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FTC v. Actavis, Inc.: Supreme Court Rules That Reverse Patent Settlements May Violate Antitrust Laws

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On June 17, 2013, in *FTC v. Actavis, Inc.*, the Supreme Court ruled that "reverse patent settlements" may violate the Sherman Act even though the anticompetitive effects of the settlement fall within the potential scope of the patent. The Court's 5-to-3 ruling resolved a circuit split between the Third Circuit, which had held reverse patent settlements presumptively unlawful under the "quick look" approach, and the Eleventh Circuit, which had held reverse patent settlements immune from antitrust scrutiny so long as the anticompetitive effects of the settlement was within the potential scope of the patent. Although the Supreme Court rejected the Eleventh Circuit's approach, the Court did not go so far as the Third Circuit. The Supreme Court held that "reverse patent settlements" were not presumptively unlawful under the "quick look" approach, but instead should be analyzed under the sliding scale of the "rule of reason."

The Court's ruling provides little guidance for lower courts, however. The dissent, authored by Chief Justice Roberts, complains about the lack of clear guidelines and sarcastically offers "[g]ood luck to the district courts" that have to scrutinize patent settlement agreements under "antitrust law's unruly rule of reason."

Reverse payment settlement agreements, which are also sometimes referred to as "pay for delay" agreements, exist in the pharmaceutical industry and more specifically within the regulatory framework of the Hatch-Waxman Act. That Act requires prospective generic drug manufacturers to certify whether the patent on the branded drug is invalid. For a variety of reasons, a certification by the generic manufacturer that the patent for the branded drug is invalid provokes the branded drug manufacturer to sue the would-be generic manufacturer. The first generic drug manufacturer to make a such a certification obtains a 180 day right of exclusivity over other generic manufacturers. Instead of risking their chances in patent litigation, the branded manufacturer often enters into a settlement agreement with the generic manufacturer. In reverse payment settlements, the branded manufacturer (the patentee) will pay the generic manufacturer (the alleged infringer) to honor its patent and drop any challenges to the validity of the patent. These payments are called "reverse" payments because the patent holder does not usually pay the alleged infringer to settle a case. The payments are also called "pay for delay" because the FTC claims that the branded manufacturer is paying the generic manufacturer to delay its entry into the market, which, given some of the unique aspects of the Hatch-Waxman Act, also delays the entry of other generic manufacturers, thus protecting the branded manufacturer from generic competition.

The FTC claims that reverse payment settlement agreements are presumptively anticompetitive. A line of cases from the Eleventh Circuit, however, has held that such agreements are not anticompetitive so long as the settlement term is within the potential scope of the patent. In other words, so long as the generic manufacturer does not promise to stay out of the market longer than the term of the patent, the settlement agreement is protected by the exclusivity grant of the patent. Under the Eleventh Circuit's approach, a court should not second-guess the validity of a patent or the motives of the parties in entering into the settlement agreement.

In *FTC v. Actavis, Inc.,* the Supreme Court reversed the Eleventh Circuit's dismissal of the FTC's challenge to a settlement agreement between a generic drug manufacturer and the manufacturer of the braded drug AndroGel. The Court held that reverse payment settlements could violate the Sherman Act even though the effect of the settlement agreement was within the potential scope of the patent. The Court, however, did not go so far as the FTC requested. The Court held that any challenge to reverse payment settlements was to be determined according to the "rule of reason," instead of being presumptively unlawful under the "quick look" approach. The Court described the "rule of reason" as a "sliding scale" approach, while the dissent characterized it as "unbounded."

Justice Robert's dissent ends with the following conclusion:

> The majority today departs from the settled approach separating patent and antitrust law, weakens the protections afforded to innovators by patents, frustrates the public policy in favor of settling, and likely undermines the very policy it seeks to promote by forcing generics who step into the litigation ring to do so without the prospect of cash settlements. I would keep things as they were and not subject basic questions of patent law to an unbounded inquiry under antitrust law, with its treble damages and famously burdensome discovery.

It is interesting that both sides of this dispute asked the Court to adopt a bright line rule. The FTC asked for a rule of presumptive illegality. The pharmaceutical industry asked for an identifiable line of protection from antitrust laws. Instead of adopting either position, the Court said that the answer would depend on the facts, under the rule of reason. Justices in the majority seem to have faith that lower courts will be able to work through the facts of individual cases and come to the correct decision. Justices in the dissent, however, were clearly dissatisfied with the existing framework for deciding antitrust cases. Justice Roberts referred to the rule of reason as "unruly" and "unbounded." Nevertheless, this case continues the trend of the Supreme Court rejecting bright line rules -- whether they be per se rules of illegality or immunity -- in favor of the more flexible but less predictable rule of reason.

Given how much money is involved in some of these disputes and the inherent uncertainty that exists in some of these complex patent cases, the natural tendency is for companies to hedge their bets by settling disputes. But the Court's ruling in *Actavis* make settlement less than safe. A company may settle a patent lawsuit, just to find itself in an even more complex antitrust lawsuit.

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