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The Supreme Court Hears Oral Arguments on the Proper Antitrust Standard Governing Reverse-Payment or So-Called "Pay for Delay" Agreements Between Brand and Generic Pharmaceutical Companies

March 26, 2013

The Supreme Court heard oral arguments yesterday in *Federal Trade Commission v. Actavis, Inc.*, No. 12-416, a closely-watched antitrust case in which the Court is expected to clarify if a district court should presume the illegality of reverse-payment (or so-called "pay for delay") agreements between brand and generic pharmaceutical companies or find such settlements to be immune to antitrust scrutiny as long as the terms of the settlement come within the scope of patent rights held by the brand pharmaceutical company. The case is significant because the FTC has made challenges to such agreements a major policy priority of the Commission for more than a decade. Only eight Justices will decide the appeal as Justice Alito recused himself.

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. There is currently a circuit court split regarding the proper standard pursuant to which a district court should examine settlement 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 have adopted the scope-of-the-patent approach, which provides that a reverse-payment settlement agreement is *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 provides for the generic company to enter the market at some point earlier than the expiration of the patent in question, the agreement will be deemed *per se* lawful, without regard for the strength or weakness of the patent.

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

On the other hand, the Third Circuit recently 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 settlement 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.

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*.

In December 2012, the Supreme Court granted the FTC's petition for writ of certiorari, accepting the FTC's articulation of the question presented: "Whether reverse-payment agreements are *per se* lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud, or instead are presumptively anticompetitive and unlawful."

"a payment from one business to another in exchange for the recipient's agreement not to compete is a paradigmatic antitrust violation"

-The Federal Trade Commission

HIGHLIGHTS FROM THE ORAL ARGUMENT

The Deputy Solicitor General began the argument on behalf of the FTC by stating that "a payment from one business to another in exchange for the recipient's agreement not to compete is a paradigmatic antitrust violation," and that reverse-payment agreements are to be treated no differently.

Shortly thereafter, Justice Scalia asked if there was any distinction between a reverse-payment settlement and a license to compete. The FTC responded that a reverse-payment settlement is a substitute for earning profits in a competitive marketplace, and that such a settlement precludes competition between the brand and generic pharmaceutical manufacturers. Justice Scalia then suggested that pay for delay may appear to be a "short-circuit" version of a license and asked whether there was a case in which a patentee acting within the scope of the patent had nonetheless been held liable under the antitrust laws for acting within the scope of the patent. The FTC provided a hypothetical but did not cite a specific case to the Justices.

Following the FTC's explanation that reverse-payment agreements should face a rebuttable presumption of illegality, Justice Kennedy expressed concern that the government's proposed test is the same for both weak and strong patents, which could diminish the effect of market forces. Justice Scalia resumed his own line of questioning, asking "why should we overturn understood antitrust law just to [] patch up a mistake [created by the Hatch-Waxman Act]"?

Justice Breyer then began to question the FTC's position. Explaining that he had never seen the rigid, "whole set of complex *per se* burden of proof rules" proposed, he asked the government to present him with a case. The FTC's example was the "quick look" approach followed in *NCAA v. Regents of the University of Oklahoma*. Justice Breyer suggested that reverse-payment challenges should be evaluated by district court judges and shaped in light of all the relevant circumstances. He explained that the "quality of proof required should vary with the circumstances, and he cautioned against creating "some kind of administrative monster" by applying the FTC's test.

Justice Sotomayor appeared sympathetic to Justice Breyer's observations and had "difficulty understanding why the mere existence of a reverse payment [] presumptively changes [] the burden from the plaintiff." She elaborated that, contrary to the quick look approach, the initial burden of proof should fall on the government. Judge Sotomayor followed with a query regarding why the rule of reason test was "so bad." The FTC suggested that the rule is difficult to administer and too complicated.

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-Respondents

Following the FTC's opening, respondents explained that "all of the cases that have found violations of the antitrust laws based on a patent-based restraint do so because the object of the agreement, the restraint that's being achieved in the agreement, is beyond the scope that could be legitimately achieved with a patent."

Suggesting again that he was not enamored of either the FTC's or respondents' position, Justice Breyer asked respondents to provide an antitrust test that "cut[s] some kind of line between a *per se* rule and the kitchen sink." Respondents responded that there is no intermediary test because anticompetitive effects cannot be measured without determining the likely outcome of a patent case if it had been litigated to conclusion.

As an alternative, Justice Kennedy suggested "rules and caps," where the government could gear the potential settlement amounts in terms of the gains and losses of the generic pharmaceutical company. Respondents pointed out that a patent gives a patent holder the legal right to exclude, so unless the patent is invalid, damages could not be accurately calculated.

Justice Kagan asked if the respondents' position was that a brand company could communicate with the generic company about a potential profit loss due to generic entry, with the brand company paying the generic company an amount less than the amount of lost profits to the brand. Consistent with the scope-of-the-patent standard, the respondents argued that such a settlement would be acceptable so long as it was made in good faith. Justice Kagan observed that if respondents' suggestion is adopted, both the brand and generic pharmaceutical companies will be incentivized to split monopoly profits "to the detriment of all consumers."

Justices Ginsburg and Kennedy proceeded to inquire about the value of the scope-of-the-patent test, which has been applied for ten years; respondents elaborated that such cases have been consistently settled 25-30% of the time. The respondents explained that each settlement must be filed with the FTC, giving the government an opportunity to examine each settlement's terms.

IMPLICATIONS

In *Actavis*, the Court has chosen to examine the intersection of the antitrust and patent laws. If the Court agrees with the FTC's (and the Third Circuit's) position that reverse-payment agreements are presumptively anticompetitive and unlawful, brand and generic pharmaceutical companies will find it more difficult to reach settlements because they will be required to overcome a presumption of illegality if their settlements involve a payment from the brand manufacturer to the generic firm. However, such a result would mean that the Eleventh Circuit's fears would come to pass: district courts may be forced to engage in the "turducken task" of re-evaluating a presumptively lawful patent, applying an unreliable test that would chill settlements. Should the Supreme Court adopt the Eleventh Circuit's opinion, reverse-payment agreements would continue to be lawful absent sham litigation or fraud in obtaining the patent, allowing brand companies to exercise their rights under a presumably valid patent.

The Justices' questions and comments suggest that a majority of the Court may not be persuaded by either the FTC's proposed "quick look" approach based on presumptive illegality or the Eleventh Circuit's scope-of-the-patent test. At least some of the Justices appear inclined to hold that reverse-payment agreements should be reviewed under a traditional rule of reason analysis with the FTC bearing the initial burden of proof or some other test that would allow a district court to consider all the relevant circumstances. Whether a majority of the Court would support the rule of reason test for

reverse-payment agreements is unclear. It does appear that most Justices are not comfortable shifting the initial burden to defendants as advocated by the FTC.

Adding a twist is that Justice Alito's recusal sets up the possibility of a 4-4 split, which would leave standing the Eleventh Circuit scope-of-the-patent ruling and postpone the day of reckoning for the proper standard governing reverse-payment cases under the antitrust laws.

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