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## COURT GIVES MIXED SIGNALS IN DRUG PATENT RIGHTS CASE

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

The U.S. Court of Appeals for the Federal Circuit issued a decision this week that provides mixed signals regarding the rights of 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. On the one hand, the court upheld the trial court's dismissal of a patent suit brought by a patent holder that alleges its patent is being infringed by a generic drug manufacturer. On the other hand, the three judges on the panel stated that they believed that the suit should be permitted to go forward but that they felt compelled by circuit precedent to dismiss the case. The decision sets the stage for a possible *en banc* rehearing before the entire Federal Circuit.

The decision is a mild setback for the Washington Legal Foundation (WLF), which filed a brief in *Allergan, Inc. v. Alcon Laboratories, Inc.*, urging that the suit be reinstated. After reviewing the decision, attorneys for WLF stated that they would support efforts to obtain a rehearing in the case. Because the three judges who heard the *Allergan* case are on record as disagreeing with their own decision, the likelihood that rehearing will be granted are reasonably high.

The case raises 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 the patented use is not covered by the pioneer manufacturer's approved New Drug Application (NDA). 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.

supporting argued that permitting early resolution of patent disputes between pioneer and generic drug companies was one 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 (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 district court dismissed Allergan's § 271(e)(2) suit. The court said that there was no cause of action under § 271(e)(2) in the absence of evidence that Alcon or Bausch & Lomb themselves were likely to infringe the patents. The court said that it was insufficient for Allergan to allege that the actions already taken by Alcon and Bausch & Lomb were likely to induce doctors to infringe the patents (by prescribing generic brimonidine for neuroprotective purposes).

In its brief in support of Allergan, WLF argued that the district court erred in dismissing Allergan's "inducing infringement" claim. The trial court held that it was prohibited under the U.S. Constitution from exercising jurisdiction over Allergan's claim, because the case was not "ripe" for review until after some infringing act has taken place. WLF argued that the district court's "no jurisdiction" argument was without merit and was based on a misunderstanding of the "case or controversy" requirement of Article III of the Constitution. WLF noted that courts regularly hear

suits in which the continued viability of the suits depends on the future occurrence of some event (in this case, approval of the ANDAs and a subsequent decision by the defendants to begin marketing brimonidine).

WLF also argued that the district court misinterpreted § 271(e)(2). WLF argued that that statute permits patent holders to proceed *either* under a direct infringement theory *or* under an inducing infringement theory. WLF also noted that the result of the district court'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 of 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.

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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](http://www.wlf.org).