



October 31, 2006

COURT DECLINES TO REVIEW DECISION INVALIDATING PHARMACEUTICAL PATENT (Ferring B.V. and Aventis Pharmaceuticals v. Barr Laboratories)

The U.S. Supreme Court yesterday declined to review 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 failed to disclose to patent examiners all past relationships between the applicant and its expert witnesses.

The Court's one-sentence order declining review was a setback for the Washington Legal Foundation (WLF), which filed a brief in the case, *Ferring B.V. and Aventis Pharmaceuticals, Inc. v. Barr Laboratories, Inc.*, urging that review be granted. WLF argued that the appeals court's decision invalidating the patent has the potential to undermine public confidence in our nation's patent system.

The patent at issue covered a new, more efficient method of administering a drug used to treat diabetes insipidus. A three-judge panel of the U.S. Court of Appeals for the Federal Circuit ruled 2-1 earlier this year that the patent should be invalidated as a penalty for alleged "inequitable conduct" committed by the patent applicant when applying to the Patent and Trademark Office (PTO) for the patent. The panel majority invalidated the patent despite the absence of any evidence that: (1) the invention was not properly patentable; (2) the declarations signed by the applicant's witnesses were in any way false or misleading; and (3) the witnesses received any sort of compensation for signing their declarations. Rather, the only wrongdoing identified was the failure of the applicant to disclose that *some* of the declarants were either former employees of or consultants for Ferring B.V., the applicant's employer and the company to whom the patent was to be assigned.

"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 following the Supreme Court's order. "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 Barr Pharmaceuticals, Inc. announced plans to market a generic version of the drug in question (DDAVP), Ferring and Aventis Pharmaceuticals (Ferring's exclusive licensee) filed a patent infringement suit. Among Barr's defenses was a claim that the patent was unenforceable because the patent applicant allegedly engaged in inequitable conduct in connection with his 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 any omission by a patent applicant in his presentation to the PTO should not be deemed sufficiently "material" to warrant invocation of the inequitable conduct defense unless the defendant demonstrates that there is a reasonable likelihood that the patent would not have been issued had there been no omission. WLF argued that the defendants cannot make such a showing in this case, because: (1) there is no suggestion that any of the testimony submitted by the applicants' witnesses was in any way inaccurate; (2) the defendants failed to show that the plaintiffs' expert witnesses (all eminently well-qualified) had any incentive to present inaccurate testimony, especially given that they had no prospect of any financial gain from their testimony; and (3) the testimony of the allegedly biased declarants was 100% cumulative -- even if the courts discarded all the testimony from the three witnesses who used to work/consult for Ferring, the record would still contain virtually identical testimony from expert witnesses whose impartiality has never been challenged.

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.

* * *

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.