6-26-2015

King Drug Co of Florence Inc v. Smithkline Beecham Corporation

PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 14-1243

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KING DRUG COMPANY OF FLORENCE, INC.;
LOUISIANA WHOLESALE DRUG CO., INC.,
on behalf of itself and all others similarly situated,
Appellants

v.

SMITHKLINE BEECHAM CORPORATION, doing
business as GLAXOSMITHKLINE; TEVA
PHARMACEUTICAL INDUSTRIES LTD.; TEVA
PHARMACEUTICALS

_____

On Appeal from the United States District Court
for the District of New Jersey
D.C. Civil Action No. 2-12-cv-00995
District Judge: Honorable William H. Walls

_____

Argued: November 19, 2014

Before: AMBRO, SCIRICA, and ROTH, *Circuit Judges*.

(Opinion Filed: June 26, 2015)

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OPINION OF THE COURT

SCIRICA, *Circuit Judge*.

In this appeal from the grant of a motion to dismiss for failure to state a rule-of-reason claim under Sections 1 and 2 of the Sherman Act under Federal Rule of Civil Procedure 12(b)(6), we are asked to determine whether *FTC v. Actavis*, 133 S. Ct. 2223 (2013), covers, in addition to reverse cash payments, a settlement in which the patentee drug manufacturer agrees to relinquish its right to produce an "authorized generic" of the drug ("no-AG agreement") to compete with a first-filing generic's drug during the generic's statutorily guaranteed 180 days of market exclusivity under the Hatch-Waxman Act[1] as against the rest of the world.

In *Actavis*, the Supreme Court held that unexplained large payments from the holder of a patent on a drug to an alleged infringer to settle litigation of the validity or infringement of the patent ("reverse payment") "can

[1] Hatch-Waxman is the short name for the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

sometimes violate the antitrust laws." *Id.* at 2227. The Court rejected the near-irrebuttable presumption, known as the "scope of the patent" test, that a patentee can make such reverse payments so long as it is paying potential competitors not to challenge its patent within the patent's lifetime.

Plaintiffs here, direct purchasers of the brand-name drug Lamictal, sued Lamictal's producer, Smithkline Beecham Corporation, d/b/a GlaxoSmithKline ("GSK"), and Teva Pharmaceutical Industries Ltd. ("Teva"[2]), a manufacturer of generic Lamictal, for violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2.[3] In earlier

[2] "Teva" refers collectively to Teva Pharmaceutical Industries Ltd. and its subsidiary Teva Pharmaceuticals USA, Inc.

[3] Plaintiffs bring their Sherman Act claims under Sections 4 (damages) and 16 (injunctive relief) of the Clayton Act, 15 U.S.C. §§ 15 & 26, respectively. The Clayton Act requires "a plaintiff to have standing to bring an antitrust claim." *Angelico v. Lehigh Valley Hosp., Inc.*, 184 F.3d 268, 273 (3d Cir. 1999). At the motion-to-dismiss stage, "a plaintiff must allege more than that it has suffered an injury causally linked to a violation of the antitrust laws." *Pace Elecs., Inc. v. Canon Computer Sys., Inc.*, 213 F.3d 118, 120 (3d Cir. 2000). The plaintiff must also "allege antitrust injury, 'which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful.'" *Id.* (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)). As noted below, we do not here address the issue of antitrust injury, nor do we preclude consideration of the issue on remand. *See infra* notes 20 & 35 and accompanying text.

litigation, Teva had challenged the validity and enforceability of GSK's patents on lamotrigine, Lamictal's active ingredient. Teva was also first to file an application with the FDA alleging patent invalidity or nonenforceability and seeking approval to produce generic lamotrigine tablets and chewable tablets for markets alleged to be annually worth $2 billion and $50 million, respectively. If the patent suit resulted in a judicial determination of invalidity or nonenforceability—or a settlement incorporating such terms—Teva would be statutorily entitled to a valuable 180-day period of market exclusivity, during which time only it and GSK could produce generic lamotrigine tablets. (The relevant statute permits the brand to produce an "authorized generic" during the exclusivity period. *Mylan Pharm., Inc. v. FDA*, 454 F.3d 270, 276-77 (4th Cir. 2006); *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 55 (D.C. Cir. 2005); *see also Sanofi-Aventis v. Apotex Inc.*, 659 F.3d 1171, 1175 (Fed. Cir. 2011).)

After the judge presiding over the patent litigation ruled the patent's main claim invalid, GSK and Teva settled. They agreed Teva would end its challenge to GSK's patent in exchange for early entry into the $50 million annual lamotrigine chewables market and GSK's commitment not to produce its own, "authorized generic" version of Lamictal tablets for the market alleged to be worth $2 billion annually. Plaintiffs contend that this "no-AG agreement" qualifies as a "reverse payment" under *Actavis* because, like the cash reverse payments the Court there warned could face antitrust scrutiny, GSK's no-AG commitment was designed to induce Teva to abandon the patent fight and thereby agree to eliminate the risk of competition in the $2 billion lamotrigine

tablet market for longer than the patent's strength would otherwise permit.

We believe this no-AG agreement falls under *Actavis*'s rule because it may represent an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition. As the Court noted, these kinds of settlements are subject to the rule of reason.

I.

"A patent . . . is an exception to the general rule against monopolies and to the right to access to a free and open market." *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965) (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945)). The Constitution's "Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'" *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) (quoting U.S. Const. art. I., § 8, cl. 8). In turn, "[f]rom their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy." *Id.*; *see* X Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 1780a (3d ed. 2011) ("Patent law . . . serves the interests of consumers by protecting invention against prompt imitation in order to encourage more innovation than would otherwise

occur."). A patent, consequently, "is a special privilege designed to serve the public purpose of promoting the 'Progress of Science and useful Arts.'" *Precision Instrument Mfg. Co.*, 324 U.S. at 816.

With the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly known as the Hatch-Waxman Act, Congress attempted to balance the goal of "mak[ing] available more low cost generic drugs," H.R. Rep. No. 98-857, pt. 1, at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48, with the value of patent monopolies in incentivizing beneficial pharmaceutical advancement, *see* H.R. Rep. No. 98-857, pt. 2, at 30 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2714. The Act seeks to accomplish this purpose, in part, by encouraging "manufacturers of generic drugs . . . to challenge weak or invalid patents on brand name drugs so consumers can enjoy lower drug prices." S. Rep. No. 107-167, at 4 (2002). The resulting regulatory framework has the following four relevant features identified by the Supreme Court in *Actavis*, 133 S. Ct. at 2227-29.

First, a new drug—that is, a pioneer, "brand-name" drug—cannot be introduced until it is approved by the Food and Drug Administration ("FDA"). 21 U.S.C. § 355(a). A New Drug Application ("NDA") requires the applicant to submit, among other things, "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use," *id.* § 355(b)(1)(A), as well as comprehensive information about the drug, *id.* § 355(b)(1). This reporting requirement entails "a long, comprehensive, and costly testing process." *Actavis*, 133 S. Ct. at 2228.

