IP Alert: FTC v. Actavis Decision Offers Guidance to Drug Manufacturers

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FTC v. Actavis Decision Offers Guidance to Drug Manufacturers

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The Supreme Court handed down a 5-3 decision yesterday in *FTC v. Actavis, Inc.*, holding pay-for-delay agreements are subject to antitrust review, but are not presumptively unlawful. The decision was authored by Justice Breyer, who was joined by Justices Kennedy, Ginsburg, Sotomayor and Kagan. Chief Justice Roberts provided a dissent, which was joined by Justices Scalia and Thomas. Justice Alito had previously recused himself from the case.
The Court overturned an Eleventh Circuit dismissal of a Federal Trade Commission complaint against Actavis, Inc., as well as additional drug companies, Solvay Pharmaceuticals, Paddock Laboratories and Par Pharmaceutical, for failing to set forth an antitrust law violation. The Court stated that pay-for-delay agreements may have significant adverse effects on competition and, therefore, found that the FTC complaint did plead an antitrust law violation. The Court went further to advise that the pay-for-delay agreement should be subject to a traditional antitrust analysis under the "rule of reason." The Court's decision resolves a circuit split as to whether pay-for-delay agreements should be analyzed under the antitrust sliding "rule of reason" standard or under a "quick look" approach.

Majority Opinion

The majority opinion states that pay-for-delay agreements should be subject to both a patent law policy and antitrust law policy analysis to determine if the agreement unlawfully restricts competition. That is, the pay-for-delay agreements should be analyzed for the scope of the exclusionary potential of the patent at issue and the possible adverse effects on competition of the agreement. The Court recognizes that subjecting pay-for-delay agreements to such an analysis may "require the parties to engage in time-consuming, complex, and expensive litigation to demonstrate what would have happened to competition absent the settlement." However, the Court sets forth a number of different considerations for why there is a concern that pay-for-delay agreements tend to have significant adverse effects on competition and should therefore be subject to antitrust analysis. These considerations include:

- "the specific restraint at issue has the 'potential for genuine adverse effects on competition.'"
- "these anticompetitive consequences will at least sometimes prove unjustified."
- "where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice."
- "an antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed."

- “the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit.”

The antitrust analysis should be conducted using a rule of reason rather than the quick look approach argued for by the FTC. A quick look approach in effect “shifts to ‘a defendant the burden to show empirical evidence of procompetitive effects.’” However, pay-for-delay agreements involve a number of complexities and variabilities that are not conducive to a quick look analysis. In fact, “‘[t]here is always something of a sliding scale in appraising reasonableness,’ and as such ‘the quality of proof required should vary with the circumstances.’” The Court has left the structuring of the rule-of-reason analysis for the lower courts.

Dissenting Opinion

The dissenting opinion disagrees with the majority’s treatment of pay-for-delay agreements as being something different from a traditional patent litigation settlement and further cautioned that the majority’s holding will likely not be limited to pay-for-delay agreements under the Hatch-Waxman act.

Additionally, the dissent argued that the Court’s decision would likely discourage the settlement of patent litigation because “there would be no incentive to settle if, immediately after settling, the parties would have to litigate the same issue — the question of patent validity — as part of a defense against an antitrust suit.” “The irony of all this is that the majority’s decision may very well discourage generics from challenging pharmaceutical patents in the first place,” the dissent stated.

Possible Impact of the Decision

Although the Court’s decision may have an impact on the formation of pay-for-delay agreements between name brand drug manufacturers and competing generic drug manufacturers in the immediate future, the impact may not be overly significant in the long term. Because all pay-for-delay agreements will be subject to review under the rule of reason, which can be a fairly flexible test, there is a real possibility that a majority of the agreements will be held to be valid and enforceable.

However, especially in the immediate future, the drug manufacturers will likely be seriously considering and balancing the costs of pursuing patent litigation, as compared to defending the validity of a pay-for-delay agreement that is subject to antitrust scrutiny. Additionally, future pay-for-delay agreements will likely be structured differently than the agreement between Solvay and Actavis, Paddock and Par. For example, pay-for-delay agreements may include compensation to the generic maker for distributing the branded drug or helping to develop the market.

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