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COURT REOPENS ANTITRUST CHALLENGE TO PHARMACEUTICAL PATENT SETTLEMENT

(In re K-Dur Antitrust Litigation)

The U.S. Court of Appeals for the Third Circuit in Philadelphia today reinstated a lawsuit claiming that “reverse payment” settlements of pharmaceutical patent disputes amount to *per se* violations of the antitrust laws. The court acknowledged that its ruling directly conflicts with the rulings of three other federal appeals courts.

The decision in *In re K-Dur Antitrust Litigation* was a setback for the Washington Legal Foundation (WLF), which filed a brief urging affirmance of the district court’s dismissal of the suit. WLF argued that parties ought to be encouraged to settle their patent disputes. By raising the possibility that settlements will routinely be challenged under the antitrust laws, the courts are unnecessarily discouraging settlements, WLF argued.

The appeals court held that if a patent settlement includes an agreement by a generic drug company to delay entry into the market, the finder of fact must treat “any payment” from a patent holder to the generic patent challenger “as *prima facie* evidence of an unreasonable restraint of trade.” The defendants could rebut that evidence “by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.” Because the decision conflicts with decisions from the Second, Eleventh, and Federal Circuits, the U.S. Supreme Court is highly likely to review today’s decision.

“Today’s decision fails to account for the patent law’s inherently anticompetitive nature; Congress has determined that society benefits when inventors are provided monopoly profits for a finite number of years, thereby encouraging innovation,” said WLF Chief Counsel Richard Samp in response to today’s decision. “So long as a patent settlement does not prevent competition for a period that exceeds the life of a patent, the antitrust laws should be deemed inapplicable,” Samp said. WLF has pledged to support efforts to obtain Supreme Court review of the decision.

The case arose in the aftermath of a patent dispute between Schering-Plough Corp. (a pharmaceutical company that is now part of Merck & Co.) and Upshur-Smith Laboratories. Schering was the initial manufacturer of a drug known as K-Dur 20. After Upshur-Smith announced plans in 1995 to produce a generic version of K-Dur 20, Schering filed a patent infringement suit, alleging that Upshur-Smith’s generic drug violated Schering’s patent, which was not scheduled to expire until 2006. The patent dispute was eventually settled, with Upshur-Smith agreeing to delay its entry into the market until 2001.

Several drug purchasers then filed suit against Schering and Upshur-Smith, alleging that

the patent settlement violated federal antitrust laws, amounting to an illegal horizontal market allocation agreement. The plaintiffs alleged that because money flowed from Schering to Upshur-Smith in connection with the patent litigation settlement, the settlement should be presumed to be anticompetitive. They alleged that if no “reverse payment” had been made from Schering to Upshur-Smith, the parties would have reached a settlement that would have permitted an earlier market-entry date – thereby driving down prices.

A federal court in New Jersey dismissed the suit, finding that “reverse payment” patent settlements do not violate antitrust laws so long as the settlement does not expand the scope of the patent by prohibiting marketing by the generic company even after the date on which the patent is set to expire. The plaintiffs appealed that dismissal to the Third Circuit. Both the Federal Trade Commission (which has repeatedly criticized “reverse payment” patent settlements) and the U.S. Department of Justice filed briefs in support of the appeal.

In its brief, WLF argued that any blanket criticism of reverse-payment patent litigation settlements is unwarranted under the antitrust laws. WLF argued that patents are, by their very nature, anticompetitive and that courts should not permit the antitrust laws to undermine the numerous benefits derived from the patent system. A patent holder who believes in good faith that another firm is violating its patent has every right both to sue for infringement and to settle the litigation on whatever terms best protects its patent rights – even if the settlement terms entail the payment of funds to the alleged infringer, WLF argued. WLF noted that the courts have long encouraged the settlement of litigation and that the antitrust rules proposed by the plaintiffs would discourage settlements by undermining their finality.

WLF also noted that the FTC previously challenged this very same patent litigation settlement. In 2005, the Eleventh Circuit in Atlanta overturned an FTC judgment and held that Schering’s settlement with Upshur-Smith did not violate antitrust laws. In reinstating the lawsuit, the Third Circuit stated that it disagreed with the Eleventh Circuit’s analysis.

WLF is a nonprofit public interest law and policy center with supporters in all 50 states. WLF devotes a significant portion of its resources to efforts designed to protect the economic and civil liberties of individuals and businesses.

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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.