Second, the Hatch-Waxman Act facilitates the development of generic drugs by allowing an applicant to file, for new drugs shown to be "bioequivalent" to a drug previously approved by the FDA, 21 U.S.C. § 355(j)(2)(A)(iv), a less onerous and less costly "Abbreviated New Drug Application" ("ANDA") in lieu of an NDA. *See id.* § 355(j); *Actavis*, 133 S. Ct. at 2228. The ANDA process "allow[s] the generic to piggy-back on the pioneer's approval efforts . . . , thereby furthering drug competition." *Actavis*, 133 S. Ct. at 2228 (citing *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012)).[4]

Third, Hatch-Waxman "sets forth special procedures for identifying, and resolving, related patent disputes." *Id.* A new drug applicant must list information on any patents issued on the drug's composition or methods of use. *See* 21 U.S.C. § 355(b)(1); *Caraco*, 132 S. Ct. at 1676. If the FDA approves the new drug, it publishes this information, without

[4] "Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Caraco*, 132 S. Ct. at 1676; *see* 21 U.S.C. § 355(j) (ANDA requirements). Before Hatch-Waxman, a company desiring to produce a generic version of a drug approved after 1962 had to conduct its own testing and trials to show that its generic version was safe and effective for human use. H.R. Rep. No. 98-857, pt. 1, at 16-17.

verification, in its *Orange Book*.[5] *Caraco*, 132 S. Ct. at 1676. In turn, any manufacturer filing an ANDA to produce a generic version of that pioneer drug must consult the *Orange Book* and "assure the FDA that [the] proposed generic drug will not infringe the brand's patents." *Id.*[6] As relevant here, the manufacturer may tender that assurance with a "paragraph IV" certification that the relevant listed patents are "invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). But "[f]iling a paragraph IV certification means provoking litigation," *Caraco*, 132 S. Ct. at 1677, because the patent statute treats paragraph IV certification as a per se act of infringement, *see* 35 U.S.C. § 271(e)(2)(A).[7] The patentee

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[5] The volume, officially known as *Approved Drug Products with Therapeutic Equivalence Evaluations*, is available at http://www.fda.gov/cder/ob/. *See generally, e.g.*, 21 U.S.C. § 355(b)(1) ("Upon approval of the application, the Secretary shall publish information submitted . . . ."); *Caraco*, 132 S. Ct. at 1676.

[6] Although the FDA performs no independent patent review, it cannot approve an ANDA if the proposed generic would infringe any of the brand's asserted patents. *See Caraco*, 132 S. Ct. at 1676.

[7] Further, an ANDA applicant making a paragraph IV certification must notify any patent holder within twenty days of the FDA's confirmation of its ANDA filing, 21 U.S.C. § 355(j)(2)(B)(ii), (iii), "of the factual and legal basis of [its] opinion . . . that the patent is invalid or will not be infringed," *id.* § 355(j)(2)(B)(iv)(II). *See also* 21 C.F.R. § 314.52 ("Notice of certification of invalidity or noninfringement of a patent").

then has an incentive to sue within 45 days in order to trigger a 30-month stay of the FDA's potential approval of the generic "while the parties litigate patent validity (or infringement) in court. If the courts decide the matter within that period, the FDA follows that determination; if they do not, the FDA may go forward and give approval to market the generic product." *Actavis*, 133 S. Ct. at 2228 (citing 21 U.S.C. § 355(j)(5)(B)(iii)).[8]

"Fourth, Hatch-Waxman provides a special incentive for a generic to be the first to file an Abbreviated New Drug Application taking the paragraph IV route." *Id.* at 2228-29. From when it first begins marketing its drug or when a court enters judgment finding the challenged patent invalid or unenforceable, the first-filing generic enjoys a 180-day period of exclusivity during which no other generic manufacturer can enter the market. *See* 21 U.S.C. § 355(j)(5)(B)(iii), (iv).[9]

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[8] Hatch-Waxman "allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 671 (1990); *see* 35 U.S.C. § 271(e)(1). As long as a generic applicant does not launch its generic "at risk" (i.e., after FDA approval after 30 months but before a determination of patent validity), it will not be forced to pay money damages. *See* 35 U.S.C. § 271(e)(4)(C). This feature also explains "the creation of a highly artificial act of infringement"—the paragraph IV certification—to permit the brand and generic to litigate patent validity. *Eli Lilly*, 496 U.S. at 678.

[9] Under current law, the specific mechanism is that an application by a non–first filer "shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug . . . by any first applicant." 21 U.S.C.

This exclusivity period belongs to first-filing ANDA applicants[10] alone and is nontransferable. *See id.* § 355(j)(5)(D); *Actavis*, 133 S. Ct. at 2229. The period does not, however, prevent the brand-patentee from marketing its own "authorized generic." *Mylan Pharm.*, 454 F.3d at 276-77; *Teva Pharm. Indus.*, 410 F.3d at 55; *see also Sanofi-Aventis*, 659 F.3d at 1175.

II.

A.[11]

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§ 355(j)(5)(B)(iv)(I). But the parties appear to agree that because the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(b)(1), amended Hatch-Waxman's exclusivity provisions only for subsequent ANDAs, the exclusivity rules in place in 2002 control. *See* Teva Br. 8 & n.1. Under those rules, the 180-day period begins from the earlier of a generic's launching "at risk" or a court's finding the patent invalid or unenforceable. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2002).

[10] "[A]ccording to the Food and Drug Administration, all manufacturers who file on the first day are considered 'first applicants' who share the exclusivity period. Thus, if ten generics file an application to market a generic drug on the first day, all will be considered 'first applicants.'" *Actavis*, 133 S. Ct. at 2246 (Roberts, C.J., dissenting) (citing 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb)).

[11] The facts recounted in this opinion are taken from the well-pleaded, nonconclusory factual allegations in plaintiffs'

Plaintiffs, a putative class represented by King Drug Company of Florence, Inc., and Louisiana Wholesale Drug Co., Inc., are direct purchasers of Lamictal from Defendant GSK. GSK pioneered Lamictal, a brand-name drug used to treat epilepsy and bipolar disorder, and secured U.S. Patent No. 4,602,017 ("the '017 patent") on lamotrigine, Lamictal's active ingredient. The patent expired on July 22, 2008. GSK sells both Lamictal tablets and Lamictal chewable tablets, although most Lamictal prescriptions are for the nonchewable tablets (most relevant here). Lamictal tablet sales exceeded $2 billion between March 2007 and 2008, while chewable sales measured about $50 million over a yearlong span around 2005.

In April 2002, Defendant Teva filed the first paragraph IV ANDAs to market generic lamotrigine tablets and chewables. Teva certified that its proposed generics did not infringe the '017 patent and/or that the '017 patent was unenforceable. GSK soon sued in federal court, *see* Complaint, *Smithkline Beecham Corp. v. Teva Pharm. USA, Inc.*, No. 02-3779 (D.N.J. Aug. 5, 2002) (ECF No. 1), staying the FDA's approval of Teva's ANDAs for 30 months. In late January 2005, the parties tried the patent case before Judge Bissell, who ruled that the patent's main claim, for the invention of lamotrigine, was invalid. Plaintiffs allege that "it was highly likely that Teva would prevail with respect to the remaining patent claims," which "were extremely weak in view of Judge Bissell's ruling that claim 1 was invalid."

Amended Complaint and all reasonable inferences to be drawn therefrom. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009).

In February 2005, the parties settled their dispute before Judge Bissell could rule on the validity of the '017 patent's remaining claims. GSK agreed to allow Teva to market generic lamotrigine chewables by no later than June 1, 2005, or 37 months before the patent was to expire on July 22, 2008.[12] GSK further agreed to permit Teva to sell generic lamotrigine tablets on July 21, 2008, if GSK received a "pediatric exclusivity" extension,[13] or March 1, 2008, if GSK did not. (With a pediatric exclusivity extension, the patent would still have expired on July 22, 2008, but the FDA would have been foreclosed from approving ANDAs filed by competing generics until January 22, 2009. *See generally AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1341, 1343 (Fed. Cir. 2015).)

Most relevant here, GSK also agreed not to market an authorized generic until January 2009, after Teva's 180-day market exclusivity period was to expire (the "no-AG agreement" component of the settlement). In fact, plaintiffs allege, Teva "had an interest in delaying a final court decision finding the '017 patent invalid" because the FDA had not yet approved Teva's ANDAs, and Teva therefore wanted time to secure FDA approval so it could "take advantage of its valuable 180-day period," which would have begun to run

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[12] Because Teva's ANDAs had not yet been approved, GSK also agreed to supply Teva with lamotrigine chewables.

