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"Reverse Payment" Settlements Face Greater Antitrust Scrutiny Following U.S. Supreme Court Ruling in FTC v. Actavis

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Federal Trade Commission v. Actavis, Inc.

Resolving a split among the U.S. Courts of Appeals, the U.S. Supreme Court ruled that patent infringement settlement agreements between branded and generic drug manufacturers containing "reverse payment" ("pay-for-delay") provisions "can sometimes violate the antitrust laws" and that courts must apply the rule of reason when adjudicating antitrust challenges to them. A reverse payment settlement restricts the generic from entering the market until a future date (even if that date is before the patent at issue expires) and includes a transfer of value from the brand to the generic firm, typically in the form of payments arising from an ancillary agreement for services or products provided by the generic. ***Federal Trade Commission v. Actavis, Inc.***, Case No. 12-416 (U.S. Supr. Ct., June 17, 2013 (Breyer, J.) (Roberts, Chief Justice, dissenting; joined by Thomas and Scalia, Justices).

The Supreme Court reversed the U.S. Court of Appeals for the Eleventh Circuit's ruling that affirmed dismissal of a **Federal Trade Commission** (**FTC**) challenge to a reverse payment settlement. The Eleventh Circuit held that because the settlement allowed for generic competition before the brand's patent expired, the agreement was within the "scope of the patent" and thus beyond the reach of antitrust law. The Court rejected this "scope of the patent test" and remanded for adjudication under the rule of reason, which requires the FTC to prove that the agreement's anticompetitive effects outweigh its procompetitive effects. The Court also rejected the FTC's position (which the U.S. Court of Appeals for the Third Circuit had adopted in a different case) that reverse payment agreements are "presumptively anticompetitive" and that defendants should have the burden at trial to overcome the presumption.

Justice Breyer wrote the opinion, to which Chief Justice Roberts and Justices Scalia and Thomas dissented. Justice Alito did not participate. According to the Court, a patent that is valid and infringed conveys a right to exclude, but an invalidated patent and a valid patent as to non-infringing products do not. The patent case "put the patent's validity at issue, as well as its actual preclusive scope" until settlement. Given that there is "reason for concern that settlements taking this form tend to have significant adverse effects on competition," the Court said, "i**t would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent**

law policy, rather than by measuring them against procompetitive antitrust policies as well." The Court characterized as "**novel . . . the dissent's suggestions that a patent holder may simply 'pa[y] a competitor to respect its patent' and quit its patent invalidity or noninfringement claim without any antitrust scrutiny whatever**."

Continuing, the Court attributed its decision to five sets of considerations:

- The "potential for genuine adverse effects on competition" from a payment that induces the generic to abandon its challenge for a share of the monopoly profits that would be lost in the competitive market.
- A conclusion that "anticompetitive consequences [from reverse payments] will at least sometimes prove unjustified," but not always, such as when the payment is "fair value for services."
- The observation that firms with market power, perhaps because of their patents, are best situated to pay large sums to protect their market.
- The feasibility of an antitrust trial that does not require litigation of the patent: "An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival" and that the payment is intended to maintain higher prices.
- The ability of parties to settle patent litigation without including reverse payments.

Further, the likelihood of anticompetitive effects from a reverse-payment settlement "depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." The Court "[left] to the lower courts the structuring of the present rule-of-reason antitrust litigation."

Practice Note: The FTC is likely to continue to scrutinize settlements very closely and evaluate each for a potential investigation or legal challenge. Private actions will also likely continue, to the extent enough facts about settlement terms are publicly available to support a complaint. Post-Actavis, courts for the first time must apply a rule of reason standard, as opposed to the "scope-of-patent" or "presumptively illegal" rules they have previously applied. Antitrust law precedent in this area will develop, therefore, on a case-by-case basis. Companies and their counsel, when evaluating whether to enter into a reverse-payment settlement, should closely monitor current and future court cases for guidance on what facts most directly influence judges and juries in the adjudication of antitrust challenges to reverse payments.

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