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Supreme Court Applies Rule of Reason in Antitrust Challenges to Reverse-Payment Patent Settlements

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One of the most controversial antitrust issues for the pharmaceutical industry during the last decade has been the treatment of patent settlements in which a patent-holding branded manufacturer made payments to its generic competitors challenging the patents under procedures set forth in the Hatch-Waxman Act (so-called "reverse payments"). In return, the generic competitors agreed to honor the patent and refrain from competing with the branded product for some period of time. According to Federal Trade Commission statistics, there were 66 "reverse payment" settlements between 2004 and 2009. The FTC contends that the agreements protected at least $20 billion in sales of brand pharmaceuticals from generic competition and cost American consumers $3.5 billion per year. Those opposing such "reverse payment" settlements (including the FTC) argued that the settlements constitute agreements not to compete that violate the antitrust laws. Those favoring such settlements argued that they are lawful as long as the settlement agreement did not go beyond the exclusionary effect of the patent provided under patent law. Both sides could cite supporting decisions from the lower federal courts.

In *Federal Trade Commission v. Actavis, Inc.*[1], the United States Supreme Court held, in a 5-3 decision, that reverse payment settlements are neither *per se* unlawful nor *per se* lawful, but must instead be evaluated under a traditional rule of reason analysis. Consequently, challenges to such settlements are going to be more fact-intensive and difficult to resolve on motions to dismiss or summary judgment. The Court's decision may also open other types of patent settlements, and patent licenses, to antitrust challenge.

The Case Before the Supreme Court

In 2006, Solvay Pharmaceuticals, the manufacturer of the branded drug AndroGel, settled its patent infringement litigation against three generic drug manufacturers' who were seeking to enter the market with a competitive generic product. The generic manufacturers defenses against the patent infringement claims were that Solvay's patent was invalid and that their generic products did not infringe the patent. Under the settlement agreement, the generic manufacturers agreed to drop their challenge to Solvay's patent. They also agreed that they would delay the introduction of their generic products until August 2015, over five years before the Solvay patent expired. The generic manufacturers also agreed to promote Solvay's product to doctors. In return for the generics' promises, Solvay agreed to pay the generic manufacturers between $250 and $350 million.

In January 2009, the FTC sued Solvay and the settling generic manufacturers, alleging that the settlement agreements violated Section 5 of the Federal Trade Commission Act, which prohibits unfair methods of competition and unfair or deceptive acts and practices and encompasses practices that violate the Sherman Act and other antitrust laws.

The District Court dismissed the FTC's complaint, and the Eleventh Circuit affirmed.

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The Supreme Court's Rule of Reason Analysis

The Supreme Court noted that the AndroGel patent might or might not be valid or infringed and rejected the argument (which had been accepted by the Eleventh Circuit) that the settlement agreements are lawful as long as the exclusionary effects of the settlement "fall within the scope" of the patent (absent sham litigation or the use of fraud to obtain the patent). The Court explained that accepting such settlement agreements as legal *per se* eliminates all antitrust policy considerations from any patent dispute without regard to whether the patent involved is infringed—*i.e.*, whether there even exists a valid patent right relevant to the dispute. The Court emphasized that the settlements resulted in the payment of substantial monies by the plaintiff patent holder to the defendant alleged infringers, even though the infringers did not have a damage claim against the patent holder. And the sizeable settlement payments would be funded by the patent holder's high prices to consumers, an outcome in tension with the purposes of the antitrust laws.

The Court, however, expressly rejected the positions advanced by both those who oppose reverse payment settlements and those who favor them. The Court held that such settlements are neither *per se* legal when within the scope of the patent, nor *per se* illegal. The Court also declined to resort to a truncated or "quick look" rule of reason analysis, which would shift the burden of proof to the settling parties.

