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COURT REVERSES DECISION INVALIDATING PHARMACEUTICAL PATENT *(Purdue Pharma L.P. v. Endo Pharmaceuticals)*

The U.S. Court of Appeals for the Federal Circuit yesterday reversed its earlier decision to invalidate a multi-billion dollar pharmaceutical patent, and remanded the case to the district court to consider the invalidity issue anew.

The decision was a major victory for the Washington Legal Foundation (WLF), which filed a brief in *Purdue Pharma L.P. v. Endo Pharmaceuticals* last summer, urging the three-judge appeals court panel to reverse its prior decision. Particularly gratifying to WLF was that the panel reversed itself based on the precise arguments raised by WLF in its brief.

The case now returns to the U.S. District Court for the Southern District of New York for reconsideration of the patent invalidity issue. Based on guidance provided by the appeals court regarding how the issue should be resolved, WLF attorneys said that it was likely that the district court will ultimately uphold the patent.

The patent at issue covers OxyContin, a powerful pain relief medication. A federal district court ruled in 2004 (and the appeals court panel affirmed in June 2005) 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 those rulings, Purdue Pharma 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 was brought to the edge of financial ruin," WLF Chief Counsel Richard Samp said after reviewing the latest appeals court decision. "By lowering the bar for those charging patent invalidity due to inequitable conduct, the initial appeals court decision considerably weakened intellectual property rights and thereby reduced incentives for companies to invest in new, life-saving therapies. We are gratified that the appeals court has now recognized the error of its prior approach," 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.

Yesterday's decision affirmed the district court's finding that Purdue Pharma had failed to disclose material information to the PTO. But the panel agreed with WLF that the trial court erred in basing its key finding (that Purdue Pharma had intended to deceive) largely on evidence that the omission was material -- particularly where, as here, the materiality of the undisclosed information was (in the words of the appeals court) "relatively low." The court agreed with WLF that the "intent to deceive" finding could not stand for the additional reason that it was based in part on the trial court's erroneous understanding of certain Purdue Pharma correspondence. The appeals court also agreed with WLF that the appropriate course of action was to remand the case to the district court with instructions to: (1) reconsider the "intent" issue under a proper set of legal standards; and (2) to consider, even if "intent" could be shown, whether any Purdue Pharma conduct was sufficiently egregious to warrant the ultimate sanction of patent invalidity. The panel also affirmed the trial court's finding that Endo had infringed the OxyContin patent.

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.