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Supreme Court Holds that "Reverse Payment" Patent Settlements are Subject to Potential Antitrust Condemnation, but only After Full-Blown Rule of Reason Review

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SUMMARY OF DECISION

In *FTC v. Actavis, Inc.*, 570 U.S. ____ (Slip Op. June 17, 2013), the Supreme Court addressed for the first time the underlying antitrust merits of the Federal Trade Commission's long-running campaign against so-called "reverse payment" patent settlements, which the FTC calls "pay-for-delay" settlements. These settlements involve consideration from the patent holder to the patent challenger or alleged infringer in exchange for the resolution of the underlying patent litigation, with the challenger agreeing not to practice the patent for some defined period. In *Actavis*, the FTC sought review of an Eleventh Circuit ruling that had rejected the agency's challenge on the ground that antitrust law did not reach such agreements unless the contract rights obtained by the patent holder exceeded the scope or duration of the patent. By a 5-3 margin, the Court overturned this dismissal, though it also rejected the FTC's position that such settlements are "presumptively unlawful." The Court thus remanded to the district court with instructions to analyze the agreement under the rule of reason rather than the "quick look" doctrine.

BACKGROUND

In *FTC v. Actavis*, Solvay Pharmaceuticals had sued two generic drug manufacturers, Actavis and Paddock, for patent infringement when the two manufacturers applied to the Food & Drug Administration (FDA) to sell a generic version of Solvay's AndroGel. The defendants counterclaimed, alleging that Solvay's patent was invalid. After three years of litigation, the parties settled the suits in 2006. Solvay agreed to pay the generic companies hundreds of millions of dollars and to allow them to launch their generic products sixty-five months before Solvay's patents expired, and the generic firms agreed in exchange not to enter the market prior to that date and to assist Solvay in marketing AndroGel. In 2009, the FTC challenged the settlement under Section 5 of the FTC Act.

This and similar settlements with "reverse payments" in pharmaceutical patent cases have for many years attracted the attention of the FTC. The FTC, recently joined by the Department of Justice Antitrust Division, has argued in several cases that reverse payment settlements are presumptively unlawful, with the parties bearing the burden of justifying their agreement. Slip Op. at 20. The agencies claim that these settlements allow brand-name drug manufacturers to prolong the life of potentially invalid patents by sharing the monopoly profits available under those patents with the generic firms that might otherwise succeed in entering the market and competing away those profits. The impact of settlements with first-mover generic firms is enhanced by the Hatch-Waxman

Act, which regulates the introduction of new drugs. Only the first generic manufacturer to apply to the FDA (along with others applying on the same day) is eligible to sell the generic product for a 180-day period after it begins to market its drug commercially. *Id*. at 4.

In *Actavis*, the FTC sued in federal district court, contending that Solvay maintained its monopoly on AndroGel despite the potential (i.e., yet-to-be-litigated) invalidity of its patents by settling with the most likely challengers of that patent. The district court found that such a settlement could not violate the antitrust laws, and the Eleventh Circuit agreed, hewing to its own precedent from the 2005 *Schering* case that similarly rejected an FTC challenge to a settlement with a reverse payment. Slip Op. at 6. The Eleventh Circuit reasoned that patent holders are granted a legal monopoly within the scope of their patent and that any settlement that does not exceed that scope cannot give rise to an antitrust violation. *Id.* at 6-7. The court of appeals also credited the public policy interests that favored settlement of patent claims over continued litigation. *Id.* at 7. The Eleventh Circuit joined the Federal Circuit and the Second Circuit in this view. Because the Third Circuit had recently concluded that reverse payment settlements should be treated as presumptively unlawful under the antitrust laws, the Supreme Court granted certiorari to resolve the circuit split. *Id.*

ANALYSIS

The Supreme Court reversed the Eleventh Circuit's decision, ruling 5-3 that patent litigation settlements are neither immune from antitrust attack nor presumptively unlawful. Rather, they are subject to full-blown antitrust review under the rule of reason.

