No. _____

IN THE

Supreme Court of the United States

SMITHKLINE BEECHAM CORPORATION, D/B/A GLAXOSMITHKLINE; TEVA PHARMACEUTICAL INDUSTRIES LTD.; TEVA PHARMACEUTICALS, USA,
Petitioners,

v.

KING DRUG COMPANY OF FLORENCE, INC.; LOUISIANA WHOLESALE DRUG CO., INC., ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

PETITION FOR A WRIT OF CERTIORARI

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February 19, 2016

QUESTION PRESENTED

In *FTC v. Actavis*, 133 S. Ct. 2223 (2013), the Supreme Court held that a patentee who settles a patent challenge by making a "large" and "unexplained" reverse payment to the patent challenger is not protected by the antitrust immunity generally afforded to patentees.

The question presented is:

Whether the Third Circuit's sweeping holding that a patentee's grant of an exclusive license must undergo antitrust scrutiny by courts and juries—even though such a license is specifically permitted under the patent laws—is inconsistent with this Court's decision in *Actavis* and decades of this Court's earlier precedents.

PARTIES TO THE PROCEEDING

Petitioners, the Appellees below, are GlaxoSmithKline LLC (formerly SmithKline Beecham Corporation, d/b/a GlaxoSmithKline), Teva Pharmaceutical Industries Ltd., and Teva Pharmaceuticals, USA.

Respondents, the Appellants below, are King Drug Company of Florence, Inc. and Louisiana Wholesale Drug Co., Inc., who sued on behalf of themselves and all others similarly situated.

RULE 29.6 DISCLOSURE

Petitioner Teva Pharmaceuticals USA, Inc. is an indirect wholly-owned subsidiary of petitioner Teva Pharmaceutical Industries Ltd. through the following parent companies: (i) Orvet UK (Majority Shareholder), which in turn is directly owned by TEVA Pharmaceuticals Europe B.V., which in turn is directly owned by Teva Pharmaceutical Industries Ltd.; Teva Pharmaceutical Holdings Coöperatieve U.A. (Minority Shareholder), which in turn is directly owned by IVAX LLC, a direct subsidiary of Teva Pharmaceuticals USA, Inc. Teva Pharmaceutical Industries Ltd. is the only publicly traded direct or indirect parent company of Teva Pharmaceuticals USA, Inc., and no other publicly traded company owns more than ten percent of its stock.

Petitioner Teva Pharmaceutical Industries Ltd. has no parent corporation, and no publicly held company owns ten percent or more of its stock.

Petitioner GlaxoSmithKline LLC ("GSK") is

owned, through several layers of wholly-owned subsidiaries, by GlaxoSmithKline plc, a publicly traded limited company organized under the laws of England. To the knowledge of GlaxoSmithKline LLC and GlaxoSmithKline plc, none of the shareholders of GlaxoSmithKline plc owns beneficially ten percent or more of its outstanding shares. However, the Bank of New York Mellon ("BNYM") acts as Depositary in respect of Ordinary Share American Depositary Receipts ("ADRs") representing shares in GlaxoSmithKline plc. In that capacity, BNYM is the holder of more than ten percent of the outstanding shares of GlaxoSmithKline plc.

TABLE OF CONTENTS

Page

APPENDIX CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Constitutional Provisions

Other Authorities

PETITION FOR A WRIT OF CERTIORARI

Petitioners respectfully request a writ of certiorari to review the judgment of the United States Court of Appeals for the Third Circuit in this case.

INTRODUCTION

Patent law is rooted in the principle that granting inventors the right to exclude competitors for a specified period is essential to encouraging innovation. *See* U.S. Const. art. I, § 8, cl. 8; *Grant v. Raymond*, 31 U.S. 218, 241 (1832). By Constitutional and Congressional design, a patent is therefore an "exception to the general rule against monopolies and to the right of access to a free and open market." *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). This Court has long recognized that express patent rights include a right to grant a license to practice the patent. *See, e.g.*, *United States v. Gen. Elec. Co.*, 272 U.S. 476, 489-90 (1926); *see also* 35 U.S.C. § 261 (patent holder "may … grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States").

The Third Circuit's decision—that a grant of an exclusive license as part of a settlement agreement can give rise to potential treble damages under the Sherman Act—contradicts this well-settled law. The court justified this extraordinary holding by relying on *FTC v. Actavis*, 133 S. Ct. 2223 (2013), which considered whether a settlement agreement resolving patent litigation can ever give rise to an antitrust claim. *Actavis* held that a settlement that the Court deemed "unusual"—because it involved alleged mon-

etary payments from the patent holder to the patent challenger totaling tens of millions of dollars—could give rise to such a claim.

