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COURT URGED TO RESPECT RIGHTS OF DRUG FIRMS IN PATENT CHALLENGES

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

The Washington Legal Foundation (WLF) this week urged the U.S. Supreme Court to review an appeals court decision that denies a pharmaceutical company legal recourse when 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. WLF argued that the decision below significantly undermines the financial incentives that the patent system normally provides to induce research and development of new, life-saving therapies.

In a brief filed in *Allergan, Inc. v. Alcon Laboratories, Inc.,* WLF argued that the court below, the U.S. Court of Appeals for the Federal Circuit, ignored clear federal statutory provisions permitting patent holders to file such infringement suits. 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 appeals court's decision dismissing the pioneer company's claim for failure to state a cause of action 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 (who initially develop a drug) and generic manufacturers (who wish to market a drug after its patent has expired)," said WLF Chief Counsel Richard Samp after filing WLF's brief. "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

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 turns 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 turn on whether the listed patent is valid and, if so, whether approval of the ANDA will result in infringement of the patent.

The appeals court affirmed the district court's dismissal of Allergan's § 271(e)(2) suit. The court said that there was no cause of action under § 271(e)(2) when (as here) the patented use has not been approved by FDA and the ANDA does not seek approval for such use.

In its brief in support of Allergan, WLF argued that the Supreme Court should review the Federal Circuit's decision. WLF noted that the three members of the appeal court panel that dismissed Allergan's claims stated explicitly that they believed that § 271(e)(2) *does* provide Allergan with a cause of action but that they were compelled by existing Federal Circuit precedent to rule otherwise. WLF argued that Supreme Court review was warranted in light of the conflicting views held by Federal Circuit judges on this issue.

WLF also argued that the circuit precedent upon which the *Allergan* panel relied had misinterpreted § 271(e)(2). WLF argued that § 271(e)(2) permits infringement actions to go forward regardless whether the allegedly infringing use has been approved by FDA, so long as the patent holder can demonstrate that the ANDA filer intends either to infringe the patent or to induce others to do so. WLF also noted that the result of the panel's decision was to reduce significantly manufacturer incentives to develop new, off-label uses for their FDA-approved products. Reducing those incentives will slow the discovery of new, life-saving uses for existing products, 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. WLF also filed a brief in this case in July 2002 before the Federal Circuit.