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Supreme Court Holds Reverse-Payment Agreements to be Tested Under Rule of Reason

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On June 17, 2013, in Federal Trade Commission v. Actavis, Inc.,\(^1\) the Supreme Court for the first time addressed the antitrust implications of reverse-payment agreements.\(^2\) In a win for the FTC, the Court held that reverse payments can sometimes run afoul of the antitrust laws, and that courts should scrutinize those agreements by conducting a full “rule of reason” analysis to determine whether they have pro-competitive justifications that outweigh any anticompetitive effects. At the same time, the Court rejected the FTC’s argument that such arrangements were presumptively unlawful. Writing in broad strokes, the Court left much to the lower courts to flesh out.

Background

In Actavis, the FTC challenged a 2006 settlement entered into by a patent holder, Solvay Pharmaceuticals (Solvay), and three companies that had partnered to challenge Solvay’s patent on the drug AngroGel\(^3\). Actavis (formerly Watson Pharmaceuticals), Paddock Laboratories (Paddock), and Par Pharmaceuticals (Par). After several years of patent litigation, Solvay agreed to drop its infringement case against the generic companies, and these companies in turn agreed to refrain from entering the market for a number of years. The generic companies also agreed to perform certain marketing services for Solvay. Solvay agreed to pay the generic companies several millions of dollars. The FTC sued, taking the position that the settlement was in effect an agreement by the companies to avoid competition and instead share in Solvay’s monopoly profits.\(^4\)

The US District Court for the Northern District of Georgia dismissed the FTC’s complaint, and the Eleventh Circuit affirmed, both adopting a “scope of the patent” test. Under this test, reverse-payment settlement agreements are problematic only if they exceed the scope of the patent – that is, if they require the challenger to stay out of the market beyond the expiration date of the patent, or if they incorporate additional products not covered by the patent.\(^5\)

The Second and Federal Circuits have adopted this patent-deferential approach as well.\(^6\) However, a circuit split emerged when the Third Circuit sided with the plaintiffs in In re K-Dur Antitrust Litigation. It held that a “quick-look rule of reason” test is appropriate for analyzing reverse-payment agreements. Under the quick-look rule of reason test, courts treat any payment from a patent holder to a generic manufacturer as prima facie evidence of an unreasonable restraint of trade.\(^7\) (For more details on the circuit split and the issues at play in Actavis, see the March 2013 edition of Antitrust Health Care Chronicle.)

The Supreme Court’s Decision

The FTC urged the Supreme Court to reverse the decision of the Eleventh Circuit and adopt the “quick-look rule of reason” standard, treating reverse payments as presumptively unlawful and shifting the burden to the settling companies to show the agreement is actually pro-competitive.\(^8\) The defendants asked the Court to approve the deferential “scope of the patent” standard and approve reverse payments that do not require the challenger to stay out of the market beyond the length of the patent or encompass additional products.\(^9\)

In a divided (5-3)\(^10\) decision, the Court chose an alternative path. It reversed the decision of the Eleventh Circuit and held that the Eleventh Circuit should have allowed the FTC’s lawsuit to proceed. But it concluded that plaintiffs must prove their case under a full rule of reason analysis. “[R]everse payment settlements such as the agreement alleged in the complaint before us can sometimes violate the antitrust laws,” the Court said.\(^11\)

The Court laid out five considerations that led to its conclusion. First, the Court concluded, the agreement entered by Solvay, Actavis, Paddock, and Par had the potential for adverse effects on competition.
It was possible a court could have declared Solvay’s patent invalid (or not infringed). In such a situation, the Court explained, Solvay’s continued supra-competitive pricing of AndroGel® – made possible only by the settlement – would be unfair to consumers. Second, the Court reasoned, such settlements would not always be justified. True, some restraints with anticompetitive effects pass muster because they have offsetting virtues and are on balance beneficial to competition. When it comes to reverse payments, though, at least sometimes the settlement could reflect a patentee’s desire to use (share) monopoly profits to protect its patent monopoly and avoid a finding of invalidation or noninfringement.13

Third, the Court noted the FTC had offered evidence that reverse payments were associated with higher-than-competitive profits, an indicator of market power. Fourth, in response to practicality concerns of the Eleventh Circuit, the Court reasoned it would normally not be necessary to litigate patent validity to determine the antitrust question. The Court stated 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.”16

And fifth, antitrust risk would not prevent parties from settling in other ways. For example, the companies could simply allow the generic manufacturer to enter early without a reverse payment. The Court reasoned that this alternative would prevent the chilling of desirable settlement activity.17

