Fed. Trade Comm'n v. Actavis, Inc. 133 S. Ct. 2223 (2013)

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BACKGROUND

A pharmaceutical drug manufacturer attempting to introduce a new brand-name drug to the market must first submit a New Drug Application ("NDA") to the Food and Drug Administration ("FDA"). While the FDA reviews the application, the drug is subjected to a lengthy and vigorous testing procedure. If it survives this process, the FDA then approves the brand-name drug, and the manufacturer receives the green light to commence marketing and sales. The door then opens to generic drug manufacturers to seek approval for the marketing of identical, generic versions of the drug.

The generic drug manufacturer's process for approval is usually much shorter and less strenuous, allowing for a quicker entry to market, which ultimately increases competition in the pharmaceutical industry. The Hatch-Waxman Act,[1] which regulates the industry, permits generic drug manufacturers to file an Abbreviated New Drug Application ("ANDA") with the FDA so long as the manufacturer specifies that the generic drug "has the same active ingredients as, and is biologically equivalent to, the already-approved brand-name drug."[2]

The ANDA must include assurances that the generic drug does not infringe upon the brand-name drug manufacturer's patents. There are various methods of making such assurances, but the most common way is for the generic manufacturer to attest to the invalidity or inapplicability of the brand-name drug manufacturer's patent(s). This process, commonly referred to as "Paragraph IV,"[3] nearly always results in litigation to determine the validity of the patent(s). If, within forty-five days, the brand-name drug manufacturer decides to move forward with an infringement lawsuit, the FDA delays the generic drug manufacturer's application for a thirty-month period, leaving time for the two parties to litigate the validity of the patent(s) in question. So long as a court returns a verdict on the infringement issue within the thirty-month period, the FDA bases its decision to approve the ANDA on the finding of the court. If a decision is

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1. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of the U.S. Code).

2. Fed. Trade Comm'n v. Actavis, Inc., 133 S. Ct. 2223, 2228 (2013) (internal quotations omitted).

3. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2012).

not made within that time, the FDA retains the power to grant or deny the generic drug manufacturer's application.

THE CASE

In *Fed. Trade Comm'n v. Actavis, Inc.*, the Federal Trade Commission ("FTC") claimed that a reverse payment settlement between the holder of a drug patent and two generic drug manufacturers was an unfair restraint on trade in violation of federal antitrust laws. Respondent Solvay Pharmaceuticals ("Solvay") completed a NDA, which was approved by the FDA in 2000, for a brand-name drug called AndroGel. Solvay obtained the necessary patent for AndroGel in 2003. Later that same year, Actavis, Inc. ("Actavis"), another respondent, filed an ANDA for a generic drug based on AndroGel, utilizing "Paragraph IV" to allege that Solvay's patent for AndroGel was invalid. Solvay promptly initiated an infringement lawsuit against Actavis.

In 2006, Actavis and Solvay settled their patent dispute out of court. The settlement agreement forbid Actavis from bringing its generic drug to market until 2015, sixty-five months before Solvay's patent for the brand-name drug expired. The terms of the settlement also required Actavis to promote AndroGel to urologists. In return, Solvay agreed to pay Actavis an estimated annual $19–30 million sum for nine years and pay similar large amounts to other generic manufacturers. This type of settlement scheme is commonly known as a reverse payment settlement.

On January 29, 2009, the FTC brought suit against Solvay, Actavis, and two other generic manufacturers for allegedly violating § 5 of the Federal Trade Commission Act.[4] In its complaint, the FTC argued that by accepting payments from Solvay, Actavis was unlawfully agreeing to take a cut of Solvay's "monopoly profits."[5] The FTC further asserted that the payments from Solvay to Actavis were made solely to keep Actavis' generic drug from competing against AndroGel. The United States District Court for the Northern District of Georgia initially dismissed the FTC's complaint for failure to state a relevant antitrust violation. The FTC then appealed to the Court of Appeals for the Eleventh District.[6] The appeals court affirmed the district court's decision, stating, among other things, that reverse payment settlements are immune from antitrust scrutiny due to the importance of certain patent law policies, such as the need to protect patent holders. The FTC requested, and was granted, certiorari.

ISSUE

The Supreme Court was faced with two issues. First, did the court of appeals err when it measured the effects of the settlement's potential

4. 15 U.S.C. § 45 (2012).

