But Decision Raises as Many Questions as it Answers

The Supreme Court yesterday held that it may be unlawful under the antitrust laws for a brand-name drug manufacturer to resolve patent litigation against an allegedly infringing generic drug maker by paying the generic to forestall market entry. Pharmaceutical companies might have legitimate, procompetitive reasons for agreeing to such “reverse-payment settlements,” but as Justice Breyer writes for five of the Court’s justices, “the relevant antitrust question is: What are those reasons?”

The Court suggests a few possible answers, but otherwise leaves litigants and district courts to navigate an undefined “rule of reason” framework on their own. In so doing, the majority stresses that litigating the strength of the patent (i.e., its scope and validity) should not be necessary. Frankly, that remains to be seen.

In holding that the rule of reason applies, the Court rejected the polar-opposite approaches urged by the parties. The FTC had argued that reverse-payment settlements should be presumptively unlawful, albeit subject to rebuttal and justification. Actavis argued, on the other hand, that so long as the settlement falls within the scope of the brand manufacturer’s patent, the settlement should be deemed lawful.

Applying the Rule of Reason to Reverse-Payment Settlements

The courts of appeals had grappled with the legality of so-called “reverse-payment settlements” (sometimes called “pay-to-delay” deals) for over a decade before the Supreme Court decided Federal Trade Commission v. Actavis, which it handed down today. In this decision, the Court directs district courts to employ a full “rule of reason” analysis in pharmaceutical competition cases arising under the Hatch-Waxman Act.
The majority, per Justice Breyer, emphasizes that in past antitrust cases involving patents, the Supreme Court has “answered the antitrust question by considering traditional antitrust factors,” including likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations. Slip Op. at 9–10. Despite the traditional judicial preference for patent settlements, the Court holds that such agreements may “sometimes” violate the antitrust laws. *Id.* at 10.

The Court explains that payments flowing from a brand to a generic may provide “strong evidence” of anticompetitive intent and effect. *Id.* at 15. Companies nonetheless should be permitted to show that their agreement has “offsetting or redeeming virtues.” *Id.* at 17. A reverse cash payment may, for example, “amount to no more than a rough approximation of the litigation expenses saved through the settlement,” or “reflect compensation for other services that the generic has promised to perform.” *Id.*

These and possibly other unspecified “traditional settlement considerations” provide an exonerating defense under the antitrust rule of reason, which weighs procompetitive benefits against anticompetitive harm. *Id.*

The majority writes that “five sets of considerations lead us to conclude that the FTC should have been given the opportunity to prove its antitrust claim” against Actavis. *Id.* at 14. Those are:

1. The specific restraint at issue has the potential for genuine adverse effects on competition.
2. The alleged anticompetitive consequences may at least sometimes prove unjustified. The key question is whether the reverse payment can be justified by “traditional settlement considerations.”
3. Where a reverse payment threatens to have an anticompetitive effect, the patent holder likely possesses the power to actually bring about that harm in the marketplace.
4. It will not normally be necessary to litigate patent validity in order to answer the antitrust question. Thus, an antitrust action can be more feasible administratively than the court of appeals feared.
5. Pharmaceutical patent litigants may still settle their disputes in other ways, such as by allowing the generic manufacturer to enter the market before patent expiration, but without a reverse payment.

"In sum," the majority concludes, "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects." *Id.* at 20. The considerations listed above led the Court to reject what it characterizes as the Eleventh Circuit's rule of "near-automatic antitrust immunity to reverse payment settlements." *Id.*

The Dissent: Patent Scope and Strength Are Too Important to Downplay or Ignore

Writing for three dissenters, Chief Justice Roberts argues that the “correct approach” is to “ask whether the settlement gives [the brand manufacturer] monopoly power beyond what the patent already gave it.” Dissent Op. at 1.
The dissenting justices would “keep things as they were,” and refrain from “unsettl[ing] the established relationship between patent and antitrust law.” *Id.* at 9, 18. The dissenters would have adhered to the rule adopted by most courts of appeals—namely, that a patent creates a “zone within which the patent holder may operate without facing antitrust liability.” *Id.* at 2.

Despite the majority’s assurances to the contrary, the Chief Justice fears that under the “amorphous rule of reason,” antitrust litigants will necessarily have to litigate the validity of the underlying patents—which he views as a matter of patent law, not antitrust law. *Id.* at 1, 12.

