A victory for generics suppliers

By James Huston, Erin Bosman, Julie Park & Joanna Simon


Erin Bosman


James Huston


Julie Park


Joanna Simon

In late June the Supreme Court issued its ruling in the much-anticipated Mutual Pharms. Co. v. Bartlett, No. 12-142 (on appeal from the First Circuit Bartlett v. Mutual Pharms. Co., 678 F.3d 30 (1st Cir. 2012)). As we predicted, the Court reversed the First Circuit's decision and held that "(s)tate-law design defect claims that turn on the adequacy of a drug's warnings are pre-empted by federal law under PLIVA [Inc. v. Mensing]."

Bartlett's background

Bartlett's facts are undeniably tragic. The plaintiff, Karen Bartlett, took generic sulindac (manufactured by Mutual) for shoulder pain. She developed Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN) and suffered permanent injury and disfigurement. By the time of trial, the only remaining claim for the jury to decide was whether sulindac was defectively designed. The jury found in Bartlett's favor and awarded her $21.06 million in compensatory damages.

The First Circuit affirmed, holding that because Mutual "certainly c(ould) choose not to make the drug at all," there was no impossibility preemption. Mutual petitioned for a writ of certiorari, which the Supreme Court granted in December 2012. In addition to the parties' briefs, the Solicitor General filed a brief arguing that all "duty to recall" claims should be rejected. The Supreme Court heard oral argument in March.

Questioning at oral argument focused on two main issues: (1) whether design-defect claims can be independent of failure-to-warn claims; and (2) whether this case represented anything other than a challenge to the FDA's authority to allow drugs to be sold on the market.

The decision squarely addressed both issues.

Mutual's duties

Justice Alito authored the opinion for the Court, joined by Chief Justice Roberts and Justices Scalia, Kennedy and Thomas (the same five Justices who ruled for preemption in Mensing). In its impossibility preemption analysis, the Court began by "identifying (Mutual's) duties under state law." First, the Court rejected the notion that New Hampshire recognized an "absolute-liability regime," i.e., one that makes drug manufacturers insurers of their products.

Second, the Court analyzed design defect under New Hampshire law, which imposes liability "only where the design of the product created a defective condition unreasonably dangerous to the user." Factors to be considered include: (1) the usefulness of the product to the general public (2) whether the risk at issue could have been reduced without significant impact to the product's efficacy or manufacturing cost, and (3) "the presence and efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers or foreseeable uses."

The Court concluded that the first two factors would require redesign of a drug, which is impossible in this case for the following two reasons. First, because Mutual's sulindac was a generic drug, it was required to "have the same ingredients, route of administration, dosage form, strength and labeling as the brand-name drug on which it is based." Second, the Court concluded that the single-molecule drug was incapable of being redesigned.

After eliminating the first two factors from its analysis, the Court was left with a failure-to-warn claim: "Given the impossibility of redesigning sulindac, the only way for Mutual to ameliorate the drug's 'risk-utility' profile — and thus to escape liability — was to strengthen the presence and efficacy of sulindac's warning in such a way that the warning avoided an unreasonable risk of harm from hidden dangers or from foreseeable uses." Essentially, "New Hampshire's design-defect cause of action imposed a duty on Mutual to strengthen sulindac's warnings."

Bartlett provides generics manufacturers with another tool to defend against liability claims.

According to the Court, "The duty imposed by federal law is far more readily apparent . . . . (It) prevents generic drug manufacturers from changing their labels." Based on this reasoning, the Court held that the case fit squarely within the bounds of its decision in Mensing and that "federal law prohibited Mutual from taking the remedial action required to avoid liability under New Hampshire law."

"Duty to withdraw" argument

The most closely watched aspect of this case was the question whether Bartlett represented a challenge to the FDA's authority to approve a drug — did impossibility preemption apply if a manufacturer could withdraw a drug from the market? The response from the Court was unequivocally negative: "We reject this 'stop-selling' rationale as incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.' "

In addition to rejecting the "duty to withdraw" argument, the majority's opinion spent several pages refuting Justice Sotomayor's passionate dissent. While the majority recognized the "dreadful injuries" giving rise to product liability cases, "sympathy for (the plaintiff) does not relieve us of the responsibility of following the law." The majority also refused to accept that it has "ignored Congress' explicit efforts to preserve state common-law liability." Instead, the Court reiterated its statement from Mensing that "Congress and the FDA retain the authority to change the law and regulations if they so desire" and the Court once again exhorted Congress to provide " 'explicit' resolution to the difficult preemption questions that arise in the prescription drug context. That issue has repeatedly vexed the Court — and produced widely divergent views — in recent years."

Justice Breyer's dissent

Justice Breyer, joined by Justice Kagan, authored a brief dissent, essentially concluding that nothing in the federal regulatory scheme conflicts with a state's requirement that the manufacturer pay damages or exit the market. Part of this conclusion was based on Justice Breyer's refusal to give special weight to the FDA's views, as there had been no hearings or regulations enforcing those views.

During oral argument in March, Justice Breyer had expressed misgivings about allowing a jury to decide whether a potentially lifesaving drug should be withdrawn. Yet in his dissent, Justice Breyer implied that juries should do exactly that — the issue should be left to the trier of fact and decided on a case-by-case basis. Indeed, in this case he "found no convincing reason to believe that removing this particular drug from New Hampshire's market, or requiring damage payments for it there, would be so harmful that it would seriously undercut the purposes of the federal statutory scheme." He further noted that other defendants "remain free" to demonstrate impossibility preemption in their own particular cases.