Instead of *per se* or truncated analysis, the traditional rule of reason is to be applied to the reverse payment settlement to examine the procompetitive and anticompetitive effects of the specific settlement in issue, including an evaluation of legitimate justifications for the payment to the alleged infringers.[2] The Court specifically cited the following for consideration: (i) the amount of the payment, (ii) the order of magnitude of the payment compared to the future litigation costs in the absence of a settlement, (iii) the presence of other services rendered by the generic manufacturers to the patent holder in exchange for the payments (*e.g*., promoting the patented product), (iv) the presence or absence of market power created by the patent at issue, and (v) the actual magnitude of any anticompetitive consequences. However, the Court declared, "[i]f the basic reason [for the reverse payment] is a desire to maintain and to share patent-generated monopoly profits, in the absence of some other justification, the antitrust laws are *likely* to forbid the arrangements."[3]

While it may not be the only pertinent question, the core antitrust concern with "reverse payment" settlements is the possibility that the consideration paid is greater than an objective evaluation of the patent's earning potential, measured by a reasonable belief about the patent's strength, coupled with its length and scope. Nevertheless, somewhat surprisingly, the Court predicts that in most cases the rule of reason analysis will not require litigating the issue of "patent validity to answer the antitrust question" of whether the reverse payment agreement is unlawful.[4] The Court reasons that the presence of a large and unexplained reverse payment "would normally suggest that that patentee has serious doubts" about the patent's validity or infringement. "[T]he size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness."[5] Such doubt "suggests that the payment's objective is to maintain supra competitive prices to be shared among the patentee and the challengers."[6] As the Court emphasized, the payment may be made "to induce the generic challenger to abandon its claim with a share of [the brand's] monopoly profits that would otherwise be lost in the competitive market."[7] Logic would seem to suggest, however, that in every challenge to a reverse payment settlement, one side or the other will want to show the strength or weakness of the patent in issue.

The Court noted that prohibiting unreasonable reverse payments does not preclude the settlement of patent disputes. Avenues of settlement include allowing the generic manufacturer to enter the market before the patent expires, with or without a licensing fee paid to the patentee. Notably, however, the agreement at issue in *Actavis* permitted Actavis to enter the market with its generic product fully 65 months *before* the expiration of the relevant patent. While it seems likely that branded and generic manufacturers will look for innovative ways to resolve their patent disputes in a manner that makes them easier to defend against antitrust challenge, the FTC will likely not be shy about challenging any agreement that it views as including any form of consideration paid to the potential generic competitor that may extend the brand's ability to capture (and thus share with a would-be competitor) monopoly profits.

The Supreme Court's decision raises many more questions than it answers and virtually guarantees that litigation over patent settlements in the pharmaceutical industry will increase, both in number and in complexity. Future litigation over reverse payment settlements will see the parties litigating these and a number of similar issues left unresolved by the Supreme Court:

- How will courts define a "reverse payment" settlement? The FTC has taken a very broad approach. The *Actavis* opinion sheds little light on this question.
- Under what circumstances will the courts permit the parties to present evidence on the strength of the patent claims and the presence of infringement?
- The Court noted that reverse payments may reflect valid consideration for services to be performed by the generic manufacturer. But how are services to be performed by the erstwhile patent challenger for the patent holder to be valued and compared against the reverse payments, especially where they involve any element of risk sharing?
- How large a disparity between the reverse payments and the value of the services is necessary before market power concerns arise?
- What role in the rule of reason balancing of procompetitive and anticompetitive effects will be played by the settlement's shortening of the patent law's exclusion of the generic competitors?
- Given the available substitutes for the potential product, how much market power does the patent really bestow?
- What impact does a counterclaim for damages have on the reverse payment analysis, given the Supreme Court's emphasis on the stark contrast between the reverse payments and the absence of a damages counterclaim?

The *Actavis* opinion will not only encourage the FTC to challenge "reverse payment" settlements, it is likely also to increase litigation by private parties, such as consumers, pharmacies, and third-party payors, challenging "reverse payment" settlements on antitrust grounds. Since the Third Circuit's decision in *K-Dur*[8], dozens of such private-party lawsuits have been commenced in courts around the country. The Court's decision highlights the importance of involving antitrust counsel in patent settlement negotiations and the need to engage in a thorough antitrust analysis of any proposed settlements.

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[1] Case No. 12-416 (U.S. Supreme Court, June 17, 2013).
[2] *Id.* Slip op. 18-19.
[3] *Id*. at 19 (emphasis added).
[4] *Id*. at 18.
[5] *Id*. at 18-19.
[6] *Id.*
[7] *Id*. at 15-16.
[8] In Re: K-Dur Antitrust Litigation 686 F.3d. 197 (3d Cir. 2012).

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