US Supreme Court Rejection of the “Scope of the Patent” Test in FTC v. Actavis Has Wide-Ranging Implications

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Key Points:

- Patent settlements must be analyzed under the rule of reason, requiring a full analysis of the net competitive effects.
- Payments to an alleged infringer may be permissible if justified by, for example, avoided litigation costs or the value of goods and services to be provided by the infringer.
- Parties should carefully document, and be prepared to support, the valuation of such goods and services.
- Litigation over settlements will likely be difficult to terminate prior to summary judgment.
- Plaintiffs may try to extend the Court’s reasoning to other types of patent agreements, including license agreements between potential competitors.

In FTC v. Actavis, Inc., the Supreme Court rejected the “scope of the patent” test that has been adopted by the majority of courts of appeals in reviewing antitrust challenges to “reverse payment” settlement agreements; the Court held that such agreements must be analyzed under the rule of reason. No. 12-416, 2013 WL 2922122, at *14 (June 17, 2013). Parties wanting to settle patent infringement lawsuits under the Hatch-Waxman Act framework will need to pay much closer attention to the value received by the patent holder in exchange for any payment. The settling parties now carry the burden to demonstrate—with precious little guidance from the Supreme Court—that any consideration exchanged in the settlement has legitimate business justifications that are consistent with the antitrust laws. Moreover, antitrust plaintiffs may try to use the Court’s rationale in Actavis in matters arising outside of the Hatch-Waxman framework, such as cases involving other types of patent licensing agreements.

In Actavis, the Court expressed particular concern for patent settlement agreements in which an alleged infringer gained more out of settling the case than it would have gained if it had prevailed in the underlying patent infringement action. Concern regarding what the Court deemed potentially “excessive” payments flows through the entirety of the opinion, and yet the Court offers little guidance regarding how lower courts should determine whether a payment is, in fact, “excessive.” The FTC may also use the Court’s rationale in Actavis to challenge patent settlement agreements that include non-monetary consideration that the agency deems “excessive,” such as a brand-name drug manufacturer’s agreement not to promote an authorized generic.

Patent Settlements and the “Scope of the Patent” Test

Settlement agreements between brand-name drug manufacturers and generic drug makers often resolve the uncertainty of patent litigation by a payment from the brand-name company to the generic combined with an agreement by the generic producer not to enter the market until an agreed-upon date prior to patent expiration. Lower courts have almost uniformly held that these settlements were lawful as long as (1) the exclusion from market entry did not exceed the patent’s scope, (2) the patent holder’s claim of infringement was not objectively baseless, and (3) the patent was not procured by fraud on the U.S. Patent and Trademark Office (“PTO”). See, e.g., FTC v. Watson Pharms., Inc., 677 F.3d 1298, 1306-15 (11th Cir. 2012); Ark.
In a split decision authored by Justice Breyer, the Court held that antitrust challenges to reverse payment settlement agreements should be analyzed under the rule of reason. The Court recognized that the “scope of the patent” test was grounded on a strong policy consideration favoring settlements, and that the rule of reason would likely reduce the litigating parties’ incentive to settle patent infringement suits. See 2013 WL 2922122, at *10, *12. Nevertheless, the Court agreed with the FTC that “there is reason for concern” that reverse payment settlements “have significant adverse effects on competition,” and that the “scope of the patent” test therefore did not subject such agreements to a sufficient amount of antitrust scrutiny. Id. The Court expressed special distaste for settlement agreements in which an alleged infringer gained more out of settling the case than it would have gained if it had won the underlying patent infringement action.

The Court rejected the FTC’s argument that reverse payment agreements are presumptively unlawful, but also rejected the “scope of the patent” test that had been the standard applied by the majority of the lower courts during the past several years. In making its determination, the Court specifically pointed to “five sets of considerations,” id. at *10, which it summarized as follows: “[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,” id. at *13.

Implications of the Actavis Decision
The Court’s decision in Actavis has a number of implications for the pharmaceutical industry, both within and outside the Hatch-Waxman Act framework.

- **Does Actavis Require an Inquiry into the Merits of the Underlying Patent Dispute?**

  As the Court recognized, if parties are forced to litigate the validity of the underlying patent to defend against antitrust challenges to patent settlement agreements, the incentive to settle would be significantly diminished. *See id.* at *10. The Court claimed, however, that “normally,” it is “not necessary to litigate patent validity to answer the antitrust question” because “[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival. And that fact, in turn, suggests that the payment’s objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequences that underlies the claim of antitrust unlawfulness.” *Id.* (emphasis added).

  The Court did not provide clear guidance on how lower courts are to distinguish “large” payments from “small” or “reasonable” payments. In other words, if each case is to be judged on its own facts, then what factors could a court legitimately consider in determining whether a payment is “too large,” other than evaluating the size of the payment relative to the strength of the underlying patent (i.e., relitigating the underlying patent case)? Moreover, the Court’s reasoning suggests that a district court’s determination that a payment is “too large” may undermine the defendants’ ability to demonstrate that the payment is, in fact, justified. *See id.* (suggesting that the size of a reverse payment may permit a court to end its inquiry without a “detailed exploration of the validity of the patent itself”).

- **Payments May Be Justified By the Value of Goods or Services Provided By the Alleged Infringer**

  Importantly, the Court acknowledged that there may be legitimate justifications for a payment, such as where the payment “reflects compensation for other services that the generic promised to perform—such as distributing the patented item or helping to develop a market for that item.” *Id.* at *11. Yet the Court shifted the burden to the defendants in an antitrust suit to show that the payment aligns with the value of the goods and services being provided. *Id.* Thus, while the Actavis decision does not bar such deals in settlements, it certainly increases the associated risks. Now more than ever, it is important to make sure that any payments in such deals are consistent with the market value of the services or products being provided by the generic. Otherwise, such arrangements will be easier to characterize as involving a premium which is really a payment for delayed entry.

