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Defending Design Defect Claims? High Court Has Your Back

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Law360, New York (June 28, 2013, 5:35 PM ET) -- On June 24, 2013, the U.S. Supreme Court ruled 5-4 that under *PLIVA Inc.* v. *Mensing* (2011), state-law design defect claims against generic drug manufacturers that turn on the adequacy of a drug's warning are preempted by federal law. The court in Mutual Pharmaceutical Co. Inc. v. Bartlett — in a highly anticipated move — soundly rejected the First Circuit Court of Appeals' rationale that because Mutual could have opted to stop selling the drug, impossibility preemption did not apply.

Bartlett further insulates generic drug manufacturers from state tort liability and forecloses one plaintiffs' strategy that emerged in the wake of Mensing — pursuing design defect claims against them. Bartlett will also conclusively end the "stop-selling" rationale that a minority of courts have adopted.

An open question is how Bartlett will impact state design defect claims against branded pharmaceutical companies. Attorneys representing drug companies certainly will argue that its reasoning applies to all pharmaceutical design defect claims.

Background

The Supreme Court decision reversed a $21 million jury verdict against Mutual in favor of Karen Bartlett, who developed toxic epidermal necrolysis after taking generic sulindac manufactured by Mutual in December 2004. In 2005, the U.S. Food and Drug Administration recommended changes to the labeling of all nonsteroidal anti-inflammatory drugs (NSAIDs) — including sulindac — to more explicitly warn against the risk of toxic epidermal necrolysis.

However, this change came only after Bartlett developed the rare skin condition, which left her severely disfigured and permanently disabled.

Bartlett sued Mutual in New Hampshire state court, asserting both failure-to-warn and design defect claims. Following removal to federal court, the district court dismissed the failure-to-warn claims after Bartlett's doctor admitted to never reading the drug label or insert. The case proceeded to trial on a design defect theory.

The Opinion

The court focused its preemption analysis on whether New Hampshire's design defect cause of action imposed a duty or "requirement" on Mutual that conflicted with federal law. It ultimately concluded, over a strongly worded dissent by Justice Sotomayor, that New Hampshire's design defect cause of action essentially imposed on Mutual a duty to strengthen sulindac's label, which a generic company could not do. As such, the court viewed the case as on all fours with Mensing and found it to be preempted.

The court began its analysis by noting that under New Hampshire law, the duty to sell a product that is not unreasonably dangerous can be satisfied in one of two ways: by

changing the product's design or by strengthening its warnings. Because Mutual could not change its drug's design ("as a matter of federal law and basic chemistry"), the court found that the state-law duty to ensure that a product is not "unreasonably dangerous" "boils down" to one thing — a state-law duty to strengthen the warning.

As in Mensing, the court found that it was impossible for Mutual to comply with both its state-law duty to strengthen the warnings on sulindac's label and its federal-law duty not to alter sulindac's label. The court rejected the dissent's argument that strengthening the warning was not a "legal obligation" that New Hampshire law imposed on Mutual but simply an action that Mutual might be incentivized to take to avoid state tort liability.

Whether imposed by a jury under the common law or by the legislature in a statute, a state-imposed obligation is a legal duty. The court held that a state cannot impose a legal duty to take steps that federal law prevents.

Finally, the court rejected as "incompatible with [its] pre-emption jurisprudence" the First Circuit Court of Appeals' reasoning that Mutual could escape the impossibility of complying with both its federal and state law duties if it simply stopped selling sulindac. The court explained that in every instance where it has previously found impossibility preemption, the "direct conflict" between federal and state law duties could easily have been avoided if the regulated actor simply ceased acting.

Even in Mensing, the impossibility could have been overcome in that way; indeed, as the court pointed out, the plaintiff in Mensing urged just that.

Implications of the Opinion

Bartlett represents the latest in a line of Supreme Court precedent governing the state tort liability of brand-name and generic drug manufacturers.

In Wyeth v. Levine (2009), the Supreme Court held that failure-to-warn claims brought by personal injury plaintiffs against brand-name manufacturers were not preempted by federal law. The court found that brand-name manufacturers could comply with both state and federal law obligations by strengthening their warnings through the FDA's "changes being effected" (CBE) process.

In its 2011 Mensing decision, however, the court held that federal law preempted failure-to-warn claims against generic manufacturers because, unlike their brand-name counterparts, generic companies could not utilize the CBE process.

Bartlett now extends Mensing to preempt state-law "warning-based" design defect claims against generic drug manufacturers. But Bartlett calls into question whether there are any nonwarning-based claims left to make. The court reasoned that Bartlett's design defect claim "boil[ed] down" to an adequacy of the warning inquiry. The logic of that reasoning does not stop with generic products.

This is because, in finding that Mutual could not alter sulindac's design, the court explained that any change in the chemical composition of a drug yields "a new drug ... requir[ing] its own [new drug application]." Neither brand nor generic companies can unilaterally change the chemical composition of its drug, rendering compliance with state and federal law impossible.

To the majority, this is the essence of impossibility preemption. To Justice Sotomayor, this reaches too far. She recognized in her dissent that a drug manufacturer's legal inability to unilaterally change its products' designs was true of both brand-name and generic manufacturers. She therefore accused the majority of conferring de facto immunity to all drug companies from pure (i.e., nonwarning-based) design defect liability.

Finally, in recognizing that any change in a drug's design results in a new drug and that certain drugs — like sulindac — are simply "chemically incapable" of being redesigned, the Bartlett court casts doubt generally on the viability of design defect claims in the context of pharmaceuticals.

This further supports the rationale behind comment k to §402A of the Restatement (Second) of Torts, which holds that "unavoidably unsafe" products are not defective if accompanied by proper warnings.

Looking Forward

Notwithstanding its language about warning-based design defect claims and its having arisen the generic drug context, the Supreme Court appears to implicitly recognize that alternative designs are simply not possible in the prescription drug context and consequently, that all design defect claims are effectively failure-to-warn claims.

Thus, the opinion will undoubtedly be helpful to those seeking to defend against "pure" design defect claims or to bolster a comment k argument.

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