SCOTUS: State Law Design-Defect Claim Alleging Inadequate Drug Label Warning is Pre-empted by Federal Law

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On June 24, 2013, the United States Supreme Court issued an opinion in *Mutual Pharmaceutical Co., Inc.* v. *Bartlett*, finding that state-law design-defect claims that turn on the adequacy of a drug's warnings are preempted by federal law under *PLIVA, Inc.* v. *Mensing*. Under the Supremacy Clause, state laws are impliedly preempted where it is impossible for a party to simultaneously comply with both state and federal requirements. In Bartlett, the Court determined that it was impossible for Mutual Pharmaceutical ("MP") to comply with both the federal duty of a generic drug maker not to alter a drug's label or chemical composition, and the state duty to either strengthen the drug's warnings or change its design to prevent it from being "unreasonably dangerous." The Court found that the First Circuit's reasoning – that MP could escape the impossibility of complying with both its federal and state-law duties by ceasing sale of the drug or continuing to sell and paying compensation as a cost of doing business – was incompatible with the Court's pre-emption jurisprudence. The Court, in a 5-4 opinion, reversed the First Circuit and reaffirmed the protection PLIVA grants generic drug manufacturers faced with the impossibility of complying with both U.S. Food and Drug Administration ("FDA") and state requirements.

Attorney

- Charles A. Gilman