

# CLIENT UPDATE

## SUPREME COURT EXPANDS “IMPOSSIBILITY” PREEMPTION TO DESIGN DEFECT CLAIMS AGAINST GENERIC DRUG MANUFACTURERS

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On June 24, 2013, the U.S. Supreme Court issued a ruling in *Mutual Pharmaceutical Co., Inc. v. Bartlett* expanding the reach of the Court’s developing “impossibility” preemption doctrine. Specifically, the Court held that state law design defect claims that impose a duty to alter generic drug labeling inconsistent with federal law are preempted under *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), which held that state-law failure-to-warn claims are preempted by the federal “Sameness Requirement”<sup>1</sup> applicable to generic drug manufacturers. In so holding, the *Bartlett* Court vacated a controversial 2012 decision by the U.S. Court of Appeals for the First Circuit, *Bartlett v. Mutual Pharm. Co., Inc.*, 678 F.3d 30 (1st Cir. 2012), which held that a generic drug manufacturer can satisfy conflicting state and federal duties by simply ceasing production of the drug in question.

Mutual Pharmaceutical Co. produced sulindac, a nonsteroidal anti-inflammatory drug (NSAID) which is the generic equivalent of the branded drug Clinoril. The plaintiff was prescribed Clinoril and dispensed the generic sulindac. Soon thereafter, she developed a permanently disfiguring case of toxic epidermal necrolysis. At the time of the plaintiff’s prescription, sulindac’s label did not contain a specific warning relating to toxic epidermal necrolysis, but did warn that the drug could cause severe, and potentially fatal, skin reactions.

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<sup>1</sup> The “Sameness Requirement” mandates that any generic drug must have the same chemical composition and product labeling as its branded drug equivalent. See 21 U.S.C. § 355(j)(2)(A).

The plaintiff brought suit in New Hampshire state court, asserting a state law claim for design defect. Following a trial in which much of the evidence focused on the adequacy of sulindac's labeling, the jury found Mutual Pharmaceutical liable and awarded over \$21 million in damages. On review, the First Circuit affirmed, holding that the state-law design defect claim was not preempted because, although Mutual Pharmaceutical could not change either the drug composition or drug labeling of sulindac consistent with federal law, it could have complied with both state and federal law by ceasing production altogether.

### **FIRST CIRCUIT'S "STOP-SELLING" RATIONALE "IS NO SOLUTION"**

The Court rejected the First Circuit's "stop-selling" rationale, holding that such an escape hatch would render impossibility preemption "all but meaningless." Slip Op. at 15 (internal quotations omitted). The Supreme Court determined that the duty imposed by New Hampshire tort law required Mutual Pharmaceutical to either change the design of sulindac to ameliorate the risk or to strengthen the warnings in the drug labeling. Because federal law requires that a generic drug have the same chemical composition as its branded equivalent, *see* 21 U.S.C. § 355(j)(2)(A)(ii)-(v), redesign was not possible.

Given that impossibility, the only way for Mutual Pharmaceutical to escape liability and satisfy the duty imposed by New Hampshire tort law was to "strengthen the presence and efficacy of sulindac's warning." Slip Op. at 11 (internal quotations omitted). As a result, although pleaded as a design defect claim, the cause of action in reality imposed a duty to change sulindac's labeling. Federal law mandates that generic drug labeling be identical to that of its branded equivalent. *See* 21 U.S.C. § 355(j)(2)(A)(v). It was therefore "impossible for Mutual Pharmaceutical and other similarly situated manufacturers to comply with both state and federal law," Slip Op. at 13, and therefore the warning-based design defect cause of action was preempted.

### **SIGNIFICANCE FOR PHARMACEUTICAL COMPANIES BATTLING STATE-LAW CLAIMS**

The *Bartlett* decision is the latest in a series of recent Supreme Court decisions, including *PLIVA, Inc. v. Mensing* and *Wyeth v. Levine*, 555 U.S. 555 (2009), addressing impossibility preemption in the context of pharmaceutical products. *Bartlett* is significant in several respects, not least because it confirms that, for purposes of preemption, it is not appropriate for a court to conclude that a pharmaceutical manufacturer can comply with opposing state and federal legal requirements by simply ceasing to sell a product.

*Bartlett* also clarifies that the preemptive reach of *PLIVA vs. Mensing* is not limited to failure-to-warn claims, but covers any state-law cause of action that would require a

pharmaceutical manufacturer to change its product labeling in a manner inconsistent with federal statutes and regulations. Pharmaceutical manufacturers are often subjected to a wide range of state-law claims in connection with the sale of their products, including negligence, design defect, failure to warn, fraud, misrepresentation, and breach of warranty, as well as violations of consumer protection statutes. Many of these state-law causes of action may in application seek to impose duties on pharmaceutical manufacturers to change their product labeling in order to provide additional safety warnings or disclosures—changes that may be inconsistent with federal statutes and regulations or require pre-approval by the U.S. Food and Drug Administration.

Both branded and generic pharmaceutical manufacturers facing state-law claims should carefully study the state-law duties being imposed to determine whether those duties may impossibly conflict with obligations under federal law. This includes analyzing whether the FDA has taken specific action with respect to product labeling that may conflict with a state-law duty. In addition, although the *PLIVA*, *Wyeth*, and *Bartlett* decisions all arose in the context of personal injury claims, companies should evaluate the impact of impossibility preemption on economic loss claims such as breach of warranty, fraud, and misrepresentation.

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Please do not hesitate to contact us with any questions.

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