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Driving on both sides of the road: Supreme Court hears *Bartlett* oral argument

Contributed by **Morrison & Foerster LLP**

April 02 2013

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Introduction

The Supreme Court recently heard oral arguments in the much-anticipated *Mutual Pharmaceuticals v Bartlett* case.(1) The court is to determine what most thought had already been decided by *PLIVA, Inc v Mensing*:(2) whether design defect claims against generic drug manufacturers are pre-empted by federal law, and whether manufacturers can be held liable when their only other option is to withdraw from the market.

Case history

Plaintiff Karen Bartlett was prescribed generic sulindac for shoulder pain and developed Stevens-Johnson syndrome/toxic epidermal necrolysis, which left her permanently injured and disfigured.(3) By the time of trial, the only remaining claim for the jury to decide was whether sulindac was defectively designed.(4)The jury found in Bartlett's favour and awarded her $21.06 million in compensatory damages.(5)

On appeal to the First Circuit, Mutual Pharmaceuticals argued that design defect claims against generic companies are pre-empted by federal requirements that generic drugs be the 'same' as brand-name drugs in all material respects.(6)

Mutual pointed to *Mensing* and its holding that the 'sameness' provisions make it impossible for generic manufacturers to comply with federal labelling requirements and stricter state law requirements arising from failure to warn claims.(7) However, 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".(8) The First Circuit's decision marked a departure from the string of cases previously rejecting such a duty to recall.(9)

In December 2012 the Supreme Court granted Mutual's *certiorari* petition. The solicitor general of the United States filed an *amicus* brief representing the Food and Drug Administration (FDA), 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:

- whether design defect claims can be independent, rather than based on failure to warn; and
- why this case was anything more than a challenge to the FDA's approval of a drug.

Independent design defect claims

Justice Kagan spoke first and asked Mutual's lawyer whether design defect claims against both branded and generic drugs are pre-empted by federal law. She recognised that the court's previous distinction between branded and generic drugs in two landmark decisions – *Wyeth v Levine*(10) and *Mensing*(11) – revolved around the label and a generic manufacturer's statutory inability to change its label. She implied that this distinction may not apply when the issue is one of pure design and therefore independent of the label's content. Although counsel for Mutual dodged the issue, the

lawyer from the solicitor general's office unequivocally stated that pre-emption of pure design defect claims would apply to both branded and generic drugs.

Justice 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 pre-eminent in her mind: if the FDA approves a drug, does that mean that there can be no tort liability for the manufacturer? "Absolutely not," was the response.

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

During the argument of Bartlett's counsel, 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. 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 minimising the risk posed by an unreasonably dangerous drug. Justice Breyer seemed sceptical about the distinction.

Challenging FDA's approval authority

The second key issue in the 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 Kagan on whether impossibility pre-emption 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 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 Scalia seemed sceptical about the wisdom of allowing a jury to decide the cost-benefit analysis for novel drugs that could save lives. Finally, Breyer expressed deep reservations about empowering a jury with the authority to decide whether a potentially life-saving drug should be withdrawn from the market.

Recognising the pivotal question implicit in Bartlett's argument, Justice 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 the respondent simply criticising 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.

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

Comment

Across the board, the justices seemed uneasy with the idea of requiring 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 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 the 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 go as far as the solicitor general argued and hold that a duty to withdraw an FDA-approved drug is pre-empted for both a branded and generic drug. The opinion is expected before the end of June 2013, but it will be surprising if the First Circuit's decision is affirmed by the Supreme Court.

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Endnotes

(1) 12-142 (on appeal from the First Circuit *Bartlett v Mutual Pharms Co*, 678 F 3d 30 (1st Cir 2012)).

(2) 131 S Ct 2567 (2011).

(3) *Bartlett*, 678 F 3d at 34.

(4) *Id.*

(5) *Id.*

(6) *Id* at 37.

(7) *Id.*

(8) *Id.*

(9) See, for example, *Lance v Wyeth*, 4 A.3d 160 (PA Super Ct 2010); *Moore v Mylan, Inc*, 840 F Supp 2d 1337, 1352 n 14 (ND GA 2012); *Coney v Mylan Pharms, Inc*, No 6:11-cv-35, 2012 WL 170143, at *5 (SD GA Jan 19 2012); *In re Fosamax Prods Liab Litig (No II)*, MDL 2243, 2011 WL 5903623, at *6 n 5 (DNJ Nov 21 2011).

(10) 555 US 555 (2009).

(11) 131 S Ct 2567.