In sum, the Court held that reverse-payment agreements were not immune from antitrust scrutiny even though their terms did not exceed the scope of the patent. In the future, it held, courts should examine the circumstances surrounding such an agreement and determine why the companies decided to settle. If the basic reason was a desire to maintain and to share patent-generated monopoly profits, then, in absence of competitive justifications, the antitrust laws are likely to forbid the arrangement. However, the Court has left it to the lower courts to work out the details of how the rule of reason will be applied.18

The Dissent

Chief Justice Roberts’ dissent, in which Justices Scalia and Thomas joined, criticized the majority’s approach and raised some concerns about its application. Justice Roberts favored the scope of the patent test. In his view, a patent carves out an exception to the applicability of antitrust laws.19

“This is a fairly straightforward case,” he wrote. “[A] patent holder acting within the scope of its patent does not engage in any unlawful anticompetitive behavior; it is simply exercising the monopoly rights granted to it by the Government.” He continued, “the scope of the patent – i.e., what rights are conferred by the patent – should be determined by reference to patent law.” The majority could point to no case, he argued, where a patent settlement was subject to antitrust scrutiny merely because the validity of the patent was uncertain.21

Justice Roberts took issue with the majority’s view that reverse-payment agreements are “something quite different” than traditional settlements because they involve a reverse payment. While the challenger might not have a claim for damages, it was suing for the right to use and market the intellectual property, which was worth money. The dissent also expressed concerns about how antitrust scrutiny will play out in reality. A decision to pay a “large” sum would not necessarily evidence doubts about a patent’s strength. How could a court reliably discern a patent holder’s motivations for settlement? A company could be motivated to settle by any number of things – risk aversion, litigation fatigue, and concerns about company image – and the evidence of these things would often be privileged and presumably shielded from discovery.21

Analysis: Reverse-Payment Agreements Going Forward

The majority and dissent saw the reverse payment issue through entirely different lenses. The starting point for the majority was the uncertainty surrounding the patent’s validity. “The patent here may or may not be valid, and may or may not be infringed;” the majority emphasized.24 The dissent, on the other hand, emphasized that “[a] patent carves out an exception to the applicability of the antitrust laws” and concluded 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 it to do precisely what the antitrust suit claims is unlawful.”

The takeaway from this exchange is that under the Court’s governing opinion, motivation does matter. Under Justice Roberts’ approach – and the approach endorsed previously by the Second, Eleventh, and Federal Circuits – a pharmaceutical company would have been entitled to settle a patent case in full knowledge that it was doing so to avoid the risk of an adverse judgment. Under the new regime, such a decision likely raises antitrust concerns.

So what will the new system look like? Justice Breyer refrained from describing what shape the new reverse-payment rule of reason standard will take, and the opinion is rife with qualifiers. But it appears a key question will be: does the settlement payment reflect “traditional settlement considerations?” Or, was the rationale “a desire to maintain and to share patent-generated monopoly profits” and to “avoid the risk of patent invalidation?” Courts will look at the circumstances on a case-by-case basis. Some of the factors that Justice Breyer flagged as relevant are:

1. The size of the payment. The Court repeatedly expressed concern about unjustified “large” payments. It expressed particular concern about settlements where a patentee pays 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.29

2. Agreements to perform services. In Actavis, the generic manufacturers had agreed to market AndroGel® in various ways. The Court noted that these services might justify higher sums being paid.30 Note, however, that some courts have viewed these provisions with skepticism.30
The Court described this as an alternative to risking antitrust liability due to a "large, unjustified reverse payment."\(^2\) Presumably, the amount of time between permitted entry and the expiration of the patent would also be relevant.

Other justifications. The Court emphasized that each case may be different. It is possible that courts sympathetic to Chief Justice Roberts' view could look favorably on additional justifications that he mentioned in his dissent; these include evidence of litigation fatigue and concern over the company's image.\(^2\) It is, however, far from clear.

Companies considering reverse settlements may find these sparse guidelines frustrating. But again, a key factor in the Court's opinion was motivation. Any evidence that a company believed it would suffer an adverse judgment or other explicit or implicit acknowledgment of the weakness of the patent, with a large monetary settlement as the solution, would likely increase the risk of antitrust liability. Furthermore, note that the Court referenced "collusion" as "the supreme evil of antitrust."\(^3\) Thus, evidence of an agreement to share monopoly profits among the adversarial parties would, of course, be detrimental.