[13] *See generally* 21 U.S.C. § 355a(c)(2)(B) (2002) (then in effect) (providing for situations in which the FDA may not approve ANDAs for an additional six months if the patent holder completes certain studies "relating to the use of [the] drug in the pediatric population").

with a final judgment finding the patent invalid or noninfringed.

In exchange, Teva agreed to drop its litigation challenging GSK's patent and, plaintiffs allege, delay its entry into the lamotrigine tablet market. If not for the consideration it received, plaintiffs allege, Teva would have launched its generic lamotrigine tablet "at risk" after receiving FDA approval (which occurred later, in August 2006), even if Judge Bissell had not yet ruled the patent invalid (as, they allege, he was likely to do). Indeed, Teva was later to assert, in other litigation against GSK, that GSK's no-AG agreement was "an important component of the settlement between the parties and formed part of the inducement to Teva to relinquish the rights and defenses it was asserting against GSK in the Patent Litigation." JA 76 (alteration and emphases omitted).[14] Judge Bissell approved the parties' settlement and dismissed the case on April 4, 2005.

B.

[14] In July 2008, "[j]ust prior to Teva launching its generic, GSK approached various pharmacies, group purchasing organizations, and long-term care facilities and proposed that they purchase and distribute GSK's Lamictal at a generic product price." *Teva Pharm. Indus. Ltd. v. SmithKline Beecham Corp.*, No. 08-3706, 2009 WL 1687457, at *2 (D.N.J. June 16, 2009). Teva sued GSK to attempt to prevent GSK from "develop[ing] a generic of lamotrigine" because the parties' settlement agreement "made clear that [Teva's] right [to sell generic lamotrigine] was exclusive—including as to GSK and its affiliates." *Id.* at *1, *4.

Plaintiffs here, direct purchasers of Lamictal from GSK, sued GSK and Teva in federal court in February 2012 and filed their Consolidated Amended Class Action Complaint the following June. They allege that defendants, by their no-AG agreement—in effect, a "reverse payment" from GSK to Teva—violated section 1 of the Sherman Act by conspiring to delay generic competition for Lamictal tablets and section 2 by conspiring to monopolize the lamotrigine tablet market. GSK and Teva moved to dismiss, countering that, under our decision in *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012),[15] only cash payments constitute actionable "reverse payments."

In *K-Dur*, we charted a course different from that set by several other courts of appeals by rejecting the "scope of the patent" test, under which "a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent," *Actavis*, 133 S. Ct. at 2230 (citation omitted). We reasoned that the scope-of-the-patent test "is contrary to the policies underlying the Hatch-Waxman Act and a long line of Supreme Court precedent on patent litigation and

[15] The Supreme Court later vacated *K-Dur* and remanded for reconsideration in light of *Actavis*, *see Merck & Co. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013); *Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013). *K-Dur* was inconsistent with *Actavis* in that we had directed application of "quick look rule of reason analysis," *K-Dur*, 686 F.3d at 218, rather than the traditional, full-fledged rule of reason standard that the Supreme Court subsequently decided is proper for reverse payment settlement agreements, *see Actavis*, 133 S. Ct. at 2237-38.

competition." *K-Dur*, 686 F.3d at 214. Patents, we noted, are simply legal conclusions of the Patent Office. They should not be irrebuttably presumed valid, we said, especially given "the public interest support[ing] judicial testing and elimination of weak patents," *id.* at 215-16, and "[t]he line that Congress drew [in Hatch-Waxman specifically] between the[] competing objectives" of promoting innovation and advancing the public interest, *id.* at 217. For these reasons, we held that rule of reason scrutiny is proper for reverse payment settlements. *Id.* at 218.[16]

The District Court here focused on our limitation of *K-Dur* to the pharmaceutical context, *see id.* at 216-18, and statements approving "settlements based on a negotiated entry date for marketing of the generic drug," *id.* at 217-18, to restrict *K-Dur*'s reach to "settlements when a generic manufacturer is paid off with money, which is not the case here," *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-0995, 2012 WL 6725580, at *6 (D.N.J. Dec. 6, 2012). The court observed that Teva surely "received consideration," or otherwise would have had "no incentive to settle," but it viewed the parties' settlement as "based on negotiated entry dates" rather than money. *Id.* Concluding the settlement was "not subject to antitrust scrutiny" under *K-Dur*, *id.*, and that, "from a policy perspective, this settlement did introduce generic products onto the market sooner than what would have occurred had GSK's patent not been challenged," *id.* at *7, the court granted the defendants' motion to dismiss for failure to state a claim.

[16] *See supra* note 15.

Plaintiffs appealed and we stayed proceedings pending the Supreme Court's decision in *Actavis*. After the Court's decision, we remanded for further consideration in light of *Actavis*. In January 2014, the District Court "affirm[ed] its order of dismissal." *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 561 (D.N.J. 2014). Although conceding that "there is some very broad language in the [*Actavis*] opinion regarding patent settlements of all kinds," *id.* at 566, the court read *Actavis*, as it had *K-Dur* before, as requiring antitrust scrutiny only of reverse payment patent settlements that "involve an exchange of money" rather than some other type of valuable consideration, *id.* at 568. In the alternative, the court stated, it "considered the settlement under the 'five considerations'" of *Actavis*'s rule of reason and concluded that the settlement "would survive." *Id.* at 570.

III.[17]

Plaintiffs contend that under *Actavis* antitrust scrutiny is not limited to reverse payments of cash. They assert the antitrust laws may be violated when a brand-name drug manufacturer induces a would-be generic competitor to delay market entry by agreeing not to launch an authorized generic to compete with the generic. Further, they argue, the District Court usurped the jury's role in purporting to conduct a rule of reason analysis by applying the five considerations the

[17] The District Court had jurisdiction under section 4(a) of the Clayton Act, 15 U.S.C. § 15(a), and 28 U.S.C. §§ 1331 and 1337. We have jurisdiction under 28 U.S.C. § 1291. We exercise plenary review over a district court's ruling on a Federal Rule of Civil Procedure 12(b)(6) motion to dismiss. *E.g.*, *Byers v. Intuit, Inc.*, 600 F.3d 286, 291 (3d Cir. 2010).

Actavis Court discussed to justify, not redefine, use of the already well-established rule of reason analysis. We will vacate and remand.

A.

As noted, in *Actavis*, the Supreme Court rejected the "scope of the patent" test, a categorical rule that reverse payment patent settlements in the Hatch-Waxman context were immune from antitrust scrutiny so long as the asserted anticompetitive effects fell within the scope of the patent. The Court held that "reverse payment settlements . . . can sometimes violate the antitrust laws," *Actavis*, 133 S. Ct. at 2227, because "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival," thereby "suggest[ing] 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," *id.* at 2236. Consequently, the Court held, plaintiffs should be able to prove "[t]he existence and degree of any anticompetitive consequence" of such an agreement under the traditional rule-of-reason test. *Id.* at 2237.

Justice Breyer framed the issue of reverse payments then before the Court as follows:

> Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many

> millions of dollars. Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a "reverse payment" settlement agreement. And the basic question here is whether such an agreement can sometimes unreasonably diminish competition in violation of the antitrust laws. See, *e.g.*, 15 U.S.C. § 1 (Sherman Act prohibition of "restraint[s] of trade or commerce"). Cf. *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990) (*per curiam*) (invalidating agreement not to compete).

Actavis, 133 S. Ct. at 2227.

