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Lawyers React To High Court's Generic-Drug Liability Ruling

Law360, New York (June 24, 2013, 7:46 PM ET) -- The U.S. Supreme Court ruled 5-4 Monday that users of generic drugs cannot bring state-law design defect claims against generics makers because the manufacturers cannot change a drug's design under federal law. Here, attorneys tell Law360 why the ruling is significant.

Susan Burnett, Bowman and Brooke LLP
"By one vote, the court declined to radically expand the notion of strict liability to encompass state law claims that a product maker must either exit the market or become an insurer against harm and rejected the dissenting justices' view that these two options make it 'possible' to comply with both state and federal law. This is a welcome development for both generic and brand companies. In dicta, the court left open the possibility of a 'stop selling' design defect claim that parallels the federal misbranding statute — i.e., based on 'new' scientific information not provided to the FDA. We should expect plaintiffs to scramble to come up with data they can call 'new' and argue was not presented to the FDA."

Lauren Colton, Hogan Lovells
"The court has, in essence, reinforced the dual-liability system for generic and brand-name drugs, which will broadly impact the practice of medicine, law and business: First, insured patients may urge physicians to prescribe brand-name products, which physicians generally may do under generic substitution laws. Second, the number of courts seeking to impose liability on brand-name manufacturers for injuries caused by generics will likely increase, as has happened in failure-to-warn cases. See, e.g., Wyeth Inc. v. Weeks. Finally, with generic manufacturers theoretically liability free for design and warning defect claims, concerns are increased for brand-name manufacturers, which may drive commercial considerations such as pricing and product withdrawal."

Joseph G. Falcone, Herbert Smith Freehills LLP
"[Mutual Pharmaceutical Co. Inc. v. Bartlett] precludes the practice, seen in various generic drug cases following Pliva v. Mensing, of repackaging state law failure-to-warn claims as design defect claims. The majority rejects the First Circuit's sweeping rationale that a product manufacturer is not entitled to a preemption defense because it can avoid state and federal law conflicts by removing its products from the relevant market. This stop-selling approach, per the majority, was both incoherent and incompatible with its prior preemption cases. This result arguably is not limited to generic-drug makers or even the pharmaceutical industry."

Paulyne A. Gardner-Smith and Louis H. Kozloff, Nelson Levine de Luca & Hamilton LLC
"The Bartlett decision is not surprising. A different decision would have created a conceptual conflict in how the preemption doctrine is applied to generic pharmaceutical companies. In Mensing, the Supreme Court sided with generics, and held that failure-to-warn claims were preempted because FDA regulations required generics' labeling to be identical to the brand's. In Bartlett, the court extended the reasoning to FDA regulations requiring that a generic drug be chemically identical to the brand. If the sameness requirement for labeling compels preemption in failure-to-warn claims, the sameness requirement for the chemistry should likewise compel preemption."

Ron Goldman, Baum Hedlund Aristei & Goldman PC
"The Bartlett decision is yet another notch in the Supreme Court majority's continued onslaught depriving consumers of their historic right to seek justice when they become victims of corporate misfeasance, let alone malfeasance. This opinion is in line with the philosophy that exalts corporate protectionism at the expense of the victims of their wrongdoing. Indeed, this mindset of 'the corporate five' is content to allow corporate 'rights' to trump those of human beings, an odd reversal of law and philosophy in this country."

Tripp Haston, Bradley Arant Boult Cummings LLP
"Bartlett logically extends the court's prior ruling in Pliva v. Mensing and further strengthens federal preemption of product liability claims against generic pharmaceutical manufacturers. The decision shuts down plaintiffs' creative efforts to 'plead around' Mensing by dressing up failure-to-warn claims in design-defect garb. The court recognized that a pharmaceutical product's design is inherently coupled with the product's FDA-approved label, or prescribing information. Therefore, any change in product design necessarily requires a change in labeling. Considered together, Bartlett and Mensing embody a potent defense for generic pharmaceutical manufacturers that meet their federal regulatory obligations."

