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Complex Mass Tort Product Liability Alert

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Supreme Court's *Bartlett* Decision Reaffirms Broad Scope of Generic Drug Preemption

In a significant victory for generic drug companies, the Supreme Court today issued its decision in *Mutual Pharmaceutical Co. v. Bartlett*, reversing the decision of the First Circuit, which had affirmed a multimillion dollar jury verdict in a personal injury lawsuit involving the use of a generic anti-inflammatory drug. As detailed in our previous client alert dated March 19, 2013, *Bartlett* involved the question of whether design defect claims against generic pharmaceutical defendants are preempted under *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). The First Circuit in *Bartlett* held that design defect claims against generic drug companies are not preempted by *Mensing* on the grounds that the defendant could simultaneously comply with both state and federal law by choosing not to sell the medication altogether. Today's 5-4 ruling rejected that theory, with the nine Justices split along precisely the same lines as in *Mensing*.

In *Mensing*, the Supreme Court held that claims challenging the adequacy of the labeling of generic prescription medications are barred by impossibility preemption because generic pharmaceutical defendants are prohibited by federal law from independently changing the labeling of their products. Rather, the Hatch-Waxman amendments to the FDCA require generic pharmaceutical defendants to use the same labeling, design and route of administration for their products as their brand-name equivalent. Following *Mensing*, the First Circuit in *Bartlett* held that design defect claims, unlike traditional warning-based claims, were not preempted because generic defendants could comply with both state and federal law by withdrawing from the market and simply not selling the medications at all.

The Court conclusively rejected this view, holding that the design defect claims in *Bartlett* were similarly barred by impossibility preemption. The Court rejected the First Circuit's proffered "stop selling" argument "as incompatible with our pre-emption jurisprudence." As Justice Alito explained for the majority, the Court's "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," for "if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.'" (Slip op. at 15 (quoting *Mensing*).) Chief Justice Roberts and Justices Scalia, Kennedy, and Thomas joined the opinion of the Court. Justices Breyer and Sotomayor separately dissented, and were joined by Justices Kagan and Ginsburg, respectively.

The Court's opinion in *Bartlett* marks a decisive victory for generic pharmaceutical defendants who, despite *Mensing*, have continued to face personal injury lawsuits on the grounds that they could have stopped selling the medications at issue. Following this ruling, it would appear that individuals injured by generic drugs and their attorneys may be forced to turn to legislative and regulatory avenues to address the broad reach of federal preemption of warning and design defect claims. At the close of the majority opinion, the Court stated that it "would welcome Congress' 'explicit' resolution of the difficult pre-emption questions that arise in the prescription drug context." (Slip op. at 19-20.) Whether such efforts will ultimately succeed in altering federal policy on generic drug company liability remains to be seen.