Press Release

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ANTITRUST CHALLENGE TO DRUG PATENT SETTLEMENT OPPOSED

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

The Washington Legal Foundation (WLF) today asked the U.S. Court of Appeals for the Eleventh Circuit to overturn a ruling by the Federal Trade Commission that would impose antitrust liability on two drug companies based on the settlement of a patent dispute. The case is the latest in a series of actions by the FTC alleging that patent settlements between pioneer drug companies and generic drug companies amounted to antitrust violations.

The case arises from a patent infringement lawsuit that drug company Schering-Plough Corp. brought against Upsher-Smith Laboratories, Inc., a generic drug maker seeking to introduce a generic version of a Schering-Plough product. The companies entered into a settlement on June 17, 1997, after eighteen months of litigation. The companies 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 to produce various products of Upsher-Smith's.

The FTC, in a decision made public on December 18, 2003, ruled that the agreement is an illegal restraint of trade. The FTC held that the payment from Schering-Plough to Upsher-Smith was unlawfully intended to delay Upsher-Smith's entry into the market. Overruling its Administrative Law Judge, the FTC held that the cross-licenses obtained by Schering-Plough were not worth the $60 million that the company paid for them. "Absent proof of other offsetting considerations, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise," according to the FTC's opinion.

In its brief before the appeals court, WLF contended that the FTC's view of patent settlements with payments from pioneer drug companies to generics is commercially unrealistic and counter to federal antitrust law. WLF also argued that the Commission's ruling is further undermined by its insistence that the supposedly sham nature of the firms' patent settlement can be determined without any reference at all to the strength or weakness of the underlying patent claims. Finally, WLF argued that the FTC's position would burden pioneer firms, generic firms, and the federal courts by creating new obstacles to settlement

of patent disputes, thereby chilling both new drug innovation and new generic entry

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. For example, WLF successfully challenged the constitutionality of Food and Drug Administration restrictions on the ability of doctors and patients to receive truthful information about off-label uses of FDA-approved medicines. WLF's Legal Studies Division frequently publishes papers on legal policy issues in the areas of health care, intellectual property, and antitrust, recently including Scott P. Perlman and Lily Fu Swenson, *Avoiding Collisions at the Intersection of Antitrust and Intellectual Property Laws* (2003).

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