Supreme Court Hears Oral Argument Involving "Reverse Payment" Patent Infringement Settlements

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I. The Issue

After more than a decade of litigation in the lower courts, the Supreme Court yesterday heard oral argument in a case of considerable consequence to the pharmaceutical industry. The issue is under what circumstances a "reverse payment" settlement of patent infringement litigation violates the antitrust laws.

In a so-called "reverse payment" settlement, the plaintiff brand-name manufacturer pays money or other consideration to the allegedly infringing generic firm, which then agrees not to enter the market for a period of years. In the case before the Court, the Federal Trade Commission ("FTC") is challenging the Eleventh Circuit's "scope of the patent" rule, which deems such agreements lawful – so long as they do not go beyond the temporal or the substantive limitations of the patent grant and the patent infringement suit is not a "sham."[1] In contrast, the FTC views what it calls "pay for delay" settlements as "presumptively unlawful" agreements not to compete. In the FTC's view, the likelihood of consumer injury is so great that only a narrowly circumscribed "quick look," rather than a full rule-of-reason analysis, is needed to determine if the agreement violates the antitrust laws. In practical terms, then, the FTC advocates a presumption that reverse payment agreements are unlawful, with relatively brief analysis into whether there are countervailing benefits – in effect, a rule close to *per se* illegality.

The FTC's view was recently adopted by the Third Circuit – creating, for the first time, a clear conflict in the circuits[2] and thereby setting the stage for what all concerned hope will be a ruling from the Supreme Court that makes clear what constitutes a permissible settlement.[3]

To the extent that the justices' questions at oral argument are a guide, neither side may get its way, and a fuller rule-of-reason analysis may be accorded reverse payment settlements going forward.

II. Opposing Views of the Parties

The FTC asserts that, but for the "reverse payment," either (1) the generic party to the agreement would have insisted upon an earlier date of entry, or (2) the generic would have litigated and, if it won, would have entered the market well in advance of the agreed-upon entry date embodied in the settlement agreement. In either event, the argument goes, the price decrease that occurs upon generic entry would have come earlier and the resulting delay injures consumers, insurance companies, and taxpayers who support Medicare and Medicaid programs. The FTC asserts that the majority of patent litigations involving generic drug competitors that are tried to verdict result in the patent being invalidated or held not

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[1] *Fed. Trade Comm'n v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012).

[2] *See In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012), *petitions for cert. pending*, No. 12-245 (filed Aug. 24, 2012) and No. 12-265 (filed Aug. 29, 2012).

[3] The possibility exists that the Supreme Court might split 4-4, since Justice Alito has recused himself. In that event, the Eleventh Circuit's ruling would stand as the law of that case, but there would be no definitive Supreme Court ruling on the standard for judging "reverse payment" settlements.

to have been infringed. Therefore, agreements that create incentives for generics not to challenge such patents potentially permit patent-holders to maintain exclusivity either where the patent is inapplicable or where it should not have issued.

Opponents of the FTC view respond by focusing on "dynamic efficiency" – i.e., the longer-run benefits flowing from incentives to innovate where patent rights are strong; they note that under the "scope of the patent" standard, entry is delayed for no longer than the term of the patent. Critics point to more recent studies for the proposition that it cannot be assumed that the generic firm likely would have won the litigation absent a settlement. They also note that, in those cases where the generic firm would have lost, consumers are better off with some early entry rather than none. For example, in the settlement before the Court, the generic would be able to enter five years prior to patent expiration, leaving consumers better off than they would have been had the brand-name manufacturer prevailed in the patent litigation.

The FTC's opponents have frequently advocated for a "scope of the patent" standard, which in practice comes close to a rule of *per se* legality. Under this approach, the only ground on which the settlement can be attacked as violative of the antitrust laws is that the settlement goes beyond the scope of the patent (such as by prohibiting the sale of non-infringing products) or that the brand-name manufacturer's patent litigation was "objectively baseless" or a "sham" within the meaning of the Noerr-Pennington doctrine, an exception rarely invoked successfully.

In contrast, the "presumptively unlawful" standard, at least as the FTC would have it applied, comes close to a *per se* rule of illegality. In the FTC's view, the presumption would only be rebuttable if the payment to the generic firm did not exceed litigation costs avoided by settlement, or if the payment was made in connection with a simultaneous transaction, or "side deal," where the parties can show that the reverse payment was no larger than it would have been absent settlement of the patent dispute. Indeed, the agency recently asserted that a commitment by the brand-name manufacturer not to enter with its own "authorized generic" was an unlawful "reverse payment" – even though such a provision arguably is no different than an exclusive license, something normally viewed as well within the province of a patent-holder.

