Litigation Update

Washington Legal Foundation
Advocate for freedom and justice®
2009 Massachusetts Ave., NW
Washington, D.C. 20036
202.588.0302

May 28, 2003

COURT DECLINES TO RECONSIDER DRUG PATENT-RIGHTS CASE

(Allergan, Inc. v. Alcon Laboratories, Inc.)

The U.S. Court of Appeals for the Federal Circuit this week declined to reconsider a decision that refused to permit a pharmaceutical company to seek recourse in the courts as soon as one of its patents is threatened by a generic drug company's announced plan to market a generic version of the drug covered by the patent.

The decision was a setback for the Washington Legal Foundation (WLF), which filed a brief urging the court to grant an *en banc* rehearing in the case and which also filed a brief in front of the three-judge panel that initially heard the case. The court's one-sentence order provided no explanation for its decision to deny rehearing.

The decision in *Allergan, Inc. v. Alcon Laboratories, Inc.* was somewhat surprising because judges on the Federal Circuit have expressed conflicting views on the subject. Indeed, the three judges who voted to bar assertion of the patent claims in this case stated that they believed that the suit should be permitted to go forward but that they felt compelled by circuit precedent to affirm the trial court's dismissal of the case.

The case raised an important patent law issue: whether a generic drug company can be sued for inducing infringement of a method-of-use patent when it files an Abbreviated New Drug Application (ANDA), seeking to market the product covered by the patent, but where: (1) the ANDA does not seek permission to market the product for the patented use; and (2) the patented use is not covered by the pioneer manufacturer's approved New Drug Application. In January 2003, another panel of the Federal Circuit ruled, in a case raising very similar facts, that federal law does not create a cause of action by the patent holder under these circumstances. *Warner-Lambert Co. v. Apotex Corp*. Despite agreeing with all of the arguments raised by WLF, the panel in this case held that it was bound by *Warner-Lambert* to dismiss the patent holder's claims.

In its brief seeking rehearing, WLF argued that permitting early resolution of patent disputes between pioneer and generic drug companies was one of Congress's principal purposes in adopting the Hatch-Waxman Act in 1984. WLF argued that the lower court decision dismissing the pioneer company's claim on ripeness grounds undermines congressional intent and ought to be reversed.

"WLF takes no position on the merits of the patent dispute in this or any other similar dispute between pioneer drug manufacturers and generic manufacturers," said WLF Chief Counsel Richard Samp after reviewing the court's decision to deny rehearing. "Nonetheless, the procedures adopted by Congress for resolving such disputes were intended by Congress to protect the rights of both groups and to adjudicate disputes as quickly as possible. Unless the courts adhere strictly to those procedures, they will be upsetting Congress's carefully crafted balance," Samp said.

The case involves efforts by Allergan, Inc. to enforce its method-of-use patent for the anti-glaucoma drug brimonidine, which it sells under the trade name Alphagan. Allergan's exclusive marketing rights for brimonidine expired in March 2002, and Alcon Laboratories, Inc. and Bausch & Lomb, Inc. filed ANDAs to market generic versions of brimonidine. Allergan has never had a patent on brimonidine itself, but it does hold two method-of-use patents that claim brimonidine as a neuroprotective agent to treat glaucoma. The two ANDAs did not seek approval to market brimonidine for the uses for which Allergan holds patents, but Allergan alleges that the only reason Alcon and Bausch & Lomb seek to market brimonidine is that doctors are likely to prescribe it for the patented uses. In response to the ANDA filings, Allergan filed an infringement suit.

When the manufacturer of an FDA-approved product holds any type of patent on the product, it lists the patent in the "Orange Book" maintained by FDA. This case turned on a provision of the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2), which authorizes an infringement suit by a patent holder when a generic manufacturer files an ANDA certifying that there is an Orange Book listing for a patent on the drug it seeks to market. The outcome of such an infringement suit will depend on whether the listed patent is valid and, if so, whether approval of the ANDA will result in infringement of the patent.

The Federal Circuit affirmed the district court dismissal of Allergan's § 271(e)(2) suit. The court said that there can be no cause of action under § 271(e)(2) until after the generic companies begin marketing brimonidine. But the three panel members stated in concurring opinions that, had they felt free to do so, they would have held that Congress did, indeed, intend to create a cause of action for companies in Allergan's position. The decision to deny rehearing *en banc* leaves that decision intact.

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.

* * *

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