A "Reverse Payment" Reversal for the FTC: The Eleventh Circuit in *Schering-Plough* Refuses to Condemn Patent Settlements Involving Payments From a Patentholder To Alleged Infringers

The antitrust implications of settling intellectual property litigation has been a "hot topic" in antitrust for a number of years. The inherent tension between the desire of litigants to settle litigation and the government's need to ensure that such settlements are not covers for anticompetitive agreements have resulted in significant enforcement attention and litigation – with varying results. On March 8, 2005 the United States Court of Appeals for the Eleventh Circuit issued a decision that makes it more difficult to hold defendants liable for entering into a settlement of patent infringement litigation. In *Schering-Plough Corporation v. FTC*, 2005 WL 528439 (11th Cir. Mar. 8, 2005), the Eleventh Circuit reversed a decision by the Federal Trade Commission ("FTC") finding that settlements entered into by Schering-Plough Corporation ("Schering") and two generic pharmaceutical companies violated the antitrust laws. In so doing, the court created a presumption of lawfulness for settlements of patent infringement litigation that do not exceed the scope of the patent, and rejected the FTC's attempts to portray settlements involving so-called "reverse payments" as unlawful in most cases.

The *Schering* decision has re-ignited the debate as to whether a payment from a patentholder to an alleged infringer as part of a settlement agreement should be presumed unlawful (at least where the payment is not solely attributable to a separate *bona fide* exchange of consideration between the settling parties). The FTC has advanced the position that such "reverse payments" should be unlawful in most cases, contending that where such a payment is involved, an alternative settlement usually exists which involves no reverse payment and an earlier entry date for the market entry of the allegedly infringing product. The *Schering* decision, however, squarely rejects this view, and represents a significant ideological shift towards greater deference to the settling litigants. Moreover, in making it drastically more difficult to challenge a patent settlement solely based on its terms, the court's ruling threatens to force the government (or private plaintiffs) in such cases to delve deeply into the merits of the underlying patent dispute in order to rebut the *Schering* court's presumption of patent validity. The FTC has filed a petition for a writ of certiorari with the United States Supreme Court, contending that the Eleventh Circuit's decision "could seriously impede the Commission's law enforcement efforts".

Background.

Schering is a pharmaceutical company that manufactures and markets a potassium chloride supplement named K-Dur 20. While potassium chloride itself is not subject to a patent, Schering owns a formulation patent that covers the extended-release coating it places on K-Dur 20 ("the '743 patent"). The '743 patent expires on September 5, 2006.

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In 1995, K-Dur 20 was the most frequently prescribed potassium chloride supplement. In late 1995, Upsher-Smith Laboratories ("Upsher") and ESI Lederle, Inc. ("ESI") each separately sought approval from the Food and Drug Administration ("FDA") to market generic versions of K-Dur 20. Under the Hatch-Waxman Act, a generic company may submit an abbreviated new drug application ("ANDA") to the FDA to obtain quicker approval to bring a new generic drug to the market, provided that it can show that the new drug is bioequivalent to the previously-approved pioneer drug, and that it certifies that its product does not infringe upon the patents of the pio-

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neer drug. As part of this process, the pioneer company receives notice of the ANDA and non-infringement certification, and if it files suit for infringement within 45 days of receiving such notice the FDA will automatically institute a 30 month delay of the generic company's ANDA approval. Following this procedure, Schering brought separate patent infringement actions against Upsher and ESI in 1995-1996.

In 1997-1998, Schering entered into settlements with both Upsher and ESI. Each settlement provided that the generic company could bring its product to market on an agreed upon date prior to the expiration of the '743 patent: September 2001 for Upsher and January 2004 for ESI. Additionally, each settlement provided for payments to be made from Schering to each generic company. Schering and Upsher agreed that Schering would license five of Upsher's pharmaceutical products and make the following "royalty" payments: (a) $60 million up front; (b) $10 million in milestone royalty payments; and (c) 10% to 15% royalties on sales of the licensed products. Schering and ESI also agreed to enter into a licensing transaction – Schering would pay $15 million in return for licenses to two ESI pharmaceutical products. Schering and ESI also agreed that Schering would make two additional payments to ESI: (a) $5 million as compensation for legal expenses; and (b) $10 million in the event that ESI received FDA approval for its generic potassium chloride product by a certain date (which it did). The federal judge in the ESI infringement case was involved, to some extent, in the negotiation of the ESI settlement, and some of the early settlement documents were executed in his presence.

