Washington Legal Foundation
Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

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COURT DECLINES TO RECONSIDER DECISION THAT INVALIDATED PATENT WITHOUT FAIR WARNING

(SmithKline Beecham Corp. v. Apotex Corp.)

The U.S. Court of Appeals for the Federal Circuit today declined to rehear *en banc* a case in which a three-judge panel invalidated a significant pharmaceutical patent without informing the patent holder of the grounds on which it was considering invalidating the patent, and without providing the holder with a fair opportunity to address the issue. The decision was a setback for the Washington Legal Foundation (WLF), which filed a brief urging that a rehearing be granted in the case, *SmithKline Beecham Corp. v. Apotex Corp.* WLF argued that the panel's handling of the case violated due process rights and, if allowed to stand, would undermine confidence in the nation's patent system as an effective means of protecting intellectual property rights.

"The result of today'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 reviewing the court's one-sentence order. "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. In an April 2004 decision, a panel of the Federal Circuit determined that the patent was invalid under the "public use" doctrine because (the court claimed) SmithKline had made "public use" of paroxetine in the U.S. more than a year before it applied for a patent in October 1986. The *en banc* Federal Circuit overturned that decision this spring and returned the case to the panel for consideration of other issues in the case.

On April 8, 2005, the three-judge panel once again struck down the patent -- this time finding the patent invalid on the ground that it was not novel, because it had been "inherently" anticipated by a product patented ten years earlier. What was astounding about the second decision was that: (1) the trial court had ruled against the alleged infringer on this issue; (2) the alleged infringer had not raised the issue on appeal; (3) the parties had not mentioned the issue in their appellate briefs or at oral arguments; (4) the alleged infringer did not mention the issue

in its filings in connection with *en banc* proceedings; and (5) the second decision was issued without any additional briefing or arguments and without any warning that the panel was intending to rule on an issue that had not been briefed.

In its brief urging the Federal Circuit to grant a rehearing before all the judges on the appeals court, WLF argued that the panel violated the Fifth Amendment's Due Process Clause by issuing a decision that deprived SmithKline of property rights, without providing notice of its intended action and giving SmithKline an opportunity to respond. WLF noted that had SmithKline been permitted to respond, it could have cited legal precedent supporting an argument that the alleged infringer waived the "inherent anticipation" claim (by failing to raise the issue on appeal) and could have pointed out errors in the panel's understanding of the facts relevant to the claim.

WLF also argued that by invalidating a major patent based on grounds not raised by the parties, 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 needed to bring new, lifesaving therapies to market if they lack confidence that the courts will uphold their patent rights. WLF emphasized that it did not advocate SmithKline's interpretation of its patent rights, only SmithKline's due process right to litigate an issue before having its patent invalidated.

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.