FTC v. Actavis: Supreme Court Rejects Bright Line Tests for Reverse Payment Settlements; Complex Questions Remain in Structuring Pharmaceutical Patent Infringement Settlements

June 18, 2013

I. The Basics

On June 17, 2013, the Supreme Court decided a case of considerable importance to the pharmaceutical industry. The case involved the question of whether and to what extent "reverse payment" settlements – which have been a common method for resolving patent disputes between branded and generic pharmaceutical companies – will be found to violate the federal antitrust laws.

The lower courts have been split on the issue of whether such settlements – in which the patent owner pays cash or other consideration to the alleged generic "infringer" to resolve the litigation – are unlawful. Several appellate courts have found that these settlements generally are *permissible* (with some exceptions), while one recently found that they generally are *impermissible* (with some exceptions).

In a 5-3 decision, and as predicted by some observers,[1] the Supreme Court decided to take a middle ground. It concluded that such settlements *may* violate the federal antitrust laws, but that a court will have to consider all of the relevant facts and circumstances in determining whether, on balance, the agreement is "reasonable." *FTC v. Actavis*, Slip Op. No. 12-416 (S. Ct. June 17, 2013)

Pharmaceutical companies that wish to include a reverse payment or other consideration to a generic as a component of settlements now will have to carefully consider how to do so under what the dissent termed "the unruly rule of reason."

One key question raised by the majority is how settling parties should go about justifying a reverse payment which exceeds avoided costs of litigation. The majority decision repeatedly states that "unjustified" or "unexplained" large payments would be an important factor under the rule of reason , and notes that "patentees sometimes pay a generic challenger a sum even larger than what the generic would gain in profits if it won the [patent] litigation and entered the market." But in stating that a "large, unexplained reverse payment can provide a workable surrogate for a patent's weakness", the Court seems to pave the way for settling parties to argue that a payment which leaves the generic challenger with less than it would have earned had it prevailed in the patent litigation is also a workable surrogate for a patent's strength.

And while the prevailing opinion authored by Justice Breyer makes it clear that it is not requiring courts to try patent validity and infringement in the antitrust suit challenging the settlement, the dissent is less certain this will be the case. As the dissent notes, defending brand manufacturers will often want to argue that they believed they would win the patent suit but faced an imbalance of risk as compared to the challenging generic and could not afford the risk of even a 5% chance of losing. Will such evidence of subjective intent be admissible, as it often is in a rule of reason case? If so, will parties challenging the settlement be able to rebut with evidence that the patent was weak?

---

[1] *See, e.g.*, Davis Polk Client Memorandum, "**Supreme Court Hears Oral Argument Involving "Reverse Payment" Patent Infringement Settlements**" (March 26, 2013).

Beyond that, the decision is likely to impact the dynamics of pharmaceutical patent litigation between branded and generic pharmaceutical companies. On the one hand, by potentially limiting the parties' freedom to settle patent cases, the Court's decision may lead to longer and more costly patent litigation. On the other hand, as the dissent in *Actavis* speculated, the Court's new rule may paradoxically lead to *fewer* patent challenges because generic companies will foresee fewer lucrative settlement options to justify the substantial costs and risks of challenging the patents in the first place.

II. The Details

Broadly speaking, a "reverse payment" settlement is one in which the patent owner (typically a company selling a branded drug) settles a patent infringement case by paying money or other consideration to a generic pharmaceutical company. Although such settlements vary widely, it is common for the settlement to prohibit the generic company from entering the market for a period of time but to permit it to enter before the patent would have expired. The FTC, which has vigorously criticized and challenged these types of settlements, often has referred to such settlements as "pay-for-delay" agreements.