Some have argued that neither polar position of *per se* legality or *per se* illegality is correct, because consumer injury flows from reverse payment settlements only in the "but for" world, where there is no settlement and the patent is litigated to verdict and held invalid or not infringed. While the FTC argued in the court below that the likely outcome of the patent litigation was a relevant consideration in determining the legality of the settlement, the Eleventh Circuit rejected that position and the FTC seems to have abandoned it in the Supreme Court.[4] The objection to considering the merits of the patent suit is that it reignites the very dispute that the parties sought to settle. It has also been noted that the parties to the patent litigation, having settled, now have the incentive to prove that the brand-name manufacturer would have prevailed. A partial answer to these concerns would be to shift the burden of proof to the settling parties and to utilize a preliminary injunction standard of "likelihood of success," thereby at least avoiding a full trial on the merits of the patent suit as part of the antitrust litigation.

Another approach is to look to the size of the reverse payment relative to what the generic firm would have earned had it successfully defended the patent litigation and entered earlier than permitted under the settlement.[5] Where the reverse payment approaches or exceeds what the generic would have

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[4] *Watson Pharms.*, 677 F.3d at 1313-14.

[5] *See In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 412 (2d Cir. 2005) (Pooler, J., dissenting) ("I would rely primarily on the strength of the patent as it appeared at the time at which the parties settled and secondarily on (a) the amount the patent holder paid to keep the generic manufacturer from marketing its product, (b) the amount the generic manufacturer stood to earn during its period of exclusivity, and (c) any ancillary anti-competitive effects of the agreement including the presence or absence of a provision allowing the parties to manipulate the generic's exclusivity period."); Herbert Hovenkamp, Mark D. Janis, & Mark A. Lemley, *The* (*cont.*)

earned, this is said to be strong evidence that the parties believed the brand-name manufacturer would have lost the litigation and the generic is "bought off" by means of a payment that exceeds what it would have earned by entering early after securing a litigation victory. Conversely, where the reverse payment is much lower than the generic firm would have earned by early entry, perhaps that should be considered as strong evidence that the parties viewed the likelihood that the generic would have prevailed in the patent litigation as relatively low.[6]

A problem with this approach is that there is an imbalance of risk between the parties. A brand-name manufacturer with a highly successful drug can face a potential loss of billions of dollars in sales if its patent is declared invalid. The potential generic entrant, on the other hand, can hope to attain only a small fraction of those lost sales, because a finding that the patent is invalid would, within a short period of time, lead to competitive entry by other generic manufacturers. In order to encourage generic entry, Congress established in the Hatch-Waxman Act a mechanism by which generic drugs can provoke patent infringement litigation without having actually to enter the market and risk a significant damage award. By enabling pre-marketing litigation, Congress has set up a situation in which the brand-name manufacturer of a successful drug risks the profits it would earn over the life of the patent. The generic firm risks far less: only the cost of litigation. In those circumstances, it is not surprising that a brand-name manufacturer might be willing to make a substantial "reverse" payment to avoid even a relatively small risk of losing the patent litigation, while the generic challenger might be willing to accept such a payment rather than engaging in expensive and risky litigation with uncertain results and limited rewards.

The Supreme Court has stated on several occasions that *per se* illegality is only appropriate where experience has shown that the challenged conduct appears virtually certain to reduce competition, with no offsetting efficiency gains on the other side of the balance. Here, it seems hard to say that a reverse payment settlement is always, or almost always, likely to be anticompetitive. These settlements generally are a compromise between a result in which the brand-name manufacturer prevails (in which case there is no generic competition until expiration of the patent) and a result in which the generic entrant prevails (in which case the generic product could enter the market immediately). Advocates of the Eleventh Circuit's scope of the patent standard believe that because there is no reliable way to determine which entity would have prevailed in the litigation, there is no way to determine whether the settlement led to more or less competition than would have existed but for the settlement. Similarly, there is an offsetting "dynamic efficiency" benefit in fostering future innovation by giving a pharmaceutical patent holder wide berth in settling cases which enable it to enjoy the fruits of its innovation. Nonetheless, the FTC has staked out a position very close to *per se* illegality, which could be rebutted under only the quickest of "quick looks."

