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ALERT

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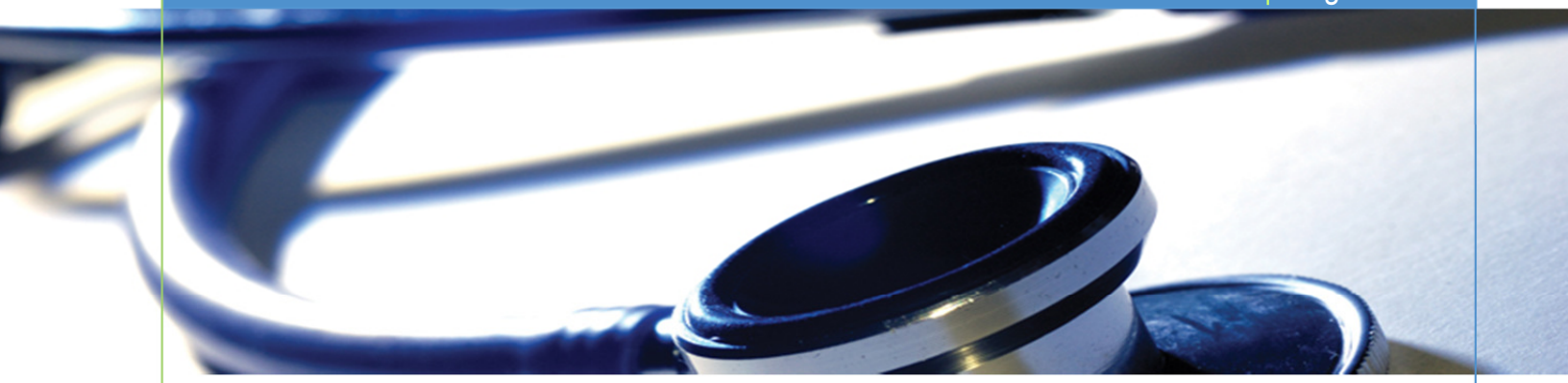

Supreme Court Extends *PLIVA* to Preempt Certain Design Defect Claims Against Generic Manufacturers

In *Mutual Pharm. Co., Inc. v. Bartlett*, No. 12-142 (U.S. June 24, 2013), the Supreme Court, in a 5—4 decision building on *PLIVA, Inc. v. Mensing*, 564 U. S. ___ (2011), held that the Food, Drug, and Cosmetic Act preempted a state law design defect action against a generic drug manufacturer that turned on the adequacy of warnings.

The case involved the application of New Hampshire state law to a generic version of Clinoril, a popular non-steroidal anti-inflammatory drug (NSAID), known as sulindac, manufactured by Mutual. In a very small number of patients, NSAIDs—including both sulindac and popular NSAIDs such as ibuprofen, naproxen and Cox2-inhibitors—have the serious side effect of causing two hypersensitivity skin reactions characterized by necrosis of the skin. At the time the plaintiff was prescribed sulindac, the drug's label did not specifically refer to toxic epidermal necrolysis, but did warn that the drug could cause "severe skin reactions" and "[f]atalities." Only the package insert indicated that one of those reactions is necrosis of the skin.

Soon after taking the drug, the plaintiff developed an acute case of toxic epidermal necrosis, causing about 65 percent of the surface of her body to burn off or turn into open wounds. She filed suit against Mutual, alleging that the drug was defectively designed. A defective warning claim was not in the cards because her prescribing physician admitted that he did not read the black box label or the package insert. A jury returned a $21 million verdict in her favor.

New Hampshire requires manufacturers to ensure that the products they design, manufacture and sell are not "unreasonably dangerous." The New Hampshire Supreme Court has recognized that this duty can be satisfied either by changing a drug's design or its labeling. Mutual could not change the design, because a generic drug of the type at issue, by definition, is one that uses the same active ingredient as the branded product. Nor could Mutual change its labeling because, under federal law (the FDCA and *PLIVA*), Mutual's labeling had to comport with the labeling of the branded product. The court of appeals

held, and plaintiff had argued, that Mutual had a third viable option, namely it could cease selling the drug.

The Supreme Court disagreed. Since it was impossible for Mutual and other similarly situated manufacturers to comply with both state and federal law, "New Hampshire's warning-based design-defect cause of action is pre-empted with respect to FDA-approved drugs sold in interstate commerce." The Court also brushed aside the court of appeal's suggestion that Mutual could stop selling sulindac "as incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.'" The Court noted that "sympathy for respondent does not relieve us of the responsibility of following the law."

Justice Alito wrote the majority opinion. Justices Breyer, Kagan, Sotomayor and Ginsburg dissented.

This *GT Alert* was prepared by **Robert P. Charrow**. Questions about this information can be directed to:

- Robert P. Charrow | 202.533.2396 | charrowr@gtlaw.com
- Or your Greenberg Traurig attorney

Albany 518.689.1400	**Denver** 303.572.6500	**New York** 212.801.9200	**Silicon Valley** 650.328.8500
Amsterdam + 31 20 301 7300	**Fort Lauderdale** 954.765.0500	**Orange County** 949.732.6500	**Tallahassee** 850.222.6891
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Austin 512.320.7200	**Las Vegas** 702.792.3773	**Philadelphia** 215.988.7800	**Tel Aviv^** +03.636.6000
Boca Raton 561.955.7600	**London*** +44 (0)203 349 8700	**Phoenix** 602.445.8000	**Tysons Corner** 703.749.1300
Boston 617.310.6000	**Los Angeles** 310.586.7700	**Sacramento** 916.442.1111	**Warsaw~** +48 22 690 6100
Chicago 312.456.8400	**Mexico City+** +52 55 5029.0000	**San Francisco** 415.655.1300	**Washington, D.C.** 202.331.3100
Dallas 214.665.3600	**Miami** 305.579.0500	**Seoul∞** 82-2-369-1000	**West Palm Beach** 561.650.7900
Delaware 302.661.7000	**New Jersey** 973.360.7900	**Shanghai** +86 21 6391 6633	**White Plains** 914.286.2900