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SUPREME COURT REBUFFS FTC'S ANTITRUST CHALLENGE TO DRUG PATENT SETTLEMENTS

(*FTC v. Schering-Plough Corp.*)

The U.S. Supreme Court this week declined a request by the Federal Trade Commission (FTC) that it review (and ultimately overturn) a federal appeals court decision that rejected FTC efforts to imposed antitrust liability on two drug companies based on the settlement of a patent dispute. The Court's order declining review was a victory for the Washington Legal Foundation (WLF), which has filed briefs throughout the case in opposition to the FTC's position.

"When litigants settle a contentious patent dispute, there is no reason to presume that the settlement is an unlawful restraint of trade, even if the result is that one party agrees not to produce a patented product," said WLF Chief Counsel Richard Samp in response to the Supreme Court's order. "A patent holder has an enforceable legal right to prevent infringing competition from others. The appeals court correctly understood that the law ought to encourage the settlement of all forms of litigation, including patent litigation, not threaten settling parties with antitrust liability," Samp said.

The case arose from patent infringement lawsuits that drug company Schering-Plough Corp. brought against Upsher-Smith Laboratories, Inc. and ESI Lederle, generic drug makers that sought to introduce generic versions of a Schering-Plough product. The companies entered into a settlement in 1997, after eighteen months of litigation. Schering-Plough agreed that Upsher-Smith could market its generic product beginning in September of 2001 – five years before the expiration of Schering-Plough's patent. Schering-Plough also agreed to pay $60 million to Upsher-Smith in return for cross-licenses of various Upsher-Smith patents. Schering-Plough and ESI Lederle entered into a similar settlement as part of a court-supervised mediation in 1998.

In a December 2003 decision, the FTC ruled that the agreements were an illegal restraint of trade. The FTC held that the payments from Schering-Plough to Upsher-Smith and ESI Lederle were unlawfully intended to delay the generic firms' entry into the market. Schering-Plough and Upsher-Smith sought review in the U.S. Court of Appeals for the Eleventh Circuit, which overturned the FTC decision.

The appeals court said that the FTC had "cavalierly dismissed" the court's previous holding in *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir.

2003), by refusing to assess the validity of the underlying patent claims in the case. The appeals court indicated that the scope of the exclusionary effect of the patent, and the extent to which the settlements exceeded that scope, was central to determining the existence of antitrust liability. The appeals court found no evidence that the patents were invalid or that the infringement claims were a "sham."

The appeals court further stated that the FTC's conclusion that the payments were intended to keep the generics off the market was "not supported by law or logic" in that the FTC had failed to consider the evidence heard by the Administrative Law Judge and the ALJ's findings regarding the credibility of witnesses. With regard to the ESI Lederle settlement, entered into with judicial approval, the appeals court stated, "We do not pretend to understand the Commission's profound concern with this settlement."

The appeals court agreed with WLF's argument that the policy of the law generally is to favor the settlement of litigation, including settlement of patent infringement suits. In the context of pharmaceutical patents, the court noted, "the caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product."

The FTC then asked the Supreme Court to review the appeals court's decision. The Supreme Court's rejection of that request was, perhaps, foreshadowed by the U.S. Department of Justice's (DOJ) view of the case. DOJ initially refused to represent the FTC in its petition to the Supreme Court, thereby forcing the FTC to represent itself. Later, after being requested by the Justices to express its views on the case, DOJ recommended that the Supreme Court deny the FTC's petition.

WLF is a public interest law and policy center with supporters nationwide. It engages in litigation and advocacy to defend and promote individual rights and a limited and accountable government, including in defense of patients' needs for medical innovation. In addition to filing a brief before the appeals court in *Schering-Plough*, WLF filed a brief before the FTC and before the Eleventh Circuit in *Valley Drug*.

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For further information, contact WLF Chief Counsel Richard Samp, (202) 588-0302. A copy of WLF's brief is available on its website, www.wlf.org.