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U.S. Supreme Court Bartlett Decision in Favor of Generic Drug Manufacturers

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In a 5-4 decision issued today, the United States Supreme Court held that state law design defect claims against manufacturers of generic pharmaceuticals are preempted by federal law when the claim hinges on the adequacy of the drug's warning. In the case at issue, the plaintiff argued at trial that the maker of sulindac (a generic form of the nonsteroidal anti-inflammatory drug Clinoril) was liable on a defective design theory because the drug "was unreasonably dangerous and had an inadequate warning." Finding that it would have been impossible for the manufacturer to have complied with both the FDA's regulations promulgated under the Hatch-Waxman Amendments and state tort law duties, the Court reversed the First Circuit's decision affirming a $21 million verdict in favor of the plaintiff based on the premise that the defendant manufacturer could have complied with both federal and state law by choosing not to make the drug.

Because generic drugs must be chemically equivalent and bioequivalent to the brand-name drug and utilize warning labels that are the same as the brand-name's, generic manufacturers are "prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients or in the specifications provided in the approved application'" and they are "prohibited from making any unilateral changes to a drug's label." *Mutual Pharmaceutical Co. Inc. v. Bartlett*, No. 12-142, Slip op. at 3-4 (U.S. June 24, 2013), 570 U.S. ___ (2013). To satisfy their duty to provide products that are not "unreasonably dangerous" under New Hampshire law, however, manufacturers must either change the drug's design or its labeling. *Id. 9-11*. According to the Court, because redesigning sulindac was not possible under the FDCA and because of the drug's simple composition, "New Hampshire's design-defect cause of action imposed a duty on [the defendant] to strengthen sulindac's warnings." *Id. at 10-11*. And, as the Court held in its decision in *PLIVA v. Mensing*, 113 S.Ct. 2567 (2011), "federal law prevents generic drug manufacturers from changing their labels." *Id. at 13*. Federal law thus prohibited the manufacturer of sulindac from taking the action required by New Hampshire law, and the plaintiff's state law design defect claims based on the adequacy of the drug's warnings were preempted. *Id.*

The Court rejected the First Circuit's reasoning that it was not "impossible" for the manufacturer of sulindac to comply with federal and state law because it could have simply stopped selling the drug. *Id. at 14-16*. Indeed, the Court recognized that the adoption of the "stop-selling" theory would mean that *PLIVA* as well as most other cases involving impossibility preemption were wrongly decided. *Id. at 16*.

In conclusion, the Court acknowledged the "passionate responses" engendered from the often serious injuries in products liability cases, "[b]ut sympathy for [the plaintiff] does not relieve [the Court] of the responsibility of following the law." *Id. at 17*.

For more information on how the *Bartlett* decision affect you, or if you have questions on other drug and device issues, please contact the author of this alert or any of our other Drug, Device & Life Science attorneys throughout the Firm.