Litigation Update

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Court Upholds Preemption Of Design Defect Suits Involving Drugs

(Mutual Pharmaceutical Co. v. Bartlett)

U.S. Supreme Court

The U.S. Supreme Court held today that federal law preempts state-law product liability suits alleging that a generic prescription drug is defectively designed, where the drug has been determined to be safe and effective by the Food and Drug Administration (FDA). The Court explained that such suits make it impossible for generic manufacturers to comply with both federal and state law because federal law does not permit them to alter either the composition of their drug or its labeling, yet such alterations are the only way that they can avoid liability under state tort law.

The 5-4 decision in *Mutual Pharmaceutical Co. v. Bartlett* was a victory for the Washington Legal Foundation (WLF), which filed a brief urging the Court to find in favor of federal preemption. WLF argued that state law judgments against a pharmaceutical manufacturer that are based on a determination that the drug is defectively designed undermine the new-drug approval process by calling into question FDA's decision that a drug's benefits outweigh its risks.

"WLF agrees with the Court that Congress intended to preempt suits that allege that a drug is unreasonably dangerous and thus defectively designed," said WLF Chief Counsel Richard Samp in response to the Court's decision. "Federal law impliedly preempts such common law causes of action because Congress has made clear that it looks solely to FDA to make those sorts of determinations," Samp said.

The case before the Court involved a generic drug, *i.e.*, a drug approved for marketing based solely on its bioequivalence to a drug that has previously been approved by FDA. WLF nonetheless urged the Court to rule that preemption of design defect claims applies not only to the generic drug manufacturers but also to manufacturers of brand-name drugs. Ruling more narrowly, the Court did not address whether its preemption decision applies to brand-name drugs. The Court noted that New Hampshire – the State whose tort law was applied in this case – considers the adequacy of product labeling in determining whether a product is defectively designed. Thus, if New Hampshire determines that a product's safety risks outweigh its usefulness, the only way that a drug manufacturer can avoid imposition of tort liability is to strengthen safety warnings included on its label. Yet, the Court noted, a decision it issued in 2011 held that a generic manufacturer (unlike brand-name manufacturers) is not entitled to make unilateral changes in its labeling; rather, it must use the labeling mandated by FDA. The Court thus determined that New Hampshire law is preempted because the only option it provides for avoiding liability – strengthening health warnings in product labeling – makes it impossible to comply with both federal and state law.

The case involves a New Hampshire woman who suffered serious and permanently disabling injuries after taking sulindac, an FDA-approved drug manufactured by Mutual Pharmaceutical Co. Sulindac has been widely used to treat arthritis since 1978. Mutual began marketing its generic form of sulindac in 1991 after the patent held by the brand-name pharmaceutical company expired. In order to keep down the costs of generic drugs, federal law prohibits FDA from requiring generic manufacturers to do their own safety testing; rather, they are entitled to rely on FDA's prior determination (following extensive safety testing by the brand-name manufacturer) that the drug is safe and effective.

A jury applying New Hampshire law awarded the plaintiff $21 million in damages, including $16.5 million in non-economic damages. A federal appeals court upheld the judgment, rejecting Mutual's argument that federal law preempted the jury's determination that sulindac was defectively designed because its risks outweighed its benefits.

In overturning the appeals court, the Supreme Court agreed with WLF that the tort suit is preempted by federal law because it is impossible for Mutual to comply with both federal law and New Hampshire law (*i.e.*, the jury's determination that sulindac is defectively designed as a matter of New Hampshire law). It noted that FDA does not permit drug companies to change the design (*i.e.*, the chemical composition) of their drugs in order to eliminate a design defect perceived by a State. Thus, Mutual could comply with both sets of requirements only by going out of business. The Court said that, under its established case law, "impossibility" preemption is established if the only way for a company to comply with both federal and state law is to stop manufacturing the product in question.

WLF further argued that preemption applies regardless whether the defendant is a brand-name manufacturer or (as here) a generic manufacturer. It noted that a brand-name manufacturer has no more rights under federal law than does a generic manufacturer to alter the design of an FDA-approved drug in order to comply with a determination under state law that the current design is defective.

The Washington Legal Foundation is a public interest law and policy center with supporters in all 50 States. WLF devotes a significant percentage of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government.

For further information, contact WLF Chief Counsel Richard Samp, (202) 588-0302. A copy of WLF's brief is posted on its web site, www.wlf.org.