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WSGR ALERT

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FTC V. ACTAVIS: "REVERSE PAYMENTS"—NOT PRESUMPTIVELY LAWFUL, NOT PRESUMPTIVELY UNLAWFUL, BUT SUBJECT TO A RULE-OF-REASON ANALYSIS

On June 17, 2013, after years of litigation in the lower courts, the United States Supreme Court issued its long-awaited decision in *FTC v. Actavis*.[1] The 5-3 decision,[2] however, did not have a clear winner, and the case was remanded to the district court for yet more litigation. The Eleventh Circuit had upheld a district court holding that, as long as the anticompetitive effects of a settlement fall "within the scope of the patent," the settlement is immune from antitrust attack. The Supreme Court reversed. The Court declined to hold that "reverse payments"[3] are presumptively unlawful, as the Federal Trade Commission (FTC) had argued. But the Court agreed that reverse payments can *sometimes* violate the antitrust laws and ruled that they should be examined under the "rule of reason."

Case Background

This case arose out of a 2006 settlement between Solvay Pharmaceuticals, a patent holder on AndroGel—a prescription gel used to increase testosterone levels in male patients—and three competing drug manufacturers seeking to offer a generic alternative to AndroGel.[4] Pursuant to the settlement, Solvay agreed to drop its patent infringement actions and its would-be competitors agreed not to market a generic version of AndroGel until 2015 (65 months before Solvay's patent expired). In addition, Solvay entered into separate agreements with each of the three generic manufacturers, providing that they would market branded AndroGel to urologists in exchange for a share of the profits collected by Solvay—$12 million to one manufacturer; $60 million to another; and $19–30 million annually, for nine years, to the third.[5]

In 2009, the FTC filed a lawsuit against all settling parties, alleging that this "reverse payment" settlement ran afoul of the antitrust laws. The district court dismissed the FTC's suit, noting that where patent settlements are concerned, neither the "rule of reason" nor "per se" analyses typically applied in antitrust actions are appropriate. Rather, the court held that reverse settlements must be analyzed according to the three-part test established by the Eleventh Circuit: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects. The district court held that there was no need to reach the question of whether the agreements at issue resulted in anticompetitive effects because the plaintiffs had failed to allege that such agreements exceeded the scope of Solvay's patent. The FTC appealed.

The Eleventh Circuit affirmed the district court's dismissal and, following its own precedents, held that "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."[6] Several other circuit courts had ruled on the issue, at times reaching opposite decisions,[7] leading the Supreme Court to take the case for review.

Majority Decision

While the Supreme Court acknowledged that the payment itself can fall within the scope of a patent, it disagreed that that fact alone could *immunize* the agreement from antitrust scrutiny.[8] Instead, the Court indicated that both patent and antitrust policies are "relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent."[9]

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[1] *FTC v. Actavis*, No. 12-416, 570 U. S. ____ (June 17, 2013), *available at* http://www.supremecourt.gov/opinions/12pdf/12-416_m5n0.pdf.

[2] Justice Samuel Alito took no part in the consideration or decision of the case.

[3] When the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a "reverse payment" settlement agreement.

[4] *In re AndroGel Antitrust Litig.* (No. II), No. 1:09-cv-00955-TWT (N.D. Ga. Feb. 22, 2010).

[5] *See FTC v. Actavis*, No. 12-416, 570 U. S. ____, at 6 (majority opinion).

[6] *FTC v. Watson Pharmaceuticals, Inc.*, 677 F. 3d 1298, 1312 (CA 11 2012).

[7] Compare, e.g., *id.*, at 1312 (case below) (settlements generally "immune from antitrust attack"); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F. 3d 1323, 1332–1337 (CA Fed. 2008) (similar); *In re Tamoxifen Citrate Antitrust Litigation*, 466 F. 3d 187, 212–213 (CA2 2006) (similar), with *In re K-Dur Antitrust Litigation*, 686 F. 3d 197, 214–218 (CA3 2012) (settlements presumptively unlawful).

[8] *FTC v. Actavis,* No. 12-416, 570 U. S. ____, at 8 (majority opinion).

[9] *Id.* at 9.

