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

The Washington Legal Foundation (WLF) this week urged the U.S. Court of Appeals for the Federal Circuit not to permit a generic drug manufacturer to file suit alleging noninfringement of a pharmaceutical patent when the patent owner has made clear that it does not believe that the generic manufacturer is violating the patent.

In a brief filed in *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*, 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. WLF urged the appeals court to grant a petition to rehear the case; last month a panel of three appeals-court judges upheld jurisdiction and reversed the district court's dismissal of the case.

"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 after filing WLF's brief. "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 two patents held by Forest Laboratories on Lexapro, a drug approved by FDA. The first of the two patents (covering Lexapro's active ingredients) is scheduled to expire in several years, and generic manufacturers have been lining up to obtain FDA approval to market a generic version once the first patent expires. Under the Hatch-Waxman Act, the first such company 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 Lexapro; Caraco Pharmaceutical's application to sell a generic version of Lexapro was filed later.

Caraco has concluded that if it were to obtain a court judgment that its application does not infringe the second patent on Lexapro, Ivax's 180-day exclusivity period might be triggered even before it has a chance to start marketing -- thus eliminating Ivax's advantage over Caraco. Accordingly, Caraco seeks to pursue litigation against Forest, seeking a court judgment declaring that it has not infringed the second Lexapro patent. After Caraco filed its declaratory judgment action, Forest concluded that Caraco's proposed sale of generic Lexapro would not infringe the second patent. Accordingly, it gave Caraco an unconditional covenant not to sue for

infringement of that patent. (In a separate lawsuit filed by Forest, Forest alleges that Caraco infringed the first Lexapro patent by filing its application with FDA.)

Despite the unconditional covenant not to sue, Caraco seeks to pursue its declaratory judgment action. A federal district court dismissed the case for lack of subject matter jurisdiction, but the Federal Circuit reversed that decision and reinstated the lawsuit. Forest has filed a petition asking the Federal Circuit to rehear the case.

WLF argued in its brief 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 establish Caraco's "standing" to challenge the second Lexapro patent, to show that a finding of noninfringement would cut short Ivax's exclusivity period and allow Caraco to begin marketing its product sooner, WLF argued.

Before this past year, the Federal Circuit did not allow declaratory judgment actions of this type unless the plaintiff could demonstrate a reasonable apprehension that it would be sued by the patent holder. In January 2007, the Supreme Court's *MedImmune* decision rejected the "reasonable apprehension" test as unduly restrictive. It held that a company has standing to file a suit for declaratory relief if a patent infringement suit is being avoided only because the plaintiff is paying royalties to the patent owner under protest. WLF argued that while *MedImmune* expanded jurisdiction somewhat, the Supreme Court never intended to expand declaratory judgment jurisdiction to cover cases of this sort.

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.