Supreme Court Rules on Generic Drug Labeling Preemption

July 29, 2011

On June 23, 2011, the Supreme Court rendered its decision in *Pliva, Inc. v. Mensing* holding that FDA regulations governing generic drug products directly conflict with and preempt state laws that would require generic drug manufacturers to modify the FDA-authorized labeling for their products to provide "adequate warnings" as defined by state law. The Court distinguished its earlier decision in *Wyeth v. Levine*, 21 U.S.C. 555 (2009), which held that similar state law requirements were not preempted by federal drug regulations that apply to brand-named prescription drug products. Justice Thomas authored the majority opinion, which reverses rulings by the Fifth and Eighth Circuits, and Justices Ginsburg, Breyer, and Kagan joined Justice Sotomayor's dissenting opinion.

The federal preemption decision is helpful to generic drug manufacturers, and the ruling has broader implications for companies that confront conflicts between the requirements imposed by federal versus state law. Click here for more information about this case.