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Complex Mass Tort Product Liability Alert

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Supreme Court Hears Oral Argument Regarding Scope of Generic Drug Preemption

Today, the Supreme Court of the United States held oral argument in *Mutual Pharmaceutical Co. v. Bartlett*, a follow-up to its landmark ruling in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), which addressed federal preemption of products liability claims against generic pharmaceutical companies. The Court in *Bartlett* considered the question of whether the preemption of claims attacking generic medication labeling in *Mensing* also extends to design defect claims.

In *Mensing*, the Supreme Court held 5-4 that claims lodged against generic pharmaceutical defendants based on labeling deficiencies are barred by impossibility preemption. Writing for the majority, Justice Thomas observed that a conflict exists between state-law claims, which require a generic defendant to use different labeling for its medication, and the Hatch-Waxman amendments to the Federal Food, Drug, and Cosmetic Act (FDCA), which require generics to use the same labeling as the branded medication. Because "[f]ederal drug regulations, as interpreted by the FDA, prevented the Manufacturers from independently changing their generic drugs' safety labels," the state-law claims against them were held preempted.

Following *Mensing*, the overwhelming majority of courts that have considered claims against generic companies have upheld or granted dismissal of all personal injury claims against them, not only those sounding in, or designated by plaintiffs as, failure to warn. These decisions have reasoned that, insofar as the Hatch-Waxman amendments require generics to use the same active ingredient and route of administration as the brand, a state-law claim challenging the design of those medications also is barred by impossibility preemption under *Mensing*.

The First Circuit's decision affirming a plaintiff's jury verdict in *Bartlett* is among the minority of decisions that have held that certain claims against generics survive *Mensing*. The First Circuit held that design defect claims against generics are not preempted by *Mensing* because the defendant could comply with both state and federal law by choosing not to market the allegedly defective product. The First Circuit acknowledged that other courts had disagreed with this conclusion, stating that "this issue needs a decisive answer from the only court that can supply it." The Supreme Court accordingly granted Mutual Pharmaceutical's petition for certiorari.

Significantly, the FDA, which had maintained in *Mensing* that failure-to-warn claims against generics were not preempted, submitted an amicus brief in *Bartlett* maintaining that design defect claims against generics are preempted. In addition, the FDA's amicus brief in *Bartlett* maintains that design defect claims against brands also are barred by conflict preemption in all but a few circumstances because they "would require a jury to revisit FDA's expert scientific determination, made ... after extensive undertakings by the manufacturers and extensive scrutiny by the FDA, that the approved uses of the drug are, in fact 'safe' for the indicated population because the drug's 'therapeutic benefits ... outweigh its risk of harm.'"

At oral argument, several of the Justices appeared to be considering the possibility that the claims at issue in *Bartlett* were not true challenges to the product's design, but rather were disguised attacks on the label prohibited by *Mensing*. In addition, Justice Alito suggested that

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the First Circuit's holding that the possibility of withdrawal from the market as a means of avoiding impossibility preemption could apply to any conflict between state and federal law and thus would not defeat preemption. On the other hand, several of the dissenters from *Mensing*, including Justices Ginsburg, Kagan and Sotomayor, appeared to suggest that FDA approval authorizes but does not require marketing of prescription medications, and thus it is not impossible for generic defendants to comply with both state and federal law. Significantly, however, Justice Breyer, the fourth dissenter in *Mensing*, appeared to be skeptical of the plaintiff-respondent's arguments and reasoned that, if carried to their logical extension, these arguments could result in jury verdicts preventing the marketing of life-saving chemotherapy medications. The Justices also grappled with the argument raised by the FDA that federal law preempts design defect claims against both generic and branded defendants.

Given the number of possible outcomes and holdings in *Bartlett*, it remains uncertain how the Court will resolve this important question of federal preemption law. A decision is expected by the end of the Court's term in June.