Litigation Update

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High Court Allows Antitrust Challenges To Patent Settlements

(FTC v. Actavis, Inc.)

U.S. Supreme Court

The U.S. Supreme Court today reversed an appeals court's holding that a routine agreement to settle a patent dispute does not violate federal antitrust law. In a 5-3 decision in *FTC v. Actavis*, the Supreme Court held that if a patent holder settles patent litigation by paying an alleged infringer a "large and unjustified" payment in exchange for the alleged infringer's agreement to honor the patent, a court should employ the antitrust rule of reason to determine whether the settlement violates antitrust law. In announcing this rule, the Court rejected the *per se* rule advanced by the Government, which would deem such settlement agreements presumptively unlawful.

The decision was a partial victory for the Washington Legal Foundation (WLF), which had filed a brief in the case urging the Court to reject the "*per se* illegal" standard advanced by the Government. In its brief, WLF argued that such a rule would deprive the holders of drug patents of critically important legal rights that are core attributes of any patent and unduly burden the efforts of generic drug makers to bring their products to market through the Hatch-Waxman Act.

"While we are pleased that the Court rejected the Government's *per se* test, today's decision does not go far enough in protecting patent holder's rights," said WLF Senior Litigation Counsel Cory Andrews, after reading the Court's opinion. "Far from being exposed to potential liability, parties ought to be encouraged to settle their patent disputes. By holding that such settlements may now be subject to invalidation under federal antitrust law, the Court's ruling will strongly discourage settlements," Andrews said.

The case arose in the aftermath of a dispute over the patent rights to AndroGel, a leading testosterone replacement medicine. Solvay Pharmaceuticals, Inc. (Solvay) held the patent for AndroGel, which was set to expire in 2020. After generic manufacturers Actavis, Inc., Paddock Laboratories, Inc. and Par Pharmaceuticals Companies, Inc. sought permission to produce a generic version of AndroGel, Solvay filed a patent infringement suit in 2003, alleging that any proposed generic drug would violate Solvay's patent. The patent dispute was eventually settled, giving the generic challengers the right to launch their products in August 2015 in exchange for monetary consideration.

After two years of investigation, the FTC filed suit challenging the AndroGel settlement on the basis that it violated federal antitrust laws. The district court dismissed the FTC's complaint, and the Eleventh Circuit affirmed, applying its "scope of the patent" test in rejecting the argument that settlements with reverse payments are presumptively unlawful. The U.S. Supreme Court granted

review and reversed.

In its brief urging affirmance, WLF argued that the Government's attempt to impose per say liability for reverse-payment patent litigation settlements is unsupported by the antitrust laws. WLF argued that patents are, by their 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 bot to sue for infringement and t settle the litigation on whatever terms best protects its patent rights—even if the settlement includes the payment of funds to the alleged infringer.

WLF also argued that Congress has carefully calibrated the rewards that ought to be conferred on successful inventors; that calibration has encompassed such steps as changing the number of years a patent stays in effect, adopting procedures that allow a drug manufacturer to obtain an extension of the patent term under certain circumstances, and adopting procedures that allow generic drug manufacturers to bring competing drugs to market relatively quickly. WLF argued that such measures indicate that Congress attempted to strike a careful balance between rewarding successful inventors and providing low-cost drugs to consumers. Because a robust patent system cannot operate under such a cloud of uncertainty, WLF argued that the balance struck by Congress should not be upset by a contrary rule imposed by the FTC.

WLF's brief was drafted with the pro bono legal assistance of Kevin McDonald, a partner with the Washington, D.C. office of Jones Day.

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 economic liberty, free enterprise, and a limited and accountable government.

For further information, contact WLF Senior Litigation Counsel Cory Andrews, (202) 588-0302. A copy of WLF's brief is posted on its web site, www.wlf.org.