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Breaking Down The Bartlett Oral Argument

Life Sciences Law360
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Life Sciences, Pharmaceutical + Medical Device, Product Liability

4/1/2013

Article

Law360, New York (April 01, 2013, 4:05 PM ET) -- The U.S. Supreme Court has heard oral argument in the much-anticipated Mutual Pharmaceuticals v. Bartlett case, No. 12-142 (on appeal from the First Circuit Bartlett v. Mutual Pharms. Co., 678 F.3d 30 (1st Cir. 2012)). The Supreme Court will determine what most thought seemed already decided by PLIVA Inc. v. Mensing, 131 S. Ct. 2567 (2011): whether design defect claims against generic drug manufacturers are preempted by federal law, and whether manufacturers can be held liable when their only other option is to withdraw from the market.

Bartlett's History

The plaintiff, Karen Bartlett, was prescribed generic sulindac for shoulder pain and developed Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN), which left her permanently injured and disfigured. Bartlett, 678 F.3d at 34. By the time of trial, the only remaining claim for the jury to decide was whether sulindac was defectively designed. Id. The jury found in Bartlett's favor and awarded her $21.06 million in compensatory damages. Id.

On appeal to the First Circuit, Mutual argued that design defect claims against generic companies are preempted by federal requirements that generic drugs be the "same" as brand-name drugs in all material respects. Id. at 37.

Mutual pointed to Mensing and its holding that the "sameness" provisions make it impossible for generic manufacturers to comply with federal labeling requirements and stricter state law requirements arising from failure to warn claims. Id. But the First Circuit did not accept Mutual's argument, affirming the jury verdict because Mutual "certainly can choose not to make the drug at all ..." Id.

The First Circuit's decision marked a departure from the string of cases previously rejecting such a duty to recall. See, e.g., Lance v. Wyeth, 4 A.3d 160 (Pa. Super. Ct. 2010); Moore v. Mylan Inc., 840 F. Supp. 2d 1337, 1352 n.14 (N.D. Ga. 2012); Coney v. Mylan Pharms. Inc., (S.D. Ga. Jan. 19, 2012); In re Fosamax Prods. Liab. Litig. (No. II), MDL 2243, (D.N.J. Nov. 21, 2011).

In December 2012, the Supreme Court granted Mutual's certiorari petition. The solicitor general of the United States filed an amicus brief representing the U.S. Food and Drug Administration, arguing that "duty to recall" claims should be rejected regardless of whether the drug in question is generic or branded because evaluation of the overall risks and benefits of a drug go to the core purpose of the FDA, and the FDA should be the final arbiter of whether a drug stays on the market. The solicitor general also requested time to argue on behalf of the FDA as amicus curiae.

Oral Argument

During the one-hour oral argument, the justices actively questioned all counsel involved. The court probed deeply on two main points: first, whether design defect claims can be independent, rather than based on failure to warn; and

second, why this case was anything more than a challenge to the FDA's approval of a drug.

Independent Design Defect Claims

Justice Elena Kagan spoke first and asked Mutual's lawyer whether design defect claims against both branded and generic drugs are preempted by federal law. She recognized that the court's previous distinction between branded and generic drugs in two landmark decisions — Wyeth v. Levine, 555 U.S. 555 (2009), and Mensing, 131 S. Ct. 2567 — revolved around the label and a generic manufacturer's statutory inability to change its label. She implied this distinction may not apply when the issue is one of pure design and therefore independent of the label's content. Though counsel for Mutual dodged the issue, the lawyer from the solicitor general's office unequivocally stated that preemption of pure design defect claims would apply to both branded and generic drugs.

Justice Sonia Sotomayor approached the pure design defect concept from a different angle. Known for her scathing dissent in Mensing, she asked counsel for Mutual the question that seems preeminent in her mind: if the FDA approves a drug, does that mean there can be no tort liability for the manufacturer? "Absolutely not," was the response.

Justice Sotomayor pressed Mutual's counsel about the fate of a truly dangerous drug — one that no reasonable practitioner would prescribe. He refused to acknowledge that a design defect claim could exist independent of the warnings. Because generic manufacturers couldn't be held liable for failure to warn, they couldn't be held liable for a design defect based on a failure to warn.

During the argument of Bartlett's counsel, Justice Kagan returned to the warnings and their relationship to the design defect claim. Despite Bartlett's argument that this was a pure strict liability case and warnings were not at issue, the record revealed otherwise. Justice Kagan noted that "[t]he adequacy of the warning is really all over this case. There was expert testimony about the adequacy of the warning, there were jury instructions about the adequacy of the warning." All of this, she continued, "does suggest that this is sort of within the four corners of Mensing."

Bartlett's counsel tried to draw a very fine distinction between the adequacy of the warning, which he said was not at issue, and the efficacy of the warning in minimizing the risk posed by an unreasonably dangerous drug. Justice Stephen Breyer seemed skeptical about the distinction.

Challenging FDA's Approval Authority

The second key issue throughout oral argument was the issue of state law infringing on the FDA's authority to approve a drug. The justices directed most of these questions at the assistant to the solicitor general and Bartlett's counsel.

When pressed by Justice Kagan on whether impossibility preemption applied if a company could simply withdraw from the market, the lawyer from the solicitor general's office stressed the importance of preserving the FDA's role. Juries should not second-guess the FDA on a state-by-state or case-by-case basis, thereby imposing different safety obligations on manufacturers.

Several justices seemed uncomfortable with the idea of allowing a jury to evaluate the safety of a drug. Chief Justice John Roberts pointed out that if a jury performed a cost-benefit analysis and determined that the risks outweigh the benefits for a given drug, the jury could conclude that the drug should not be marketed at all. Such a result would be inconsistent with the federal regulatory scheme. Similarly, Justice Antonin Scalia seemed skeptical about the wisdom of allowing a jury to decide the cost-benefit analysis for novel drugs that could save lives. Finally, Justice Breyer expressed deep reservations about empowering a jury with the authority to decide whether a potentially lifesaving drug should be withdrawn from the market.

Recognizing the pivotal question implicit in Bartlett's argument, Justice Samuel Alito pointedly asked whether it was Bartlett's position that the drug was so dangerous, and the danger so incurable by warnings, that it should never have been approved. In other words, was respondent simply criticizing the approval decision made by the FDA? In response, Bartlett's counsel admitted that the warnings "can be a factor" in determining whether there should be strict liability.

Justice Alito provided a vivid analogy: Suppose federal law required one to drive on the right side of the road, while New Hampshire law requires driving on the left. It would be impossible to comply with both, but respondent argues that one could comply with both rules by not driving. The somewhat evasive response of respondent's counsel did not alleviate Justice Alito's concern.

Conclusion and Prediction

Across the board, the justices seemed uneasy with the idea of obligating withdrawal of a generic drug from the market based on a jury's determination that the drug was "unreasonably dangerous." This unease is based in part on the key role that warnings play in a drug's dangerousness, coupled with the inability to change a generic drug's warnings. Given Justice Kagan's remark that this case is within the four corners of Mensing and the discomfort demonstrated by the other justices with Bartlett's position, it seems unlikely that First Circuit's decision will stand.

The court may hold that there is no design defect liability when the "unreasonably dangerous" claim is based on warnings that cannot be changed — which would apply only to generic drugs. Alternatively, the court may in fact go as far as the solicitor general argued and hold that a duty to withdraw an FDA-approved drug is preempted for both a branded and generic drug. We will provide our analysis once the opinion is issued (which is expected before the end of June), but we will be surprised if the First Circuit's decision is affirmed by the Supreme Court.

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