In this case, unlike *Actavis*, there is no allegation of such an "unusual" settlement. Instead, the only allegation is that the patent holder granted the patent challenger a valuable exclusive license to market its product before the patent and its related exclusivities expired. This type of licensing agreement to settle patent cases is routine and, until recently, its lawfulness has been well accepted. Indeed, at oral argument in *Actavis*, the Court expressed concern that a holding in favor of the plaintiffs might jeopardize routine exclusive licensing arrangements. *FTC v. Actavis, Inc.*, Docket No. 12-416 (S. Ct. Mar. 25, 2013) ("*Actavis* Oral Arg."), Tr. at 3-4. In response, the Deputy Solicitor General representing the Federal Trade Commission ("FTC") specifically assured the Court that the reverse payment at issue there was *unlike* a traditional exclusive license, the main difference being that "an exclusive license is expressly authorized by the Patent Act, in Section 261 of Title 35." *Id.* at 4. In that vein, *Actavis* took pains to emphasize that parties may continue to "settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration." *Actavis*, 133 S. Ct. at 2237.

Emboldened by *Actavis*, however, private plaintiffs and the FTC itself are now pushing for the broadest possible reading of the decision, asking courts to scrutinize licensing agreements for potential antitrust liability. *See, e.g.*, Br. of FTC as Ami-

cus Curiae in Supp. of Pls.-Appellants, *In re Lamictal Direct Purchaser Antitrust Litig.*, Docket No. 14-1243 (3d Cir. April 28, 2014). And the Third Circuit's ruling is indicative of the confusion that has permeated the lower courts faced with interpreting *Actavis*. Numerous courts within the First, Second, Third, Seventh, and Ninth Circuits have considered what constitutes a potentially improper "reverse payment" that is subject to antitrust review under *Actavis*, and those courts have adopted divergent tests and have reached conflicting results. Judges are asking for guidance, as are litigants. Those engaged in patent litigation need to know whether formerly routine settlement and licensing agreements are now at risk of being deemed antitrust violations.

This Court has a much-needed opportunity in this case to explain that *Actavis* was a narrow decision that built on decades of precedent about the rights of patentees and that did not tear down that precedent. Indeed, the Court declared that "there is *nothing* novel about our approach" and emphasized that it did not intend to subject "commonplace," "familiar," or "traditional" settlement forms to antitrust scrutiny. *Actavis*, 133 S. Ct. at 2233 (emphasis added). Embedded in *Actavis* is a line between conduct that is authorized by patent law even though it might restrict competition in the near term (such as the grant of an exclusive license), which is not subject to antitrust challenge for that reason, and the alleged unusual reverse payments at issue there, which the Court emphasized were not authorized by law.

The Third Circuit expanded *Actavis* well beyond its intended bounds on the basis of flawed reasoning that, if permitted to stand, will perpetuate the significant confusion (among judges and litigants alike) regarding the scope and meaning of *Actavis*, and destabilize patent rights and the settlement of patent disputes across industries. Indeed, there is nothing about the Third Circuit's holding that would be limited to the pharmaceutical context. This Court's review is warranted to restore a bright line that would provide significant guidance for a frequently recurring fact pattern: exclusive licenses are not actionable "payments" under *Actavis* because such licenses are expressly authorized by the Patent Act.

OPINIONS BELOW

The opinion of the court of appeals is reported at 791 F.3d 388 and is included in the Appendix ("App.") at 2a-50a. The order of the court of appeals amending a footnote in its opinion is included at App. 75a. The trial court's opinion is reported at 18 F. Supp. 3d 560 and is included at App. 51a-72a.

JURISDICTION

The court of appeals issued its decision on June 26, 2015 and denied a timely filed petition for rehearing and rehearing *en banc* on September 23, 2015. App. 73a-74a. On December 4, 2015, Justice Alito granted Petitioners' application to extend the date for filing a Petition for a Writ of Certiorari by extending the time to file until January 21, 2016. On December 22, 2015, Justice Alito granted Petitioners' application to further extend the date for filing a Petition for a Writ of Certiorari to February 20,

2016. No. 15A603. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Article I, Section 8, Clause 8 of the U.S. Constitution, empowers Congress, "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8.

Section 261 of Title 35 of the U.S. Code provides, in relevant part:

> Applications for patent, patents, or any interest therein, shall be assignable in law by an instrument in writing. The … patentee … 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.

STATEMENT OF THE CASE

A. Factual and Regulatory Background

As *Actavis* recognized, the "point of patent law is to grant limited monopolies as a way of encouraging innovation." *Actavis*, 133 S. Ct. at 2238. In the pharmaceutical context in particular, the cost of innovating is staggering. Recent studies estimate that the cost to develop a new FDA-approved medicine

can amount to several *billion* dollars.[1]

The reward for successful innovation is a patent monopoly, including the right to protect and administer that monopoly for the patent's duration. By statute, the patentee may license the patent to permit others to manufacture or sell potentially infringing products—specifically, the patent holder "may … grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States." 35 U.S.C. § 261.

