Litigation Update

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FTC REJECTS *PER SE* TEST IN CHALLENGES TO PATENT SETTLEMENTS

(In the Matter of Schering-Plough Corp.)

The Federal Trade Commission (FTC) has rejected claims by its own staff that agreements to settle patent disputes can amount to *per se* violations of the antitrust laws. But the FTC went on to decide that the patent dispute settlements at issue in the case before it (involving Schering-Plough Corp., Upsher-Smith Laboratories, and American Home Products (AHP)) violated the law because they unreasonably restrained commerce.

The decision was a partial victory and a partial loss for the Washington Legal Foundation (WLF), which filed a brief in the case being heard by the FTC, *In the Matter of Schering-Plough Corp.* WLF had argued both that the FTC staff's *per se* approach was faulty and that the settlement agreements being challenged by the FTC were reasonable. WLF argued that parties ought to be encouraged to settle their patent disputes. By raising the possibility that settlements will be subjected to *per se* condemnation under the antitrust laws, the FTC is unnecessarily discouraging settlements, WLF argued.

The case arose in the aftermath of a patent dispute between Schering-Plough Corp. (the initial manufacturer of a drug known by the brand name K-Dur 20) and two generic drug manufacturers, Upsher-Smith, and ESI Lederle (a division of AHP). Upsher-Smith and ESI had announced plans to produce a generic version of K-Dur 20, but Schering insisted that it still had exclusive patent rights to the drug. The patent dispute was eventually settled, with Upsher-Smith and ESI agreeing to delay their entry into the market. Schering's patent ran until September 2006; the parties agreed that Upsher-Smith could enter the market in September 2001 and that ESI could enter the market in January 2004.

The FTC thereafter filed a complaint against Schering, Upsher-Smith, and AHP, alleging that the patent settlements violated the Federal Trade Commission Act because

they amounted to illegal horizontal market allocation agreements. The FTC alleged that because money flowed from Schering to Upsher-Smith and ESI in connection with the patent litigation settlement, the settlement was a *per se* violation of the antitrust laws for which there could be no defense. An Administrative Law Judge disagreed, finding (in the case of the Schering/Upsher-Smith agreement) that money paid by Schering was solely in return for separate licenses granted to Schering by Upsher-Smith and (in the case of the Schering/ESI agreement) that the settlement should be judged under the "rule of reason" and that, under that rule, the settlement should be sustained as pro-competitive.

The FTC staff appealed to the full Commission. WLF filed its brief in connection with that appeal.

In its decision, the FTC agreed with WLF that *per se* condemnation under the antitrust laws of the defendants' patent settlement is wholly inappropriate. The FTC noted that the Supreme Court has held that business arrangements should be branded as *per se* antitrust violations with great caution and only in the few cases where sufficient experience has shown that the challenged conduct "always or almost always tend[s] to restrict competition and decrease output." The FTC agreed with WLF that a prerequisite to *per se* treatment is a long history of courts analyzing the challenged activity under the "rule of reason" and uniformly concluding that the activity is anticompetitive. WLF argued that the type of patent settlement entered into in this case has *never* been subject to *any* sort analysis by either the FTC or the federal courts; until courts and the FTC have had extensive experience with these types of settlements, they have no business short-circuiting the process of determining whether the settlements are truly anticompetitive.

The FTC disagreed, however, with WLF's argument that there were numerous valid business reasons for the settlements entered into between Schering and its generic competitors. WLF had noted in particular that the FTC staff had failed to present *any* evidence that the Schering patent was not valid and/or infringed, and thus had failed to demonstrate that the generic companies, in the absence of a settlement, could have entered the market prior to September 2006. WLF argued that patents are, by their very nature, to a certain extent anticompetitive and that courts and the FTC should not permit the antitrust laws to undermine the numerous benefits derived from the patent system. The FTC disagreed, holding that a patent settlement agreement involving payments from the patent holder to the alleged infringer can violate the antitrust laws in the absence of a good reason for such payments, even in the absence of evidence that the patent is not valid.

The defendants are contemplating an appeal to the federal appeals courts. WLF has pledged its support for any such appeal. WLF is a nonprofit pubic 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.