ALERTS AND UPDATES

Supreme Court Orders Ninth Circuit to Revisit Preemption Ruling Against Generic OTC Ibuprofen Manufacturer

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During its October 28, 2011, conference, the U.S. Supreme Court remanded to the Ninth Circuit its ruling denying federal preemption to a generic manufacturer of ibuprofen to be reassessed in light of the Court's *Mensing* decision last term. The remand potentially presents an opportunity for the Supreme Court to consider the scope of federal preemption in the context of over-the-counter medications.

The claims in *Perrigo v. Gaeta* arose from serious injuries—including the necessity of a liver transplant—sustained by a minor allegedly caused by a toxic reaction to generic, over-the-counter ibuprofen that he received following surgery to remove moles. The minor's parents brought an action against the manufacturer of the generic ibuprofen, L. Perrigo Company, contending, among other things, a failure to warn of the hepatoxic risks of ibuprofen when used in conjunction with Halothane, an anesthetic which the pediatric patient had received during the surgery.

In *Gaeta*, the Ninth Circuit reversed a district court decision dismissing the case on federal preemption grounds, finding that state-law-based duty-to-warn claims were not preempted by the Hatch-Waxman amendments to the federal Food, Drug, and Cosmetic Act (the "Act"). The circuit court reasoned that the Act provides generic manufacturers with various means to comply with their state law duties to warn that would not violate federal law. Subsequent to the Ninth Circuit's decision, the Supreme Court in *Pliva v. Mensing* held that state-law-based failure-to-warn claims were preempted by the U.S. Constitution's Supremacy Clause because generic drug manufacturers could not unilaterally strengthen drug warnings without violating federal law, and the conflict between state law requirements and federal generic drug regulations made it impossible for generics to comply with both. Now, the Supreme Court has asked the Ninth Circuit to reconsider its decision in Gaeta in light of the *Mensing* opinion.

Unlike in *Mensing*, which involved prescription pharmaceutical metoclopramide, at issue in *Gaeta* is whether a "savings clause" included in the federal regulation governing nonprescription drugs, 21 U.S.C. § 379r, precludes a preemption finding. For over-the-counter medicines, like the ibuprofen at issue in *Gaeta*, and unlike the regulatory scheme involved in *Mensing*, Congress included a savings clause—a clause used to differentiate the boundaries of state and federal authority and to *preserve* state law products liability claims—when enacting § 379r. That provision states that "[n]othing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State."

What Are the Potential Implications of the Remand?

In a case decided shortly before *Mensing*, the Supreme Court held that a federal motor-vehicle safety regulation promulgated under legislation with a similar savings clause did not preempt a products liability suit because the state-law-based tort action, when considered under traditional preemption principles, did not conflict with federal regulations. In *Williamson v. Mazda Motors*, after considering a seat-belt regulation at issue there, the Supreme Court found that a savings clause in the National Traffic and Motor Vehicle Safety Act did not preclude state court products liability claims because there were no overriding federal policies that were adversely impacted by allowing the plaintiff's suit to proceed. In a prior

Supreme Court case, *Geier v. American Honda Motor Co.*, the Supreme Court reached an opposite conclusion, evaluating a different motor-vehicle safety regulation under the same savings clause. *Gaeta* may now present an opportunity for the Ninth Circuit, and potentially the Supreme Court as well, to consider whether claims involving generic over-the-counter medications are entitled to the same preemption bar as generic prescription pharmaceuticals under *Mensing*.

For Further Information

If you have any questions about the information addressed in this *Alert*, please contact Sharon L. Caffrey, Alan Klein, Fletcher W. Moore, any member of the Products Liability and Toxic Torts Practice Group or the attorney in the firm with whom you are regularly in contact.

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