The patent holder here is defendant GSK. GSK sells Lamictal Tablets and Lamictal Chewables, which are FDA-approved drugs containing lamotrigine, a patented anticonvulsant that treats epilepsy and bipolar disorder. App. 15a. GSK's patent covering the active ingredient in and certain methods of using lamotrigine, U.S. Patent No. 4,602,017 ("the '017 patent"), did not expire until July 22, 2008. App. 15a. In addition to the patent, GSK also obtained "pediatric exclusivity" for Lamictal. App. 53a. Pediatric exclusivity is an additional statutory exclusivity, which extends the patent holder's lawful monopoly for an additional six months beyond patent expiration as a reward for studying the drug's safety and efficacy for children. 21 U.S.C. § 355a; *see In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1368 (Fed.

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[1] *See* Matthew Herper, *The Cost of Creating A New Drug Now $5 Billion, Pushing Big Pharma To Change*, Forbes (Aug. 11, 2013), *available at* http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/#7b75e0b76bfc.

Cir. 2008). In this case, the grant of pediatric exclusivity extended GSK's lawful monopoly on Lamictal to January 2009. App. 53a.

Defendant Teva wished to manufacture generic versions of lamotrigine. Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), which amended the Federal Food, Drug and Cosmetic Act, Congress established a new procedure for obtaining FDA approval to market generic drugs. *See* 21 U.S.C. § 355. The Hatch-Waxman Act allows generic drug companies to bring a preemptive patent challenge before receiving final FDA approval or marketing the generic drug.

To do so, the generic company files an Abbreviated New Drug Application ("ANDA") with a "Paragraph IV" certification that the "patent [of the equivalent brand-name drug] is invalid or will not be infringed," and notifies the patent holder of the patent challenge. 21 U.S.C. § 355(j)(2)(A)(vii)(IV), (j)(2)(B). The filing of a Paragraph IV certification is considered an act of patent infringement, 35 U.S.C. § 271(e)(2), meaning the brand company may file suit for infringement immediately. The generic company may then assert counterclaims, including that the patent is invalid. 21 U.S.C. § 355(j)(5)(B)(iii). In this way, the Hatch-Waxman Act balances two conflicting interests: (1) protecting the patent rights of brand-name drug manufacturers to reward their research and development efforts, and (2) encouraging the development of more affordable generic drugs in a timely fashion.

Teva filed ANDAs with Paragraph IV certifica-

tions for generic lamotrigine with the FDA in or around April 2002. App. 16a. GSK then filed suit for patent infringement against Teva in the U.S. District Court for the District of New Jersey. App. 52a. Teva, in turn, asserted noninfringement and challenged the validity of the '017 patent. App. 8a-9a. After several years of litigation and a bench trial, the district court found in favor of Teva on one claim of GSK's '017 patent, but did not rule on the other claims of the patent. App. 52a.

GSK and Teva subsequently settled the ongoing patent litigation approximately four years before GSK's patent and associated exclusivities were set to expire. *Id.* GSK did not make any payment to Teva as part of the settlement agreement. Instead, the parties negotiated two early-entry patent licenses that permitted Teva to market generic versions of Lamictal chewables and tablets prior to the end of GSK's patent and pediatric exclusivity period. Specifically:

- GSK granted Teva an exclusive license to market generic Lamictal chewables by June 2005, more than three years before the patent expired and approximately 43 months before the end of GSK's pediatric exclusivity period. *Id.* The license also required GSK to supply product to Teva, meaning Teva could sell a competing version of Lamictal chewables even before it received final marketing approval from the FDA for its ANDA. *Id.*

- GSK granted Teva an exclusive license to market generic Lamictal tablets months before the end of GSK's lawful monopoly period for Lamictal. In

the event GSK received a six-month pediatric exclusivity from the FDA (which it did), the license was set to start on July 21, 2008 (six months prior to the end of pediatric exclusivity). App. 52a-53a.

- GSK further agreed that the licenses would be exclusive even as to GSK. App. 53a. This exclusivity term meant that although GSK could continue to market its branded products, it could not market an "authorized generic" version of Lamictal (a product sold under the brand's original new drug application, but marketed and priced as a generic)—until the license expired in January 2009. *Id.*

The district court entered an order dismissing the patent case based on the terms of the settlement, noting that the settlement allows generic entry of lamotrigine tablets and chewable dispersible tablets in advance of Plaintiff's '017 patent and any period of pediatric exclusivity. App. 18a.