The Court of Appeals for the Eleventh Circuit had applied its scope-of-the-patent test to the following facts. *See id.* at 2227; *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298 (11th Cir. 2012), *rev'd sub nom. Actavis*, 133 S. Ct. 2223. Solvay Pharmaceuticals developed a brand-name drug called AndroGel in 1999 and obtained a relevant patent in 2003. Later in 2003, three would-be generic AndroGel manufacturers, Actavis first (soon followed by Paddock Laboratories and Par Pharmaceutical), filed ANDAs with paragraph IV certifications. Solvay sued. Thirty months into the litigation, the FDA approved Actavis's first-filed ANDA. *Actavis*, 133 S. Ct. at 2229.

The parties settled in 2006. Under the terms of the settlement,

> Actavis agreed that it would not bring its generic to market until August 31, 2015, 65 months before Solvay's patent expired (unless someone else marketed a generic sooner). Actavis also agreed to promote AndroGel to urologists. The other generic manufacturers made roughly similar promises. And Solvay agreed to pay millions of dollars to each generic—$12 million in total to Paddock; $60 million in total to Par; and an estimated $19–$30 million annually, for nine years, to Actavis. The companies described these payments as compensation for other services the generics promised to perform, but the FTC contends the other services had little value.

Id. (citations omitted).

The FTC sued the settling manufacturers for violating the antitrust laws by agreeing to share Solvay's monopoly profits. *Id.* at 2229-30. The FTC contended Solvay's reverse payments to the generic manufacturers were compensation for the generics' agreements not to compete with AndroGel. *Id.* at 2229. The Court of Appeals for the Eleventh Circuit disagreed, and affirmed the dismissal of the FTC's complaint, on the ground "that, absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *Watson Pharm.*, 677 F.3d at 1312. In its view, "patent holder[s] had a lawful right to exclude others from the market." *Id.* at 1307 (internal quotation marks omitted). Even though a patent might be found invalid if litigated, the court

thought "the FTC's approach would put that burden back on the parties and the court, undo much of the benefit of settling patent litigation, and discourage settlements," in derogation of the important public policy interests served by settlement. *Id.* at 1313-14.

The Supreme Court disagreed. It began with the premise that an asserted patent "may or may not be valid, and may or may not be infringed." *Actavis*, 133 S. Ct. at 2231. Although a valid patent gives its holder the right to "'exclude[] all . . . from the use of the protected process or product'" and charge prices of its choosing, including supracompetitive prices, "an *invalidated* patent carries with it no such right. And even a valid patent confers no right to exclude products or processes that do not actually infringe." *Id.* (emphasis in original) (quoting *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948)). And from the time of their paragraph IV certification, the generics in *Actavis* had challenged both the validity and the scope of the AndroGel patent. *Id.* The Court observed that, as alleged by the FTC, Solvay had "agreed to pay the [generics] many millions of dollars to stay out of its market, even though the [generics] did not have any claim that [Solvay] was liable to them for damages." *Id.* The Court was concerned that this "unusual" "form of settlement" could "have significant adverse effects on competition" and thought, accordingly, "that patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent." *Id.*

The Court cited several of its earlier cases for this proposition that courts must balance "the lawful restraint on trade of the patent monopoly and the illegal restraint

prohibited broadly by the Sherman Act." *Id.* (quoting *Line Material*, 333 U.S. at 310); *see also United States v. U.S. Gypsum Co.*, 333 U.S. 364, 390-91 (1948). The antitrust question, it reasoned, must be answered "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 here those related to patents." *Actavis*, 133 S. Ct. at 2231. Only then can a court conclude "[w]hether a particular restraint lies 'beyond the limits of the patent monopoly.'" *Id.* at 2231-32 (quoting *id.* at 2241-42 (Roberts, C.J., dissenting)). By contrast, Chief Justice Roberts, joined in dissent by Justices Scalia and Thomas, would have held 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 liability." *Id.* at 2238 (Roberts, C.J., dissenting). In the dissenters' view, "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." *Id.* at 2240. And, they maintained, the patent's scope "should be determined by reference to *patent law*." *Id.* (emphasis in original).

As noted, the Court explained that its "precedents make clear that patent-related settlement agreements can sometimes violate the antitrust laws." *Id.* at 2232 (majority opinion) (citing *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963); *Line Material*, 333 U.S. at 310-11; *United States v. New Wrinkle, Inc.*, 342 U.S. 371, 378-80 (1952)). The Court viewed these prior cases as "seek[ing] to accommodate patent and antitrust policies, finding challenged terms and conditions unlawful unless patent law policy offsets the

antitrust law policy strongly favoring competition," notwithstanding the possible validity or infringement of the patent in question. *Id.* at 2233; *see id.* at 2244 (Roberts, C.J., dissenting) ("The majority seems to think that *even if* the patent is valid, a patent holder violates the antitrust laws merely because the settlement took away some chance that his patent would be declared invalid by a court." (emphasis in original)). Rejecting the dissent's view "that a patent holder may simply 'pa[y] a competitor to respect its patent' and quit its patent invalidity or noninfringement claim without any antitrust scrutiny whatever," *id.* at 2233 (majority opinion) (alteration in original) (quoting *id.* at 2239 (Roberts, C.J., dissenting)), the Court reasoned that "[t]he dissent does not identify any patent statute that it understands to grant such a right to a patentee, whether expressly or by fair implication," *id.* Such a right, the Court thought, "would be difficult to reconcile . . . with the patent-related policy of eliminating unwarranted patent grants so the public will not 'continually be required to pay tribute to would-be monopolists without need or justification.'" *Id.* (quoting *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969)).[18]

[18] Unlike the majority, the dissenters read the Court's precedents to stand for the proposition that a patentee's actions are subject to antitrust scrutiny only when they "go beyond the monopoly powers conferred by the patent," with just two exceptions—settlement of sham litigation and litigation involving patents obtained by fraud on the Patent and Trademark Office. *Actavis*, 133 S. Ct. at 2239 (Roberts, C.J., dissenting); *see also id.* at 2241-42. No case cited by the majority, they said, subjected a patent settlement "to antitrust scrutiny merely because the validity of the patent was uncertain," and no reference to "a 'general procompetitive

The Court further explained that its holding should not be read to subject to antitrust scrutiny "commonplace forms" of settlement, such as tender by an infringer of less than the patentee's full demand. *See id.* But reverse payments, it said, are not such "familiar settlement forms." *Id.* In a reverse payment settlement, the patentee "pays money . . . purely so [the alleged infringer] will give up the patent fight." *Id.* These payments are said to flow in "reverse" because "a party with no claim for damages (something that is usually true of a paragraph IV litigation defendant) walks away with money simply so it will stay away from the patentee's market. That," the Court thought, "is something quite different," and something that falls outside accepted "traditional examples" of settlement. *Id.*

Notwithstanding the potential concern "that antitrust scrutiny of a reverse payment agreement would require the parties to litigate the validity of the patent in order to demonstrate what would have happened to competition in the absence of the settlement," the Court identified "five sets of considerations" militating in favor of permitting antitrust scrutiny. *Id.* at 2234. First, the Court saw in reverse payments the "potential for genuine adverse effects on competition." *Id.* (quoting *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986)). The inference may be drawn from a reverse payment that the patent holder is paying the alleged infringer to defend

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thrust'" of the Hatch-Waxman Act should be interpreted "to unsettle the established relationship between patent and antitrust law," especially when "Congress has repeatedly declined to enact legislation addressing the issue." *Id.* at 2242 (quoting *id.* at 2234 (majority opinion)).

"a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product." *Id.* Even though other settlement terms might allow a generic challenger to enter the market prior to patent expiration, and thus permit some competition benefiting consumers, a reverse payment inducing delay—i.e., a "payment in return for staying out of the market—simply keeps prices at patentee-set [supracompetitive] levels . . . while dividing that return between the challenged patentee and the patent challenger." *Id.* at 2234-35.

