IP Alert: Supreme Court Hears Arguments in FTC v. Actavis

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Supreme Court Hears Arguments in *FTC v. Actavis*

By Erin E. Bryan and Paul M. Rivard

On March 25, 2013, the Supreme Court heard oral arguments in *Federal Trade Commission v. Actavis*, a case involving a circuit split regarding "pay for delay" settlements within the pharmaceutical industry. Justice Alito previously recused himself from the case.

The Supreme Court seeks to resolve a split among the circuits as to whether a brand name drug manufacturer acts illegally by paying a competing generic drug manufacturer to stay out of the market for a specified number of years. The Eleventh Circuit favors a "scope-of-the-patent" rule in analyzing pay for delay settlements, while the Third Circuit has suggested that a "quick look" rule is the better option.

During oral arguments, several of the justices seemed skeptical that a special rule should be adopted for analyzing reverse payment agreements. At the same time, the Supreme Court also appeared concerned about the effect pay for delay settlements have on consumers. Because the Supreme Court is ruling on this case with eight justices, it is possible the case decision may be split 4-4, thereby leaving in place a split among the circuits.

The Reverse Payment Settlement Agreement

In the pending case, Solvay Pharmaceuticals, Inc., applied for and obtained a patent directed to certain pharmaceutical formulations utilized in AndroGel®, which provides a treatment for low testosterone in men. After the patent was granted and made known to the FDA, Watson Pharmaceuticals (now Actavis, Inc.) and Paddock Laboratories, Inc., submitted separate abbreviated new drug applications (ANDAs) seeking approval for a generic version of AndroGel®. Each ANDA included a paragraph IV certification asserting that the proposed generic product would not infringe Solvay's patent and that the patent was invalid. Soon after Paddock submitted its ANDA, they agreed to partner with Par Pharmaceutical Companies, Inc., by sharing in litigation costs and eventually promoting Paddock's generic version of AndroGel®.

Solvay sued Watson and Paddock for patent infringement based on the paragraph IV certifications. While the patent litigation was still pending, the FDA approved Watson's ANDA. After receiving approval of the ANDA, Watson and Paddock expected to enter the market and begin selling their respective generic products within the year. Solvay initiated a settlement with Watson and Paddock/Par where Watson and Paddock/Par agreed to defer their market entry until 2015. In return, Solvay agreed to pay an estimated $19-30 million annually to Watson, $2 million annually to Paddock and $10 million annually to Par. The FTC filed suit challenging the settlement and asserting unfair methods of competition and an unlawful extension of the AndroGel® monopoly.

The district court dismissed the FTC's complaint for failure to state a claim. This decision was affirmed by the Eleventh Circuit. The Eleventh Circuit stated 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." This view is commonly referred to as the "scope-of-the-patent" approach.

Shortly after the Eleventh Circuit's decision, the Third Circuit rejected the "scope-of-the-patent" approach and instead applied a different test in deciding *In re K-Dur Antitrust Litigation*. The Third Circuit stated that reverse payment agreements should be subject to a "quick look of reason analysis" under which "any payment from a patent holder to a generic patent challenger who

agrees to delay entry into the market [is] *prima facie* evidence of an unreasonable restraint of trade."
The split between the Eleventh Circuit and the Third Circuit has raised the question as to whether reverse payment agreements are either per se lawful unless the underlying patent litigation was a sham or the patent obtained by fraud, or instead, are presumptively anticompetitive and unlawful. In other words, does a brand name drug manufacturer act illegally by paying a competing generic drug manufacturer to stay out of the market for a specified number of years?

Arguments Made by the Government

The FTC states that the "scope-of-the-patent" rule applied by the Eleventh Circuit provides no meaningful antitrust scrutiny to the settlement agreements between drug manufacturers. The lack of antitrust scrutiny leads to an increase in reverse payment agreements, which allegedly causes a substantial increase in prescription costs for consumers.
Instead, the FTC would treat reverse payment agreements as presumptively anti-competitive under the "quick look" rule. Drug companies would then have the opportunity to rebut that presumption. The burden would be on the drug companies to show that any money that changed hands was for something other than a delay of entry into the market, such as some specific property or services unrelated to competition. The drug companies could also show that any payment from one party to another was commensurate with litigation costs that were avoided by settlement.
During oral argument, the Deputy Solicitor General argued that payments given to a potential competitor in exchange for staying out of the market violate basic antitrust principles, comparing reverse payment agreements to price fixing. The government pointed out that if the patent litigation were to proceed to conclusion, no possible outcome would involve payments going from the patentee to the generic manufacturer.

Arguments Made by the Drug Companies

In contrast, the respondents Solvay, Watson and Paddock/Par state that the "quick look" test favored by the FTC is unworkable, especially in the generic drug context because it would require the court to conduct an analysis on the underlying patent's strength and validity. Rather, the drug companies favor a "scope-of-the-patent" approach to drug patent settlements. Settlements within the scope of the patent may be subject to antitrust scrutiny, but unlawful anticompetitive conduct can be found only where the underlying patent litigation is a sham or the patent was obtained by fraud.
The drug companies additionally point out that the FTC appears to be overlooking the rights that are obtained with a patent. Specifically, that a patent is presumed valid, and a patent allows for the exclusion of would-be competitors during the life of the patent, such as through the use of settlement agreements. In this case, Solvay agreed to permit market entry to Watson and Paddock/Par five years before the expiration of the patent at issue, or within the life of the patent.
Counsel argued for the respondents that Supreme Court precedent consistently requires restraints going beyond the exercise of the scope of the patent right for an antitrust violation to be found. Counsel urged that reverse payment agreements do not intrinsically present risks of anticompetitive conduct, noting that a typical patent settlement agreement involving a period of delay before market entry followed by payment of a royalty could be viewed in the same light since the infringer conceivably could have bargained for a lower royalty rate in exchange for delaying its market entry.

The Supreme Court's Response

Several of the justices during arguments appeared reluctant to adopt a rule that reverse payment agreements are presumptively anticompetitive. Justice Breyer suggested that judges are capable of identifying collusive agreements to divide profits and questioned why the standard antitrust "rule of reason" analysis was inadequate.
Justice Sotomayor also pointed out that per se rules in antitrust law are uncommon. On the other hand, she questioned whether an agreement would be considered anticompetitive if a patentee knew it had only a 50 percent chance of prevailing in the infringement action and offered the generic company a substantial payment in exchange for not pursuing the litigation. Counsel for the respondents argued the patentee would need to pay off a large number of generics in this situation, and doing so would not be cost effective.
Another theme that came out during arguments was that Hatch-Waxman is designed to encourage the challenge of patents by generics. The Deputy Solicitor General argued the type of settlements at issue interferes with such challenges, to the detriment of consumers. Counsel for the respondents pointed out that most patent infringement suits settle, and that the nature of the settlements under Hatch-Waxman is a direct result of the legislative framework itself. Counsel urged that if a problem exists, it should be corrected by legislation rather than the court fashioning a special antitrust rule.
The court is expected to issue its decision later in 2013.

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