The case before the Court involved Solvay Pharmaceuticals, the owner of a patent covering a brand-name drug called AndroGel. In 2003, Solvay sued several generic drug manufacturers that sought to introduce a generic version of AndroGel. Under the Hatch-Waxman Act, the generic companies were able to trigger the patent litigation without having to go through the risk and expense of manufacturing and selling a generic product. Instead, all they had to do was provide notice of an intention to seek approval for the generic product prior to the expiration of Solvay's patent on the ground that the patent either was invalid or that their products did not infringe the patent.

In 2006, Solvay reached settlements with the generic companies. Under the settlements, the generics agreed not to bring their products to the market until a specified date, which was several years before the patent expired but not as quickly as if the generics had established that the patent was invalid. As part of the settlement, Solvay agreed to make cash payments to the generic companies ranging from $12 million to over $100 million. According to the Court, the companies described the payments in part as compensation for other services the generic companies agreed to perform.

The FTC challenged the settlement. It claimed that Solvay and the various generic companies had violated the antitrust laws because the generics had agreed "to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years."

The district court dismissed the FTC's claim, and the U.S. Court of Appeals for the Eleventh Circuit affirmed the dismissal. In a nutshell, the court held that the settlements did not violate the antitrust laws because: (i) Solvay's patent infringement case was not a "sham"; and (ii) the settlement did not restrain trade in any way that went beyond the scope of Solvay's patent. Because under patent law Solvay could have prevented generic competition entirely until the expiration of the patent (assuming the patent was valid and infringed), the court concluded that a settlement that permitted the generics to enter the market *before* the expiration date could not be unlawful.

III. The Decision

The Supreme Court reversed the Eleventh Circuit and reinstated the FTC's case. The Court acknowledged the legal policy favoring the settlement of litigation, but held that the settlement agreements could violate the antitrust laws even though the "restraint" was within the scope of Solvay's asserted patent rights. It identified various ways in which such an arrangement could harm competition and consumers, and that the cash payment may be "unjustified" or "unexplained" by the typical considerations favoring the settlement of litigation, and may instead indicate an intention to divide the patent owner's monopoly profits and may, if large enough, indicate that the patent is likely to be invalid.

As the Court summarized:

> "In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it;

> such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments. In our view, these considerations, taken together, outweigh the single strong consideration—the desirability of settlements—that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements." Slip op. at 19-20

Significantly, the Court did not agree with the FTC that "reverse payment" settlements should be considered "presumptively unlawful." Such a presumption is unjustified, according to the Court, because the likelihood of anticompetitive effects will vary depending on factors such as the size of payment, its relation to expected litigation costs (a neutral factor supporting settlement), its independence from other services for which it might represent payment, and the lack of any other convincing justification. In short, the Court observed that the facts of each case may be different, and it was not appropriate to categorically condemn or approve such settlements.

The Court declined to describe the details of the "rule of reason" analysis that it held was necessary, leaving the specifics to be worked out by the lower courts.

An important practical question, seized upon by the dissent, is whether the Court's decision will require the parties in antitrust cases essentially to re-litigate the patent issues (validity, infringement, etc.) that they thought they had settled. The Court suggested that such re-litigation would not be necessary because the size of the "unexplained" payment to the generic "would normally suggest" that the patent owner had doubts about the patent's survival, and that "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." As noted below, the resolution of that issue is not free from doubt.

IV. The Dissent

Chief Justice Roberts dissented. He was joined by Justices Scalia and Thomas. Justice Alito did not participate in the decision.

The thrust of the dissent is that patents provide an exception to antitrust law, and that "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 antitrust scrutiny." Although the dissent acknowledges that patent-related agreements "sometimes" violate the antitrust laws, they do so only when they confer benefits to the patent owner beyond the scope of the patent grant.

The dissent goes on to argue that the Court's decision will discourage the settlement of patent litigation. "Simply put, there would be no incentive to settle if, immediately after settling, the parties would have to litigate the same issue – the question of patent validity – as part of a defense against an antitrust suit."

The dissent also sharply criticizes the majority's assertion that the antitrust case will not involve the re-litigation of the "merits" of the patent litigation. It notes that the question of whether the patent is valid necessarily is of central importance, and that the defendant must have the ability to defend the settlement in part by defending its patent.

