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Schering-Plough Corp. v. Federal Trade Commission: Eleventh Circuit Rejects the FTC's Position on "Reverse Payments" in Patent Suit Settlements

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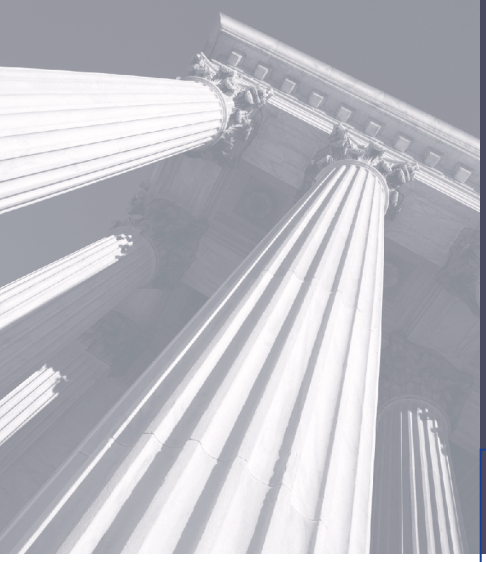
Abstract

In recent years, the Federal Trade Commission ("FTC" or the "Commission") has investigated several settlement agreements between pioneer and generic drug manufacturers involving "reverse payments." In the view of the FTC, reverse payments are cash that a pioneer drug manufacturer pays to a generic manufacturer who has challenged the patent(s) protecting the pioneer drug, in exchange for the generic manufacturer's agreement to delay market entry. Such payments sometimes occur in the settlement of patent infringement actions. The Commission has been extremely skeptical of reverse payments, viewing them as objective indicia of intent to illegally share monopoly profits that the delayed generic entry perpetuates. It has successfully challenged settlement agreements that included reverse payments involving the market entry of generic Cardizem (hypertension treatment) and generic Hytrin (hypertension and angina treatment).



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ANTITRUST AND COMPETITION LAW UPDATE

March 22, 2005

Schering-Plough Corp. v. Federal Trade Commission: *Eleventh Circuit Rejects the FTC's Position on "Reverse Payments" in Patent Suit Settlements*

Introduction

In recent years, the Federal Trade Commission ("FTC" or the "Commission") has investigated several settlement agreements between pioneer and generic drug manufacturers involving "reverse payments." In the view of the FTC, reverse payments are cash that a pioneer drug manufacturer pays to a generic manufacturer who has challenged the patent(s) protecting the pioneer drug, in exchange for the generic manufacturer's agreement to delay market entry. Such payments sometimes occur in the settlement of patent infringement actions. The Commission has been extremely skeptical of reverse payments, viewing them as objective indicia of intent to illegally share monopoly profits that the delayed generic entry perpetuates.[1] It has successfully challenged settlement agreements that included reverse payments involving the market entry of generic Cardizem (hypertension treatment) and generic Hytrin (hypertension and angina treatment).

Most recently, the Commission ruled that two settlement agreements involving the market entry of generic K-Dur 20 (hypertension and congestive heart failure treatment) ran afoul of the antitrust laws because they incorporated reverse payments to the generic drug manufacturer. On March 8, 2005, in *Schering-Plough v. Federal Trade Commission,* the Eleventh Circuit overruled the FTC's decision and held that the reverse payments, standing alone, were not evidence of anticompetitive behavior. The court observed that the settlement agreements at issue (which allowed early market entry for generic K-Dur 20) were less anticompetitive than enforcement of the patent for K-Dur 20, which is presumptively valid as a matter of law.

Although courts typically give some deference to the Commission's informed judgment that a particular commercial practice violates the FTC Act, the Eleventh Circuit's decision in *Schering-Plough* was decidedly non-deferential to the Commission's judgment that reverse payments are presumptively

1. *Thomas B. Leary, Commissioner,* Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes Address Before the American Bar Association's Antitrust Healthcare Program, *Washington DC (May 17, 2001), at http://ftc.gov/speeches/leary/learypharmaceuticalsettlement.htm (last visited November 13, 2003).*

anticompetitive. The decision may signal that patent litigants in the pharmaceutical industry will now have more flexibility to resolve their claims through negotiated settlement without prompting FTC inquiry. Parties and their counsel must still ensure, however, that reverse payments are in the context of bona fide settlements and do not represent de facto agreements between pioneer drug manufacturers and non-infringing generic suppliers to share monopoly rents.

Schering-Plough's Settlement Agreements with Upsher-Smith and ESI Lederle

Schering-Plough Corp. (Schering) owned a formulation patent on the extended-release coating of K-Dur 20, which was due to expire on September 5, 2006. In 1995, Upsher-Smith Laboratories (Upsher) and ESI Lederle, Inc. (ESI)[2] sought FDA approval to market their own generic versions of K-Dur 20. Schering separately sued Upsher and ESI for patent infringement. The parties eventually settled these suits in 1997.

As part of the settlement with Upsher, the parties agreed that Upsher would not market its generic version of K-Dur 20 until at least September 1, 2001, five years ahead of the patent's September 2006 expiration date. Schering also agreed to license certain Upsher products for $60 million in initial royalty fees and a later payment of $10 million in milestone royalties.

As part of the settlement with ESI, the parties agreed that ESI would not enter the market with a generic version of K-Dur 20 until at least January 1, 2004–more than two years ahead of the patent's expiration date. Schering agreed to pay ESI: $5 million for its legal fees, up to $10 million contingent upon FDA approval of ESI's generic product, and $15 million for certain licenses.

