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SUPREME COURT PERMITS GENERICS TO SUE TO "CORRECT" PATENT LISTINGS

(*Caraco Pharm. Labs. v. Novo Nordisk A/S*)

The U.S. Supreme Court ruled today that generic drug companies are authorized to sue brand-name companies based on claims that the latter, when listing their drug patents with the Food and Drug Administration (FDA), have described the patents too broadly.

The decision was a setback for the Washington Legal Foundation (WLF), which filed a brief in *Caraco Pharm. Labs. v. Novo Nordisk A/S* in support of the position of brand-name companies. WLF argued that federal law does not authorize generic drug companies to file such suits and that authorizing them would further undermine the value of patent rights.

"While expanding the circumstances under which generic manufacturers are permitted to file legal challenges to the exclusive marketing rights of pioneer manufacturers may result in a slight decrease in drug prices in the near term, we are concerned that it will undermine the long-term interests of the American health care system," said WLF Chief Counsel Richard Samp following the Court's decision. "Decreasing the value of drug patents inevitably leads to decreases in the research and development expenditures vital to the development of new, life-saving medical products," Samp said.

The case arose in connection with efforts by Caraco Pharmaceutical Laboratories, Ltd. to win FDA approval to market a generic version of repaglinide, a drug used to treat Type 2 diabetes. Currently, Respondent Novo Nordisk has exclusive marketing rights to repaglinide, which it sells under the brand name PRANDIN. FDA has approved three uses for repaglinide, one of which involves treating Type 2 diabetes in combination with metformin. Novo's patent on repaglinide itself expired in 2009, but it holds a method-of-use patent (the " '358 patent") covering the use of repaglinide in combination with metformin. Accordingly, drug manufacturers wishing to obtain permission from FDA pursuant to an Abbreviated New Drug Application (ANDA) to market a generic version of repaglinide must demonstrate that they are capable of doing so without infringing the '358 patent; FDA will not approve an ANDA unless it believes that the generic manufacturer's marketing plans will not entail infringement of any patents.

FDA makes that determination on the basis of information listed in the Orange Book, an FDA document that lists every FDA-approved drug and every patent that covers the patent. In accordance with federal law, Novo listed the '358 patent in the Orange Book. Based on that listing, FDA to date has not approved Caraco's ANDA.

Caraco thereafter filed a claim against Novo (as part of on-going federal court proceedings), asserting that Novo's Orange Book listing did not accurately describe the '358

patent and that the inaccuracy was preventing Caraco from winning FDA approval for its ANDA. In 2011, the U.S. Court of Appeals for the Federal Circuit dismissed Caraco's claim, holding that federal law did not permit generic companies to seek judicial review of the accuracy of Orange Book listings. The Supreme Court's ruling today reversed the Federal Circuit's decision and reinstated Caraco's suit.

Prior to 2003, federal law did not permit generic companies to file any sort of challenge to Orange Book listings. Case law had determined that policing the accuracy of the Orange Book was the sole responsibility of FDA. In 2003, Congress amended the Hatch-Waxman Act to permit generic companies, in a limited number of circumstances, to file challenges to Orange Book listings. In its brief filed in support of the Federal Circuit's holding, WLF argued that Caraco's claim was not encompassed within the 2003 Amendments. Those amendments permit a generic company to seek judicial review of a claim that a pioneer drug company never should have been permitted in the first instance to list its patent in the Orange Book – because the patent claimed neither the FDA-approved drug itself nor a method of using the drug. WLF argued that the 2003 Amendments were inapplicable to Caraco's case because the '358 patent indisputably *does* claim a method of using repaglinide. Caraco objected only to the manner in which Novo described the '358 patent, not to the fact that the patent was listed at all, WLF noted. The Supreme Court conceded that the 2003 statute was ambiguous, but it adopted Caraco's interpretation and held that Congress intended to permit broad challenges to Orange Book listings.

WLF also argued that Congress, in adopting the Hatch Waxman Act and later amendments, sought to maintain a careful balance between the rights of pioneer drug manufacturers and generic manufacturers. WLF argued that judicial expansion of the rights of generic companies to sue patent holders would upset that balance and, by decreasing the value of patents, would decrease the incentives to invest in new medical technologies. Today's decision did not address the "careful balance" argument.

WLF is a nonprofit public interest law and policy center with supporters in all 50 states. WLF devotes a significant portion of its resources to efforts designed to protect the economic and civil liberties of individuals and businesses.

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For further information, contact WLF Chief Counsel Richard Samp, (202) 588-0302. A copy of WLF's brief is posted on its web site, www.wlf.org.