Client Alert

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Mutual v. Bartlett Further Shields Generic Drug Manufacturers from Liability

By James W. Huston, Erin M. Bosman, Julie Y. Park and Joanna L. Simon

This morning 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*."[1]

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 today squarely addressed both issues.

MUTUAL'S DUTIES UNDER NEW HAMPSHIRE LAW CONFLICT WITH ITS DUTIES UNDER FEDERAL LAW

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

[1] Slip op. at 2. *See* Driving on Both Sides of the Road: Supreme Court Hears *Bartlett* Oral Argument.

design of the product created a defective condition unreasonably dangerous to the user."[2] 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."[3]

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."[4] Second, the Court concluded that the single-molecule drug was incapable of being redesigned.[5]

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."[6] Essentially, "New Hampshire's design-defect cause of action imposed a duty on Mutual to strengthen sulindac's warnings."[7]

According to the Court, "The duty imposed by federal law is far more readily apparent . . . . [It] prevents generic drug manufacturers from changing their labels."[8] 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."[9]

COURT REJECTS "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.'"[10]

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[2] Slip op. at 9 (quotation omitted).

[3] *Id.* at 10 (quotation omitted).

[4] *Id.* (citing 21 U.S.C. § 355(j)(2)A)(ii)-(v) and (8)(B); 21 C.F.R. § 320.1(c)).

[5] *Id.* at 11.

[6] *Id.* (qutoation and alterations omitted).

[7] *Id.*

[8] *Id.* at 13.

[9] *Id.*

[10] *Id.* at 15.

In addition to rejecting the "duty to withdraw" argument, the majority's opinion also 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."[11] 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"[12] 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."[13]

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.[14]

During oral argument in March, Justice Breyer had expressed misgivings about allowing a jury to decide whether a potentially lifesaving drug should be withdrawn from the market. 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."[15] 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

[11] *Id.* at 17.

[12] 131 S.Ct. 2567 at 2582.

[13] Slip op. at 19-20.

[14] Breyer Dissent at 3.

[15] *Id.* at 4.

comply with the law, whereas an incentive may only influence a choice."[16] The majority opinion criticized this aspect of Justice Sotomayor's dissent, stating that "[t]he contours of that argument are difficult to discern."[17] 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."[18] "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."[19]

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."[20] 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.'"[21] 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 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.

[16] Sotomayor Dissent at 12.

[17] Slip op. at 17-18.

[18] Sotomayor Disssent at 2.

[19] *Id.* at 26.

[20] Slip op. at 14 n.4.

[21] Sotomayor Dissent at 17-18.

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Contact:

James W. Huston
(858) 720-5154
jhuston@mofo.com

Erin M. Bosman
(858) 720-5178
ebosman@mofo.com

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