Indeed, as Justice Scalia colorfully articulated at oral argument, to consider setting aside the strength of the patent is to “leave out the elephant in the room.” In the dissenters’ view, the majority’s conclusion that antitrust law adds meaningfully to the established patent law inquiry is, at a minimum, dubious.

**Where Do We Go From Here?**

Aside from the broad mandate that district courts apply the rule of reason, the Court’s decision offers little practical guidance for litigating these cases or settling them within any safe harbor. In fact, the majority explicitly directs the district courts to figure out how to proceed. See *Slip Op.* at 20.

The majority’s opinion raises many important questions, including the following:

**What consideration is permissible?** The Court states that it is permissible to negotiate a date certain for generic entry prior to the patent’s expiration. It also states that cash payments to a generic company may be justified under certain limited circumstances. What is generally impermissible is paying the generic challenger cash to stay out of the market. However, as the dissent points out, “if antitrust scrutiny is invited for such cash payments, it may also be required for ‘other consideration’ and ‘alternative arrangements.’” *Dissent Op.* at 14.

**When is a settlement payment too large?** The Court repeatedly emphasizes that “large” settlement payments are suggestive of anticompetitive intent and effect, but it does not clearly define when a payment becomes so large as to trigger antitrust scrutiny. The Court indicates merely that the scale of reverse payments should be weighed against the brand’s anticipated litigation costs, the value of any services provided by the generic, and other justifications raised by the defendants.

**Does the need for a rule of reason necessarily mean that defense motions to dismiss under Rule 12(b)(6) will be denied?** The Court holds that the FTC should be permitted to prove its case beyond Actavis’ pleading motion. While assuring litigants that patent validity need not be litigated, the Court does not detail whether, and under what circumstances, defendants may defeat an antitrust challenge to the settlement at the motion-to-dismiss stage, and thereby avoid voluminous and what the dissent calls “famously burdensome” antitrust discovery.

**Is the Court’s holding necessarily limited to pharmaceutical patent litigation within the Hatch-Waxman framework?** Chief Justice Roberts fears that it is not. His dissent suggests that the ruling raises basic questions about the “right to settle,” which “accompanies the right to litigate in the first place.” *Id.* at 10.
Will patent challenges and generic entry be chilled? The dissenting justices suggest that the astronomical expense of patent and antitrust litigation may, ironically, discourage generic companies from challenging pharmaceutical patents and seeking to launch generic products prior to patent expiration, thus undermining one of the Hatch-Waxman Act’s chief goals: promoting consumer access to low-price generic drugs. *Id.* at 17.

**Background: The Hatch-Waxman Act and Reverse Payment Settlements**

As practitioners in the field are aware, under the Hatch-Waxman Act, pharmaceutical companies seeking to market a generic version of an existing drug can file an Abbreviated New Drug Application, or ANDA, with the FDA. The ANDA must demonstrate that the generic drug has the same therapeutic effect as the corresponding brand-name drug and, among other things, is “bioequivalent” to the branded version.

When filing an ANDA, the generic company must make one of four certifications related to any patents covering the branded drug. One of them, a Paragraph IV certification, claims that the patent covering the branded drug is either not infringed or is invalid. A Paragraph IV certification is deemed “constructive infringement,” and the patent holder generally has 45 days in which it may bring an infringement suit against the ANDA filer. If the patent holder sues, the FDA customarily imposes a 30-month stay, during which the ANDA cannot be approved.

A “reverse-payment settlement” refers to an agreement between a brand-name drug manufacturer and a generic competitor, whereby the generic company agrees not to sell a generic version of a brand-name drug until a negotiated date. The settlement customarily specifies a date certain for generic entry, subject to certain exceptions, in return for one or more payments from the brand manufacturer. These agreements are typically designed to resolve or avoid patent litigation stemming from a Paragraph IV certification. Because the settlement payment flows from the patentee to the alleged infringer, it is considered “reverse.”

The FTC has long objected to reverse-payment settlements as anticompetitive. In the FTC’s view, paying a horizontal competitor for a commitment to delay market entry is an unlawful market division. These deals are allegedly harmful to consumers, who would benefit from the earliest possible generic entry, because generic prices are usually only a fraction of brand prices. From this perspective, the FTC argues that reverse-payment settlements should be treated as presumptively unlawful under the Sherman Act.

