

COURT DECLINES TO REVIEW DECISION LIMITING DRUG FIRMS' PATENT RIGHTS

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

The U.S. Supreme Court this week declined 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.

The decision not to hear the case, *Allergan, Inc. v. Alcon Laboratories, Inc.*, was a setback for the Washington Legal Foundation (WLF), which filed a brief urging the Court to review the case. 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. The Court's one-sentence order provided no explanation for its decision to deny review.

In its brief, 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 reviewing the Supreme Court's order. "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 (Abbreviated New Drug Applications) 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 FDA's "Orange Book." The decision below relied 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 urging Supreme Court review, 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 dis-

covery 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.

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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.