Second, the Court thought "these anticompetitive consequences will at least sometimes prove unjustified." *Id.* at 2235-36. Although a payment may be justified if, for example, it approximates litigation expenses saved by the settlement or is true "compensation for other services that the generic has promised to perform," it may not be justified when used "to prevent the risk of competition" by eliminating "the risk of patent invalidation or a finding of noninfringement." *Id.* at 2236; *see also, e.g., id.* (noting that the antitrust harm occurs when "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 consequence that underlies the claim of antitrust unlawfulness"). At the same time, the Court did not rule out other justifications.

Third, the Court reasoned, in reverse payment situations "the patentee likely possesses the power to bring" about this anticompetitive harm. *Id.* Not only does a patent protect such market power, but the size of a reverse payment

may serve as a proxy for this power because a firm without such power (and the supracompetitive profits that power enables) is unlikely to buy off potential competitors. *Id.*

Fourth, "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." *Id.* at 2236-37. Instead, the anticompetitive harm from such a payment appears not to be that the patentee is reaping supracompetitive monopoly profits from a decidedly invalid or noninfringed patent, but rather that there is a risk that the patent-enabled monopoly is unwarranted, and foreclosing such a challenge harms consumers. *See id.* at 2236 ("[T]he payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm.").[19]

Fifth, parties may still find other ways to settle, such as "by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Id.* at 2237. The Court emphasized, however, that "[i]f the basic reason [for the reverse payment] is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement." *Id.*

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[19] *See also, e.g.*, *Actavis*, 133 S. Ct. at 2244 (Roberts, C.J., dissenting) ("The majority seems to think that *even if* the patent is valid, a patent holder violates the antitrust laws merely because the settlement took away some chance that his patent would be declared invalid by a court." (emphasis in original)).

The Court concluded that, because of the fact-specific nature and the complexity of reverse payment agreements, courts should apply the traditional rule-of-reason analysis. *See id.* at 2237-38.

B.

We do not believe *Actavis*'s holding can be limited to reverse payments of cash. For the following reasons, we think that a no-AG agreement, when it represents an unexplained large transfer of value from the patent holder to the alleged infringer, may be subject to antitrust scrutiny under the rule of reason. We find the allegations here sufficient to state such a claim under the Sherman Act.[20]

1.

In the *Actavis* Court's view, reverse payments are problematic because of their potential to negatively impact consumer welfare by preventing the risk of competition, which arises from expected litigation outcomes. *See Actavis*, 133 S. Ct. at 2236. The Court's reasoning was not that reverse payments per se violate the antitrust laws, or are per se anticompetitive. To the contrary, the Court declined to "abandon[] . . . the 'rule of reason' in favor of presumptive rules (or a 'quick-look' approach)," which are "appropriate only where an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets." *Id.* at 2237 (internal quotation marks omitted). Instead, the Court focused on

[20] *See supra* note 3; *infra* note 35.

whether a reverse payment could have an anticompetitive effect or, alternatively, whether it was reasonable compensation for litigation costs or the value of services. In other words, the Court reasoned that "even a small risk of invalidity" may not justify a "large payment" (presumably enabled by "patent-generated monopoly profits") that "likely seeks to prevent the risk of competition." *Id.* at 2236. And, the Court reiterated, it is the prevention of that risk of competition—eliminating "the risk of patent invalidation or a finding of noninfringement" by "paying the challenger to stay out" of the market (for longer than the patent's strength would otherwise allow)—that "constitutes the relevant anticompetitive harm," which must then be analyzed under the rule of reason. *Id.* at 2236-37.

It seems to us that no-AG agreements are likely to present the same types of problems as reverse payments of cash. The no-AG agreement here may be of great monetary value to Teva as the first-filing generic. In *Actavis*, the Supreme Court recognized generally that the 180-day exclusivity period is "possibly 'worth several hundred million dollars,'" and may be where the bulk of the first-filer's profits lie. *Id.* at 2229 (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)).[21] There are

[21] In addition, a comprehensive FTC study suggests that having to compete with an authorized generic will likely both cut the generic's sales and force down its price: "the presence of authorized generic competition reduces the first-filer generic's revenues by 40 to 52 percent, on average." FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* iii (2011), *available at*

also plausible indicia that this pattern held true here: The Amici States point out that "[p]ublic records show that generic sales of Lamictal in 2008 were some 671 million dollars," so the no-AG agreement "was clearly worth millions of dollars, if not hundreds of millions of dollars[,] to the generic." Amici States' Br. 16. And the FTC suggests, using sales of the drug Paxil as a yardstick, that GSK's no-AG agreement would have been worth hundreds of millions of dollars to Teva. Appellants' Br. 24.[22]

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http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf; *see* FTC Amicus Br. 8 ("Prices fall further when additional generic competitors enter . . . ." (citing FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf); FTC Amicus Br. 12 ("[G]eneric wholesale prices average 70 percent of the pre-entry brand-name drug price when the first-filer faces an AG, compared to 80 percent of the brand price when it does not." (citing FTC, *Authorized Generic Drugs*, *supra*, at iii)).

[22] "The U.S. sales of Paxil were roughly equivalent to those of Lamictal in the year before each product faced generic competition ($2.3 billion and $2.2 billion, respectively)." Appellants' Br. 24 (quoting FTC Br. as *Amicus Curiae* at 8, *Lamictal*, 18 F. Supp. 3d. 560 (ECF No. 89-3)). The magnitude of these figures is proportionate to the estimated $2.6 billion average cost of developing a new brand-name drug. *See* Tufts Ctr. for the Study of Drug Dev., *Briefing: Cost of Developing a New Drug* (Nov. 18, 2014), *available at* http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf.

At the same time, a brand's commitment not to produce an authorized generic means that it must give up the valuable right to capture profits in the new two-tiered market. The no-AG agreement transfers the profits the patentee would have made from its authorized generic to the settling generic—plus potentially more, in the form of higher prices, because there will now be a generic monopoly instead of a generic duopoly. Thus, "the source of the benefit to the claimed infringer is something costly to the patentee." Aaron Edlin et al., *Activating* Actavis, Antitrust, Fall 2013, at 16, 22 n.22. Absent a no-AG promise, launching an authorized generic would seem to be economically rational for the brand. For this reason, the fact that the brand promises not to launch an authorized generic (thereby giving up considerable value to the settling generic) makes the settlement something more than just an agreed-upon early entry: it "may instead provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market." *Actavis*, 133 S. Ct. at 2235.

The anticompetitive consequences of this pay-for-delay may be as harmful as those resulting from reverse payments of cash. If the brand uses a no-AG agreement to induce the generic to abandon the patent fight, the chance of dissolving a questionable patent vanishes (and along with it, the prospects of a more competitive market). As with a reverse payment of cash, a brand agreeing not to produce an authorized generic may thereby have "avoid[ed] the risk of patent invalidation or a finding of noninfringement." *Id.* at 2236. In addition, when the parties' settlement includes a no-AG agreement, the generic also presumably agrees to an early

entry date that is later than it would have otherwise accepted.[23] And during this time, the brand's monopoly remains in force. Once the generic enters, moreover, it faces no competition with other generics at all.