With respect to the "unruly rule of reason" analysis proposed by the majority to resolve the patent law issues at the heart of these cases, the dissent observes: "Good luck to the district courts that must, when faced with a patent settlement, weigh the 'likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances.'"

Finally, the dissent took issue with the majority's conclusion that "reverse" patent settlements are inconsistent with the policies underlying the Hatch-Waxman Act. Indeed, the dissent suggests that "the irony of all this is that the majority's decision may very well discourage generics from challenging pharmaceutical patents in the first place. . . . Taking the prospect of settlements off the table – or limiting settlements to an earlier entry date for the generic, which may still be many years in the future – puts a damper on the generic's expected value going into litigation, and decreases its incentive to sue in the first place."

V. Complexity of Structuring Settlements Under the Rule of Reason

The Court's decision in *Actavis* is likely to lead to a period of intense rethinking of the extent to which it is possible to structure reverse payment settlements which will pass muster under the "unruly rule of reason" described by the dissenting Justices.

1. "Rule of reason" cases tend to be difficult to dismiss at an early stage in a litigation (on motion to dismiss or even on summary judgment). By rejecting the view (adopted by several circuit courts and by the dissent) that "reverse payment" settlements are lawful if within the asserted scope of the patent, the Court's decision will require careful thought by those who wish to continue employing reverse payments as a component of settlement.

2. Although much of the Court's opinion is critical of "reverse payment" settlements, the Court may have left room for antitrust defendants to argue that a settlement payment that can be "explained" by objective factors, such as whether the payment was lower than what the generic could have expected to earn if it had prevailed in the patent case, should pass muster without the need for a lengthy litigation and trial.

3. The Court also appears to acknowledge that a settlement may be justified when the "consideration" provided by the patent owner is for independent value provided by the generic challenger. Examples may include providing contract sales forces or in some cases licensing unrelated products. Settlements with such ancillary or "side" arrangements have been far more common in recent years than settlements with straight cash payments. These settlements have only been challenged by the FTC where it concludes that a "disguised payment for delay" is involved because the consideration received by the generic challenger exceeds what would be commercially reasonable on a standalone basis absent settlement of the patent dispute. Defensible contemporaneous transactions may become even more common in light of the uncertainty which will now surround cash reverse payments.

4. Finally, "reverse payment" settlements have become a common part of patent litigation over the last ten years or more. To the extent that the Court's opinion will make such settlements more risky (and therefore less likely), it could lead to a different litigation dynamic, in which generic challengers are less able to seek or obtain settlements that they would consider beneficial to their business. Although the practical import of that change is speculative, it could shift bargaining leverage to some extent from generic companies that no longer would feel comfortable from an antitrust exposure perspective demanding certain types of settlement terms. And as the dissent warned, it could even lead to *fewer* patent challenges being pursued by generic companies because it would diminish the prospect of profitable settlements to justify the risk and cost of patent litigation. The latter certainly would be viewed by the FTC and other antitrust enforcers as an unwelcome and unintended consequence of their aggressive litigation positions attacking these types of settlements.

If you have any questions regarding the matters covered in this publication, please contact any of the lawyers listed below or your regular Davis Polk contact.

Arthur J. Burke	**212 450 4352** **650 752 2005**	**arthur.burke@davispolk.com**
Joel M. Cohen	**212 450 4592**	**joel.cohen@davispolk.com**
Arthur F. Golden	**212 450 4388**	**arthur.golden@davispolk.com**
Ronan P. Harty	**212 450 4870**	**ronan.harty@davispolk.com**
Christopher B. Hockett	**650 752 2009**	**chris.hockett@davispolk.com**
Thomas J. Reid	**212 450 4233**	**tom.reid@davispolk.com**
Michael N. Sohn	**202 962 7145**	**michael.sohn@davispolk.com**