



News Release

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Supreme Court Reverses First Circuit in *Mutual Pharmaceutical Co., Inc. v. Bartlett*

Decision Aligns with DRI Amicus Brief on Behalf of Mutual Pharmaceutical

CHICAGO – (June 24, 2013)— [The Supreme Court today reversed](#) the First Circuit decision in the case of *Mutual Pharmaceutical Co. v. Bartlett*. The case involves the question of whether federal law governing FDA approval of generic drugs preempted the design-defect theory on which the plaintiff won a \$21 million jury verdict. The decision aligns with the amicus brief supporting Mutual Pharmaceutical filed by DRI's Center for Law and Public Policy.

The case was tried on a design-defect theory of liability after the plaintiff's failure-to-warn claims were dismissed prior to trial and the district court rejected the generic manufacturer's preemption defense. Yet at trial, the trial judge instructed the jury that it could find the drug unreasonably dangerous in design if the warning was inadequate and that it should find the drug was not defective if it was accompanied by an adequate warning.

In *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), the Supreme Court had held that state-law tort claims against generic drug manufacturers based on the adequacy of drug labeling are preempted because under the Hatch-Waxman Amendments to the federal Food, Drug and Cosmetic Act, generic drug labeling must be the "same as" the labeling of the reference-listed drug. Because generic drug manufacturers cannot independently change the labeling, state-law failure-to-warn claims are preempted. In *Bartlett*, the First Circuit held that the plaintiff's state-law theory of liability could be reconciled with federal law because although the generic manufacturer could change neither the design nor the labeling, it could avoid liability if it stopped selling the drug entirely within the state.

The Supreme Court rejected the argument that a defendant does not really face an impossible conflict when state law penalizes compliance with federal law, because the defendant can satisfy both laws by paying tort judgments or refraining from selling its product in that particular state. The Supreme Court held that the plaintiff's "stop selling" theory is "incompatible" with its preemption jurisprudence, which "presume[s] 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."

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In its amicus brief, DRI supported Mutual's position that the decision of the court of appeals upholding the jury verdict should be reversed. DRI argued that experience with pharmaceutical-liability cases and trials across the country reveals that prescription drug cases are invariably about the warnings in the overwhelming majority of American jurisdictions. DRI argued that a straightforward application of the *Mensing* decision to the *Bartlett* record results in preemption. The Supreme Court agreed.

"Design-defect cases regularly come down to whether state law requires more and different warnings," said William Jay, one of the DRI brief's co-authors. "The Supreme Court reaffirmed today that when federal law specifies the exact warnings a manufacturer must give, state juries can't penalize businesses for selling their product in compliance with that federal law."

DRI amicus authors Richard A. Oetheimer, William M. Jay, and Sarah K. Frederick of Goodwin Procter LLP are available for interview or for expert comment through DRI's Communications Office. To read the brief in its entirety, [click here](#).

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