

**FOR IMMEDIATE RELEASE****September 26, 2007**

## **COURT URGED TO LIMIT JURISDICTION OVER UNCONTESTED PATENT CLAIMS**

*(Merck & Co. v. Apotex Corp.)*

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 challenging the validity of pharmaceutical patents when the patent owner has made clear that it does not believe that the generic manufacturer is violating its patents.

In a brief filed in *Merck & Co. v. Apotex Corp.*, 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 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 patents on Fosamax, a drug approved by the Food and Drug Administration (FDA) for the treatment of osteoporosis. Merck & Co. holds ten separate patents covering the ingredients of Fosamax and/or its use. The patent on Fosamax's active ingredient is scheduled to expire in February, 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. Teva Pharmaceuticals holds that first position with respect to Fosamax; Apotex's application is well down the line in terms of its application date.

Apotex has concluded that if it were to obtain a court judgment invalidating the other nine Fosamax patents, Teva's 180-day exclusivity period might be shortened considerably. Accordingly, Apotex seeks to pursue federal court litigation with Merck, for the purpose of obtaining a court judgment declaring the nine patents invalid. After concluding that Apotex's proposed sale of generic Fosamax would not infringe any of the nine patents (and after receiving Apotex's assurances that it would not seek to begin marketing generic Fosamax until after the February 2008 expiration of the active-ingredient patent), Merck provided Apotex with an unconditional covenant not to sue over any of the Fosamax patents.

Despite that unconditional covenant, Apotex seeks to pursue its claim that the nine Fosamax patents are invalid. A federal district court in Delaware dismissed the case for lack of subject matter jurisdiction, and Apotex appealed to the Federal Circuit.

WLF argued in its brief that federal courts lack Article III jurisdiction to hear a suit seeking a declaration that a patent is invalid 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 Apotex can make neither showing in light of Merck's unconditional covenant not to sue. WLF argued that it is the absence of marketing approval from FDA, rather than any actions by Merck, that is preventing Apotex from marketing its generic version of Fosamax. It is not sufficient, to give Apotex "standing" to challenge the nine Fosamax patents, to show that a finding of invalidity would cut short Teva's exclusivity period and allow Apotex 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, the Supreme Court ruled in *MedImmune, Inc. v. Genentech* that the "reasonable apprehension" test unduly restricted federal court jurisdiction. *MedImmune* 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 to cover cases in which the declaratory judgment plaintiff 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, 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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