A few final points to note: first, that procedurally, the case was presented after a motion to dismiss had been granted. The Court's reversal simply permits the FTC to proceed with its case. This suggests, though, that in future cases the lower courts are likely to deny motions to dismiss and perhaps motions for summary judgment, even where the facts mirror those in Actavis where the agreement included provisions of services and an entry date before expiration of the patent. Second, while Actavis is limited to its facts, the majority's rejection of the "scope of the patent" defense could have implications beyond reverse-payment settlement agreements; we anticipate plaintiffs will seek to use Actavis to argue that even conduct well within the scope of a patent can be attacked under the rule of reason. That too remains an issue for the lower courts.

Finally, it is interesting that neither the majority nor the dissent addressed the legal argument that, in the underlying patent litigation, the grant of a patent is presumed valid until affirmatively proved otherwise.\(^3\) Although there is a thread of this argument in Justice Roberts' dissent, and perhaps a reference to it in the majority opinion,\(^4\) neither directly addressed the point. Going forward, it appears courts will apply the rule of reason regardless of whether validity, infringement, or both were at issue in the patent case. And while the majority decision directly states that examination of the validity of the patent is not necessary, in at least some cases, validity and the potential strength or weakness of the underlying patent may be important in assessing the antitrust consequences of a reverse-payment settlement. As an example, while the majority noted that a high payment to the alleged infringer could be a sign the patent was weak, the opposite may also be true. A very strong patent with the potential for billions of dollars in sales may warrant a large payment to avoid litigation even when the risk of losing an infringement suit is small. This will be yet another issue to consider as Actavis' bare bones are fleshed out by the lower courts.

Endnotes (📞 returns to text)


In a reverse-payment agreement, pharmaceutical companies agree to settle patent litigation commenced in response to a generic manufacturer's effort to enter the market under the provisions of the Hatch-Waxman Act (codified at 21 U.S.C. 355(b), (j), (l) and 35 U.S.C. 156, 271, 282). Typically, the branded company drops its patent case and compensates the generic manufacturer in exchange for the generic manufacturer's agreement to delay entry. Also, the agreement normally permits the generic company to enter the market before the expiration of the patents covering the drug. Such settlement agreements are called "reverse payment" because the party asserting a claim for damages is compensating the alleged infringer. The FTC has claimed these agreements permit branded manufacturers to effectively "pay off" potential generic competitors to stay out of the market, resulting in supra-competitive prices. The companies have argued that they have the right to do so in the exercise of their patent rights, and that the agreements reflect normal, pro-competitive decisions to settle costly and uncertain patent litigation.\(^3\)

The case was formerly named FTC v. Watson before Watson took the name of acquisition target Actavis in January 2013.\(^3\)


Androgel, 687 F. Supp. 2d at 1382; Watson, 677 F.3d at 1310-12, 1315.\(^3\)

See In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006); In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008).\(^3\)

In re K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012).\(^3\)
See Watson, 677 F.3d at 1310-12.
Justice Alito did not take part.
Id. at *10-11.
Id. at *11.
Id. at *12.
Watson, 677 F.3d at 1315. The Eleventh Circuit had criticized an approach that required judges “to decide how some other court in some other case at some other time was likely to have resolved some other claim . . . a turducken task.”
Actavis, 2013 WL 2922122, at *12.
Id. at *12.
Id. at *13-14.
Id. at *16 (Roberts, C.J., dissenting) (emphases in original).
Id. at *16, *18 (Roberts, C.J., dissenting).
Id. at *11, *12.
Id. at *10.
Id. at *11.
See, e.g., In re K-Dur, 686 F.3d at 205-06.
Actavis, 2013 WL 2922122, at *12.
See, e.g., Brief for Respondent Solvay Pharms., Inc. on Petition for a Writ of Certiorari, Actavis, 133 S. Ct. 787 (U.S. 2012) (No. 12-416), 2012 WL 5769670, at *15, *33 (noting that both validity and infringement were at issue in Actavis, unlike In re K-Dur, which involved only a dispute over infringement); see also Brief of Appellants and Appendix Vol. 1, In re K-Dur, 686 F.3d 197 (3d Cir. 2012) (No. 10-2077), 2011 WL 1979816, at *36-38 (arguing that the scope of patent test should not apply in particular to cases where only infringement is at issue, because unlike validity, infringement is never presumed).
See Actavis, 2013 WL 2922122, at *8 (reasoning that the Court in United States v. Singer, 374 U.S. 174 (1963) “did not examine whether, on the assumption that all three patents were valid, patent law would have allowed the patent holders to [settle claims, but rather] held that the agreements … violated the antitrust laws”).