Client Alert.

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Supreme Court to Hear Design Defect Preemption Case

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Generic drug manufacturers were encouraged on Friday when the Supreme Court granted *certiorari* in the case of *Mutual Pharmaceutical Co. v. Bartlett*, No. 12-142 (on appeal from the First Circuit, *Bartlett v. Mutual Pham. Co.*, 678 F.3d 30 (1st Cir. 2012)). The petition asked the Supreme Court to determine the outer edges of what seemed clearly decided in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011): whether design defect claims against generic drug manufacturers are preempted by federal law. While *Mensing* held that failure to warn claims against generics are preempted because generic labeling must be identical to brand drug labeling, *Bartlett* concerns a design defect claim. Plaintiff alleged that even though the generic drug had to be the "same" as the branded drug, the manufacturer should have withdrawn the generic from the market.

The facts underlying the *Bartlett* case are undeniably tragic. The plaintiff, Karen Bartlett, was prescribed generic sulindac for shoulder pain and developed Stevens-Johnson Syndrome/toxic epidermal necrolysis (SJS-TEN), which left her permanently injured and disfigured. *Bartlett*, 678 F.3d at 34. By the time of trial, the only remaining claim for the jury to decide was whether sulindac was defectively designed. *Id.* The jury awarded Bartlett $21.06 million in compensatory damages. *Id.*

On appeal, Mutual argued that design defect claims against generic companies are preempted by federal requirements that generic drugs be the "same" as brand name drugs in all material respects. *Id.* at 37. Mutual pointed to *Mensing* and its holding that the "sameness" provisions make it impossible for generic manufacturers to comply with federal labeling requirements and stricter state law requirements arising from failure to warn claims. *Id.*

Although the First Circuit recognized that "Mutual cannot legally make sulindac in another composition," the jury verdict was upheld because Mutual "certainly can choose not to make the drug at all . . . ." *Id.* This decision marked a departure from numerous cases that had previously rejected a duty to recall. *See, e.g., Lance v. Wyeth, 4 A.3d 160 (Pa. Super. Ct. 2010); Moore v. Mylan, Inc., 840 F. Supp. 2d 1337, 1352 n.14 (N.D. Ga. 2012); Coney v. Mylan Pharms, Inc., No. 6:11-cv-35, 2012 WL 170143, at *5 (S.D. Ga. Jan. 19, 2012); In re Fosamax Prods. Liab. Litig. (No. II), MDL 2243, 2011 WL 5903623, at *6 n.5 (D.N.J. Nov. 21, 2011).*

The *Bartlett* opinion mobilized the generic pharmaceutical industry, prompting an amicus brief by the Generic Pharmaceutical Association ("GPhA"). The GPhA urged the Court to accept *certiorari* in light of Congress's intent to make generic drugs more accessible through the Hatch-Waxman Amendments. Allowing *Bartlett* to stand "would drive generics from the market—essentially winding back the clocks to 1983, when skyrocketing healthcare costs prompted Congress to take action in the first place." GPhA Amicus Brief, at 18-19.

While generic pharmaceutical manufacturers and the plaintiffs' bar are sure to monitor *Bartlett* with a close eye, if *Bartlett* is affirmed the implications are likely to reach far beyond just the pharmaceutical industry. A duty to withdraw from the

market could potentially affect any product manufacturer subject to federal requirements. Under *Bartlett*, any "conflict" with federal law could simply be avoided by withdrawing a product from the market, essentially eliminating all implied preemption defenses. Where the Court is leaning may become more apparent during oral argument, which is likely to occur in March, and product manufacturers should look for the Court's opinion around June 2013.

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