Justice Breyer, writing for the Court (joined by Justices Kennedy, Ginsburg, Sotomayor, and Kagan), first addressed the question of whether settlements within the scope of a patent were "immunized" from antitrust scrutiny by virtue of the monopoly given the patent holder under the patent laws. The Court rejected this position, concluding that the conduct of a patentee, even within the scope of a valid patent, must comport with antitrust principles. The Court noted that the patent at issue "may or may not be infringed" and that settlements involving reverse payments in exchange for settling invalidity charges "tend to have significant adverse effects on competition." *Id.* at 8. Therefore, the Court reasoned, patent law policy alone could not dictate the outcome of the antitrust case. *Id.* at 8-9.

The Court explained that it saw no reason for complete deference to patent law in the context of settlements alleged to be anticompetitive. It explained that the right to exclude granted by a patent has always been subject to limitations based on antitrust concerns. Citing *United States v. Line Material Co.*, 333 U.S. 287 (1948); *United States v. Gypsum*, 333 U.S. 364 (1948); and *Walker Process Equip. Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), the Court noted that antitrust questions arising in the patent context have always been answered not by reference to patent law but "by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances, such as those related to patents." Slip Op. at 9-10. Moreover, the Court observed that it had previously found that patent settlements (*e.g.*, *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963); *United States v. New Wrinkle, Inc.*, 342 U.S. 371 (1952)) and patent licensing agreements (*e.g.*, *Line Material*; *United States v. General Elec. Co.*, 272 U.S. 476 (1926)) can violate the Sherman Act in various circumstances.

Examining the conduct at issue here, the Court accepted the logic of the FTC's anticompetitive thesis: Solvay could have lost $500 million in profits if its patent had been found invalid or not infringed, which would “flow in large part to consumers in the form of lower prices” stimulated by early generic entry. Slip Op. at 15. Instead, Solvay agreed to pay the generic manufacturers a portion of those profits, potentially delaying the competitive entry that would have followed a victory in their patent litigation. *Id.*

Although the Court acknowledged the value of settlement, as well as the potential consumer benefits from the settlement terms allowing the generic challengers to enter the market *before* Solvay’s patents expired, it concluded that the FTC should have been given the opportunity to prove its antitrust claim. The Court pointed to several considerations that supported this conclusion. They included the “special features” of the Hatch-Waxman Act that inhibit entry by subsequent generic challengers. The court viewed the settlements as likely precluding or deterring other generic companies from attempting to challenge the patent because of the effect of the Hatch-Waxman Act’s 180-day exclusivity period. *Id.* at 15-16. The Court rejected the notion that applying the antitrust laws would require antitrust plaintiffs to litigate the validity of the patent, since “an unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival.” Id., at 18. And the Court also dismissed concerns that exposing settlements to antitrust litigation would chill the settlement of patent litigation, observing that parties have many settlement options available that do not include reverse payments. *Id.* at 19.

Notwithstanding the Court’s fairly antagonistic view of reverse-payment settlements, the Court nonetheless rejected the FTC’s position that such settlements should be deemed presumptively unlawful under a version of the “quick look” doctrine. Instead, they are properly subject to analysis under the full rule of reason. *Id.* at 20. As the Court observed:

> That is because the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification. The existence and degree of any anticompetitive consequence may also vary as among industries.

Writing in dissent, Chief Justice Roberts (joined by Justices Scalia and Thomas) offered a vigorous defense of the view that a settlement within the scope of the claimed patent could not be subject to antitrust scrutiny. Dissent Slip Op. at 1 (Roberts, C.J., dissenting). He explained that patent law and antitrust law both aim to promote consumer welfare, which is best promoted by an “exception to antitrust law” regarding a patentee’s “rights conferred by the patent.” *Id.* at 2. Because Solvay merely paid its generic rivals to respect its patent—and there were no allegations of sham litigation or fraud—the settlement agreement could not have violated the antitrust laws. *Id.* at 3.