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Interface Between Intellectual Property Law and Antitrust Law: Anticompetitive Settlement of Intellectual Property Disputes, 87 MINN. L. REV. 1719, 1727-28 (2003); Carl Shapiro, *Antitrust Analysis of Settlements Between Rivals*, ANTITRUST 70-77 (Summer 2003); *see also* J. Thomas Rosch, Commissioner, Fed. Trade Comm'n, Remarks at the World Generic Medicine Congress: Pay-for-Delay Settlements, Authorized Generics, and Follow-on Biologics: Thoughts on How Competition Law Can Best Protect Consumer Welfare in the Pharmaceutical Context (Nov. 19, 2009), at 11-12.

[6] One amicus brief filed by law, economics, and business professors espoused this view, but it did not directly address whether a small reverse payment (below what a generic would have earned by earlier entry) provides strong evidence that the brand-name manufacturer would have prevailed in the patent litigation. Brief of Amicus Curiae of 118 Law, Economics, and Business Professors and the American Antitrust Institute in Support of Petitioners, *Fed. Trade Comm'n v. Watson Pharms., Inc.*, No. 12-416 (Jan. 29, 2013). Other respected economists have previously supported this view. *See, e.g.*, Shapiro, *Antitrust Analysis of Settlements Between Rivals*, *supra* note 5.

III. The Oral Argument

A. Scope of the Patent, Narrow Quick Look, or Fuller Rule-of-Reason Analysis

It is always perilous to attempt to predict the outcome in the Supreme Court by the tenor of the justices' questions at oral argument. That said, there were some clues in the questions as to a possible outcome.

At one point, Justice Scalia seemed to express support for the "scope of the patent" test when he asked whether there had ever been an antitrust case in which the patentee was held liable for doing something within the scope of its exclusionary rights under the patent. Other justices, however, did not explicitly pick up that theme. Rather, several justices – with the possible exception of Justice Kagan – seemed uncomfortable with the polar positions of either party. In one way or another, questions from Justices Breyer, Sotomayor, and Kennedy all seemed to push the advocates to state why the more flexible rule-of-reason analysis commonly employed in antitrust cases should not be the governing standard here. Justice Breyer, for example, commented that the Court's prior precedents applied the "quick look" approach advocated by the FTC only in cases that were relatively close to price-fixing – but not to novel situations like the one before the Court. At another point, Justice Sotomayor asked, "Why is the rule of reason so bad?" She added that she was "having difficulty understanding why the mere existence of a payment presumptively changes the burden." The advocates each stuck with their positions and never conceded that there was a viable middle ground, but it remains to be seen whether either of their views prevail.

B. Strength or Weakness of the Underlying Patent

Other questions from the justices seemed to suggest concern that both parties' polar positions ignored what Justice Scalia termed "the elephant in the room" – i.e., the merits of the patent challenged in the infringement litigation. Justice Kennedy raised a concern with the Solicitor General's defense of the FTC position that its test for a weak patent is the same for a strong one, without altering the analysis based upon the strength of the patent. Along the same lines, in response to a question from Justice Ginsburg, the Solicitor General conceded that the U.S. Department of Justice ("DOJ") had changed its position; it had previously agreed that the likelihood that the patent would have been upheld was relevant to the antitrust analysis, but the DOJ no longer holds that view.

On several occasions, Justice Kennedy asked whether it would make sense to cap reverse payments at what the generic would have earned if it had won the patent case, a proposal to which Justice Kennedy and Justice Ginsburg returned later in the argument. As noted above, this is the test suggested by some economists who have written on this topic, but it arguably does not take into account the imbalance of risk faced by the litigants in the patent dispute.

IV. Conclusion

The parties have argued the case as if the only choice before the Court is to hold reverse payments presumptively unlawful, with only very narrow defenses available under a circumscribed "quick look" approach, or to adopt the Eleventh Circuit's view that all reverse payment settlements are *per se* lawful, so long as entry is not delayed beyond the life of the patent and the patent litigation being settled is not a "sham." While it remains possible that one or the other position will be adopted by the Court, there is also a reasonable chance that the Court will reject both positions and conclude instead that such settlements should be subject to a flexible rule-of-reason analysis. Such an approach may have certain advantages, though as a practical matter it may well diminish the core benefit of settling a patent case (i.e., certainty and finality) and also lead to complex and expensive antitrust litigation.

Parties contemplating settlements should probably begin to think about the risks of having to live with either a full-blown rule-of-reason analysis or an expansive quick-look approach. If either of these "middle

ground" positions prevail, it would seem that the risks of significant reverse payment settlements will be far greater than if the Eleventh Circuit's scope of the patent test were the applicable rule of law.

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