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Supreme Court Ruling Preempts State Law Design Defect Claims For Generic Drugs

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On June 24, 2013, the generic drug industry let out a collective sigh of relief. That is when the United States Supreme Court issued its highly anticipated ruling in *Mutual Pharmaceutical Co. v. Bartlett*. In a huge win for the giant generic drug industry, the Court, in a 5-4 decision written by Justice Alito (and joined in by Chief Justice Roberts and Justices Scalia, Kennedy and Thomas) held that state law design defect claims that turn on the adequacy of a generic drug's warnings are preempted by the FDC Act and under the Supreme Court's 2011 decision in *PLIVA, Inc. v. Mensing*, 131 S.Ct.2567 (2011).

Background

The drug at issue in *Bartlett* is Sulindac tablets, a non-steroidal anti-inflammatory drug. Mutual Pharmaceutical Co. markets the drug under an Abbreviated New Drug Application, FDA-approved in 1991. Mutual's product is a generic version of Merck's Clinoril tablets, which FDA approved in September 1978 under a New Drug Application. In December 2004, Karen Bartlett's doctor prescribed her Clinoril for shoulder pain. However, when Bartlett filled her prescription, instead of dispensing Clinoril, Bartlett's pharmacist dispensed Sulindac, Clinoril's generic equivalent. In rare instances, Sulindac has been known to cause allergic reactions known as Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis. Both SJS and TEN cause the skin to deteriorate by either being burned off or turning into an open wound. As a direct result of using Sulindac, Bartlett began suffering from SJS and TEN in early 2005. Between 60-65% of the skin on Bartlett's body either disintegrated or became an open sore.

Bartlett's Claim in the Lower Courts

The Bartletts filed a lawsuit against Mutual alleging a number of claims, including breach of warranty, fraud, negligence, design defect and manufacturing defect. These claims were ultimately winnowed down to a state law design defect claim that proceeded to trial. Specifically, the claim was that "Sulindac's risks outweighed its benefits making it unreasonably dangerous to consumers, despite the FDA having never withdrawn its statutory safe and effective designation that the original manufacturer had secured." A jury eventually awarded respondent over $21 million in damages. The Federal District Court denied various post-trial motions filed by Mutual, including Mutual's renewed preemption defense based on the Supreme Court's decision in *Mensing*.

Mutual appealed the trial court's decision to the First Circuit, which affirmed the District Court's decision. The First Circuit found that *Mensing* merely "carved out an exception to *Wyeth*, finding that the FDCA preempts failure to warn claims against generic drug manufacturers . . . [because] the generic maker cannot alter the label." That is, the Supreme Court "adopted a

general no preemption rule in *Wyeth* . . . ." Based on this, the First Circuit concluded that to avoid state tort law liability a company could simply stop making its generic drug product.

Supreme Court Holding in Favor of the Generic Pharmaceutical Industry

Mutual Pharmaceutical's petition for Writ of Certiorari to the Supreme Court presented the following question:

> Whether the First Circuit erred when it created a circuit split and held—in clear conflict with this Court's decisions in *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011); *Regal v. Medtronic, Inc.*, 552 U.S. 312 (2008); and *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)—that federal law does not preempt state law design defect claims targeting generic pharmaceutical products because the conceded conflict between such claims and the federal laws governing generic pharmaceutical design allegedly can be avoided if the makers of generic pharmaceuticals simply stop making their products.

The Supreme Court's holding overturning the First Circuit's decision is summarized in Justice Alito's opening paragraphs below:

