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## The Supreme Court Rules that Antitrust Challenges to Reverse Payment Agreements Between Brand and Generic Pharmaceutical Companies Are Governed by the Rule-of-Reason Standard

June 18, 2013

Yesterday, in *Federal Trade Commission v. Actavis, Inc.*, No. 12-416, the Supreme Court held that reverse payment (or so-called “pay for delay”) agreements between brand and generic pharmaceutical companies are not immune from antitrust challenge, even where the settlement is within the scope of patent rights held by the patent holding brand pharmaceutical company. In a 5-3 decision, the Court explained that whether a particular restraint exceeds the scope of a patent monopoly is a “conclusion that flows from the analysis and not . . . its starting point.” However, rather than adopting the FTC’s position of presumptively assuming the illegality of reverse payment agreements, the Court ruled that the appropriate governing standard for such cases is the traditional rule-of-reason test. Had the Court endorsed the scope-of-the-patent test, the FTC’s ability to challenge such agreements would have been largely eviscerated. By staking out a middle ground approach and adopting the rule-of-reason test, albeit with some special gloss, the Court has ensured that the FTC will likely step up its investigations of reverse payment settlements and bring more enforcement cases in circumstances it deems appropriate—in many instances in FTC administrative proceedings rather than in district courts—and that private antitrust plaintiffs will redouble efforts to bring parallel suits seeking treble damages. Pharmaceutical companies will face a period of uncertainty and volatility as administrative law judges and courts undertake the searching inquiry required by the rule-of-reason test and grapple with the Court’s unanswered questions.

### BACKGROUND AND CIRCUIT SPLIT

Under the Hatch-Waxman Act, a generic pharmaceutical company may obtain FDA clearance for a generic version of a drug for which there is already an approved brand version. A generic company need only establish that the generic and brand drugs are bioequivalent, as well as make a certification, one of which is that the drug’s patent is invalid and/or not infringed. This “Paragraph IV” certification is considered constructive patent infringement, and the brand company may immediately bring a patent infringement case against the generic company.

Should the companies decide to settle their patent infringement case, the companies are required to submit their settlement agreements to U.S. antitrust regulators. Prior to the Supreme Court decision, there was a circuit court split regarding the proper standard pursuant to which a district court should examine settlement

The Report From Washington is published by the Washington, D.C. office of Simpson Thacher & Bartlett LLP.

agreements that include a payment by the brand manufacturer to the generic company to refrain from marketing a competing generic product until a later date, known as a "reverse payment agreement" and by some as a so-called "pay for delay" agreement.

In assessing such challenges, the Eleventh Circuit and other circuits adopted a "scope-of-the-patent" approach, which provided that a reverse payment settlement agreement was *per se* lawful as long as the agreement's purported anticompetitive effects fall within the exclusionary scope of the patent. Thus, if the agreement in question provided for the generic company to enter the market at some point earlier than the expiration of the patent in question, the agreement would be deemed *per se* lawful, without regard for the strength or weakness of the patent.

On the other hand, the Third Circuit adopted a different approach in *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 209 (3d Cir. 2012), applying a "quick look" or "truncated rule of reason" analysis for reverse payment settlement agreements under which a reverse payment agreement is presumed to be anticompetitive, forcing an antitrust defendant to bear the burden of establishing a procompetitive justification for the agreement. The Third Circuit applied this analysis because the *K-Dur* respondents "engaged in practices similar to those subject to [a] *per se* [antitrust] analysis."

## THE ACTAVIS CASE

In 1995, the petitioner and a nonparty co-developed AndroGel, a new drug to treat men with chronically low testosterone, and obtained a patent for AndroGel's formulation, which is currently set to expire in August 2020.

In 2003, two generic companies (Watson and Paddock) sought approval for a generic version of AndroGel, and made a Paragraph IV certification as to the patent in question. The brand manufacturers responded by pursuing patent infringement lawsuits against the generic firms.

