News Release

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COURT URGED TO REVIEW DECISION INVALIDATING PHARMACEUTICAL PATENT

(*Aventis Pharma v. Amphastar Pharmaceuticals,* No. 08-937)

The Washington Legal Foundation (WLF) this week urged the U.S. Supreme Court to review (and ultimately overturn) an appeals court decision that invalidated an immensely valuable pharmaceutical patent on the ground that, when applying for the patent 15-20 years ago, the applicant omitted dosage information regarding previously discovered drugs. The appeals court held that the omission constituted "inequitable conduct" that warranted a ruling that the patent be deemed unenforceable.

In a brief filed in *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, 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 Lovenox, a drug approved by the Food and Drug Administration (FDA) for prevention and treatment of thromboses (*i.e.*, blood clotting). A three-judge panel of the U.S. Court of Appeals for the Federal Circuit ruled 2-1 last year that the patent should be invalidated as a penalty for alleged "inequitable conduct" committed by Aventis when applying to the Patent and Trademark Office (PTO) for the patent. The panel majority invalidated the patent despite: (1) uncontroverted evidence that the PTO would have issued the patent even if Aventis had included the omitted information; (2) the omission of the information did not mislead the patent examiner; and (3) the absence of any direct evidence that Aventis's representatives intended to deceive the patent examiner, or that he even knew that the information had been omitted.

"Based on the largely trivial flaws identified by a generic competitor, an innovator drug company whose product brought relief to hundreds of thousands of patients finds itself wholly deprived of its property rights," 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 Amphastar Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. announced plans to market a generic version of Lovenox, Aventis filed a patent infringement suit. Among the defenses raised by Amphastar and Teva was a claim that the patent was unenforceable because Aventis allegedly engaged in inequitable conduct in connection with its patent application. Historically, the Supreme Court has likened such inequitable conduct defenses to "unclean hands" claims traditionally raised by defendants in cases arising in courts of equity. Under the "unclean hands" doctrine, courts traditionally have declined to grant equitable relief (*e.g.*, an injunction) to plaintiffs who come into court with "unclean hands" -- meaning that the plaintiff has acted so unconscionably with respect to the defendant that it would be unjust to grant him the relief he requests. But the Federal Circuit has expanded the "inequitable conduct" doctrine as applied to patents in a manner that has far outstripped its narrow "unclean hands" origins, WLF charged. WLF noted that the Federal Circuit has so broadly interpreted the inequitable conduct doctrine that such defenses are now raised in the great majority of all patent infringement suits, and that some Federal Circuit judges refer to such defenses as a "plague."

WLF urged the Supreme Court to grant review in order to make clear that a patent should not be struck down on inequitable conduct grounds except in the most extreme circumstances. WLF argued that at the very least, courts should not sustain inequitable conduct defenses -- even in cases in which there are findings that the patentee intentionally withheld material information from the PTO for the purpose of deceiving that office -- without first determining that the defendant's conduct was particularly egregious, that the balance of equities favors the patent challenger, and that holding the patent unenforceable would further the public interest.

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.