News Release

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COURT URGED TO RECONSIDER DECISION INVALIDATING PHARMACEUTICAL PATENT

(Purdue Pharma L.P. v. Endo Pharmaceuticals)

The Washington Legal Foundation (WLF) yesterday urged the U.S. Court of Appeals for the Federal Circuit to rehear a case in which a multi-billion dollar pharmaceutical patent was invalidated on the ground that, when applying for the patent in 1993, the applicant failed to provide some relevant information that the patent examiner might have been interested in learning. In a brief filed in *Purdue Pharma L.P. v. Endo Pharmaceuticals*, WLF argued that the court's decision invalidating the patent has the potential to undermine public confidence in our nation's patent system.

The patent at issue covers OxyContin, a powerful pain relief medication. A three-judge panel of the Federal Circuit ruled earlier this month that the patent should be invalidated as a penalty for alleged "inequitable conduct" committed by the drug's manufacturer, Purdue Pharma, when applying to the Patent and Trademark Office (PTO) for the patent. As a result of the ruling, Purdue Pharma now faces scores of antitrust suits from plaintiffs seeking to recover billions of dollars in alleged overcharges -- they would have paid far less for OxyContin if Purdue Pharma had not eliminated competition by claiming exclusive patent rights.

"Based on the largely trivial flaws identified by a generic competitor, an innovator drug company whose ground-breaking products have brought pain relief to millions of patients finds itself at the edge of financial ruin," WLF Chief Counsel Richard Samp said after filing WLF's brief. "By lowering the bar for those charging patent invalidity due to inequitable conduct, the appeals court has considerably weakened intellectual property rights and thereby reduced incentives for companies to invest in new, life-saving therapies," Samp said.

After Endo Pharmaceuticals, Inc. announced plans to market a generic version of OxyContin, Purdue Pharma filed a patent infringement suit. Among Endo's defenses was a claim that the patent was unenforceable because Purdue Pharma allegedly engaged in inequitable conduct in connection with its patent application. A party making such a claim faces a "heavy" burden of proof. First, the party must demonstrate by "clear and convincing" evidence *both* a misrepresentation or omission of a material fact in the patent application *and* an intent to deceive the PTO. Second, if materiality and intent are established, the party must still convince the court that the misconduct was so extremely severe that the ultimate penalty of patent unenforceability is warranted.

The trial court ruled in Endo's favor. Purdue Pharma's patent application asserted that it had "surprisingly discovered" that the controlled-release formula it had developed for administering the pain reliever oxycodone worked more effectively in humans than did existing formulas. That claim has been borne out over the past decade as millions of patients have turned to OxyContin for pain relief. But when Purdue Pharma made its "surprisingly discovered" claim, it had not yet completed any of its clinical trials of OxyContin on humans. That fact was hardly unusual; most clinical testing of new drugs is performed after a patent is obtained but before a marketing application is submitted to the Food and Drug Administration. The trial court determined that Purdue Pharma's failure to mention in its patent application that its "surprisingly discovered" claim was not supported by clinical data constituted a "material" omission, and that it acted with an intent to deceive the PTO. It found the conduct to be sufficiently inequitable to justify invalidation of the patent.

On appeal, a three-judge panel of the Federal Circuit affirmed, applying a deferential standard of review and finding that the trial judge did not abuse his discretion by invalidating the patent. In its brief urging a rehearing in front of all the Federal Circuit judges, WLF focused on the issue of intent. WLF argued that it is not enough to show (as the panel held) that the patent applicant intended to withhold the material information. Rather, WLF argued, one must show through affirmative evidence that the applicant intended to deceive the PTO. WLF argued that all the evidence in this case indicates that Purdue Pharma believed in good faith that its patent application was accurate, that no reasonable patent examiner would have assumed that Purdue Pharma had already performed clinical trials, and that the patent examiner in this case did not, in fact, make that assumption.

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.