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NEWS

Winston Files Reply Brief in U.S. Supreme Court's First Review of Hatch-Waxman Drug Competition Provisions

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Earlier this week, Winston & Strawn LLP filed a reply brief in *Caraco Pharmaceutical Labs., Ltd*. v. *Novo Nordisk A/S* (No. 10-844), the U.S. Supreme Court's first case involving the Hatch-Waxman Act's provisions governing competition between generic and brand-name pharmaceuticals. The issue—whether the Act enables generics to correct branded drug makers' filings with FDA that overstate the scope of the brands' patents, causing FDA to block generic marketing—is vitally important to patients, FDA, and the $300 billion pharmaceutical industry.

Drugs approved by FDA often have multiple uses—some patented and some unpatented. In that situation, the Act allows generics to market a drug for specific uses not claimed by any patent. But FDA defers to brand-name drug makers' descriptions of the scope of their patents. Thus, a brand can block FDA's approval of a generic drug by submitting overbroad descriptions of its patent to the agency, such that a patent covering one use of the drug is effectively expanded to cover non-infringing uses. Here, Novo, brand-name manufacturer of repaglinide, a diabetes drug, overstated the scope of its patent's coverage, leading FDA to deny Caraco approval to sell generic repaglinide for uses that all agree are non-infringing.

The question presented boils down to whether the Act remedies such gamesmanship. A fractured Federal Circuit panel said it does not. But on behalf of Caraco, Winston & Strawn successfully sought Supreme Court review, and the United States has since weighed in on Caraco's side. As Winston's reply brief demonstrated, the Act *does* remedy situations where brands overstate their patents, thereby manipulating FDA into blocking concededly non-infringing drugs.

Argument is scheduled for December 5, 2011.

The Winston & Strawn team involved in this matter included partner Chuck Klein.

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