The FTC Complaint

On March 30, 2001, the FTC filed an administrative complaint against Schering, Upsher and ESI's parent, American Home Products Corporation (AHP). The complaint alleged that Schering's settlements with Upsher and ESI were illegal agreements in restraint of trade, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. §45, and Section 1 of the Sherman Act, 15 U.S.C. §1.[3]

After a long trial, the FTC's administrative law judge held that both agreements were lawful settlements of legitimate patent lawsuits and dismissed the complaint. He found specifically that FTC complaint counsel had failed to establish that Schering's royalty payments to Upsher and ESI were not legitimate consideration for the respective, licensed products or that the additional settlement payment to EDI was solely for the purpose of delayed generic entry.

Further, the ALJ found that the anticompetitive affects of these settlement agreements had to be assessed in light of Schering's presumptively valid patent for K-Dur 20, which remained in effect until September 2006. Thus, the ALJ reasoned, the settlement agreements were no more anticompetitive then Schering's enforcement of its patents. There was, moreover, no basis in the record for concluding that (1) Schering's patent was invalid; or (2) Upsher's or ESI's products did not actually infringe the patent.

The FTC's complaint counsel appealed the ALJ's decision to the full Commission. On December 8, 2003, the Commission reversed the ALJ, holding that Schering's

2. ESI's former parent company, American Home Products Corporation, now Wyeth, is a Wilmer Cutler Pickering Hale and Dorr LLP client.

3. On October 12, 2001, the complaint against AHP was withdrawn to consider a proposed consent agreement, which the FTC approved on April 2, 2002. AHP was not a party to either the trial before the ALJ or the subsequent proceedings. The legality of Schering's settlement with ESI/AHP, however, remained at issue with respect to Schering.

settlements with Upsher and ESI had violated the FTC and Sherman Acts. In so ruling, the Commission rejected the ALJ's factual finding that the "reverse payments" to Upsher and ESI were legitimate consideration; instead the Commission found they were a quid pro quo for delayed entry of generic versions of K-Dur 20.

In addition, the Commission gave no weight to the ALJ's reasoning that the anticompetitive effects of the settlement agreements had to be assessed in light of the exclusionary effects of Schering's presumptively valid patents. Instead, the Commission *assumed* that the generic versions of K-Dur 20 would have entered the market earlier absent the reverse payments and did not consider the merits of the patent litigation in which Schering asserted the generic versions violated its patents.

Schering and Upsher timely petitioned the Eleventh Circuit for review of the Commission's ruling.

The Eleventh Circuit's Decision

The Eleventh Circuit set aside the FTC's decision in a sharply worded, 43-page decision, handed down just over one month after oral argument. The court held that the Commission had inappropriately ignored the ALJ's factual findings, such as the determination that the $60 million payment from Schering to Upsher was a bona fide royalty payment for licenses that Schering obtained. The court criticized the Commission for relying on "somewhat forced evidence" in concluding that Schering's royalty payments were part of a quid pro quo arrangement aimed at preserving Schering's monopoly in the potassium chloride supplement market.[4]

The court also emphasized the inherent exclusionary effect of Schering's patent for K-Dur 20 and the legal presumption that the patent was valid. To that effect, the Court wrote: "By their nature, patents create an environment of exclusion, and consequently cripple competition."[5] Thus, the "proper analysis" for antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent in question; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive affects.[6] As to the first two considerations, the court readily found that Schering's agreements with Upsher and ESI were, in fact, less exclusionary than the K-Dur 20 patent because they allowed entry of generic versions of the drug substantially before the patent's expiration.

With respect to the third consideration, the court found that any cognizable anticompetitive effects must be more than merely "hypothetical or presumed." Any anticompetitive effects from Schering's payments were ancillary to the parties' goal of efficiently ending expensive and contentious litigation.[7]

Finally, the court criticized the Commission for failing to account for the fact that "[r]everse payments are a natural by-product of the Hatch-Waxman process" by which generic manufacturers are granted standing to mount prospective patent validity challenges, without incurring the cost of entry or risking enormous damages flowing from possible infringement. The court also noted that prohibiting reverse payment settlements,

4. Schering-Plough v. Federal Trade Commission, *No. 04-10688, 2005 WL 528439 at 28 (11th Cir. Mar. 8, 2005).*

5. Id. *at 19.*

6. *The Eleventh Circuit first articulated this standard in* Valley Drug Co. v. Geneva Pharm. Inc., *344 F.3d 1294 (11th Cir. 2003), a private lawsuit in which a generic drug manufacturer sought to strike down a settlement agreement between its rival and a pioneer drug maker.*

7. Schering-Plough, *2005 WL 528439 at 39.*

itself, could be anticompetitive. Such a prohibition would risk chilling generic manufacturers from challenging patents by limiting their settlement options should they be sued for patent infringement.

Conclusion

With the Eleventh Circuit rejecting its position on reverse payments, the FTC will now need to rethink its analysis. In the interim, carefully-tailored reverse payments may have found something of a safe harbor in the Eleventh Circuit, so long as: (1) the scope of the settlement agreement is properly tailored to be less exclusionary than the patent at issue; and (2) nothing suggests that the underlying patent litigation is not a bona fide dispute.

ANTITRUST AND COMPETITION LAW UPDATE

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