

Federal Trade Commission v. Actavis Inc
570 U.S. 136 Supreme Court (2013)

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Summary

The U.S. Supreme Court decided that reverse payment settlement agreements are not immune from antitrust scrutiny. It opted for the antitrust “rule of reason” approach in order to determine whether such agreements violate antitrust law, rejecting thereby both the “scope of patent” test and the “presumptive illegality” approach.

The facts

Solvay Pharmaceuticals obtained in 2003 a patent for the drug AndroGel used to treat low testosterone levels. Shortly afterwards, Actavis¹ and Paddock, two pharmaceutical companies, filed Abbreviated New Drug Applications (ANDA) for a generic version of AndroGel. In response, Solvay sued them for patent infringement. In 2006, however, the parties settled the patent litigation. Actavis and Paddock agreed not to bring their generic to market until August 31, 2015 – approximatively five years before Solvay's patent expired – in exchange of several millions of dollars. The Federal Trade Commission (hereinafter ‘the FTC’) filed suit claiming that these “reverse payment” settlement agreements unreasonably diminish competition in violation of antitrust laws. According to the FTC, Actavis and Paddock unlawfully agreed to abandon their patent challenges, to refrain from launching their low-cost generic drugs, and to share in Solvay's monopoly profits. In 2010, the District Court dismissed the FTC's complaint, holding that the agreements did not provide unreasonable restraints outside the scope of the patent and was therefore lawful.² The FTC appealed to the U.S. Court of Appeals for the Eleventh Circuit (hereinafter ‘the Eleventh Circuit’), which affirmed the District Court's decision in 2012. In the view of the Eleventh Circuit, a reverse payment settlement, such as the agreement alleged in the FTC's complaint, is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.³ It noted *inter alia* that although a patent holder may be able to escape the jaws of competition by sharing monopoly profits with the first one or two generic challengers, those profits will be eaten away as more and more generic companies enter the waters. The U.S. Supreme Court (hereinafter ‘the Court’) however granted certiorari to review the Eleventh Circuit's judgment and, eventually in 2013, reversed and remanded the case for further proceedings.

The legal issues

"Reverse payment settlement" or "pay-for-delay" agreements typically arise in the context of pharmaceuticals and are used as an alternative to patent litigation: the holder of a pharmaceutical patent pays the generic drug manufacturer in exchange for an agreed-upon generic entry date. The generic drug manufacturer recognizes thereby the validity of the patent and agrees not to

¹ Formerly known as Watson Pharmaceuticals.

² *In re Androgel Antitrust Litigation* (No. II), 687 F. Supp. 2d 1371 (N.D. Ga. 2010).

³ *FTC v. Watson Pharms.*, 677 F.3d 1298 (11th Cir. 2012).

challenge it. Opinions in the literature are split on whether such behavior is covered by the patentee's right to enforce and defend its intellectual property, or whether this may violate antitrust laws. In *Federal Trade Commission v. Actavis Inc*, the Court addressed this issue and examined: (1) whether a reverse payment settlement agreement is immune from antitrust attack so long as it does not exceed the scope of the patent; (2) whether the FTC's antitrust lawsuit against the settling parties should have been allowed to proceed; and finally (3) whether reverse payment settlement agreements are presumptively unlawful. The Court found:

1. Reverse payment settlement agreements of many millions of dollars in order to keep temporarily generic drug manufacturers outside the market, such as the agreement alleged in the case at hand, are unusual and should draw attention of antitrust authorities because of their potential (significant) adverse effects on competition. Even if the anticompetitive effects of a reverse payment settlement agreement fall within the “potential exclusionary scope” of the patent, this fact does not automatically immunize the agreement from antitrust attack. Patent law and antitrust policies are both relevant when assessing the scope of the patent monopoly – and antitrust immunity –conferred by the patent. It is not sufficient that from a patent law perspective, the holder of a patent is legitimately within its rights; a reverse payment settlement agreement can still have implications of antitrust law. Accordingly, “it 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”.⁴ The “scope of the patent” test adopted by the District Court and the Eleventh Circuit in the case at hand must therefore be rejected.
2. Although consuming, complex and expensive patent litigations can be avoided thanks to reverse payment settlement agreements between the parties, these agreements ‘can sometimes’ violate the antitrust laws. In the case at hand, the FTC should have been given the opportunity to prove its antitrust claim based on the following considerations that can be used as guiding factors to determine the legitimacy of reverse settlements:
 - The rationale behind a payment of the size of Solvay’s one is not always supported by traditional settlement considerations. Did the payment amount to a rough approximation of the litigation expenses saved through the settlement and reflect compensation for other services that the generic manufacturer promised to perform? If not, such payment suggests that the patent holder paid a generic challenger an amount of money larger than what the generic would have gained in profits if it had won at patent litigation and entered the market. In sum, the patentee and the challenger gain while the consumer loses due to the lack of a competitive market (higher drug prices).
 - A reverse payment settlement with the first-to-file generic manufacturer provides strong evidence that the patentee seeks to induce the most motivated generic challenger and the closest one to introducing competition to abandon its claim with a share of monopoly profits otherwise lost in a competitive market.
 - Where a reverse payment threatens to generate unjustified competitive harm, the patentee likely possesses the power to turn that harm into practice, and the size of

⁴ Opinion of the Court, pp. 8/9.

the payment is a strong indicator of such power, namely the power to charge prices higher than competitive level.

- The size of an unexplained reverse payment can provide a workable surrogate for a so-called “weak patent”. It might suggest that the patentee has serious doubts about its patent validity and seeks, through the payment, to prevent the risk of competition.
 - The relevant antitrust question regarding reverse payment settlement is: What are the reasons for such a payment? If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, the agreement is likely to harm the competitive process and to be forbidden by the antitrust laws.
3. The likelihood of a reverse payment creating anticompetitive effects depends on its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services from the generic manufacturer and the lack of any other convincing justification. These considerations have to be taken into account and thus, reverse payment settlements need to be examined under the antitrust “rule of reason” analysis, rather than under a “quick look” test as the FTC suggested. Reverse payment settlement agreements are therefore neither presumptively unlawful, nor presumptively lawful.

Points of significance

- Even where reverse payment settlements fall within the exclusionary potential of a valid patent, they are subject to antitrust scrutiny. This is so because the legal scope of the patent is not only determined by patent considerations, but also by antitrust factors, such as anti-competitive effects.
- Reverse payment settlements potentially affect competition, as they benefit the parties involved in the agreement, but to the detriment of the consumer, who potentially has to pay a higher drug price than if the patent at issue would have been invalidated as a result of infringement litigation.
- There is, however, no presumption that reverse payment settlements are unlawful. They should be scrutinized on a rule of reason and case-by-case basis, examining if their anti-competitive effects are offset on efficiency grounds.
- The consequence of this decision is that patent owners can no longer engage in settling agreements with competitors without fear of triggering antitrust scrutiny. This could make it harder for pharmaceutical patent holders to block the market entry of generic pharmaceuticals.

Key words

Reverse payment settlement agreement, pay for delay agreement, pharmaceutical patent, antitrust laws, patent and antitrust policies, generic competition, patent infringement.

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