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The Supreme Court considered the following five factors and concluded that the FTC should have been given an opportunity to prove its case:

1. sometimes patent settlements will have "genuine adverse effects on competition";
2. "these anticompetitive consequences will at least sometimes prove unjustified";
3. "where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice";
4. "it is normally not necessary to litigate patent validity to answer the antitrust question" because "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival," and using a "payment . . . to prevent the risk of competition . . . constitutes the relevant anticompetitive harm"; and
5. parties may still "settle in other ways" such as "by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point."[10]

While explaining in detail why antitrust policies should be considered as part of the patent settlement analyses, the Court did not specify the precise framework for evaluating such agreements, and instead left "to the lower courts the structuring of the present rule-of-reason."[11] Generally, the Court stated, rather than mechanically measuring the length or amount of a restriction solely against the length of the patent's term or its earning potential (as was the case in the Eleventh Circuit), courts should answer the antitrust question by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as those related to patents here. The only more specific guidance appears to be that payments of "large" sums are suspect:

- "The payment may instead provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market."[12]
- "The 'size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power'—namely, the power to charge prices higher than the competitive level."[13]
- "An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival."[14]
- "In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself."[15]

The Court did not comment on the impact of price effects. Going forward, the FTC and other plaintiffs are sure to argue that delay of generic entry raises prices to consumers, and that the presence of that effect establishes a prima facie case sufficient to shift the burden of going forward to the defense to present evidence of justifications for the settlement. It remains to be seen how the courts will deal with this argument.

Dissent's Concerns

Chief Justice John Roberts, however, writing for the dissenting minority, took issue with the majority's focus on the assumption that offering a "large" sum is reliable evidence that the patent holder has serious doubts about the patent. The minority argued that a patent holder may be very sure about the validity of its patent, but could just be particularly averse to risk or litigation.

Additionally, according to Chief Justice Roberts, the true motivation of a patent holder to enter into a settlement agreement would be hard to ascertain. Specifically, "whether a patent holder is motivated by uncertainty about its patent, or other legitimate factors like risk aversion, will be made all the more difficult by the fact that much of the evidence about the party's motivation may be embedded in legal advice from its attorney, which would presumably be shielded from discovery."[16]

Conclusion

In the meantime, both camps claimed a measured victory from the decision.

FTC Chairwoman Edith Ramirez claimed the Supreme Court's "decision is a significant victory for American consumers, American taxpayers, and free markets."[17] The FTC issued a statement praising the Court for making "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 agreements from the antitrust laws."[18]

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[10] *Id.* at 14-19.

[11] *Id.* at 21.

[12] *Id.* at 15-16.

[13] *Id.* at 18.

[14] *Id.*

[15] *Id.* at 19.

[16] *FTC v. Actavis,* No. 12-416, 570 U. S. ____, at 13 (dissent).

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

[18] *Id.*

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At the same time, Paul Bisaro, president and CEO of Actavis, issued a similar statement on behalf of Actavis: "We are pleased that the Court rejected the FTC's proposed 'quick look' test, and did not rule that settlement agreements are presumptively unlawful. . . . We believe this decision continues to provide for a lawful and legitimate pathway for resolving patent challenge litigation in a manner that is pro-competitive and beneficial to American consumers. . . . We plan to continue to defend the propriety of such settlements against any further legislative or judicial challenges."[19] Left unsaid is another aspect in which the decision is somewhat helpful to pharmaceutical companies. Had the FTC lost in the Supreme Court, there would have been considerable pressure for congressional legislation—legislation that, if passed, likely would have included the rule of presumptive illegality that the FTC has championed. That almost certainly will not happen now.

In the end, however, the Supreme Court's decision is a clear win for the FTC. How significant a win it is will play out as the lower courts develop a rule-of-reason approach to these cases in the coming years. The decision represents the culmination, at least for now, of the FTC's 15-year campaign against reverse settlements. The "scope of the patent" doctrine had been adopted both by the Eleventh Circuit and the Second Circuit and, because companies can appeal a final FTC decision to any circuit in which they do business, the rulings from those courts threatened to gut the FTC's approach completely. Instead, the cases now will proceed.

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For more information on antitrust, generic products litigation, or related patent matters, please contact Seth Silber, Susan Creighton, Stu Williams, Valentina Rucker, Jonathan Lutinski, or another member of Wilson Sonsini Goodrich & Rosati's antitrust practice.

[19] Actavis Press Release, U.S. Supreme Court Reverses U.S. Court of Appeals Decision in *FTC v. Actavis* (June 17, 2013), http://ir.actavis.com/phoenix.zhtml?c=65778&p=irol-newsArticle&ID=1830404.

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