Angela M. Higgins, Baker Sterchi Cowden & Rice LLC
"While Bartlett is expressly limited to the generic-drug context, it presents a tantalizing glimpse of the court's potential receptiveness to similar arguments regarding supposed feasible safer alternative design in the context of branded pharmaceuticals. The court noted that redesign of the generic drug was not possible for two reasons, the first being requirements that the generic be equivalent to the branded drug, but the second, and more interesting to branded manufacturers, being that an alteration to the chemical composition of the drug results in an entirely different drug that would require new FDA approval."

Tarek Ismail, Goldman Ismail Tomaselli Brennan & Baum LLP
"Bartlett will be of interest to brand manufacturers for primarily two reasons. First, the court makes clear that the risk-utility test for design defect claims imposes strict, not absolute, liability, and thus the feasibility of alternative warnings is a factor in imposing 'strict' liability for brand manufacturers. Second, the court rejected the argument that impossibility preemption does not apply when the manufacturer could simply stop selling the product. This holding, that ceasing to sell is irrelevant to impossibility preemption, should be equally applicable to brand manufacturers, who are similarly under FDA mandate in a variety of contexts."

John Lavelle, Morgan Lewis & Bockius LLP
"In Bartlett, the Supreme Court today confirmed that state law design defect claims against a generic-drug manufacturer that turn on the adequacy of warnings are impliedly preempted as a matter of law. As [Justice Samuel Alito] wrote for a 5-4 majority, because a generic manufacturer cannot change the approved drug's composition or labeling under federal law, it would be impossible to comply with both federal law and a state law duty imposed by a jury to alter the composition or labeling. ... The Supreme Court's decision today should foreclose future efforts to evade preemption by asserting the manufacturer could have simply 'stopped selling' the product."

Victoria Davis Lockard, Greenberg Traurig LLP
"Although we could also see new complaints attempting to plead a 'parallel claim' in the form of a design defect claim that 'parallels' the federal misbranding statute, as plaintiffs have done in the medical device arena, even if such a claim theoretically could survive preemption, the evidentiary burden of showing the availability of 'new and scientifically significant information' would be prohibitive in virtually all cases."

Payam Moradian, Adli Law Group PC
"The decision seems unfair. A generic pharmaceutical company can avoid liability while at the same time taking away profits from an NDA pharmaceutical company who would likely be liable under similar circumstances."

Roger Morris, Quarles & Brady LLP
"Today's decision provides generic-drug makers with almost 'bulletproof' protection from tort liability when choosing to produce a generic drug. Not only are generic-drug makers immune from adequate warnings on labels — see Pliva v. Mensing — today the court holds generic-drug maker Mutual Pharmaceutical Co. Inc. harmless for alleged design defect of the active ingredient in its medication. Generic-drug consumers appear to have little to no remedy in tort claims against generic-drug makers. This may cause more patients to pause before requesting a generic drug from their pharmacist and a review of federal law by Congress."

Peter Neger, Bingham McCutchen LLP
"Today's Supreme Court ruling in favor of the generic-drug manufacturer shouldn't be rocking anyone's world. It was pretty predictable, given the trend in pharmaceutical and device preemption jurisprudence coming out of the court in the last several years — most notably, [Riegel v. Medtronic Inc.] and Pliva. The principal outlier — Wyeth v. Levine, which upheld a Vermont tort law claim against a federal preemption argument — was written by [since-retired Justice John Paul Stevens] over a vigorous dissent by [Justice Samuel Alito], who wrote the majority opinion in today's decision. Moreover, the decision is fully consistent with the principles underlying the Hatch-Waxman Act."

David Oliver, Vorys Sater Seymour and Pease LLP
"Bartlett had tried to avoid Pliva by arguing that FDA regulations are mandates whereas New Hampshire tort laws are mere 'incentives,' so that it was not impossible for Mutual to comply with both since it was only required to comply with one, the federal, and was free to 'exit the market' in New Hampshire. ... Noting that New Hampshire's courts have repeatedly declared that 'liability without negligence is not liability without fault,' the Supreme Court decided New Hampshire's product liability jurisprudence is akin to the usual 'complementary' regulatory function exercised by the states in such cases. Since the manufacturer could not simultaneously provide only the FDA-mandated warning and a different warning in New Hampshire, and because a molecule cannot be redesigned without turning it into something else, the court determined that this case triggered 'impossibility preemption.'"

