# *FTC V. ACTAVIS:* WILL WE SEE A SPLIT DECISION?

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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.

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, i.e. whether "reverse payment agreements" are per se lawful or presumptively unlawful. The Eleventh Circuit, for example, 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.

## REVERSE PAYMENT SETTLEMENT AGREEMENTS

Within the pharmaceutical industry, there is a certain amount of rivalry and competition between drug companies who produce brand name drugs, and drug companies who produce or seek to produce generic versions of those same brand name drugs. The Drug Price Competition and Patent Term Restoration Act, otherwise known as the Hatch-Waxman Amendments, was implemented in 1984 to provide a framework to address the competing interests of the brand name manufacturer and parties seeking to market generic versions of the drug.

Initially, the manufacturer of a new drug must file a new drug application (NDA) with the Food and Drug Administration (FDA), which identifies specific required details regarding that drug. Additionally, if any patents have been obtained that cover aspects of that drug, then they must also be disclosed to the FDA. Once the NDA is approved by the FDA, a certain exclusivity period is provided to the manufacturer of the drug. During this exclusivity period, any other manufacturer may seek approval to market a generic version of the brand name drug by filing an abbreviated new drug application (ANDA) with the FDA. The ANDA may include a paragraph IV certification that states that any patents identified as corresponding to the relevant name brand drug are either invalid or will not be infringed by the generic. Once an ANDA with a paragraph IV certification is filed, the manufacturer of the brand name drug may file a patent infringement suit in response to the ANDA, which triggers an automatic stay of the ANDA approval process for 30 months. Litigation may proceed between the name brand manufacturer and the generic manufacturer during this 30-month period. Often the brand name drug manufacturer will reach a reverse payment or pay for delay settlement with the generic drug manufacturer in which the generic manufacturer will defer market entry to some later date within the life of the patent in return for an annual payment from the name brand manufacturer.

## CIRCUIT SPLIT AND COMPETING RULES

A circuit split has arisen regarding how reverse payment settlements are treated by the courts. The Eleventh Circuit has 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. In contrast, the Third Circuit has 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 Federal Trade Commission (FTC) argued to the Court that reverse payment settlements are similar to price fixing and, therefore, violate basic antitrust principles. For example, if the patent litigation were to proceed to conclusion, there would be no possible outcome that would involve the generic manufacturer receiving payments from the patentee. In addition, the "scope-of-the-patent" rule applied by the Eleventh Circuit provides no meaningful antitrust scrutiny to the settlement agreements between the drug manufacturers. Instead, the reverse payment agreements should be treated as presumptively anticompetitive under the "quick look" rule applied by the Third Circuit. 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.

In contrast, the respondents Solvay, Watson and Paddock/Par argued that reverse payment agreements do not intrinsically present risks of anticompetitive conduct. Additionally, the drug companies pointed out that the "quick look" test favored by the FTC is unworkable, especially in the generic drug context because it would require the district courts to conduct an analysis on the underlying patent's strength and validity. Rather, the drug companies argued for a "scope-of-the-patent" approach to drug patent settlements. In these settlements, 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 SUPREME COURT'S RESPONSE

After oral arguments it appeared unlikely that the Court would issue a broad ruling in *FTC v. Actavis*. Rather, it is more likely the Court will adopt a narrow ruling that falls somewhere between the positions taken by the FTC and the drug companies. Several of the justices during arguments appeared reluctant to adopt a rule that reverse payment agreements are presumptively anticompetitive as requested by the FTC. Specifically, as pointed out by Justice Sotomayor, per se rules in antitrust law are generally uncommon.

In attempting to discern what type of analysis should be applied by the district courts to reverse payment agreements, the Court was concerned that any analysis would require considering the validity of the underlying patent. Specifically, Justice Kennedy questioned whether the test for the validity of a reverse payment agreement would be the same for a strong patent versus a weak patent. Additionally, Justice Sotomayor asked 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.

An additional concern recognized by the Court is the effect of reverse payment settlement agreements on consumers. Specifically, the Hatch-Waxman Amendments were designed to encourage the challenge of patents by generics so as to increase generic entry into the market. However, the increase in challenges to patents by generics has led to an increase in the number of reverse settlement agreements. This results in more generics delaying entry into the market. The longer generics are out of the market, the longer consumers are

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expected to pay higher prices for name brand drugs. Justice Scalia questioned whether there is a problem with the Hatch-Waxman Amendments itself, and if so, then it is the place of Congress not the Court to fix the amendments.

Based on the oral arguments, it appears the Court is unlikely to rule broadly in favor of either the FTC or the drug companies. It is possible that because the case is being decided by eight justices[1], the decision could result in a 4-4 split, leaving in place a split among the circuits. However, the Court appeared to favor a narrow ruling on reverse payment settlement agreements. Justice Breyer suggested that judges are capable of identifying collusive agreements to divide profits and that the "rule of reason" analysis was adequate in assessing such agreements. Further, a "rule of reason" analysis has been applied in a variety of antitrust cases for at least 40 years and it is reasonable to assume that such a rule can continue to be applied by the district courts. If such a rule is implemented, then it will be up to the district courts to balance the anticompetitive aspects of any reverse payment settlement agreements and the burden will be on the FTC to show each agreement is anticompetitive.

A judgment is expected from the Court by early summer 2013.

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1. Justice Alito recused himself from the case. No reason has been given for the recusal.