5. *Actavis*, 133 S. Ct. at 2225.

6. Fed. Trade Comm'n v. Watson Pharms., Inc., 677 F.3d 1298 (11th Cir. 2012).

antitrust violations solely against patent law policy instead of also measuring those effects against federal antitrust policy? Second, is a reverse payment settlement presumptively unlawful?

DECISION

On the first issue, the Supreme Court reversed the decision of the court of appeals and remanded the case for further proceedings, finding that both patent and antitrust policies are relevant when establishing the scope of patent monopolies. Accordingly, the Court held that the appellate court should have afforded the FTC a chance to prove the antitrust claim. In response to the second issue, the Supreme Court did not find reverse payment settlements to be presumptively unlawful. Instead, it advised trial courts to decide future cases in a manner consistent with the Court's discussion in the opinion.

REASONING

The Supreme Court began its analysis by determining that it is possible for patent-related settlement agreements to violate federal antitrust laws. In making this determination, the Court relied on *United States v. Singer Mfg. Co.*,[7] a patent case that illustrates the broad reach of antitrust laws and the strict limitations these laws place on patent owners. The Court then turned to the Hatch-Waxman Act and found that the Act retains a "procompetitive thrust"—shown by specific provisions that welcome challenges to the patents held by brand-name drug manufacturers and make plain the need to consider antitrust and monopolistic concerns.[8]

After recognizing the lower court's discussion of policy that favors settlement, the Court provided a basis for its own antitrust analysis. The Court discussed five considerations that led to its conclusion that the FTC should have had the opportunity to prove its antitrust claim.

1. FIRST CONSIDERATION

The Court first contemplated whether reverse settlement agreements could negatively affect competition. The Court did not blatantly state that the settlement agreement at issue negatively affected competition. However, the Court suggested that an agreement where a brand-name drug manufacturer pays generic drug manufacturers to stay out of the market could lead to higher prices for pharmaceuticals. The brand-name and generic drug manufacturers would share profits from the high-priced drug, while the consumer was denied the lower-cost generic drug, resulting in a net loss for the consumer and the market.

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7. 374 U.S. 174 (1963).

8. *Actavis*, 133 S. Ct. at 2225.

2. SECOND CONSIDERATION

The Court then noted that the suggested anticompetitive consequences might not be justifiable. While conceding that reverse payment settlements might sometimes be justified by "traditional settlement considerations," the Court asserted that antitrust defendants should be required to present specific justifications to a court for the agreement. The defendants should also be required to demonstrate that the settlement does not violate applicable antitrust laws.

3. THIRD CONSIDERATION

Third, the Court considered whether reverse payment settlements could lead to increased market power for the brand-name drug manufacturer. The Court expressed the concern that increased power could lead not only to "higher-than-competitive profits" but could also create a barrier of entry for smaller and less powerful companies.[9]

4. FOURTH CONSIDERATION

Fourth, the Court discussed the possibility that antitrust litigation could be more administratively feasible than litigation over the validity of every patent. The Court suggested that large and unexpected reverse payments could strongly indicate that the company making these payments was not doing so for any legitimate reason, but instead, as a result of doubt. Larger payments, the Court stated, might reveal that the company did not want to engage in market competition due to doubts about the validity of its patent. Thus, by utilizing an antitrust analysis and considering the market effects of reverse payments, courts would be more likely to force transparency in brand-name companies, which could result in less complex litigation centered on the validity of patents.

5. FIFTH CONSIDERATION

Finally, the Court proposed that a reverse payment settlement subject to antitrust scrutiny would not prevent litigating parties from settling their lawsuits in other fashions. The Court suggested various alternate options for settlement, such as allowing a genetic manufacturer to enter a market before a brand-name patent expires without prior reverse payments. While the Court conceded that this course of action would probably not be economically preferable to either party, the Court challenged the parties to justify their reverse payment settlement agreement. If it were revealed that the only justification for the settlement was to share "patent-generated monopoly profits," then antitrust laws would come into play and prevent the parties from reaching such a settlement.[10]

9. *Id.* at 2231.
10. *Id.* at 2237.

The Court concluded by briefly discussing the FTC's request for the Court to create a rule that would presumptively outlaw reverse payment settlements. The Court, however, did not extend its holding to include a presumption of unlawfulness due to the possibility of situations in which a reverse payment settlement would not create anticompetitive effects.