Antitrust law is designed to protect consumers from arrangements that prevent competition in the marketplace. *See*, *e.g.*, *Actavis*, 133 S. Ct. at 2234-35; *id.* at 2238 (Roberts, C.J., dissenting); *accord* XII Areeda & Hovenkamp, *supra*, ¶ 2046c (2014 Supp.). The District Court here held that "the Supreme Court considered a reverse payment to involve an exchange of money" because "when the Supreme Court said 'payment' it meant a payment of money." *Lamictal*, 18 F. Supp. 3d at 568. But, we think, a no-AG agreement could likewise "prevent the risk of competition." *Actavis*, 133 S. Ct. at 2236; *cf.* XII Areeda & Hovenkamp, *supra*, ¶ 2046c1 (2014 Supp.) (explaining that under a "pay-for-delay settlement . . . consumer welfare remains the same as it would be under continued monopoly production by a single firm"); FTC Amicus Br. 22 ("It is not the transfer of cash or the form of reverse payment that triggers antitrust concern; it is the impact of that payment on consumer welfare."). We do not

[23] When parties compromise on an early-entry date alone—rather than an early-entry date plus valuable consideration—it is possible that they may compromise on an early-entry date reflecting their assessment of the strength of the patent. The concern with combining an early-entry date with the valuable consideration of a no-AG agreement is that the generic manufacturer may be willing to accept a later early-entry date without any corresponding benefit to consumers.

believe the Court intended to draw such a formal line.[24] Nor did the *Actavis* Court limit its reasoning or holding to cash payments only.[25]

2.

Defendants contend that no-AG agreements are distinguishable from reverse payments because they are in essence "exclusive licenses" and patent law expressly

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[24] *Cf., e.g.*, *Cont'l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 58-59 (1977) ("[D]eparture from the rule-of-reason standard must be based upon demonstrable economic effect rather than . . . upon formalistic line drawing."); *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 189 (3d Cir. 2005) ("The Supreme Court on more than one occasion has emphasized that economic realities rather than a formalistic approach must govern review of antitrust activity." (citing *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 466-67 (1992))); Michael A. Carrier, *Payment After* Actavis, 100 Iowa L. Rev. 7, 41-44 (2014).

[25] The dissent recognized the majority's reasoning could reach noncash transactions. *See Actavis*, 133 S. Ct. at 2239 (Roberts, C.J., dissenting) ("As in any settlement, Solvay gave its competitors something of value (money) and, in exchange, its competitors gave it something of value (dropping their legal claims)."); *id.* at 2245 ("[The majority's] logic . . . cannot possibly be limited to reverse-payment agreements . . . . The Government's brief acknowledges as much, suggesting that if antitrust scrutiny is invited for such cash payments, it may also be required for 'other consideration' and 'alternative arrangements.'").

contemplates exclusive licenses.[26] They argue the *Actavis* Court rejected the dissent's arguments in part because the dissent could "not identify any patent statute that it understands to grant such a right to a patentee, whether expressly or by fair implication." *Actavis*, 133 S. Ct. at 2233; *see* GSK Br. 22-23, 34; Teva Br. 22-26. They suggest that if "the patent statute specifically gives a right to restrain competition in the manner challenged," *Actavis*, 133 S. Ct. at 2231 (internal quotation marks omitted), such conduct is immune from antitrust scrutiny. *See* GSK Br. 22-23; Teva Br. 22-26, 34. In short, defendants argue GSK's concession not to produce an authorized generic during Teva's 180-day exclusivity period is an "exclusive license" exempt from antitrust scrutiny.

But the "right" defendants seek is not in fact a patentee's right to grant licenses, exclusive or otherwise.[27]

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[26] *See* 35 U.S.C. § 261 ("The . . . patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.").

[27] We do not believe the no-AG agreement was in fact an "exclusive" license. "Ordinarily, to say that a licensee's right is exclusive is to mean that no one other than that licensee, not even the licensor/patentee, may practice the patent." III Areeda & Hovenkamp, *supra*, ¶ 707a (3d ed. 2008). Here, of course, the no-AG agreement permitted both the patentee (GSK) and the challenger (Teva) to make bioequivalent drugs. Because both GSK and Teva could practice the patent, Teva's license was therefore not exclusive, but rather imposed a restriction on the patentee that prevented a certain form of competition (on bioequivalent drugs labeled

Instead, it is a right to use valuable licensing in such a way as to induce a patent challenger's delay. The *Actavis* Court rejected the latter. The thrust of the Court's reasoning is not that it is problematic that money is used to effect an end to the patent challenge, but rather that the patentee leverages some part of its patent power (in *Actavis*, its supracompetitive profits) to cause anticompetitive harm—namely, elimination of the risk of competition. There, the patentee gave the challenger a license to enter 65 months before patent expiration, *plus* a reverse payment of "millions of dollars." *Actavis*, 133 S. Ct. at 2229. This reverse payment was not immunized, of course, simply because of that early-entry

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"generics"). And, as we have said before, "Where the license restriction results primarily in benefits for the licensees rather than the patentee, the anticompetitive restriction cannot be justified as a subsidy for the patentee's inventive activity." *Mannington Mills, Inc. v. Congoleum Indus., Inc.*, 610 F.2d 1059, 1071 (3d Cir. 1979). Indeed, "[p]atents give no protection from the prohibitions of the Sherman Act . . . when the licenses are used, as here, in the scheme to restrain." *New Wrinkle*, 342 U.S. at 378; *see also, e.g.*, *Moraine Prods. v. ICI Am., Inc.*, 538 F.2d 134, 145 (7th Cir. 1976) ("Where a patent license is used to protect the licensee in addition to the patentee or is used to allow the licensees to divide a market among themselves, thus enabling them jointly to regiment an industry under the guise of a patent license, there is good reason to declare such a restrictive scheme illegal."). The *Actavis* Court reaffirmed this broader principle. *See, e.g.*, 133 S. Ct. at 2231 ("[P]atent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent.").

"license." Similarly, the fact that a patent holder may generally have the right to grant licenses, exclusive or otherwise, does not mean it also has the right to give a challenger a license along with a promise not to produce an authorized generic—i.e., a promise not to compete—in order to induce the challenger "to respect its patent and quit [the competitor's] patent invalidity or noninfringement claim without any antitrust scrutiny." *Id.* at 2233 (internal quotation marks omitted). In the *Actavis* Court's view, the question is not one of patent law, but of antitrust law, the latter of which invalidates "the improper use of [a patent] monopoly." *Id.* at 2231 (alteration in original) (quoting *Line Material*, 333 U.S. at 310). *But see id.* at 2243 (Roberts, C.J., dissenting). And as we read the Court's opinion, even exclusive licenses cannot avoid antitrust scrutiny where they are used in anticompetitive ways. *See id.* at 2227 (citing *Palmer*, 498 U.S. 46); *Palmer*, 498 U.S. at 50 (holding an agreement not to compete based on an exclusive copyright license[28] "unlawful on its face"). We make no statement about patent licensing more generally. But in this context we believe the fact that the Patent Act expressly authorizes licensing does not necessarily

[28] The Supreme Court opinion does not say what kind of "exclusive license" it is referring to, but the Eleventh Circuit's opinion states, "BRG and HBJ disavow any intent to restrain trade and claim that their agreement is nothing more than an ordinary copyright royalty arrangement which courts have routinely sustained." *Palmer v. BRG of Ga., Inc.*, 874 F.2d 1417, 1434 (11th Cir. 1989) (internal quotation marks omitted), *rev'd*, 498 U.S. 46.

mean it also authorizes reverse payments to prevent generic competition.[29]

We also disagree with defendants' attempt to recharacterize Teva's gain as resulting from its early entry alone. First, that characterization is inaccurate as a descriptive matter: What GSK gave Teva was a 180-day monopoly over the generic market. The first-filing generic cannot capture this value by early entry alone. It can only hope to obtain this value with the brand's self-restraint, and here, without GSK's no-AG commitment, GSK allegedly would have introduced an AG. Second, although we agree that the *Actavis* "Court

