Clients&FriendsMemo

Supreme Court Decision Compels Brand-Name and Generic Drug Manufacturers Alike to Rethink Hatch-Waxman Litigation Strategies

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On June 17, 2013, in a decision long-awaited by antitrust and intellectual property practitioners, the U.S. Supreme Court ruled that so-called pharmaceutical "reverse payment" agreements are not immune from antitrust scrutiny but must be analyzed under the rule of reason.[1]

The question presented to the Supreme Court was:

> Whether reverse payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud (as the court below held), or instead are presumptively anticompetitive and unlawful (as the Third Circuit has held).

Pharmaceutical reverse payment settlement agreements between branded and generic pharmaceutical companies, which are facilitated by the Hatch-Waxman Act, have long been an enforcement priority for the FTC. Over the past several years the FTC has initiated many litigations against the parties to these settlement agreements, with mixed results. While the Eleventh, Second and Federal Circuits adhered to the theory that these agreements were immune from antitrust scrutiny so long as the terms did not exceed the exclusionary protections conferred by the patent itself, the Third Circuit took the opposite position holding that these agreements were presumptively anticompetitive. In the *Actavis* decision, the Supreme Court rejected both the FTC's leading argument that such deals are presumptively unlawful and defendants' argument that such deals are effectively immune from antitrust challenge if they fall within the scope of a patent, but rather adopted a middle-of-the-road position that courts must take a rule of reason approach analyzing the agreement's anticompetitive effects within the context of the scope of patent law protections.

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1 *FTC v. Actavis, Inc.*, 570 U.S. ___ (2013).

The Supreme Court's Decision and Analysis

At issue in *Actavis*, was an agreement between Solvay Pharmaceuticals and Actavis, then known as Watson Pharmaceuticals. After Solvay obtained a patent for its drug, AndroGel, Actavis filed an Abbreviated New Drug Application (ANDA) with the Food & Drug Administration for a generic version of AndroGel. Actavis certified that Solvay's patent was invalid and that Actavis' drug did not infringe that patent. Solvay sued Actavis and others (the "generics") claiming that their drugs infringed Solvay's patent. After the FDA approved Actavis' drug in 2006, however, the lawsuit settled, with Solvay dropping its infringement claims and paying each generic millions of dollars, including $19 to $30 million annually to Actavis for nine years. In return, Actavis agreed that it would not bring its generic to market until 2015, and that it would promote AndroGel to urologists. The FTC sued, claiming that the purpose of the payments was to ensure that Actavis would keep its generic drug off the market, which it asserted was presumptively anticompetitive.

The district court dismissed the FTC's complaint, ruling that the FTC had failed to state a claim under Section 5 of the FTC Act. The Eleventh Circuit affirmed the dismissal, as, "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent."[2] The Supreme Court has now rejected this analysis. However, the Court also rejected the FTC's position that reverse payment agreements are presumptively illegal.

Relying on its decision in *United States v. Line Material*, the Court advised that courts must consider both patent policy and antitrust policy in analyzing reverse payment agreements.[3] The Court noted that under *Line Material* the "scope of the exclusionary effects of the patent" is itself determined through an analysis of antitrust factors.[4]

The Court also rejected the Eleventh Circuit's argument that the legal policy favoring the settlement of disputes required the "scope of the patent" test. Instead, the Court enumerated five factors that led to the conclusion that the FTC should have been given the opportunity to prove its antitrust claim: i.e., (1) consider whether the specific restraint at issue has the potential for genuine adverse effects on competition, (2) consider whether the anticompetitive consequences will at least sometimes prove unjustified, (3) where the reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice, (4) an antitrust action is more feasible than the Eleventh Circuit believed (i.e., a validity challenge is not necessary), and (5) large unjustified reverse payments increase the risk of antitrust liability.

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2 *FTC v. Watson Pharms.*, 677 F.3d 1298, 1312 (11th Cir. 2012).

3 *FTC v. Actavis*, 570 U.S. ___, at * 9.

4 *Id.*

The Court also made clear that not all reverse payment agreements will constitute antitrust violations under the *Actavis* rule. The Court's primary focus in declaring that reverse settlement payments may constitute violations was to redirect the analysis onto the *purpose* of the settlement. Where the settlement "reflects traditional settlement considerations, such as avoided litigation costs or fair value for services," the agreement may pass muster under the rule of reason.[5] To analyze this, the Court repeatedly pointed to the size of the payments being made, noting that large payments suggested that the patentee was attempting to protect a monopoly by sharing the monopoly profits with its potential competitor.[6] Thus, under *Actavis*, smaller payments, and those that appear to bear a closer relation to litigation costs and services provided by the alleged infringer, may be less susceptible to antitrust challenge.

Chief Justice Roberts' Dissent

In his dissenting opinion, Chief Justice Roberts (joined by Justice Scalia and Justice Thomas) argued that the Court should have applied the "scope of the patent" test in this decision. In particular, Chief Justice Roberts stated that "[i]f actions are within the scope of the patent, they are not subject to antitrust scrutiny" so long as the settlement is not a sham and the underlying litigation does not involve a patent that was obtained by perpetrating a fraud on the PTO.[7] Overall, the dissent lamented that the majority "weakens the protections afforded to innovators by patents, frustrates the public policy in favor of settling, and likely undermines the very policy it seeks to promote by forcing generics who step into the litigation ring to do so without the prospect of cash settlements."[8]

Implications

While it will take time to parse through the practical effect of the ruling, it appears the decision will have several ramifications. The Supreme Court's ruling in this case likely will embolden the FTC and private litigants to challenge future reverse payment settlements. FTC Chairwoman Edith Ramirez suggested as much in response to the decision, stating, "The Court has made it clear that pay-for-delay agreements between brand and generic drug companies are subject to antitrust scrutiny, and it has rejected the attempt by branded and generic companies to effectively immunize these

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5 *Id.* at 17-18.

6 *Id.* at *15-*17, *19

7 *FTC v. Actavis*, 570 U.S. ___ at *3 (2013) (Roberts, C.J., dissent).

8 *Id.* at *18.

agreements from the antitrust laws. . . . [The FTC is] studying the Court's decision and assessing how best to protect consumers' interests in other pay for delay cases."[9]

The decision will also require fresh thinking on strategies for crafting settlement agreements in the Hatch-Waxman context. As a result, the *Actavis* decision will increase the expenses associated with Hatch-Waxman litigation and potential settlement agreements containing reverse payments provisions. And, at least in the short term, the decision may reduce the number of these settlement agreements. Regardless of whether it reduces the number of reverse payment settlements, the decision will put a premium on obtaining early antitrust and intellectual property counseling in connection with these kinds of settlements.

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[9] Fed. Trade Comm'n, Statement of FTC Chairwoman Edith Ramirez on the U.S. Supreme Court's Decision in *FTC v. Actavis, Inc.* (Jun. 17, 2013), http://www.ftc.gov/opa/2013/06/actavis.shtm.