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**U.S. Supreme Court Rules That “Reverse Payment” Settlements in ANDA Litigation Are Not Presumptively Unlawful But Must Be Assessed Using “Rule of Reason”**

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The Supreme Court ruled 5-3 on June 17, 2013 in favor of the Federal Trade Commission in *FTC v. Actavis*. Writing for the majority that included Justices Kennedy, Ginsburg, Sotomayor and Kagan, Justice Breyer’s opinion reversed the decision of the Eleventh Circuit Court of Appeals dismissing the FTC’s complaint that a “reverse payment” settlement agreement between an innovator drug maker and generic challengers in ANDA litigation was anticompetitive and violated the antitrust laws. The Court refused to accept the FTC’s position that such agreements are presumptively unlawful, holding that lower courts should apply an antitrust “rule of reason” analysis when evaluating such agreements.

Reverse payment settlement agreements involve situations where a patentee settles a patent lawsuit, generally in litigation brought under the Hatch-Waxman framework, by paying the generic challenger(s) to remain off the market for a time longer than if they had prevailed in their challenge to the innovator’s patent. In making this ruling the Court rejected Respondents’ arguments that these agreements should be presumptively lawful provided that the exclusion remains within the “scope of the patent” and that other antitrust violations (such as sham litigation or litigating a patent obtained through fraud on the Patent Office) are not implicated. The “scope of the patent” test had been applied to find reverse payment settlement agreements lawful in cases before the Second, Eleventh and Federal Circuits (including the case at issue before the Court), although earlier this year the Third Circuit agreed with the FTC that such agreements should be presumptively unlawful.

The majority reversed based on their belief that the FTC should be allowed to challenge such agreements, using antitrust law to check the application and exercise of the patent grant. Using prior Supreme Court precedent open to alternative interpretations (as evidenced in a dissent by

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the Chief Justice coming to the opposite conclusion citing this self-same precedent), the Court held that *sometimes* patent litigation settlements *could be* anticompetitive *enough* to raise antitrust liability, and that the FTC (and the courts) needed to be able to address these concerns.

The Court announced five factual considerations relevant to be the question for lower courts to use in assessing the legality of such agreements:

- 1) whether the settlement has a “genuine adverse effect[] on competition,” primarily related to the size of the settlement;
- 2) where “these anti-competitive consequences [] prove unjustified under antitrust principles”;
- 3) where a patentee has market power so that a “reverse payment threatens to work unjustified anticompetitive harm”;
- 4) if “[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival,” and using a “payment . . . to prevent *the risk* of competition . . . constitutes the relevant anticompetitive harm” (and thus it is “not necessary to litigate patent validity to answer the antitrust question”); and
- 5) whether parties that may still “settle in other ways” such as “by allowing the generic manufacturer to enter the patentee’s market prior to the patent’s expiration, without the patentee paying the challenger to stay out prior to that point” instead (or in addition to) include a large cash payment in the settlement

The dissent, by Chief Justice Roberts joined by Justices Scalia and Thomas (Justice Alito recused himself from consideration of this case), contends that these considerations beg the question of whether the patent provides justification for such settlements, which the Chief says the Court has always assessed using patent law rather than antitrust law. According to the Chief, the existence of a patent, properly cabined within its proper scope, should be enough to justify a reverse payment settlement of ANDA litigation. Calling the rule of reason “amorphous” the dissent asserts that “settling a patent claim *cannot possibly* impose unlawful anticompetitive harm if the patent holder is acting within the scope of a valid patent and therefore permitted to do precisely what the antitrust suit claims is unlawful” (*emphasis in opinion*).

The Court’s decision will likely end reverse payment settlement agreements. Because they will be unable to settle, innovator patentees will litigate every case to conclusion in order to avoid

antitrust scrutiny involving the same or similar infringement and validity questions better settled in ANDA litigation. Coupled with the FTC's position that transfer of "anything of value" from the branded drug maker to a generic competitor should also merit antitrust scrutiny, there may be little advantage for either party in an ANDA lawsuit to settle and thus greater costs that should deter rather than incentive generic challenges. This is not the likely consequence that the majority envisioned, but it is almost certainly the outcome they are likely to get.

The opinion can be found at [http://www.supremecourt.gov/opinions/12pdf/12-416\\_m5n0.pdf](http://www.supremecourt.gov/opinions/12pdf/12-416_m5n0.pdf)

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