Product Liability Advisory

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Product Liability Preemption—Pursuing the Possibility of Impossibility

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On June 24, 2013, the Supreme Court issued one of its more lucid product liability preemption decisions of the past twenty years. The Court held 5-4 in *Mutual Pharmaceutical Co., Inc. v. Bartlett*, No. 12-142, that state-law design-defect claims are federally preempted if they would impose liability upon a generic drug manufacturer for failing to provide label warnings that the federal regulatory scheme for prescription drugs did not allow the manufacturer to add to its label. To avoid liability, New Hampshire tort law effectively required Mutual, a generic drug manufacturer, to independently change its product labeling to provide warnings stronger than those approved by the Food and Drug Administration (FDA)—something that the Court held in *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011), a generic drug manufacturer (unlike a brand name drug manufacturer) cannot do.

The Court's majority opinion, authored by Justice Alito, explained that "state law imposed a duty on Mutual *not* to comply with federal law." *Slip op.* at 1. As the Court has held many times, most state-common law causes of action for negligence and strict liability "impose affirmative duties." *Id.* at 8 n.1. If those state-law duties (i.e., requirements) conflict with federal regulatory requirements—such as when it is impossible to comply with both—the state law is preempted and thus "without effect." *Id.* at 2. Because it would have been impossible for Mutual to comply with both state and federal law, the Court held under the doctrine of "impossibility preemption"—a form of implied conflict preemption derived directly from the Constitution's Supremacy Clause—that the seriously injured plaintiff's design defect claims are preempted.

The *Mutual Pharmaceutical* opinion should be of substantial interest to manufacturers and distributors of any type of federally regulated (or government-specified) product. Here are some key take-aways:

1. **"Impossibility preemption" remains a viable ground for seeking pretrial dismissal of some product liability claims.** In fact, the majority opinion emphatically rejected the plaintiff's argument that simply stopping to sell a product within a particular state would avoid a preemptive state vs. federal conflict. The Court indicated that "if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.'" Slip Op. at 15. The Court said that "[a]dopting the . . . stop-selling rationale would mean that . . . the vast majority—if not all—of the cases in which the Court has found impossibility pre-emption, were wrongly decided." *Id.* at 16. That would "render impossibility pre-emption a dead letter." *Id.* at 2.

2. **Impossibility pre-emption is a demanding defense that is difficult to demonstrate**. Whether confronted with a failure-to-warn claim or a design defect claim, or both, a product manufacturer must show that "federal law forbids an action that state law requires." *Id.* at 13. Or conversely, the manufacturer must show that federal law requires an action that state law prohibits. Either way, the manufacturer must show that it would be impossible to comply with both a state-law duty and a conflicting federal-law duty concerning the same product. *See id.* at 7.

To demonstrate impossibility, it often is necessary to delve deeply into specifics— the details of federal regulatory requirements or prohibitions and the specific state-law duties that a particular cause of action would impose, and sometimes, facts relevant to a product's design or risks. For example, in *Mutual Pharmaceutical*, the Court explained that redesigning the generic drug's composition was not feasible for both regulatory and chemistry-related reasons. Thus, the drug manufacturer's only option for satisfying state-law tort duties for avoiding strict product liability was to violate federal law by unilaterally strengthening the warnings on the product labeling.

3. **A federal regulatory agency's views on preemption may be given special weight—sometimes.** Justices Breyer and Sotomayor each wrote dissenting opinions. In his dissent, Justice Breyer declined to give "special weight" to the FDA's views, which supported preemption and were presented in an *amicus curiae* brief filed by the Solicitor General. Justice Breyer indicated that the FDA's views were not sufficiently informed because that agency "held no hearings on the matter or solicited the opinions, arguments, and views of the public in other ways." Slip. op. at 2 (Breyer, J., dissenting). He further indicated that "the FDA has set forth its positions only in briefs filed in litigation, not in regulations, interpretations, or similar agency work product." *Id.* And he noted that "the FDA has set forth conflicting views on this general matter in different briefs filed at different times." *Id.* at 3.

Manufacturers of federally regulated products should take heed of Justice Breyer's comments. Urging a federal regulatory agency, or the Department of Justice, to adopt a pro-preemption position in an *amicus* brief in a particular product liability case may not be enough. Manufacturers or their trade associations also should consider petitioning a federal regulatory agency to promulgate regulations, or issue guidance, on the preemptive effect of the statutes that it administers following notice-and-comment rulemaking or other proceedings that provide opportunity for agency consideration of stakeholders' and the public's views.