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COURT OVERTURNS RULING INVALIDATING PATENT BASED ON TECHNICALITY

(SmithKline Beecham Corp. v. Apotex Corp.)

The U.S. Court of Appeals for the Federal Circuit this week overturned one of its own decisions that had invalidated a significant pharmaceutical patent based on nothing more than a minor technicality. The latest ruling in *SmithKline Beecham Corp. v. Apotex Corp.* eliminates a worrisome patent law doctrine; WLF had been sufficiently concerned that it had filed a brief in the case, urging reversal. WLF's brief warned that the initial decision by a three-judge panel incorrectly applied patent law, could have resulted in numerous patents being invalidated, and would undermine confidence in the nation's patent system as an effective means of protecting intellectual property rights.

The initial panel decision invalidated a patent based on the "public use" doctrine. The initial panel held that the patent holder had not submitted its patent application until more than one year after its first "public use" of its product -- even though the only alleged "public use" consisted of a clinical trial designed to test the product's effectiveness. The new panel decision, issued this week, eliminates all discussion of the patent holder's experimental use of its product.

The new ruling reached the same result -- it invalidated the patent -- but on an unrelated rationale. It held that the patent was invalid because its principal claim was anticipated by an earlier patent held by the plaintiff. While the new ruling has less potential to upset existing patents than did the first ruling, WLF expressed concern over the manner in which it was reached. "The new decision invalidates the patent based on an issue won by the patent holder in the trial court, not appealed by the defendant, and not briefed by the parties on appeal," said WLF Chief Counsel Richard Samp. "Before a court strikes down a patent, basic notions of due process require giving the patent holder an opportunity to address the potentially invalidating rationale," Samp said. WLF has pledged to continue its support for any further appeals filed by the patent holder.

The case involves a patent on crystalline paroxetine hydrochloride hemihydrate ("paroxetine"), which SmithKline Beecham Corp. has marketed under the name Paxil to treat depression. Paxil generates more than $1 billion in sales annually. The initial panel decision turned on whether SmithKline made "public use" of paroxetine in the U.S. more than a year before it applied for a patent in October 1986. If so, the patent would be invalid under the "public use bar," 35 U.S.C. § 102(b).

The record is uncontested that SmithKline never offered paroxetine for sale before 1986; indeed, sales did not begin until after FDA approved paroxetine in 1993 for treatment of depression. Rather, the generic manufacturers who are challenging the patent point to a clinical trial undertaken by SmithKline beginning in March 1985. The trial was a tightly controlled, double-blind study of paroxetine, designed to determine whether it was effective in treating depression.

The trial court rejected the "public use" challenge to the patent, ruling that the clinical trial did not constitute public use of the drug. The court noted that experimental use of a product, undertaken for the purpose of testing the product, has never been deemed a public use of the product sufficient to trigger the public use bar. But the Federal Circuit reversed by a 2-1 vote. The appeals court held that a clinical trial undertaken to determine whether a product has any utility does not qualify as an experimental use; rather, it qualifies as experimental use only if the clinical trial tests the product for a specific claim set forth in the patent application. Because SmithKline's application sought a patent on paroxetine itself, rather than a specific method of using paroxetine, its pre-patent clinical trial constituted a "public use," the appeals court held.

In its brief urging the Federal Circuit to grant a rehearing before all the judges on the appeals court, WLF argued that the panel's decision directly conflicted with numerous court decisions regarding the scope of the public use bar. WLF argued that the purpose of the public use bar is to prevent an inventor who has granted outsiders general access to his product to later seek to reclaim the invention for himself. WLF argued that the well-controlled clinical study undertaken by SmithKline is in no way comparable to an inventor who has allowed the public unrestricted access to his product before seeking a patent. WLF also argued that by invalidating a major patent based on a technicality that has no precedent in patent law, the Federal Circuit is sending a signal that it is unwilling to uphold intellectual property rights in the face of public demands for lower drug prices. WLF warned that if the panel decision were allowed to stand, other drug companies could expect similar challenges to their patents, since clinical trials of a drug's effectiveness often begin before a patent application is filed. The appeals court apparently agreed, because it voted unanimously to vacate the panel's decision and directed the panel to issue a new decision without reference to the public use doctrine.

WLF is a public interest law and policy center with supporters in all 50 States. WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. In particular, WLF has appeared in numerous federal and state courts in cases raising issues related to health care delivery.

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