The parties litigated the case for several years, but in 2006, before the district court decided any substantive motions, the parties settled the case. As part of the settlement terms, petitioner's parent company (Solvay) agreed to grant a license to Watson and Paddock to launch generic versions of AndroGel in 2015, five years *before* the patent at issue expired. As a side business arrangement, from 2006 to 2012, Solvay agreed (1) to pay Watson and another firm (Par) to promote AndroGel and (2) to compensate Paddock for providing manufacturing capacity.

After investigating the case, the FTC filed suit, alleging that Solvay, Watson, Par, and Paddock violated the antitrust laws by entering into the settlement and concurrent business agreements. Specifically, the FTC alleged that (1) the business agreements were not "independent business transactions," (2) Solvay overpaid for the services, and (3) the agreements induced the generic manufacturers to accept a later entry date for their versions of AndroGel.

The district court granted the defendants' motion to dismiss the complaint on existing Eleventh Circuit precedent holding that the scope-of-the-patent test was the proper way to examine a Hatch-Waxman patent settlement. In applying this test, the district court must evaluate (1) the scope of the exclusionary potential of the patent, (2) the extent to which the agreements exceed the scope, and (3) the resulting anticompetitive effects. In ruling for the defendants, the court explained that the settlements did not exceed the scope of the patent's exclusionary potential given the lack of any allegation by the FTC that any product other than AndroGel was involved. The court also noted that the reentry date was five years earlier than the patent allowed.

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**-Supreme Court**

On appeal, the Eleventh Circuit affirmed, holding 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." The FTC argued for a change in law, proposing that reverse-payment agreements be deemed presumptively unlawful through a "quick look" analysis, but the Circuit disagreed, finding that a "retrospective predict-the-likely-outcome-that-never-came" inquiry would be unmanageable, as it would essentially require a second evaluation of a patent's presumed validity. The Court of Appeals explained that the district courts should not have to undertake the "turducken task" of "attempt[ing] to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to [a] judgment" that never came to fruition. In other words, a district court would have the herculean task of deciding a patent case within an antitrust case about the settlement of the patent case. In conclusion, the panel provided that such a "retrospective" approach was likely to be (1) unreliable, (2) too burdensome for both parties and the court, (3) would "undo much of the benefit of settling," and (4) would discourage settlements. The Circuit denied a rehearing *en banc*.

## SUMMARY OF THE DECISION

In a 5-3 decision written by Justice Breyer and joined by Justices Kennedy, Ginsburg, Sotomayor, and Kagan, the Court held that although the anticompetitive effects of a reverse payment agreement might fall within the exclusionary potential of a patent, such potential does not immunize reverse payment agreements from antitrust attack. In reversing the Eleventh Circuit's decision, the Court explained that "it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well." Accordingly, "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent."

While recognizing the "general legal policy favoring the settlement of disputes," Justice Breyer wrote that there were five considerations requiring reversal of the Eleventh Circuit. First, the Court noted that reverse payment agreements have the potential for genuine adverse effects on competition because the payment "amounts to a purchase by the patentee of the exclusive right to sell its product," which it already has but would lose if the patent litigation were to continue. Second, the Court found that these anticompetitive consequences "will at least sometimes prove unjustified." Justice Breyer recognized that "offsetting or redeeming virtues are sometimes present." For example, a reverse payment "may amount to no more than a rough approximation of the litigation expenses saved through the settlement" or "may reflect compensation for other services that the generic has promised to perform." But the possibility of such legitimate justifications did not, in the majority's view, "justify dismissing the FTC's complaint." Third, the Court observed that where a pay-for-delay settlement may cause anticompetitive harm, the patentee likely has the power to bring about the harm through its exercise of market power in the form of higher-than-competitive profits. Fourth, Justice Breyer held that an antitrust action is more feasible administratively than the Eleventh Circuit believed, as high reverse payments can provide a "surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." Finally, he noted that there are multiple ways to settle a

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**-Justice Breyer**

lawsuit that do not require a large, unjustified reverse payment.