  Because, under *Actavis*, it is more likely that settling parties will be required to prove that the payments are aligned with the value provided, it is important for parties to thoroughly document the valuation. Moreover, such documentation should be created at the time of the settlement agreement, and any side deal should be valued in the same manner, and by the same people, who would evaluate such a deal in the ordinary course of business. Further support for the settlement agreement may be gleaned by comparing the terms of any side deals against other similar deals entered into outside of the settlement context. Such precedents should be very helpful in proving that the payments reflect the value of services rendered and are not made to delay generic entry.

- **Actavis May Open the Door to Antitrust Challenges to Patent Settlement Agreements that Do not Contain an Actual “Payment”**
Notably, any settlement agreement involves some sort of consideration to the defendant—whether in the form of monetary payment or other benefit. Otherwise, there is no reason to settle. Because there is no logical way to distinguish between monetary payments and other valuable consideration exchanged in the course of settling a case, the Court’s adoption of a rule of reason test in Actavis, broadly read, may stimulate antitrust challenges to patent settlement agreements that do not involve a monetary payment, but that instead implicate some other form of consideration that an antitrust plaintiff alleges is designed to keep generics off the market. The theory would be that agreements entailing any consideration—short of an agreement that simply allows the generic to enter before the underlying patent expires—must be defended by showing that the value of the consideration does not include a premium to the generic to stay out of the market.

Indeed, the FTC has already challenged patent settlements that involve consideration beyond monetary payments, such as a settlement in which a branded company agreed not to launch an authorized generic drug. See, e.g., Brief of Amicus Federal Trade Commission, In re: Effexor XR Antitrust Litig., No. 3:11-cv-05479 (D.N.J. Aug. 10, 2012) (asserting that an agreement by a branded company not to launch an authorized generic functions as a “payment” for delayed entry and constitutes prima facie evidence of an unreasonable restraint of trade). The FTC emphasized that because the introduction of the branded authorized generic would cut into the revenues of a competing generic, a no-authorized generic commitment can induce the generic company to delay entry, constituting an unlawful settlement agreement.

Notably, measuring the value of a nonmonetary benefit—such as a brand-name drug manufacturer’s promise not to launch its own generic—is often difficult, time consuming, and expensive. Such a trial within a trial can undermine significantly the parties’ incentive to settle the underlying patent dispute.

• Horizon Issue: Does Actavis’s Rationale Apply in Matters Outside of the Hatch-Waxman Context?

Antitrust plaintiffs may attempt to use the Actavis decision outside of the Hatch-Waxman context. For example, patent licensing agreements are often viewed as anticipatory settlements, for they are commonly entered into to avoid or resolve patent disputes. Though patent licensing agreements occur outside the Hatch-Waxman framework, an antitrust plaintiff, following the rationale of Actavis, may try to challenge a patent licensing agreement by arguing that the consideration involved does not reflect the value of the patent rights granted under the agreement, and instead includes a premium not to compete with full force.

Courts should, at the very least, view such efforts to expand Actavis with great skepticism, given the unique set of circumstances surrounding Actavis. The Supreme Court recognized that the Hatch-Waxman regulatory framework generates unique concerns and granted review merely to resolve the circuit split regarding the “application of the antitrust laws to Hatch-Waxman-related patent settlements.” 2013 WS 2922122, at *4; *6. Actavis’s holding should therefore be confined to Hatch-Waxman settlements. A broader reading would risk eroding the rights of patent holders and would undermine the incentives to innovate.

• Actavis Makes it Difficult for Settling Parties to Prevail on a Motion to Dismiss

Because the Court’s rule of reason analysis shifts the burden to the defendants to justify the reverse payment involved in a settlement agreement, the decision makes it very difficult for defendants to prevail on a motion to dismiss. And because discovery is time
consuming and expensive, *Actavis* increases significantly the costs of settling patent infringement lawsuits. In settling a patent infringement lawsuit, parties must now also consider the potential costs of discovery should their settlement agreement be challenged under the antitrust laws. Furthermore, it also remains to be seen how courts will apply the “amorphous rule” announced in *Actavis* on summary judgment in terms of the ease with which an antitrust plaintiff could create a disputed issue of fact. This uncertainty further raises the cost of settling patent disputes.

**Footnotes**

1) The Sixth Circuit held that a reverse payment settlement agreement was per se unlawful. *See In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003). Cardizem, however, was the first appellate decision in a pay-for-delay case, and was largely disregarded by subsequent appellate courts.

2) After the Court granted review in the case, it was renamed *FTC v. Actavis, Inc.*

3) Chief Justice Roberts filed a dissenting opinion, joined by Justices Scalia and Thomas. Justice Alito was recused from the case.

4) Furthermore, the Court’s proposition that having “serious doubts” about one’s case is enough to make a settlement suspect under the antitrust laws is quite revolutionary. The primary reason for settlement, after all, is to hedge against the risk of losing the lawsuit. Short of a case where the litigation is a “sham” or where a party settles purely to avoid litigation costs, a settling party must have at least some doubts about its chances of victory to make the decision to settle. Defining “serious doubts” is often in the eye of the beholder and has never before been a factor in evaluating whether an agreement violates the antitrust laws.

5) The U.S. District Court for the District Court of New Jersey issued a stay in this case pending the resolution of the Supreme Court proceedings. Order, No. 3.11-cv-05479 (D.N.J. Oct. 23, 2012).

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