

U.S. Supreme Court Grants Winston's Petition for Certiorari on Behalf of Generic Drug Manufacturers

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In a case with major implications for the \$300 billion pharmaceutical industry, the U.S. Supreme Court recently granted Winston & Strawn's petition for certiorari on behalf of generic drug manufacturers Caraco Pharmaceutical Labs Ltd. and Sun Pharmaceutical Industries Ltd. The case presents the question whether courts hearing cases under the Hatch-Waxman Act may order brand-name drug makers' to correct inaccurate descriptions of their patents submitted to the FDA, where those descriptions erroneously suggest that the patents cover FDA-approved uses of a drug that are no longer within a patent's claims. Winston's petition for certiorari was one of just four cases this year that garnered the support of the U.S. Solicitor General, and the case has received extensive media coverage—in publications ranging from *Law360* to the *Wall Street Journal*.

In the article "Prandin Use Code Case Taken up by High Court," featured in the June 26, 2011 issue of *Law360*, the publication described Winston's representation in the case which has been ongoing for six years, and has been watched closely by many in the generics industry.

Beginning in 2005, Novo sued Caraco for patent infringement after Caraco filed an abbreviated new drug application to launch a generic version of Prandin. During the litigation, Novo changed its patent description (referred to as a "patent use code") submitted to the U.S. Food and Drug Administration. Novo's new, broadly worded patent use code prevented FDA from confirming that Caraco's generic drug would be labeled solely for non-patented uses, thus blocking Caraco's application. Caraco filed a counterclaim under the Hatch-Waxman Act, and the district court entered an injunction that required Novo to restore its original patent use code. The Federal Circuit reversed in a panel ruling that splintered three ways, with the majority holding that the Hatch-Waxman Act does not authorize such a counterclaim. The Federal Circuit's ruling creates a loophole in the law that can delay generic drug competition. The U.S. Supreme Court agreed to review the case.

After the Federal Circuit reversed the injunction, the merits of Novo's infringement claim were tried before Judge Cohn of the Eastern District of Michigan. The district court found Novo's patent invalid because of obviousness and unenforceable due to inequitable conduct before the U.S. Patent and Trademark Office. Novo filed an appeal before the Federal Circuit, which is pending.

Representing Caraco is Winston & Strawn partner [Chuck Klein](#) based in Winston's Washington, D.C. office.

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Charles B. Klein