Following its reasoning, the Court rejected the FTC's proposed "quick look" approach that would presume all such settlements to be illegal and shift the burden of proof to defendants. Justice Breyer found that a rule-of-reason standard was more appropriate given the complexities involved with reverse payment settlements, such as the size of the payment itself, the payment's "scale in relation to the payor's anticipated future litigation costs," "its independence from other services for which it might represent payment," and "the lack of any other convincing justification." Accordingly, the Court ruled that the FTC is required to prove its case "as in other rule-of-reason cases," and left lower courts with the task of "the structuring of the present rule-of-reason antitrust litigation." In oral argument, Justice Breyer had highlighted the ability of the lower courts to handle such complex matters through the many litigation tools at their disposal.

Chief Justice Roberts, joined by Justices Scalia and Thomas, dissented, arguing that the majority's reasoning that "a patent holder violates the antitrust laws merely because the settlement took away some chance that his patent would be declared invalid by a court" is inherently flawed. First, Chief Justice Roberts stressed that patents are presumptively valid, and simply because a court has not rendered an answer does not mean that one does not exist. Second, the dissent argued that the majority's position may lead to absurd results where a patent holder pays a reverse payment settlement to one party and be held in violation of the antitrust laws for litigating the same patent against a different party. Third, the majority's presentation of the issue—"taking away any chance that a patent will be invalidated is itself an antitrust problem"—must also factor in other forms of consideration, as the other forms may take away "some chance that the generic would have litigated until the patent was invalidated."

## IMPLICATIONS

In *Actavis*, the Court rejected the scope-of-the-patent test and chose to apply the rule-of-reason to decide the legality of reverse payment agreements. By embracing the rule-of-reason test, the Court struck a middle ground between the FTC's and pharmaceutical companies' positions. The decision ensures that the FTC's enforcement efforts will likely increase and that private plaintiffs will redouble efforts to bring parallel cases seeking treble damages. After years of fighting in the district courts, the FTC will probably bring many of its challenges now in FTC administrative proceedings. Interestingly, that will permit respondents in such proceedings to appeal an adverse FTC decision to any circuit court in a jurisdiction where the respondent does business. Pharmaceutical companies will face a period of uncertainty and volatility as administrative law judges and courts undertake the intensive inquiry required by the rule-of-reason test and wrestle with questions left unanswered by the Court.

The majority opinion does contain some special gloss on the rule-of-reason test as applied to reverse payment agreements. Thus, Justice Breyer appeared to put an important limit on the scope of challenges by observing that it "is normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham)." Justice Breyer noted that "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." Somewhat inconsistently, in the same passage, he recognized that the "owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity



justifies a large payment.” That observation at least suggests that a brand pharmaceutical manufacturer should be permitted to explain that a large payment was justified despite a small risk of patent invalidity. How far such a defendant may go without litigating the validity of the patent itself will be left to administrative law judges and lower courts to sort out. Moreover, an argument can be made that private plaintiffs must offer some evidence on the patent’s invalidity (or at least defendants must be given leeway to adduce evidence of the patent’s validity) because private plaintiffs must establish what the “but for” world would have been absent the settlement. If the “but for” world would be one in which the patent’s validity would be upheld, plaintiffs will not be able to establish damages. Logically, the same argument should apply even in an administrative proceeding because the FTC should have difficulty establishing anticompetitive effects if the generic firm likely would have failed to prove invalidity and not entered the market prior to the patent’s expiration. Finally, Justice Breyer focused on a few factors in particular that would indicate the “likelihood of a reverse payment bringing about anticompetitive effects.” These include not only the “size” of the payment, but also the payment’s “scale in relation to the payor’s anticipated future litigation costs” and the payment’s “independence from other services for which it might represent payment.” Pharmaceutical companies will want to consider each of these factors carefully when deciding whether to enter into reverse payment settlements in the future as they are likely to be the battleground in cases challenging such agreements on antitrust grounds.

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