Justice Sotomayor's dissent

As in Mensing, Justice Sotomayor's dissent exceeded the majority opinion in length. Joined by Justice Ginsberg, Justice Sotomayor found the majority opinion an "unnecessary" and "unwise" extension of Mensing.

Justice Sotomayor began by taking the majority to task for ignoring the presumption against preemption that laid the groundwork for the Court's opinion in Wyeth v. Levine, 555 U.S. 555 (2009). This presumption should have left Mutual facing "an uphill climb" to show federal preemption of plaintiff's claims, and Justice Sotomayor would have held that Mutual did not meet its burden.

According to Justice Sotomayor, New Hampshire's design-defect law provided "incentives" for Mutual to alter the drug's design or label. In contrast, failure-to-warn law imposed "requirements" that drug manufacturers maintain up-to-date labels. "This difference is a significant one: A mandate leaves no choice for a party that wishes to comply with the law, whereas an incentive may only influence a choice." The majority opinion criticized this aspect of Justice Sotomayor's dissent, stating that "(t)he contours of that argument are difficult to discern." State failure-to-warn claims seem to provide similar "incentive" to maintain a current label and could just as easily be avoided by withdrawing from the market (or remedied by paying damages).

The dissent was very troubled with the lack of compensation to the plaintiff for her injuries: "responsibility for the fact that Karen Bartlett has been deprived of a remedy for her injuries rests with this Court."

"As a result (of the majority's decision), the Court has left a seriously injured consumer without any remedy despite Congress' explicit efforts to preserve state common-law liability."

Parallel claim for misbranding

Both the majority and the dissent referenced the FDA's misbranding prohibition. The majority explicitly stated that it was not addressing "state design-defect claims that parallel the federal misbranding statute." The dissent recognized that federal law "bars the sale of previously approved drugs if new information comes to light demonstrating that the drug is 'dangerous to health' and thus 'misbranded.' " This was partly the basis on which the dissent rejected the notion that "drug manufacturers have a right to continue to sell a drug free from liability once it has been approved." Additionally, the dissent discredited the FDA's contention that "design-defect claims are pre-empted unless they parallel the FDA's misbranding prohibition," concluding that the FDA's views need not be given weight here.

Impact of Bartlett decision

Bartlett reinforces the Supreme Court's opinion in Mensing and provides generic manufacturers with another tool to defend against product liability claims. Bartlett recognizes that many of the common causes of action against pharmaceutical manufacturers are simply failure-to-warn claims disguised as other causes of action. However, the Court left the door slightly ajar to claims alleging parallel violation of the FDA's misbranding prohibition. Though such a cause of action would likely be available in only a sliver of pharmaceutical product liability cases and has little chance of success, we would expect plaintiffs to begin asserting these claims where they think they might have sufficient basis to do so. The FDA may respond to the Court's repeated

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various points on the globe

were more than 100 sildenafil "brands" in distribution.

This writer had dinner at the home of a very wealthy Indian family that owns an oncology manufacturing business. The foreign markets for their oncology products included Russia, the Middle East, China and South America. What was never mentioned but readily understood was that the products were all knockoffs of patent-protected oncology brands from internationally known manufacturers.

Many developing and semi-developed countries do not have a federal equivalent of our Food and Drug Administration. Therefore, the policing of brand patent protection, the source of medications or products commonly in distribution is virtually absent. Brand knockoffs and counterfeit products are commonly in distribution. In fact, heads seem to be turned away from the shady practice, for the sake of product accessibility and profit.

Similarly, many countries lack the breadth and depth of pharmaceutical and over-the-counter products commonly in distribution in the developed world. In Ghana, for instance, a robust hair care section in a leading food retailer or drug store would struggle to fill a 3-foot section 4 feet high.

And almost all products must be imported either by a retailer or wholesaler. In the Caribbean, suitcase traders, as they are commonly referred to, sell an internationally sourced range of products such as Centrum vitamins directly to chain retailers. Are all such products the genuine article? Who knows?

Pharmacy retailing formats, including those I consulted with during their development, vary widely from country to country. GNRC MediShops in India range from 600 to 1,200 square feet and are the largest in the Assam area of India. Guardia Life Care pharmacies in the Delhi area are generally around 2,500 square feet and include a General Nutrition Cos. (GNC) franchise offering. Pillbox pharmacies in Ghana are 400 to 600 square feet. Farmatodo in Venezuela and Super Pharm in Trinidad, complete with pharmacy drive-through and ample parking, resemble a Walgreen Co. or CVS/pharmacy unit here in the United States.

A commonality among the investors with whom I worked was this: They look at pharmacy chains in the United States and say to themselves, "That's what I would like to be when I grow up."

Robert Coopman is president of Robert Coopman Consultants, which is based in San Antonio. He can be contacted at rcoopman67@gmail.com.

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requests to resolve some of the confusion and controversy surrounding product liability for generic drug manufacturers in the coming months. We think it is less likely that Congress will respond, as any measure is unlikely to pass both the Democratic Senate and Republican House of Representatives.

James Huston and Erin Bosman are partners in the law firm Morrison & Foerster LLP. Julie Park and Joanna Simon are associates there.