News Release

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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. Court of Appeals for the Federal Circuit 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.

In a brief filed in *Allergan, Inc. v. Alcon Laboratories, Inc.,* 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's brief urges the court to rehear *en banc* a case decided on March 28, 2003 by a three-judge panel of the court. WLF argued that the panel'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 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. FDA is unlikely to complete review of the ANDAs for several more months, and thus Alcon and Bausch & Lomb are not yet marketing generic brimonidine.

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 panel 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 court should rehear the case *en banc*. WLF noted that the members of the 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 rehearing 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 delay resolution of the parties' dispute until after marketing of generic brimonidine has begun. WLF argued that such delay is directly contrary to a chief purpose of the Hatch-Waxman Act, which is to expedite the resolution of patent disputes between pioneer and generic manufacturers.

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 original Federal Circuit panel.

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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.