



## U.S. Supreme Court Rules That ‘Reverse Payments’ in Hatch-Waxman Litigation Settlement Agreements Must Be Scrutinized Under Antitrust Laws

On June 17, 2013, the Supreme Court of the United States issued a 5-3 decision in *FTC v. Actavis*.<sup>1</sup> The Court reversed an 11<sup>th</sup> Circuit decision dismissing a Federal Trade Commission (FTC) antitrust suit against Solvay Pharmaceuticals, the owner of the patent covering brand-name drug AndroGel®, and generic drug manufacturers Actavis, Paddock and Par, all of which had settled their Hatch Waxman patent infringement litigations by agreements that included, *inter alia*, millions of dollars of so-called “reverse payments” by Solvay to the generics, in return for dropping their patent challenges, refraining from launching generic versions of Androgel until about five years before patent expiry, and providing certain promotional services. The Court ruled that while agreements in which a patentee pays a generic drug company to stay out of the market as a means of settling patent litigation are not presumptively unlawful, they may “sometimes” violate antitrust laws and, as such, must be subject to antitrust scrutiny under a “rule of reason” analysis.

### Reverse Payment Settlement Agreements

Unlike the more typical patent infringement lawsuits which generally involve claims for monetary damages, “reverse payment” agreements arise in the context of Paragraph IV invalidity and/or non-infringement patent challenges under the Hatch Waxman Act, which generally do not involve damages claims. In “reverse payment” patent settlements, the patentee makes a monetary payment to a generic patent challenger in exchange for, *inter alia*, the accused infringer’s agreement not to produce or market

<sup>1</sup> The opinion is available here. Justices Kennedy, Ginsburg, Kagan and Sotomayor joined the majority opinion written by Justice Breyer.

a generic version of the patented product regardless of whether the accused infringer has already obtained FDA approval to do so. Such agreements may include other considerations such as “early entry” provisions, services that a generic will perform for the patentee such as assistance in the marketing and manufacturing of the patented product during the exclusionary period, and other business arrangements.

**Five Justice Majority Determines That “Size” Matters and Reverse Payment Agreements Must Be Scrutinized Under Traditional Antitrust Factors -- Not Just Patent Law Policy**

The FTC’s suit alleged that the parties violated Section 5 of the FTC Act, which prohibits unfair methods of competition and conspiracies that violate the federal Sherman Act, by entering into a reverse payment settlement agreement even though Solvay allegedly was “unlikely to prevail” in its infringement suit and, therefore, the patent had “no exclusionary potential.” Accordingly, the FTC contended that the reverse payment necessarily exceeded the patent’s “potential exclusionary scope,” and thus was tantamount to “buying off a serious threat to competition.” The FTC argued that such an excessive payment should presumptively be unlawful under the antitrust laws.

According to the Court, the public policies supporting patent monopolies and the settlement of litigation do not necessarily outweigh those against anti-competitive activity. The Court noted that when litigants strike such a deal, the businesses profit, the consumer loses:

We concede that settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumer’s benefit. But settlement on the terms said by the FTC to be at issue here—payment in return for staying out of the market—simply keeps prices at patentee-set levels, potentially producing the full patent-related \$500 million monopoly return while dividing that return between the challenged patentee and the patent challenger. The patentee and the challenger gain; the consumer loses.

In ruling that reverse payments are not presumptively unlawful, the Court held that such payments should be analyzed under the antitrust “rule of reason” involving traditional antitrust factors, such as anticompetitive effects, redeeming virtues, market power and potentially offsetting legal considerations present in the circumstances (such as those relating to patents) *before* concluding whether a particular restraint lies “beyond the limits of the patent monopoly.”

The Court indicated that the “size” of the payment is relevant to both the potential “genuine adverse competitive effects” as well as being a strong indicator of patentee “power,” with an “unexplained large” reverse payment being suggestive of patent weakness and anticompetitive objectives. As a result, courts must evaluate the “reasons” for the payment at issue and whether it is “justified” by offsetting or redeeming virtues such as where it is “no more than a rough approximation of the litigation expenses saved through settlement,” or “fair value” for other services to be performed by the generic, or other evidence that the patentee is not “using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.”

Other findings of interest by the Court included:

- > Finding significant that reverse payment agreements “remove from consideration the most motivated challenger, and the one closest to introducing competition,” leaving only later filers with significantly less potential rewards;
- > Using terms like “collusion” (“the supreme evil of antitrust”) to refer to reverse payment settlements, the Court contrasted them from traditional patent settlements “as something quite different” because “a party with no claim for damages ... walks away with money simply so it will stay away from the patentee’s market”; and
- > Holding that an “unexplained, large” reverse payment by itself can obviate the costly and time-consuming determination of patent validity.

### The Dissent

In a vigorous dissent, Chief Justice Roberts<sup>2</sup> declared 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.” The dissent stressed that the majority’s ruling “will discourage the settlement of patent litigation,” adding that patent law “provides an exception to antitrust law, and the scope of the patent —i.e., the rights conferred by the patent—forms the zone within which the patent holder may operate without facing liability,” and that the only time a settlement violates antitrust law is when it goes beyond the boundaries of the patent grant. In particular, the Chief Justice warned that the majority’s view of antitrust legality under the rule of reason being answerable without considering the validity of a patent is unrealistic, and to deprive the patentee of such a defense defeats the point of the patent, which is to confer a lawful monopoly on its holder.

### Further Observations and Considerations

#### *“Other Ways” to Settle Hatch Waxman Suits Per the Court*

The Court made a point of noting that its decision concerning the antitrust risks of “a large, unjustified reverse payment” does not prevent settlement of these lawsuits “in other ways.” The example used by the Court was where parties settle “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.*”

#### *The Role of Patent Validity in Antitrust Analysis*

The Court’s opinion indicated that it may not be necessary for the parties to determine patent validity in order to answer the antitrust question, explaining that a “large, unexplained” reverse payment itself not only provides a workable surrogate for a patent’s weakness, but can also be suggestive of a patentee’s “serious doubts about the patent’s survival” and, thereby, an anticompetitive objective. The Court did not address, however, what role, if any, a finding of patent validity may have on the antitrust analysis and whether a payment can be found anti-competitive regardless of patent strength. The dissent correctly notes, however, that patent validity will still remain a focus of any antitrust defense.

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<sup>2</sup> Justices Scalia and Thomas joined in the dissent. Justice Alito was recused and took no part in the consideration or decision of the case.

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