For their part, pharmaceutical companies argue that reverse-payment deals are not unlawful so long as they do not exceed the scope of the relevant patent or patents. Patent holders may exclude arguably infringing competitors without running afoul of the antitrust laws, so long as they do not bring “sham” patent litigation or commit fraud on the USPTO. Because reverse-payment deals often provide for generic entry in advance of patent expiration (sometimes by several years), the pharmaceutical industry argues that these deals should actually be seen as *beneficial* to consumers.
After a Decade of Litigation, a Stark Circuit Split Finally Develops

Early circuit court decisions disapproved of reverse-payment settlements, but without providing consistent or concrete guidance as to how they should be treated under the antitrust laws. See In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003), cert. denied, 543 U.S. 939 (2004); Andrx Pharms., Inc. v. Biovail Corp. Int’l, 256 F.3d 799 (D.C. Cir. 2001), cert. denied, 535 U.S. 931 (2002).


Finally, in 2012, the circuit split crystallized. Within months of each other, the Eleventh Circuit decided FTC v. Watson Pharmaceuticals, Inc., 677 F.3d 1298 (11th Cir. 2012), and the Third Circuit decided In re K-Dur Antitrust Litigation, 686 F.3d 197 (3d Cir. 2012). The Eleventh Circuit reaffirmed the scope-of-the-patent test in Watson, but the Third Circuit rejected that test in K-Dur—becoming the first circuit to affirmatively do so. The Third Circuit held that reverse-payment agreements should be viewed as presumptively anticompetitive. Both decisions resulted in petitions for certiorari to the Supreme Court.

After having denied a string of petitions in previous reverse-payment cases, the Supreme Court granted cert in Watson (now styled as FTC v. Actavis, reflecting Watson’s change in corporate structure) in October 2012.

The Actavis Case

The Actavis case centers on AndroGel, a drug used to treat hypogonadism. The FDA approved AndroGel in February 2000. The original patent covering the drug had previously expired, but in January 2003, the USPTO issued a new patent to Solvay Pharmaceuticals, covering certain formulations used in AndroGel. Shortly thereafter, Watson Pharmaceuticals and Paddock Laboratories submitted separate ANDAs to the FDA, each with a Paragraph IV certification asserting that Solvay’s patent was invalid and not infringed.

In August 2003, Solvay sued Watson and Paddock for infringement. When the 30-month stay expired in January 2006, the litigation had not yet been resolved. At that point, the FDA approved Watson’s ANDA. Both Watson and Paddock expected to launch no later than 2007. Solvay hoped to secure a later entry date via settlement, but in settlement discussions, both generic companies allegedly indicated that they would not agree to Solvay’s later date absent payment. Ultimately, Solvay agreed to pay an estimated $19 to $30 million annually to Watson, and a combined $12 million annually to Paddock and its corporate partner Par Pharmaceutical Companies, in exchange for an agreement not to compete before 2015.
Notably, in neither case did the settlement agreement contemplate a “naked payment” in exchange for delayed market entry. The Watson agreement provided that Watson would market AndroGel to urologists on Solvay’s behalf. Under the Paddock/Par agreement, Paddock committed to serve as a back-up supplier of AndroGel and Par agreed to market the drug to primary care physicians.

The FTC sued under Section 5 of the Federal Trade Commission Act to challenge the two settlement agreements, seeking a declaration that the agreements were unlawful and a permanent injunction. The district court in the Northern District of Georgia dismissed the FTC’s complaint for failure to state a claim. On appeal, the Eleventh Circuit affirmed on the basis of its prior rulings, stating that reverse-payment settlements are “immune from antitrust attack so long as [their] anticompetitive effects fall within the scope of the exclusionary potential of the patent[s].” 677 F.3d at 1312.

The Supreme Court heard oral argument in *Actavis* on March 25, 2013. Justice Alito recused himself from the decision. Justice Breyer’s majority opinion was joined by Justices Kennedy, Ginsburg, Sotomayor, and Kagan. Chief Justice Roberts’ dissent was joined by Justices Scalia and Thomas.

For questions about this report, please contact O’Melveny lawyers Richard Parker (Washington D.C.), Kenneth R. O’Rourke (Los Angeles), Jonathan Sallet (Washington D.C.) or Stephen McIntyre (Los Angeles).


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