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Procedural History.

On March 30, 2001, the FTC filed an administrative complaint against Schering, Upsher, and American Home Products Corporation (ESI's parent corporation) alleging that the Schering-Upsher and Schering-ESI settlements violated the antitrust laws. An administrative law judge ("ALJ") initially found for the defendants on the grounds that, *inter alia*, no anticompetitive effect could be shown in the absence of a demonstration that the '743 patent was invalid, or that the generic products did not infringe the patent. However, the full Commission reversed the ALJ in a unanimous decision released on December 8, 2003. While the Commission did not declare that the "reverse payments" from Schering to Upsher and ESI were *per se* unlawful, the Commission did hold that the coupling of reverse payments with an agreement by the generics not to enter the market until a specified date "raise[d] a red flag . . . and mandate[d] further inquiry." The Commission found that the parties' characterization of certain payments as royalty payments was not supported by the facts, and that the license transactions were "shams." The Commission ultimately concluded that the *quid pro quo* of the payments by Schering to each generic company was an agreement by that generic company to delay the date of competitive entry, and that such delay was injurious to competition and consumers in violation of the antitrust laws.

Eleventh Circuit Decision.

The Eleventh Circuit unanimously reversed the FTC's decision. The court first noted that while its review of FTC decisions was deferential, it may "examine the FTC's findings more closely where they differ from those of the ALJ." The court then explained that neither the rule of reason nor the per se rule were appropriate methods for analyzing the legality of patent settlements. Because patents, by their nature, have exclusionary and anticompetitive effects that are completely lawful, the court held that a proper antitrust analysis of patent settlements requires an examination of: "(1) the scope of

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the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects."

With respect to the exclusionary potential of the '743 patent, the court noted that federal law provides that patents should be "presumed valid," and concluded that Schering therefore had the presumed legal right to exclude Upsher's and ESI's products from the market until September 5, 2006. While not explicit, the court's presumption of validity appears to have extended to infringement as well. The court noted that a showing of either invalidity or non-infringement would be necessary to rebut the presumed right to exclude, and the FTC had not made such a showing.

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The court then considered whether either of the settlement agreements exceeded the exclusionary scope of the '743 patent. In particular, the court considered whether the evidence supported the FTC's conclusion that reverse payments were in exchange for a delay in generic entry beyond the date that the parties otherwise would have found to be an appropriate compromise. In analyzing the Upsher settlement, the court overruled the FTC's findings that the payments from Schering to Upsher were not *bona fide* royalty payments, instead concluding that Schering had a genuine desire for the licenses, and paid a "fair price" for them in an arms-length transaction. Under these circumstances, the court held that one could not infer that the payments from Schering were "solely for [delayed entry] rather than the licenses."

With respect to the ESI settlement, the court found that the FTC had essentially premised liability on the mere "inclusion of monetary payments," particularly the contingent $10 million payment. Noting that it is not unlawful to exchange consideration to settle litigation, the court expressed its concern that the FTC's apparent rule would "leave settlements, including those endorsed and facilitated by a federal court, with little confidence." The court rejected the FTC's conclusion that the parties would have entered into a settlement with an earlier date for entry absent the reverse payment, finding that given the "fierce and impassioned" nature of the patent litigation, the FTC had failed to establish that such a "simpl[er] compromise" was available. Emphasizing that "[t]he general policy of the law is to favor the settlement of litigation," the court found that the terms of the settlement "'reflect[ed] a reasonable interpretation' of the protections provided by patent law."

