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COURT URGED NOT TO INVALIDATE PATENTS BASED ON TECHNICALITIES

(SmithKline Beecham Corp. v. Apotex Corp.)

The Washington Legal Foundation (WLF) this week urged the U.S. Court of Appeals for the Federal Circuit to rehear *en banc* a case in which a three-judge panel invalidated a significant pharmaceutical patent based on nothing more than a minor technicality. In a brief filed in *SmithKline Beecham Corp. v. Apotex Corp.*, WLF argued that if allowed to stand, the initial Federal Circuit decision will undermine confidence in the nation's patent system as an effective means of protecting intellectual property rights.

"The result of the panel's decision will be a net decrease in research and development expenditures for new, life saving therapies," said WLF Chief Counsel Richard A. Samp after filing WLF's brief. "Drug companies will be less willing to invest the hundreds of millions of dollars necessary to bring those therapies to market if they lack confidence that the courts will protect their patent rights sufficiently to allow them an adequate return on investments," Samp said.

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; SmithKline's patent on the drug is not scheduled to expire until 2006. The case turns 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 patent 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 conflicts with numerous Supreme Court and Federal Circuit 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 argued that that signal harms public health, because inventors are unwilling to invest the hundreds of millions of dollars to bring new, lifesaving therapies to market if they lack confidence that the courts will uphold their patent rights. WLF argued that the panel's decision in this case is particularly objectionable because it upsets settled expectations of companies that processed patent claims based on prior case law regarding the public use bar. WLF warned that if the panel decision is allowed to stand, other drug companies can expect similar challenges to their patents, since clinical trials of a drug's effectiveness often begin before a patent application is filed.

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.