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Supreme Court Requires Full Rule of Reason Analysis in So-Called "Reverse Payment" Settlements of Patent Litigation

The US Supreme Court in *Federal Trade Commission v. Actavis, Inc., et al.*(*Actavis*) planted the seeds for future complicated litigation over so-called "reverse payment" settlement of patent litigation when it rejected both sides' arguments for clear presumptions, requiring instead a full rule of reason analysis of such settlements. Technically, the Court, in a 5-3 decision, reversed the Court of Appeals for the Eleventh Circuit's ruling for the defendants, and the "scope of the patent" test earlier adopted by the Eleventh Circuit and others, in what the FTC and its supporters are claiming as a victory. But the Court also rejected the FTC's proffered approaches – a presumption of illegality based on the mere presence of the so-called "reverse payment" or a truncated "Quick Look" analysis. As a result, the FTC in this case, and others like it, will have to prove that the challenged settlement was anticompetitive under a full Rule of Reason analysis, a requirement the agency and private plaintiffs may well find challenging.

Background

At issue in this case, and in others like it, was an agreement between a branded drug company (here, Solvay, the manufacturer of AndroGel®), and a generic drug company (here, Actavis, among others), that had challenged the branded company's patent rights by filing a Paragraph IV certification in support of an Abbreviated New Drug Application (ANDA) to the FDA. Solvay sued for infringement and the parties subsequently settled the case with an agreement that included, among other things, payments from Solvay to Actavis. As in many such settlements, the payment ran from the patent owner to the alleged infringer, rather than taking the more common pathway from the infringer to the patent owner (such as where an infringing product is already on the market and damaging the patent owner's economic rights). As a result, the agreement fell into the category of agreements often called "reverse payment" settlements.

The FTC challenged the settlement. For more than a decade, the agency has campaigned against such agreements on multiple fronts – and has dubbed them "pay-for-delay" agreements – arguing that any patent litigation settlement that includes payment from the branded company to the generic company beyond nominal payment of litigation costs should be presumed to be an unreasonable restraint of trade. The Eleventh Circuit rejected the FTC's challenge, consistent with its earlier adoption of the "scope of the patent" test, a rule that requires one challenging such a settlement to show that the settlement precluded competition beyond the exclusion provided by the patent itself. After the Third Circuit Court of Appeals rejected the "scope of the patent" test in *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012) (*K-Dur*), notably evaluating the very same agreement at issue in *Actavis*, the Supreme Court accepted the *Actavis* case.

The Parties' Positions and the Supreme Court's Decision

The FTC argued for a rule that a so-called "reverse payment" is presumptively illegal, and that in antitrust litigation challenging patent litigation settlements that include such payments the burden should shift to the defendant to establish that the payment was not "for delay" (i.e., that it was for some other value commensurate with the size of the payment). The defendants argued for the Eleventh Circuit rule – which had also been adopted by other circuit courts – that such settlements are lawful if the exclusion is within the scope of the patent (i.e., the alleged infringer gets to enter the market by the time the patent expires).

The majority opinion, written by Justice Breyer, explicitly rejected both sides' positions, holding that such settlements are potentially – but not presumptively – anticompetitive, and that plaintiffs bear the burden of establishing that the settlement is anticompetitive under a full Rule of Reason analysis. The dissent, written by Chief Justice Roberts, argued for the adoption of the Eleventh Circuit rule (the "scope of the patent" test).

Further underscoring its view that patent settlements of the type at issue in the case require full Rule of Reason analysis, the Court also rejected the FTC's argument that a Quick Look analysis could suffice in such cases. As a result, plaintiffs bear the burden of establishing that the settlement constitutes an unreasonable restraint of trade under the Rule of Reason.

Attempting to respond to the argument that such an approach would essentially require courts in antitrust cases to litigate the underlying merits of the patent case in order to determine whether the settlement excluded entry where it would otherwise have taken place, the majority offered that a "large unjustified payment" could be an evidentiary proxy for a patentee's lack of confidence in the quality of the underlying case. The suggestion raises more questions than it answers, however. For example, how large does such a payment have to be to warrant scrutiny? What would be the "justification" for such a payment? Given that the Court explicitly rejected the FTC's and Third Circuit's position, and its rejection of anything short of a full Rule of Reason analysis, it is clear that the mere presence of a "large" payment cannot be enough – and the burden of establishing that the payment was "unjustified" falls squarely on the FTC or private plaintiffs.

The suggestion that trial courts can avoid examining the patent claims arguably ignores that – as the dissent pointed out – the defendant has a right to argue and present evidence that its patent was valid and infringed, and that the generic challenger stood very little chance of getting into the market sooner, in order to refute the fundamental underlying presumption of the FTC's claim – that but for the settlement agreement the generic product would have entered the market sooner than it did (or would) under the agreement. If the FTC, or a private plaintiff, cannot establish that proposition in a Rule of Reason case, it ought not be able to prevail. Thus, the majority's "evidentiary work-around" is more than a little unclear, and it remains to be seen how lower courts will flesh it out.

The Take Away

In sum, while the decision opens the door to litigation that under the previously existing majority rule would have been precluded, it is far from an unbridled "win" for the FTC, or private plaintiffs. The Court has made clear that – on the facts of each case – the agency or private plaintiffs will have to prove, in a full Rule of Reason case, that the settlement unreasonably restrained trade. Moreover, the majority's suggestion that one can use the size and alleged lack of "justification" for the payment as evidence should not be taken by lower courts as license to ignore the Court's rejection of both of the FTC's arguments for a lower standard.

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