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LEGAL DEVELOPMENTS

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Eleventh Circuit Overrules FTC's *Schering-Plough* Decision, Possibly Reducing Antitrust Risk of Settling Patent Disputes

A recent court decision might lessen antitrust risk in settling pharmaceutical patent litigation. The settlement of such disputes has drawn increased scrutiny over the last decade, resulting in multiple consent decrees and substantial monetary damages. In particular, agreements involving so-called "reverse payments" – payments made by the patent owner to the alleged infringer – have been found by the Federal Trade Commission and various courts to violate the antitrust laws under both the *per se* rule and the rule of reason. In many cases, the merits of the underlying dispute are largely ignored and the reverse payment found to be inherently suspect. The Eleventh Circuit's decision in *Schering-Plough Corp. v. FTC*, Dkt. No. 04-10688, 2005 U.S. App. LEXIS 3811 (11th Cir. March 8, 2005), however, redirects the inquiry to the exclusionary power of the patent at issue, and rejects the idea that "reverse payments" are inherently suspect.

Background

In 1995, Upsher-Smith and ESI Lederle sought FDA approval to market generic versions of Schering's K-Dur 20 potassium supplement. Schering brought suit for infringement of its patent on the extended-release coating for the product, which will expire in September 2006.

In 1997, Schering settled with Upsher, agreeing to permit Upsher to launch as early as September 1, 2001. In the settlement, Schering agreed to pay $60 million to Upsher (and future royalties) in exchange for a license to market Upsher's Niacor product outside North America. In 1998, Schering settled with ESI, agreeing on a January 1, 2004 entry date for ESI. In addition, Schering agreed to pay ESI $5 million, with another $10 million payment contingent upon ESI receiving FDA approval by a certain date. Schering and ESI also entered into a license agreement in which ESI granted Schering licenses to enalpril and buspirone in exchange for $15 million. In both settlements, the agreed generic entry dates were earlier than the expiration of Schering's K-Dur 20 patent.

The FTC filed a complaint against Schering, Upsher and ESI parent American Home Products ("AHP"), alleging that the settlements were illegal agreements in restraint of trade. AHP entered into a consent decree, but the legality of the ESI settlement with respect to Schering was still at issue. An Administrative Law Judge ruled that the settlements did not violate the antitrust laws, finding that the presence of payments was not anticompetitive *per se*. The ALJ indicated that the strength of the patent and its exclusionary power needed to be assessed in a rule of reason analysis.

On December 8, 2003, the Commission reversed the decision, first determining that the payments were not legitimate consideration for the Schering licenses. The Commission then stated that earlier entry dates might have been agreed upon in the absence of the payments. Although not finding the reverse payments *per se* illegal, the Commission found them to be "red flags" and declined to consider the strength of the patent. Ultimately, the FTC order prohibited the parties from entering settlements in which a generic company: (i) receives anything of value (in excess of legal fees, not to exceed $2 million); and (ii) agrees to defer its own research, development, production or sales activities.

The Eleventh Circuit Decision

The parties petitioned for review before the Eleventh Circuit. In vacating the order involving Upsher, the court applied the substantial evidence standard set forth in

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California Dental Ass'n v. FTC, 128 F.3d 720, 725 (9th Cir. 1997), *rev'd on other grounds*, 526 U.S. 756 (1999), and determined that the Commission's "conclusion that Niacor was not worth $60 million and that settlement payment was to keep Upsher off the market 'is not supported by law or logic.'" *Schering-Plough*, 2005 U.S. App. LEXIS at *38. This aspect of the decision suggests that companies should enjoy greater latitude in structuring contemporaneous business deals not involving the products at issue.

In vacating the order involving ESI, the court affirmed its holding in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003). Although the *Valley Drug* court conceded that an agreement to allocate markets is "clearly anticompetitive," the court reasoned that a patent conveys an exclusionary power that requires primary consideration. Accordingly, neither the *per se* rule nor the rule of reason is appropriate and the proper analysis requires consideration of: (i) the scope of the exclusionary potential of the patent; (ii) the extent to which the agreements exceed that scope; and (iii) the resulting anticompetitive effects. At the same time, the Eleventh Circuit reaffirmed that patentees may not extend their monopoly beyond the scope of the patent. For example, a patent owner who knows a patent is invalid may not use the patent to mask otherwise anticompetitive conduct, such as market division.

Following *Valley Drug* and Judge Posner's decision in *Asahi Glass Co., Ltd. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003), the Eleventh Circuit also reasoned that reverse payments should not be inherently suspect because they are a "natural by-product" of the Hatch-Waxman regulatory regime, which allows for the patent issues to be litigated prior to generic entry. Thus, "ESI and Upsher gained considerable leverage in patent litigation: the exposure to liability amounted to litigation costs, but paled in comparison to the immense volume of generic sales and profits." *Schering*, 2005 U.S. App. LEXIS at *49-50. Under the FTC's approach, which largely ignored the exclusionary power of the patent, the Eleventh Circuit expressed concern that patent settlements would be highly risky and discouraged. The court explained that strong public policy interests favor the settlement of patent litigation and that the FTC's approach could undermine these interests.

Schering makes clear that the Eleventh Circuit discourages the second-guessing of patent settlement terms unless the litigation (or the settlement) is shown to be a sham. In fact, if the words "exclusionary potential" are read to mean the life of the patent, *Schering* supports the argument that virtually any settlement of non-sham patent litigation that is not a facade for other anticompetitive activity is permissible, even if significant monetary or other compensation flows from the patentee to the defendant. Under *Schering*, therefore, antitrust plaintiffs would be left to argue that the likelihood of the patentee prevailing on both validity and infringement issues should be taken into account in assessing the "exclusionary potential" of the patent. For example, it might be argued that the settlement of weak (though not necessarily sham) patent claims involving extraordinary payments to the defendant and significant entry delays remains open to scrutiny to determine whether the settlement merely masks an anticompetitive agreement to stay off the market. Such an argument, however, runs contrary to many aspects of *Schering* and would nonetheless encounter substantial problems of proof.

Conclusion

The FTC has played the leading role in shaping antitrust policy regarding the settlement of Hatch-Waxman patent disputes, and its reverse payment doctrine has become the centerpiece of that policy. If *Schering* remains the law of the Eleventh Circuit, however, the future of the reverse payment doctrine at the FTC is in grave doubt, because virtually all pharmaceutical cases may be appealed to that circuit. The FTC has 90 days to seek Supreme Court review of the *Schering* decision.

Other circuits have taken a different view of the reverse payment issue, however, so substantial uncertainty remains. (The Upsher "side-deal" issue will largely be determined by juries in circuits applying the reverse payment doctrine, and their determinations would be subject to a less rigorous standard of review than was applied to the Commission's decision.) Thus, antitrust law in this area will be primarily determined in the context of private litigation. For example, the Sixth Circuit has found a reverse payment to be a *per se* violation of the antitrust laws, in a somewhat different case involving the interim settlement of a patent dispute. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *cert. denied*, 125 S. Ct. 308 (Oct. 12, 2004). Perhaps even more striking, the district court overseeing the private class action suits involving the very facts at issue in *Schering* denied the defendants' motions to dismiss the antitrust claims in September 2004, stating that *per se* treatment of reverse payments may be appropriate. *In re K-Dur Antitrust Litigation*, 338 F. Supp. 2d 517 (D.N.J. 2004). The law is uncertain in other circuits as well. *See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003). Thus, parties contemplating the settlement of pharmaceutical patent disputes will have to pay close attention to developments in the courts.

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