hope. Although a red herring, we expect plaintiffs injured by generic drugs to continue to capitalize on the Bartlett footnote.

[1] 133 S. Ct. 2466 (2013).

[2] Id. at 2470.

[3] Id. at 2477 n.4.

[4] In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig. (Miller v. Eli Lilly), No. 12-5929 (6th Cir.).

[5] 131 S. Ct. 2567 (2011).

[6] Id. at 2577.

[7] 133 S. Ct. at 2472.

[8] Id.

[9] Id. at 2470, 2475. It is worth noting that in November 2013, the FDA issued a proposed rule that would effectively overrule Mensing and Bartlett and permit generic manufacturers, like branded manufacturers, to initiate labeling changes. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985-02 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314 & 601). If finalized, plaintiffs injured by generic drugs would very likely be able to bring claims against generic manufacturers without having to develop end-runs around preemption. Comments on the proposed rule closed on March 13, 2014.

[10] Bartlett, 133 S. Ct. at 2477 n.4 (citations omitted).

[11] See, e.g., In re Fosamax Prods. Liab. Litig., No. 06 MD 1789 (JFK), --- F. Supp. 2d ---, 2013 WL 4306434, at *6 (S.D.N.Y. Aug. 15, 2013) ("[P]laintiffs proffer that the decision in Bartlett turned on New Hampshire law, which strictly applies comment k to § 402A of the Restatement (Second) of Torts. Therefore, according to plaintiffs, Bartlett does not provide a basis for wholesale dismissal of plaintiffs' design defect claims.'").

[12] Wilson v. Amneal Pharm., LLC, No. 1:13-cv-00333-CWD, 2013 WL 6909930, at *13-14 (D. Idaho Dec. 31, 2013). See also In re Fosamax, 2013 WL 4306434, at *7; Strayhorn v. Wyeth Pharm., Inc., 737 F.3d 378, 396 (6th Cir. 2013) ("[T]o the extent that plaintiffs allege that the drug itself should have been modified to conform to the properties described in the label, generic manufacturers are prohibited by their federal duty of sameness from designing their drugs differently from the [reference listed drug].") (citation omitted); Gardley-Starks v. Pfizer, Inc., No. 4:10-CV-099-SA-JMV, 2013 WL 5423951, at *3 (N.D. Miss. Sept. 26, 2013) ("[T]he Court finds that pursuant to Bartlett, the Court's prior determination that Plaintiff's [design defect] claims were preempted are confirmed."). But see Fullington v. Pfizer, Inc., 720 F.3d 739, 746-47 (8th Cir. 2013) ("[I]t is not immediately clear whether Arkansas, unlike New Hampshire, offers generic drug manufacturers an opportunity, consistent with federal obligations, to somehow alter

an otherwise unreasonably dangerous drug. Therefore, we reverse the dismissal of Fullington's design defect allegations and remand to the district court for further consideration in light of Bartlett."); Neeley v. Wolters Kluwer Health, Inc., No. 4:11-CV-325 JAR, 2013 WL 3929059, at *10 (E.D. Mo. July 29, 2013) (same).

[13] See supra note 4; Eckhardt v. Qualitest Pharm., Inc., No. 13-40151 (5th Cir.).

[14] Amicus Br. of FDA, at 23, Mutual Pharm. Co. v. Bartlett, 133 S. Ct. 2466 (2013) (citation omitted).

[15] Bartlett, 133 S. Ct. at 2477 n.4.

[16] 2013 WL 5423951, at *2.

[17] Id. at *3.

[18] 74 A.3d 202, 216 (Pa. Super. Ct. 2013) (citation omitted); In re Reglan/Metoclopramide Litig., 81 A.3d 80, 95 (Pa. Super. Ct. 2013).

[19] Appellants' Br. at 12, In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig. (Miller v. Eli Lilly), No. 12-5929 (6th Cir.); Appellees' Br. at 10, In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig. (Miller v. Eli Lilly), No. 12-5929 (6th Cir.).

[20] Appellees' Br., supra note 19, at 10-11

[21] Id.

[22] Id. at 11.

[23] Id.

[24] Id. at 11-12.

[25] Id. at 12.

[26] Id. at 13 (citation omitted, emphasis added).

[27] Appellants' Br., supra note 19, at 22-26 ("Where federal law itself requires the defendant to stop selling its product, it would not be impossible for the defendant to satisfy its state law duty no to sell an unreasonably dangerous product.").

[28] Id. at 24.

[29] Compare Amicus Br. of FDA in Bartlett, supra note 14, at 24, with Amicus Br. of FDA, at 25-30, PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011).

[30] The FDA in Mensing argued that the failure-to-warn claims were not preempted because they paralleled the federal misbranding statutes. See Amicus Br. of FDA in Mensing, supra note 29, at 25-30. The Court nevertheless held that failure-to-warn claims involving generic drugs were preempted. Mensing, 131 S. Ct. at 2576-78. Moreover, post-remand, the plaintiffs in the Mensing action petitioned the Supreme Court, arguing that under Bartlett, "there may be design

defect claims asserted against generic manufacturers that are not preempted by federal law." Petitioner's Suppl. Br., Demahy v. Schwarz Pharma, Inc., No. 12-1093, 2013 WL 5324707, at *12 (S. Ct. Sep. 20, 2013) ("Given this Court's indication in Bartlett that there may be design defect claims asserted against generic drug manufacturers that are not preempted by federal law, summary reversal for consideration of [plaintiff's] claims in light of Bartlett would be appropriate."). The Supreme Court rejected the petition. Demahy v. Schwarz Pharma, Inc., 134 S. Ct. 57 (2013) (mem.) (denying petition for writ of certiorari).

[31] But see Hassett, 74 A.3d at 216.

[32] Bartlett, 133 S. Ct. at 2477 n.4 (emphasis added).

[33] Bartlett, 133 S. Ct. at 2477 n.4 (internal quotation marks omitted). See also id. at 2492 (Sotomayor, J., dissenting) ("Federal law itself bars the sale of previously approved drugs if new information comes to light demonstrating that the drug is 'dangerous to health' and thus 'misbranded.'") (citations omitted).

[34] Mensing, 131 S. Ct. at 2581 n.9 (citation omitted). See also, e.g., Drager v. PLIVA USA, Inc., 741 F.3d 470, 475 (4th Cir. 2014) ("[W]e find that the complaint did not allege any violation of the federal misbranding laws or parallel state duties."); Schrock v. Wyeth, Inc., 727 F.3d 1273, 1290 (10th Cir. 2013) ("[T]he Bartlett court indicated in dicta that 'a drug is misbranded under federal law only when liability is based on new and scientifically significant information that was not before the FDA' and that allegations of dangerousness based on 'the medical literature or published FDA analyses' would not qualify. A misbranding claim along these lines has not been advanced.") (citation omitted).

[35] 2014 WL 661058, at *4 (5th Cir. Feb. 21, 2014).

[36] Alyssa E. Lambert, Supreme Court Expands Preemption to Design Defect Claims, FDA to Release New Generic Labeling Rule, Am. Ass'n for Justice (July 11, 2013), available at http://www.justice.org/cps/rde//justice/hs.xsl/21443.htm.

Anand Agneshwar is a partner in Arnold & Porter's New York office, where he is the co-chairman of the firm's product liability litigation practice group and represents pharmaceutical and consumer product companies as national, strategic, trial and appellate counsel in product liability litigation and related litigation.

Anna Thompson is an associate in Arnold & Porter's Washington, D.C., office.