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COURT URGED TO REVIEW DECISION INVALIDATING PHARMACEUTICAL PATENT

(SmithKline Beecham Corp. v. Apotex Corp.)

The Washington Legal Foundation (WLF) yesterday urged the U.S. Supreme Court to review (and ultimately overturn) an appeals court decision that invalidated a significant pharmaceutical patent based on a finding that the drug was not "novel" when the patent application was filed in 1986 -- even though it is undisputed that if the drug existed before then, it was in such minute quantities as to be undetectable. In a brief filed in *SmithKline Beecham Corp. v. Apotex Corp.*, WLF argued that if allowed to stand, the decision of the U.S. Court of Appeals for the Federal Circuit will undermine confidence in the nation's patent system as an effective means of protecting intellectual property rights.

"The result of the appeals court'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 ("PHC hemihydrate"), which SmithKline Beecham Corp. has marketed under the name Paxil to treat depression. Paxil generates more than $1 billion in sales annually. The case turns on whether, at the time that SmithKline sought to patent PHC hemihydrate, the drug was "anticipated" (either explicitly or inherently) by the prior art. If so, the patent would be invalid for lack of novelty under 35 U.S.C. § 102(b).

Scientists invented another crystalline form of paroxetine ("PHC anhydrate") in the late 1970s, and it is possible that scientists experimenting with PHC anhydrate might have created minute quantities of PHC hemihydrate. But the record is undisputed that no one was aware of (or suspected) the existence of PHC hemihydrate until it was discovered serendipitously by SmithKline scientists in 1985, and that if PHC hemihydrate existed before then, its existence was undetectable in light of the minute quantities involved.

In its brief urging the Supreme Court to review the case, WLF argued that under the doctrine of "accidental prior use," an invention should not be deemed to have been "anticipated" by the prior art if the prior art's disclosure of the claimed invention is accidental

or unwitting and no one -- not even experts in the field -- would have recognized the existence of the disclosure. WLF argued that the SmithKline patent should have been upheld under the "accidental prior use" doctrine.

WLF argued that the Federal Circuit, in a series of recent decisions, has effectively written the "accidental prior use" doctrine out of the law. It noted that the Federal Circuit has taken the position that prior art inherently anticipates a claimed invention even if experts in the field did not and would not have been able to recognize the prior art. WLF noted that because all patent appeals now go through the Federal Circuit, only the Supreme Court is in a position to revive the "accidental prior use" doctrine.

WLF argued that the Federal Circuit's position conflicts with a series of Supreme Court decisions that date back to 1881. WLF argued that those decisions created the "accidental prior use" doctrine, and that the Federal Circuit is not free to ignore them.

WLF also argued that by invalidating a major patent based on a position that conflicts with long-settled patent law precedents, 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 "accidental prior use" doctrine. WLF warned that if the panel decision is allowed to stand, other drug companies can expect similar challenges to their patents.

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.