> We must decide whether federal law preempts the New Hampshire design defect claim under which respondent, Karen Bartlett, recovered damages from Petitioner Mutual Pharmaceutical, the manufacturer of Sulindac, a generic, non-steroidal, anti-inflammatory drug (NSAID).
>
> New Hampshire law imposes a duty on manufacturers to ensure that the drugs they market are not unreasonably unsafe, and a drug's safety is evaluated by a reference to both its chemical properties and the adequacy of its warnings. Because Mutual was unable to change Sulindac's composition as a matter of both federal law basic chemistry, New Hampshire's design defect cause of action effectively required Mutual to change Sulindac's labeling to provide stronger warnings. But, as this Court recognized, just two terms ago in *PLIVA, Inc. v. Mensing*, 564 U.S. (2011), federal law prohibits generic drug manufacturers from independently changing their drugs' labels. Accordingly, state law imposed a duty on Mutual not to comply with the federal law. Under the Supremacy Clause, state laws that require a private party to violate federal law are preempted and, thus, are "without effect."
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> The Court of Appeals' solution—that Mutual should simply have pulled Sulindac from the market in order to comply with both state and federal law—is no solution. Rather, adopting the Court of Appeals' stop selling rationale would render impossibility preemption a dead letter and work a revolution in this Court's preemption case law.

> Accordingly, we hold that state law design defect claims that turn on the adequacy of a drug's warnings are preempted by federal law under *PLIVA*. We thus reverse the decision of the Court of Appeals below.

In two separate dissenting Opinions, Justice Breyer and Sotomayor take issue with the majority's decision. For his part, Justice Breyer does not believe that it is literally impossible for a generic drug manufacturer to comply with conflicting state and federal law.

For her part, Justice Sotomayor sees the majority decision as expanding the scope of impossibility preemption, leaving injured consumers without any remedy. "Today, the Court unnecessarily and unwisely extends its holding in *Mensing* to preempt New Hampshire's law governing design defects with respect to generic drugs . . . . If our established preemption principals were properly applied in this case, and if New Hampshire law were correctly construed, then federal law would pose no barrier to Karen Bartlett's recovery."

The net effect of the *Bartlett* decision is to insulate generic drug manufacturers from liability for the injuries caused by its failure to provide appropriate warnings regarding the risks associated with its products.

Impact on Public Safety

"Generic drug manufacturers' inability under current regulations to update the labeling of their products poses a threat to the safety of prescription drugs, creating unnecessary risks to patients," stated Michael Carome, M.D., Director of Public Citizen's Health Research Group.

To assess the scope of the safety gap, Public Citizen looked at significant labeling changes made after a generic drug came on the market during a five-year period. The organization found 53 drugs for which the FDA required a new black box warning—the most serious type of warning, calling attention to serious or life-threatening risks—after a generic entered the market. Of the 53, 11 are currently marketed only as generics, while 38 are still marketed in both brand name and generic versions. One is sold only as a brand name drug, and 3 are no longer sold at all.

With many drugs, the dangers take years—sometimes decades—to emerge. Reglan, for instance, was approved in various forms between 1979-1983 to treat gastrointestinal issues. It received its first black box warning in 2009—more than 30 years later—after doctors discovered it could cause tardive dyskinesia, a serious, irreversible movement disorder. When the FDA announced the warning, more than 2,000,000 people were taking products containing the drug.

Similarly, Darvon, was first approved for pain relief in 1957, and Darvocet in 1972. The FDA called for an additional black box warning in 2009 due to the risk of overdose when used with other pain medications. At the FDA's request, manufacturers took the drugs off the market in 2010—53 years after Darvon first came onto the market—citing the potential to cause serious heart damage.

Where Do We Go From Here?

Patient safety and compensation for those who have been injured by improperly labeled generic drugs will only happen if Congress changes the law or the FDA promulgates regulations that permit and require parity between brand name and generic manufacturers. Several Congressmen and Senators have petitioned the FDA in the aftermath of the *Bartlett* decision urging expedited revisions to the FDA's drug labeling regulations to enable generic manufacturers to update patient safety labeling. Fortunately, it appears that the FDA is listening and recognizes the danger posed by improperly labeled generic drugs. FDA has proposed regulation changes that would allow generic manufacturers the ability to submit label changes through the "changes being effected" (CBE) creating parity between brand name and generic manufacturers with respect to CBE labeling supplements. Creating parity will require that generic manufacturers update their label, provide proper warnings to their consumers and would presumably remove the preemption roadblock for victims, like Bartlett, in pursuing compensation for injuries and harm in the Courts.