In considering the potential "anticompetitive effect" of the two settlements, the court found that the settlement terms were reasonably ancillary to legitimate procompetitive transactions that "preserved public and private resources" and reduced uncertainty – ultimately leading to more competition. The court held that the FTC's "inflexible compromise-without-payment theory neglects to understand that reverse payments are a natural by-product of the Hatch-Waxman process." Because of the leverage that generic companies received by being able to "mount a validity challenge without incurring the cost of entry or risking the enormous damages flowing from any possible infringement," the court found that even a patentholder confident of victory might make a substantial settlement payment to an alleged infringer. The court again emphasized that the FTC had not established that an alternative settlement involving an earlier entry date was possible or even considered by the parties and concluded that the FTC's assumption to that effect was "myopic." The court therefore found that the settlements did not violate the antitrust laws.

Key Implications.

The *Schering* decision (if it stands) has several important legal and practical implications. First, and most obviously, it means that parties settling patent infringement suits need not automatically avoid including as a settlement term a payment from the patentholder to the alleged infringer.

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However, even after *Schering* a settlement that includes a reverse payment will carry significant antitrust risk – at the very least because litigants cannot be confident that they will be defending any future antitrust case in the Eleventh Circuit. The parties in *Schering* could choose the Eleventh Circuit under the rules for appealing FTC administrative decisions, but private plaintiffs will not be so constrained. The government may also explore ways to bring enforcement actions without ceding to the parties control of the appellate forum (for example, the FTC recently chose to challenge an agreement between Warner Chilcott and Barr Laboratories affecting generic competition in federal district court rather than in administrative litigation). Additionally, parties entering into a separate licensing arrangement as part of a patent settlement should still assume that the FTC and courts will carefully scrutinize such deals.

The decision in *Schering* means that those mounting antitrust challenges to patent settlements will now likely have to delve deeply into the merits of the underlying patent infringement action in order to show that the alleged harm to competition was not within the exclusionary scope of a valid patent. Recognizing the inherent difficulties and complications of performing such an analysis, the FTC's attempt to use reverse payments as a proxy for anticompetitive settlements was likely intended to avoid just this result. It is unclear whether *Schering* will cause the FTC to re-think its policy on patent settlements, and whether (or how closely) other courts will follow this decision. One possible outcome is that the FTC or courts may develop more detailed or convincing markers of anticompetitive settlements in a further attempt to avoid a full-blown analysis of the merits of each infringement case. Examples might include reverse payments in interim settlements (*see In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003)) or in patent settlements where *infringement*, not validity, was the key unresolved issue (the legal basis for *Schering*'s apparent presumption of infringement is not entirely clear). However, after *Schering-Plough*, courts are likely to be more reluctant to find patent settlements unlawful absent some evidence that the patentholder would have lost the infringement case. Accordingly, post-*Schering*, the emphasis of the cases is likely to return, to a significant extent, to this analysis.

A practical implication of this renewed focus on the merits of the underlying infringement action is that much of the crucial evidence is likely to appear in documents protected by the attorney-client privilege. On the one hand, parties to an investigation will be able to review their own privileged documents and produce them only where the documents are supportive (although in such cases parties will have to produce all documents of the same type/category if they produce any of them). On the other hand, parties under investigation might find themselves under increased pressure to waive privilege to avoid an adverse inference (and perhaps an adverse enforcement action) by the government. Producing privileged documents may be difficult because of the possibility of a broad subject matter waiver – potentially affecting related or unrelated litigation. Where parties believe that their privileged documents will exonerate them, they will have to measure the risks and benefits of producing them, particularly in light of the uneven acceptance of the so-called "limited waiver" doctrine.

In sum, the decision in Schering gives parties considering settling a patent dispute (or, for that matter, any type of IP dispute) with more comfort that their settlement will not be viewed with automatic suspicion by the courts. The decision takes the focus of the antitrust scrutiny off of the precise terms of the settlement, and places it squarely on the merits of the underlying IP dispute – thus making it much more difficult to mount a successful antitrust challenge to the settlement. Where IP owners are confident in the strength of their IP (and their documents support this confidence) they should feel more comfortable in settling their IP disputes in a manner that also benefits the alleged infringer. However, parties to such settlements should still expect attention from the FTC and the plaintiffs' bar, and plan ahead to be fully prepared to defend the key issues of validity and infringement. Also, given that the FTC is expected to appeal *Schering* and, if it stands, look for other ways to limit the decision, parties considering such deals may want to take advantage of the current, relatively more attractive enforcement environment.

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