SCOTUS: Rule of Reason Applies to Reverse Payment Settlements of Patent Cases

Addressing a conflict that had divided the federal courts and sparked considerable debate in the antitrust community for more than a decade, the Supreme Court held in *FTC* v. *Actavis, Inc.* that "reverse payment" settlements of pharmaceutical patent disputes "can sometimes violate the antitrust laws."[1] The Court decided that while such settlement agreements are not immune from antitrust scrutiny notwithstanding the ability of the owner of a valid patent to exclude or limit competition from infringers, they should not, as the FTC urged (and at least one Circuit had held), be deemed presumptively unlawful, and should instead be evaluated under the Rule of Reason. In so doing, the Supreme Court rejected the approach, adopted by a number of Circuits, that upheld settlement agreements imposing restrictions within the "scope of the patent."

I. The Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act ("the Act"),[2] provides a framework for regulating the pharmaceutical drug industry and is intended to encourage innovation and to facilitate the introduction of generic competition by, among other things, challenges to invalid patents.

The Act requires that manufacturers of new prescription drugs submit a New Drug Application and undergo a lengthy testing process in order to obtain FDA approval to market their drugs. Upon FDA approval of a brand-name drug, the Act allows generic manufacturers to "piggy-back" on the brand-name manufacturer's efforts by filing an Abbreviated New Drug Application ("ANDA") to obtain marketing approval.[3] The Act provides valuable incentives for generics to be the first to file an ANDA, including granting the first generic applicant a 180-day period of exclusivity during which time they are the only generic authorized to compete with the brand-name drug. However, the generic manufacturer must provide the FDA with assurances that its drug will not infringe any of the brand-name's patents.

One way for generic manufacturers to provide this assurance is to certify under paragraph IV of the Act that any relevant patents either are invalid or will not be infringed, a path that "automatically counts as patent infringement" and usually provokes a patent infringement suit by the branded drug maker.[4] This kind of litigation has often been settled with a sizable payment from the brand-name drug manufacturer to the generic manufacturer, together with a corresponding agreement from the generic drug maker to delay its entry into the market. These settlement agreements are known as "pay-for-delay" or "reverse payment" agreements. (The latter term is applied because of the unusual posture of a patent plaintiff settling a case by paying the defendant, a reversal of the usual settlement arrangement). Such agreements have been repeatedly challenged by the FTC and private parties as antitrust violations.

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[1] *FTC* v. *Actavis, Inc.*, 570 U.S. ____ (2013), No. 12-416, slip. op. (June 17, 2013) at 2 ("*Opinion*"), *available at* http://www.supremecourt.gov/opinions/12pdf/12-416_m5n0.pdf.

[2] 21 U.S.C. § 355(j).

[3] *Opinion* at 3.

[4] *Id.* at 4. Under the Act, if the brand-name manufacturer files an infringement suit within 45 days, the FDA must withhold approval of the generic for approximately 30 months while the parties litigate. *See* 21 U.S.C. §355(j)(5)(B)(iii). If the suit is not decided within this period, the FDA can approve the generic. *See id.*

II. Facts and Procedural History

In 2003, Solvay Pharmaceuticals obtained a patent for its brand-name drug AndroGel. Later that same year, Actavis, Inc. and two other generic drug manufacturers sought approval from the FDA to market generic versions of AndroGel, certifying under paragraph IV of the Hatch-Waxman Act that Solvay's patent was invalid and that their drugs did not infringe it.

Solvay subsequently initiated a patent infringement suit against the generic manufacturers, and 30 months later the FDA approved Actavis's generic product, but in 2006, all of the parties settled. Under the terms of the settlement, Actavis and the other generic manufacturers agreed not to market their drugs until August 31, 2015 (a date 65 months before the expiration date of the Solvay patent) and also agreed to promote AndroGel to doctors.[5] Solvay agreed to pay each of the generic manufacturers millions of dollars — $12 million to Paddock, $60 million to Par, and between $19-$30 million annually, for nine years, to Actavis — "as compensation for other services the generics promised to perform."[6]

In 2009, the FTC filed suit against all of the settling parties alleging that the settlements violated § 5 of the Federal Trade Commission Act. After the District Court dismissed the FTC's complaint, the Court of Appeals for the Eleventh Circuit affirmed, stating that "'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.'"[7] The Eleventh Circuit emphasized the public policy favoring settlements and noted that patent holders "have a 'lawful right to exclude others from the market.'"[8]

The Supreme Court granted the FTC's petition for certiorari, noting that "different courts have reached different conclusions about the application of the antitrust laws to Hatch-Waxman-related patent settlements."[9]

III. The Supreme Court's Decision

In a 5-3 opinion (with Justice Alito recused) delivered by Justice Breyer, the Court reversed the decision of the Eleventh Circuit Court of Appeals, holding that reverse payment settlements "can sometimes violate the antitrust laws" and should be evaluated using a Rule of Reason approach, which requires a balancing of procompetitive justifications and anticompetitive effects.[10]

Holding that "the FTC should have been given the opportunity to prove its antitrust claim,"[11] the Court based its conclusion on the following five considerations: (1) reverse payment settlements have the "'potential for genuine adverse effects on competition;'"[12] (2) such "anticompetitive consequences will at least sometimes prove unjustified;"[13] (3) "where a reverse payment threatens to work unjustified anticompetitive harm, the patentee

[5] *Opinion* at 5.

