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COURT DECLINES TO LIMIT JURISDICTION OVER UNCONTESTED PATENT CLAIMS (*Forest Laboratories v. Caraco Pharmaceutical Laboratories*)

The U.S. Supreme Court yesterday declined to consider the issue of whether to permit a generic drug manufacturer to file suit seeking a declaration that it is not violating a patent, when the patent owner has made clear that it does not believe that the generic manufacturer is violating the patent. The Court's one-sentence order denying review in *Forest Laboratories, Inc. v. Caraco Pharmaceutical Laboratories, Ltd.* was a setback for the Washington Legal Foundation (WLF), which filed a brief urging the Court to grant review.

An appeals court ruled last year that federal courts possess jurisdiction to hear such suits. In urging the Supreme Court to review that ruling, WLF argued that federal courts lack jurisdiction over such suits because there can be no justiciable dispute when there does not exist a controversy between parties having adverse interests. WLF argued that permitting courts to exercise jurisdiction in cases of this sort would expand federal court jurisdiction well beyond limits imposed by Article III of the Constitution and would put federal courts in the business of rendering advisory opinions.

"Congress established a detailed set of rules governing the marketing of generic drugs, when it adopted the Hatch-Waxman Act in 1984," said WLF Chief Counsel Richard Samp in response to the Supreme Court's order. "If a generic drug company is unhappy with those rules, it should take its case to Congress and request a revision of the rules, not complain to a court about the fairness of those rules," Samp said.

The case concerns patents on Lexapro, a drug approved by the Food and Drug Administration (FDA) for the treatment of depression and generalized anxiety disorder. Forest Laboratories holds several patents covering the ingredients of Lexapro and/or its use. The patent on Lexapro's active ingredient is scheduled to expire in 2012, and generic manufacturers have been lining up for years to obtain FDA approval to market a generic version.

Under the Hatch-Waxman Act, the first generic manufacturer to seek FDA marketing approval is granted a 180-day exclusivity period, during which no other generic manufacturer is permitted to sell the drug. Ivax Pharmaceuticals holds that first position

with respect to each of the Lexapro patents; Caraco's application is well down the line in terms of its application date.

Caraco has concluded that if it were to obtain a court judgment that its marketing application does not infringe a secondary Lexapro patent (the '941 patent, scheduled to expire in 2023), Ivax's 180-day exclusivity period might be eliminated, thereby permitting Caraco to begin marketing sooner. Caraco thus filed a declaratory judgment action against Forest, even though Forest did nothing to suggest that it planned to sue Caraco for infringement, and even though -- after Caraco filed suit -- Forest granted Caraco an unconditional covenant that it would not sue.

Despite that unconditional covenant, Caraco seeks to pursue its claim that it has not infringed the '941 patent. A federal district court in Michigan dismissed the case for lack of subject matter jurisdiction, but the U.S. Court of Appeals for the Federal Circuit reversed, finding that Caraco had standing to maintain its suit. In its ruling yesterday, the U.S. Supreme Court denied Forest's petition asking the Court to review the case.

In a brief supporting Forest's petition, WLF argued that federal courts lack Article III jurisdiction to hear a suit seeking a declaration that a patent is not infringed unless the plaintiff can establish: (1) a reasonable apprehension that it will be sued for violating the patent; or (2) it is forgoing activity that it would otherwise engage in but for the likelihood that doing so would lead to a potentially ruinous patent infringement suit. WLF argued that Caraco can make neither showing in light of Forest's unconditional covenant not to sue. WLF argued that it is the absence of marketing approval from FDA, rather than any actions by Forest, that is preventing Caraco from marketing its generic version of Lexapro. It is not sufficient, to give Caraco "standing" to challenge the '941 patent, to show that a finding of invalidity might cut short Ivax's exclusivity period and allow Caraco to begin marketing its product sooner, WLF argued.

WLF is a public interest law and policy center with members in all 50 states. WLF devotes a substantial portion of its resources to defending the property rights of the business community, including patents and other intellectual property.

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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.