Courtney Saleski, DLA Piper
"In my opinion, the court's decision is not surprising and correct, in light of the court's preemption precedents including Pliva Inc. v. Mensing. This was a fairly straightforward conflict between state and federal law because, as the court recognized, avoiding liability under New Hampshire law required, in effect, the generic medicine manufacturer to either alter the composition of the medication or alter its label and federal laws 'prohibit [generic-medicine] manufacturers from unilaterally altering drug composition or labeling.'"

Marc J. Scheineson, Alston & Bird LLP
"Today's decision is a significant victory for the generic-drug industry. The decision, and the preemption of state tort law that it embodies, will likely encourage continued development of generic drugs at lower costs. However, the FDA may now be encouraged to eliminate generics from the market more quickly based on the improved safety profile of new innovators, similar to the restricted development of non-abuse-deterrent oxycodone. State attorneys general may also use this decision to argue that FDA can no longer depend on the product liability system to prevent generic manufacturers from making and selling generic copies of dangerous drugs."

Scott Smith, Nilan Johnson Lewis PA
"The breadth of the Supreme Court's rejection of the 'stop selling' argument in Bartlett stands out as extremely significant, affecting not just generic-drug manufacturers, but potentially all manufacturers of U.S.-regulated products. Since 2011's PLIVA Inc. v. Mensing decision, the importance of conflict or 'impossibility' preemption has grown in importance, with manufacturers increasingly arguing they cannot simultaneously comply with federal standards governing product design, manufacture and labeling and also state common-law tort duties imposing higher standards. By pointing to its entire 'impossibility' preemption jurisprudence, the Supreme Court arguably signaled that the 'stop selling' argument cannot circumvent 'impossibility' preemption in any context where that doctrine applies."

Dr. Gurpreet Walia, Cohen & Gresser LLP
"The decision reaffirms the fundamental principle of the Hatch-Waxman Act: Generic manufacturers must follow FDA requirements for pharmaceutical compositions and labels. A manufacturer of generic drugs cannot change a generic drug's design or labeling under federal law, and therefore should not be penalized for following federal law. By clarifying this issue, the court has removed an obstacle to Hatch-Waxman and the availability of generic drugs. Having more generic drugs in the market inevitably produces economic and health benefits, including reduced medical costs and increased availability of critically important medication to patients throughout the United States."

Mike Walsh, Strasburger & Price LLP
"Three things I would watch for: First, Congress may render Mensing inapplicable by taking a look at the bill proposed by [Sen. Patrick Leahy, D-Vt.,] permitting generic manufacturers to revise labeling; second, tort claimants may refocus on emerging issues such as alleging violations of state statutes that parallel the [Federal Food, Drug and Cosmetic Act]; and third, post [Sorrell v. IMS Health Inc.] and [U.S. v. Caronia], the FDA's power to limit a manufacturer's dissemination of truthful information has been seriously questioned. With today's decision, the court has not addressed misbranding claims and the stage may be set for potential state tort law duties, particularly as they relate to the use of the Internet and social media."

David J. Walz, Carlton Fields
"The Bartlett opinion should conclusively end the 'stop-selling rationale' that plaintiffs have used to attempt an end run around the court's prior holding in Pliva Inc. v. Mensing. More subtly, Bartlett will impact design defect claims generally by its recognition that prescription drugs are different than other products as a matter of 'basic chemistry.' Prescription drugs aren't like lawn mowers. Changing a prescription drug's design, which is its chemical composition, fundamentally alters the drug into another compound. Courts testing design defect claims against prescription drugs should view them in this unique light under Bartlett."

--Editing by Katherine Rautenberg.