[29] The defendants' arguments are much like those rejected by the majority in *Actavis*. The disagreement in the Court was fundamental. In the dissenters' view, "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 to do precisely what the antitrust suit claims is unlawful." 133 S. Ct. at 2244 (Roberts, C.J., dissenting) (emphasis in original). The dissenters viewed the majority as "impos[ing] antitrust liability based on the parties' subjective uncertainty about [a] legal conclusion," namely, whether a patent is valid (and it is one or the other), because "[t]he majority seems to think that *even if* the patent is valid, a patent holder violates the antitrust laws merely because the settlement took away some chance that his patent would be declared invalid by a court." *Id.* (emphasis in original). In fact, the dissenters perceived a slippery slope in that the majority's "logic—that taking away any *chance* that a patent will be invalidated is itself an antitrust problem—cannot possibly be limited to reverse-payment agreements, or those that are 'large.'" *Id.* at 2245 (emphasis in original) (quoting *id.* at 2236 (majority opinion)).

expressly identified early-entry licensing as a traditional form of settlement whose legality the opinion took pains not to disturb," Teva Br. 25-26,[30] a no-AG agreement is no more solely an early-entry licensing agreement than the settlement in *Actavis* itself, where entry was permitted 65 months before patent expiration. *Actavis*, 133 S. Ct. at 2229. Notwithstanding such "early entry," the antitrust problem was that, as the Court inferred, entry might have been earlier, and/or the risk of competition not eliminated, had the reverse payment not been tendered. *See Actavis*, 133 S. Ct. at 2237 ("They may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point."); *see also* FTC Amicus Br. 21-22 ("[C]ompetitors do not normally raise antitrust concerns if they agree on a date for generic entry but do *not* simultaneously agree that the brand-name manufacturer will compensate the generic company for staying out of the market until that date, thereby sharing (while enlarging) their aggregate pool of monopoly profits.").

3.

Defendants present additional arguments as to why no-AG agreements, as "exclusive licenses," should not be subjected to antitrust scrutiny. Noting that public policy

[30] *See Actavis*, 133 S. Ct. at 2237; *cf. K-Dur*, 686 F.3d at 217-18 ("[N]othing in the rule of reason test that we adopt here limits the ability of the parties to reach settlements based on a negotiated entry date for marketing of the generic drug . . . .").

favors settlements, they contend that subjecting such agreements to scrutiny will discourage settlements. GSK Br. 37. Furthermore, they contend that "courts should not review pro-competitive conduct to determine whether an even more pro-competitive transaction exists." GSK Br. 37 (citing *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415-16 (2004) ("The Sherman Act . . . does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition." (citation omitted))); *see* Teva Br. 32.

But *Actavis* addressed and rejected these arguments. First, the Court thought the possible discouragement of settlements was "outweigh[ed]" by other considerations and stated that "parties may well find ways to settle patent disputes without the use of reverse payments." *Actavis*, 133 S. Ct. at 2237.[31] But whatever the effect on settlements, we do

[31] The Court was unpersuaded by the dissenters' arguments in this vein. The dissenters contended there was no empirical evidence that most reverse payment settlements occur in the Hatch-Waxman context, and that payments from patentee to alleged infringer "are a well-known feature of intellectual property litigation, and reflect an intuitive way to settle such disputes." *Actavis*, 133 S. Ct. at 2242-43 (Roberts, C.J., dissenting). The Court, however, thought that "[a]pparently most if not all reverse payment settlement agreements arise in the context of pharmaceutical drug regulation, and specifically in the context of suits brought under statutory provisions allowing a generic drug manufacturer (seeking speedy marketing approval) to challenge the validity of a patent owned by an already-

not perceive how the noncash nature of no-AG agreements alters that balance. Second, we think *Trinko* inapposite. *Actavis* does not stand for the proposition that parties must reach the most procompetitive settlements possible. Instead, we read *Actavis* to hold that antitrust law may prohibit settlements that are anticompetitive because, without justification, they delay competition for longer than the patent's strength would otherwise permit.[32]

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approved brand-name drug owner." *Id.* at 2227 (majority opinion). Similarly, although the dissenters contended that "[w]hile the alleged infringer may not be suing for the patent holder's *money*, it is suing for the right to use and market the (intellectual) property, which is worth money," *id.* at 2243 (Roberts, C.J., dissenting) (emphasis in original), the Court thought reverse payments "unusual," *id.* at 2231 (majority opinion). The dissenters also thought that the Court's holding would discourage settlement even though "the right to settle generally accompanies the right to litigate in the first place." *Id.* at 2243 (Roberts, C.J., dissenting). They postulated that "the majority's decision may very well discourage generics from challenging pharmaceutical patents in the first place" by "[t]aking 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." *Id.* at 2247.

[32] In addition, *Trinko* dealt with different questions regarding unlawful monopolization and the refusal to deal—set against the background of "the long recognized right of [a] trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal," 540 U.S. at 408 (alteration in original) (quoting *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919))—and the role of the

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For the reasons we have explained, we think this no-AG agreement, because it may represent an unusual, unexplained transfer of value from the patent holder to the alleged infringer that cannot be adequately justified—whether as compensation for litigation expenses or services, or otherwise[33]—is subject to antitrust scrutiny under the rule of reason. But even if that is the rule, defendants contend, plaintiffs fail to state a claim under *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), because their "allegations are far too speculative to satisfy their burden of plausibly alleging that the settlement was anticompetitive." *See* GSK Br. 44-45. In particular, defendants argue that "[p]laintiffs fail to plausibly allege that in this but-for world, the parties would have successfully negotiated an alternative, competition-maximizing agreement," Teva Br. 44; that continued litigation in favor of settlement "would have yielded a more competitive result," Teva Br. 45; or that Teva would have launched their generics "at risk," Teva Br. 46.

We believe plaintiffs' allegations, and the plausible inferences that can be drawn from them, are sufficient to state a rule-of-reason claim under *Twombly* and *Iqbal* for violation of the Sherman Act on the ground that GSK sought to induce Teva to delay its entry into the lamotrigine tablet market by

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Telecommunications Act of 1996, which focuses on a different goal of eliminating certain monopolies, *id.* at 415.

[33] *See Actavis*, 133 S. Ct. at 2236 ("There may be other justifications.").

way of an unjustified no-AG agreement. As recited earlier, plaintiffs alleged that GSK agreed not to launch a competing authorized generic during Teva's 180-day exclusivity period, which was to begin near the expiration of the '017 patent; that such promises can be worth "many millions of dollars of additional revenue"; that "GSK had an incentive to launch its own authorized generic versions of tablets"; that Teva had a history of launching "at risk"; and that the '017 patent was likely to be invalidated—as, in fact, its main claim had been. Because marketing an authorized generic was allegedly in GSK's economic interest, its agreement not to launch an authorized generic was an inducement—valuable to both it and Teva—to ensure a longer period of supracompetitive monopoly profits based on a patent at risk of being found invalid or not infringed. (Indeed, Teva asserted in other litigation that the no-AG agreement "formed part of the inducement to Teva to relinquish the rights and defenses it was asserting against GSK in the Patent Litigation." JA 76 (alteration and emphases omitted).) And although plaintiffs concede that Teva entered the lamotrigine chewables market about 37 months early, *see, e.g.*, GSK Br. 7, the chewables market, allegedly worth only $50 million annually, was orders of magnitude smaller than the alleged $2 billion tablet market the agreement is said to have protected. Accordingly, at the pleading stage plaintiffs have sufficiently alleged that any procompetitive aspects of the chewables arrangement were outweighed by the anticompetitive harm from the no-AG agreement.[34]

[34] It may also be (though we do not decide) that "procompetitive effects in one market cannot justify anticompetitive effects in a separate market" (i.e., the lamotrigine tablet market). Amicus Br. Nat'l Ass'n Chain

