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

October 1, 2007

COURT DECLINES TO HEAR CASE INVOLVING OBVIOUSNESS OF DRUG PATENTS

***(Pfizer Inc. v. Apotex Corp.*, No. 06-1440)**

The U.S. Supreme Court today declined to review an appeals court decision that undercuts patent rights by defining far too broadly the circumstances under which a patent can be invalidated on the basis of obviousness. The one-sentence order declining review was a setback for the Washington Legal Foundation (WLF), which filed a brief in the case, *Pfizer Inc. v. Apotex Corp.*, urging that review be granted.

WLF's brief argued that a newly-created drug should not be deemed non-patentable on obviousness grounds simply because it is not shown to be more *effective* than pre-existing drugs that are chemically similar. WLF argued that when, as here, a new drug exhibits improved properties (*e.g.*, superior stability, solubility, and stickiness properties) that would not have been obvious to trained chemists, the new drug is patentable without regard to whether it provides improved clinical effectiveness.

"The decision below throws into question the validity of a wide range of pharmaceutical patents," said WLF Chief Counsel Richard Samp after reviewing the Supreme Court's order. "The appeals court decision could undermine confidence in the nation's patent system as an effective means of protecting intellectual property rights, and thus reduce incentives for companies to invest in new, life-saving therapies," Samp said.

The case involves a patent on amlodipine besylate, a drug marketed by Pfizer (under the brand name Norvasc) to treat hypertension. Pfizer filed suit for patent infringement against Apotex after Apotex announced plans to market a generic version of the drug. Apotex responded by asserting that Pfizer's patent should be invalidated based on obviousness.

A federal district judge rejected that defense and upheld Pfizer's patent, finding that amlodipine besylate was superior to pre-existing versions of the amlodipine compound, in ways that would not have been obvious to one of ordinary skill in the pharmaceutical arts. In a March 2007 decision, the U.S. Court of Appeals for the Federal Circuit reversed, finding that Norvasc was, indeed, obvious at the time it was invented in 1984. The Supreme Court today declined review of that decision.

WLF's brief argued that the Federal Circuit's obviousness analysis inappropriately discounted evidence of unexpected results in an unpredictable technology. The Federal Circuit noted that the amlodipine compound was discovered in 1981 (three years prior to the discovery of amlodipine besylate), and argued that a skilled practitioner would have known to try to create an assortment of "salt" variants of amlodipine and to see which salt form provided the best combination of favorable qualities (with respect to, for example, stability, solubility, and stickiness). WLF responded that the Federal Circuit's analysis oversimplified what actually occurred. WLF noted that there were a virtually unlimited number of salt forms that Pfizer could have tested, and that a skilled practitioner would not necessarily have thought to try the besylate salt (the one eventually used in Norvasc), which has rarely been successful in FDA-approved drugs.

WLF argued that the Federal Circuit's decision calls into question the validity of numerous valuable pharmaceutical patents, because many if not most pharmaceutical inventions are discovered through a routine screening protocol or through an established trial and error process. WLF further argued that by undermining confidence in the validity of existing patents, the decision could have a profoundly negative effect on investments into the design and development of new life-saving pharmaceutical products.

WLF noted that, in *KSR International Co. v. Teleflex*, the Supreme Court recently set down a new test for determining when a patent should be invalidated based on obviousness. WLF argued that this case provided the Supreme Court with a good opportunity to consider how *KSR* should be applied in the pharmaceutical context. Noting that the Federal Circuit issued its decision before the *KSR* decision was released, WLF argued that -- at the very least -- the Supreme Court should vacate the Federal Circuit decision and remand the case with directions that it be reconsidered in light of *KSR.*

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 intellectual property rights.

* * *

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.