The dissent also predicted that the Court’s approach will “discourage settlement of patent litigation” and thereby increase costs and burdens on the court system. *Id.* at 11. The dissent observed that reverse payments may be commonplace in the resolution of patent disputes, particularly when a patent holder is eager to resolve claims of invalidity. And large settlements should not always be interpreted as indicating uncertainty about the patent but could instead merely reflect the risk tolerance of the settling parties. *Id.* at 13. The dissent noted that *all* patent settlements, not merely those arising in the pharmaceutical context, will be subject to the rule of reason under the Court’s logic. *Id.* at 15. “Good luck to the district courts that must . . . weigh the ‘likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances." *Id.*

Perhaps with an eye to future rule-of-reason adjudications, the dissent also opined that patent settlements are unlikely to be anticompetitive because other challengers will emerge if the patentee gives the first challenger a large payout. Even though later challengers won't have 180-day exclusivity available under the Hatch-Waxman Act, they would still stand to gain from introducing their own products. *Id.* at 16. Therefore, a large payment on a weak patent would be "putting blood in the water where sharks are always near." *Id.*

POTENTIAL IMPLICATIONS

The settlement of commercial disputes among competitors (or potential competitors) can give rise to material antitrust issues, and the Court makes clear that patent disputes are no different. The Court's *Actavis* ruling confirms what the FTC and other antitrust authorities have been saying for years: pharmaceutical companies especially should be wary of reverse payment settlements that delay the introduction of a generic competitor. The FTC has consistently brought suit against such settlements and the European Union has fined participants in such settlements affecting the EU market (with fines against nine pharmaceutical companies announced by the EU on June 4, 2013).

The more interesting implications of the ruling flow from its view regarding the primacy of antitrust law, the nature of the rule-of-reason inquiries the Court has commanded, and the potential reach of the decision outside the pharmaceutical arena.

First, the decision reflects a Court that is willing to treat the body of federal antitrust law as the equal of the patent laws. Though it is important to resist reading too much into this outcome—especially given that the decision was authored by the same Justice who wrote the decision in *Credit Suisse v. Billing* just six years ago (finding certain SEC-regulated securities underwriting activities impliedly immune from antitrust attack)—the case can be seen as an indication that the Court views the antitrust laws as central to the operation of the economy and is comfortable that the lower courts can manage complex antitrust litigation under the rule of reason without wreaking too much havoc. This attitude may have particularly important implications as the lower courts consider other difficult issues at the intersection of patent and antitrust law, such as standard essential patents and challenges to patents under the America Invents Act.

Second, by embracing a full rule-of-reason inquiry, the decision raises the key question of *how* the lower courts will structure a rule-of-reason inquiry into patent settlements. At times the majority suggests that condemnation of large reverse payments will be a *fait accompli* when market power is proven and the patent holder offers no compelling justification. But the Court's instructions leave unclear what weight lower courts will give to the strength of the patent, the regulatory environment, the size of the settlement, or the extent of the delay. The Court suggests that trial courts will need to consider some of these factors but not necessarily all of them. Slip Op. at 21. The Court acknowledges the uncertainties but is content to "leave to the lower courts the structuring of the present rule-of-reason antitrust litigation." *Id.*

Third, the core principles underlying the decision—that the patent laws do not trump antitrust laws and that eliminating the chance that a patent will be found invalid (or not infringed) is potentially anticompetitive—indicate that the ruling necessarily applies to patent settlements in all industries, not just the pharmaceutical arena, and even to settlements that do not involve a large reverse payment. The dissent takes the majority to task on precisely that ground. Slip Op. at 14 (Roberts, C.J., dissenting). But both the industry context and the features of proposed settlements undoubtedly will shape the antitrust analysis in the lower courts, especially in light of the majority's reliance on Hatch-Waxman exclusivity as a deterrent to entry by subsequent challengers.

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