Moreover, we do not read *Actavis* to require allegations that defendants could in fact have reached another, more competitive settlement. *Actavis* embraces the concept that a patent "may or may not be valid, and may or may not be infringed," 133 S. Ct. at 2231, and holds that the anticompetitive harm is not *certain* consumer loss through higher prices, but rather the patentee's "avoid[ance of] the risk of patent invalidation or a finding of noninfringement"—that is, "prevent[ion of] the risk of competition," *id.* at 2236, beyond what the patent's strength would otherwise allow—and, thus, consumer harm. In other words, under the substantive standard, the question is not whether the defendants have only possibly acted unlawfully, *but see* Teva Br. 43, but whether they have acted unlawfully by seeking to prevent competition. Plaintiffs have sufficiently pleaded as much.[35]

Drug Stores in Support of Appellants 27-28 (citing, inter alia, *Paladin Assocs., Inc. v. Mont. Power Co.*, 328 F.3d 1145, 1157 n.11 (9th Cir. 2003)); *see Paladin Assocs.*, 328 F.3d at 1157 n.11 ("It may be . . . that this procompetitive effect should not be considered in our rule of reason analysis, based on the theory that procompetitive effects in a separate market cannot justify anti-competitive effects in the market for pipeline transportation under analysis.") (citing *United States v. Topco Assocs.*, 405 U.S. 596, 610 (1972); *see also Topco*, 405 U.S. at 610 ("[Competition] cannot be foreclosed with respect to one sector of the economy because certain private citizens or groups believe that such foreclosure might promote greater competition in a more important sector of the economy.").

[35] We do not decide the question of antitrust injury in private actions such as this litigation, *see generally, e.g.*, Ian

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In the alternative, the District Court stated that "[i]t finds that the settlement . . . would survive *Actavis* scrutiny and is reasonable." 18 F. Supp. 3d at 570. This was error. As explained above, plaintiffs have sufficiently pleaded violation of the antitrust laws so as to overcome defendants' motion to dismiss. If genuine issues of material fact remain after discovery, the rule-of-reason analysis is for the finder of fact, not the court as a matter of law.[36]

In addition, the District Court mistook the "five sets of considerations" that persuaded the *Actavis* Court "to conclude that the FTC should have been given the opportunity to prove

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Simmons et al., *Viewing* FTC v. Actavis *Through the Lens of Clayton Act Section 4*, Antitrust, Fall 2013, at 24; *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 755-77 (E.D. Pa. 2014), nor do we preclude the parties from raising the issue on remand.

[36] *See, e.g.*, *Arizona v. Maricopa Cnty. Med. Soc'y*, 457 U.S. 332, 343 (1982) ("[T]he rule of reason requires the factfinder to decide whether under all the circumstances of the case the restrictive practice imposes an unreasonable restraint on competition."); *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 316 & n.12 (3d Cir. 2010) (discussing the fact-bound, burden-shifting standard and noting that "[i]n the event a genuinely disputed issue of fact exists regarding the reasonableness of the restraint, the determination is for the jury").

its antitrust claim" under the rule of reason, 133 S. Ct. at 2234, as a redefinition of the "rule of reason" itself. But the general contours of the rule of reason are well-mapped. *See generally, e.g.*, *id.* at 2236 (citing *Ind. Fed'n of Dentists*, 476 U.S. at 459); *Deutscher Tennis Bund v. ATP Tour, Inc.*, 610 F.3d 820, 829-30 (3d Cir. 2010). We recognize the *Actavis* Court "le[ft] to the lower courts the structuring of [this type of] rule-of-reason antitrust litigation," 133 S. Ct. at 2238, and that there may be some uncertainty as to how, exactly, a "defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason," *id.* at 2236 (citing *Ind. Fed'n of Dentists*, 476 U.S. at 459). But the Court noted that justifications might include "litigation expenses saved through the settlement" or "compensation for other services that the generic has promised to perform." *Id.* And although the Court left such details of how to apply the proper antitrust theories to "the basic question—that of the presence of significant unjustified anticompetitive consequences," *id.* at 2238—it suggested "the antitrust laws are likely to forbid" payment *for delay* (or, that is, to eliminate risk of patent invalidity or noninfringement), *id.* at 2237.

Here, the District Court thought the no-AG agreement was "justified" because, although the settlement amount was likely greater than litigation costs, "the consideration which the parties exchanged in the settlement [wa]s reasonably related to the removal of the uncertainty created by the dispute." *Lamictal*, 18 F. Supp. 3d at 570. That conclusion is in tension with *Actavis* in that, without proper justification, the brand cannot pay the generic simply to eliminate the risk of competition. Nor did the court properly conclude "that the

potential for adverse effects on competition [wa]s minimal," or that the settlement was reasonable, because "the duration of the No-AG Agreement was a relatively brief six months." *Id.* The anticompetitive harm plaintiffs allege—consistent with *Actavis*—is that the promise of no authorized-generic competition during those six months induced Teva to quit its patent challenge. As discussed above, plaintiffs plausibly allege this no-AG promise was of considerable value and thus designed to protect GSK's patents against the risk of invalidation or noninfringement, rather than reimburse litigation costs or compensate for services. Accordingly, the District Court should have permitted the litigation to proceed under the traditional rule-of-reason approach.

2.

Under the traditional rule-of-reason analysis, the factfinder must

> weigh all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition. The plaintiff bears an initial burden under the rule of reason of showing that the alleged combination or agreement produced adverse, anti-competitive effects within the relevant product and geographic markets. The plaintiff may satisfy this burden by proving the existence of actual anticompetitive effects, such as reduction of output, increase in price, or deterioration in quality of goods or services. Such proof is often impossible to make, however, due to the

> difficulty of isolating the market effects of challenged conduct. Accordingly, courts typically allow proof of the defendant's market power instead. Market power, the ability to raise prices above those that would prevail in a competitive market, is essentially a surrogate for detrimental effects.
>
> If a plaintiff meets his initial burden of adducing adequate evidence of market power or actual anti-competitive effects, the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective. . . . To rebut, the plaintiff must demonstrate that the restraint is not reasonably necessary to achieve the stated objective.

United States v. Brown Univ., 5 F.3d 658, 668-69 (3d Cir. 1993) (alteration, citations, internal quotation marks, and footnotes omitted).

The *Actavis* Court provided initial guidance on how to structure rule-of-reason litigation in the reverse payment context. The Court explained that such antitrust questions must be answered "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 here those related to patents." *Actavis*, 133 S. Ct. at 2231.

First, to prove anticompetitive effects, the plaintiff must prove payment for delay, or, in other words, payment to prevent the risk of competition. *See id.* at 2235-36. "[T]he 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." *Id.* at 2237.

Second, the burden then shifts to the defendant to show "that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." *Id.* at 2235-36.

> The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement. That payment may reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item. There may be other justifications.

Id. at 2236. The Court does not foreclose other justifications, and we need not decide today what those other justifications might be.

Finally, the plaintiff will have the opportunity to rebut the defendant's explanation.[37]

[37] *See generally, e.g.*, *King Drug Co. of Florence v. Cephalon, Inc.*, --- F. Supp. 3d ----, ----, No. 06-1797, 2015 WL 356913, at *7-16 (E.D. Pa. Jan. 28, 2015).

On remand, we invite the District Court to proceed with the litigation under the traditional rule of reason, tailored, as necessary, to the circumstances of this case.[38]

IV.

For the foregoing reasons, we vacate the judgment of the District Court and remand for further proceedings consistent with this opinion.

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[38] We note that the rule of reason allows the court, depending on the circumstances, to

> structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences.

Actavis, 133 S. Ct. at 2238. In addition, nothing in this opinion precludes a defendant from prevailing on a motion to dismiss or motion for summary judgment if, for example, there is no dispute that, under the rule of reason, the procompetitive benefits of a reverse payment outweigh the payment's alleged anticompetitive harm.