[6] *Id.* at 6.

[7] *Id.* at 6-7 (internal citation omitted).

[8] *Id.* at 7 (internal citation omitted).

[9] *Id.*

[10] *Id.* at 2, 20-21.

[11] *Id.* at 14.

[12] *Id.* (quoting *FTC* v. *Indiana Federation of Dentists*, 476 U.S. 447, 460-61 (1986)).

[13] *Id.* at 17.

likely possesses the power to bring that harm about in practice;"[14] (4) antitrust actions are "likely to prove more feasible administratively than the Eleventh Circuit believed" given that "it is normally not necessary to litigate patent validity to answer the antitrust question" and that "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness;"[15] and (5) litigating parties have the option of settling "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."[16]

While recognizing the desirability of settlements, especially given the expense and complexity of patent litigation, the Court emphasized that "this patent-related factor should not" immunize pay-for-delay settlements from antitrust scrutiny given that "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly.'"[17] The majority focused upon the unique position occupied by first filers under the Hatch-Waxman Act, stating that "a reverse payment settlement with the first filer" removes "'the most motivated challenger, and the one closest to introducing competition.'"[18]

Although the FTC advocated that reverse payment settlements should be presumptively unlawful, the Court noted that "abandonment of the 'rule of reason' . . . is appropriate only where 'an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets.'"[19] Given that the likelihood that a reverse payment will have anticompetitive effects depends, *inter alia*, upon "its size, its scale in relation to the payor's anticipated future litigation costs, [and] its independence from other services for which it might represent payment," the Court held that the more nuanced analysis of the Rule of Reason approach was appropriate.[20] While the Court left it "to the lower courts the structuring of the present rule-of-reason antitrust litigation," it noted that "by examining the size of the payment" courts may be able to assess the likely anticompetitive effects "without litigating the validity of the patent."[21]

Chief Justice Roberts, together with Justices Scalia and Thomas, dissented, emphasizing that patents "carve[] out an exception to the applicability of antitrust laws" and that therefore the "correct approach" is to examine whether a settlement gives "monopoly power beyond what the patent already gave."[22] The dissenting justices noted that the motivations of patent holders in paying reverse settlements may be difficult to determine, as they may not be driven by uncertainty about the strength of their patent but instead by "other legitimate factors like risk aversion."[23] The dissenting justices further argued that the majority's decision will have the effect of discouraging settlements and may "discourage generics from challenging pharmaceutical patents in the first place."[24]

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[14] *Id.* at 18.

[15] *Id.* at 18-19.

[16] *Id.* at 19.

[17] *Id.* at 14, 9 (internal citation omitted).

[18] *Id.* at 16 (internal citation omitted).

[19] *Id.* at 20 (quoting *California Dental Association* v. *FTC*, 526 U.S. 756, 770 (1999)).

[20] *Id.* at 20-21.

[21] *Id.* at 19-21.

[22] Dissent at 1.

[23] *Id.* at 13.

[24] *Id.* at 17.

IV. Significance of the Decision

The Court's decision makes clear that it views reverse payment settlements as presenting genuine anticompetitive concerns and that patents will no longer be presumed to be valid in this context. While antitrust scrutiny of pay-for-delay agreements need not necessarily involve a full examination of the validity of the patent, the Court noted that the size of the payment may indicate a need for concern and more in-depth scrutiny. It remains to be seen whether the decision's impact will be restricted to the context of settlements arising under the unique and complex scheme fashioned by the Hatch-Waxman Act, as it should, or whether plaintiffs will try to expand its impact to other contexts involving patents and settlements. The dissent predicted that the strength of the patent would likely play a significant role in any assessment of agreements.

In the Hatch-Waxman arena itself, one can expect to see any settlement agreements in the future attempt to take account of those factors, such as nonpretextual payment for other services, that the Court recognized were not paying for delay and not anticompetitive. With respect to existing agreements, it is unclear whether the burdens of establishing a Rule of Reason analysis will limit private actions (as opposed to governmental efforts at enforcement) or whether the relatively limited types of justifications explicitly identified by the Court's majority as legitimate for such agreements may embolden private litigants. It also remains unclear what effect, if any, the Supreme Court's decision will have on legislation that has been introduced in Congress that would make reverse payment settlements in the pharmaceutical patent context presumptively unlawful.

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If you have any questions about the issues addressed in this memorandum or if you would like a copy of any of the materials mentioned, please do not hesitate to call or email Elai Katz at 212.701.3039 or ekatz@cahill.com; Dean Ringel at 212.701.3521 or dringel@cahill.com; Laurence T. Sorkin, Senior Counsel, at 212.701.3209 or lsorkin@cahill.com; Jamie Gottlieb at 212.701.3138 or jgottlieb@cahill.com.