The parties submitted the settlement to the FTC and U.S. Department of Justice ("DOJ") as required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, codified at 21 U.S.C. § 355. Although the FTC has challenged a number of patent settlement agreements through internal actions, lawsuits in federal court, or both, neither it nor DOJ filed any action challenging the settlement.

Per the licenses granted in the settlement agreement, and before the legal exclusivities associated

with the '017 patent expired in January 2009, Teva began selling Lamictal chewables in May 2005 and Lamictal tablets in July 2008. App. 52a-53a.

B. Proceedings Below

Plaintiffs, direct purchasers of Lamictal from GSK, filed suit in February 2012 alleging that the settlement agreement violated federal antitrust law. Defendants filed a motion to dismiss under Rule 12(b)(6), which the district court granted, holding that plaintiffs failed to state a claim under the antitrust laws. App. 51a. Plaintiffs appealed and the Third Circuit stayed proceedings pending this Court's decision in *F.T.C. v. Actavis*. App. 55a.

The Third Circuit then remanded the case to the district court to reconsider its ruling in light of *Actavis*. App. 56a. Again, the district court dismissed. It held that "*Actavis* requires [antitrust] scrutiny only of patent settlements that contain reverse payments" and that this settlement—which involved early-entry licenses and no monetary exchange—contained no such reverse payment. App. 64a-65a. The district court rejected plaintiffs' sweeping argument that a reverse payment is present when "the parties to the settlement each received something of value." App. 67a. Because parties always "receive[] consideration in [a] settlement" (like with any other contract), the court explained that plaintiffs' rule would make it all but impossible to settle patent litigation. App. 68a.

The Third Circuit reversed. The court acknowledged that a patent generally affords the right to exclude competitors. App. 38a. Yet the court held that

the exclusive licensing arrangement between GSK and Teva, which it referred to as a "no authorized generic" or "no-AG" agreement, was subject to antitrust scrutiny. The court concluded that the 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." App. 10a. The Court reasoned that the agreement resembled the reverse payment in *Actavis* because it "could likewise 'prevent the risk of competition.'" App. 35a (quoting *Actavis*, 133 S. Ct. at 2236).

Petitioners argued that their agreement was different from the agreement in *Actavis* because the "payment" respondents challenged was nothing more than a lawful, and statutorily-authorized, license term. By agreeing not to launch an authorized generic, GSK was merely doing what the Patent Act expressly authorizes: granting Teva an early-entry license for generic Lamictal products that precluded GSK from launching its own generic product for the period of the license.[2] What the Third Circuit

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[2] The license granted by GSK extended into GSK's FDA-granted period of pediatric exclusivity. Courts routinely view this blanket exclusivity as equivalent to a patent extension. *See, e.g., Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1304 n.1 (D.C. Cir. 2010) (describing pediatric exclusivity as "a six-month extension of the time [of the patent] during which all generic competition against a branded drug is prohibited"); *see also In re Gabapentin Patent Litig.*, 648 F. Supp. 2d 641, 643 (D.N.J. 2009) ("The '544 Patent would have expired on May 2, 1995, but its term was extended under 35 U.S.C. § 156 until

termed a "no-AG" clause, in other words, was in fact an exclusive license, where "the patentee has promised … that 'others shall be excluded from practicing the invention' within the field covered by the license." *Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1484 (Fed. Cir. 1998) (citation omitted); *Waterman v. Mackenzie*, 138 U.S. 252, 256 (1891) ("[A] grant of an exclusive right to make, use, and vend two patented machines within a certain district … excludes all other persons, even the patentee, from making, using, or vending like machines within the district.").[3]

The Third Circuit acknowledged the indisputable fact that "a patent holder may generally have the right to grant licenses, exclusive or otherwise." App. 37a. But according to the court, the "'right' defendants seek is not in fact a patentee's right to grant licenses." App. 36a. Rather, the court confusingly insisted, "it is a right to use valuable licensing in such a way as to induce a patent challenger's delay." App. 37a. Drawing on this supposed distinction, the court asserted that under *Actavis*, "even ex-

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January 16, 2000 (and subsequently until July 16, 2000 pursuant to the FDA's pediatric exclusivity regulations)."); *Astra Aktiebolag v. Andrx Pharm., Inc.*, 222 F. Supp. 2d 423, 439 n.7 (S.D.N.Y. 2002) ("U.S. Patent No. 4,255,431 expired on April 5, 2001. However, the FDA granted Astra a six-month pediatric exclusivity extension of the patent term pursuant to 21 U.S.C. § 355a.").

[3] If anything, the license that GSK granted Teva enabled *more* competition than a typical exclusive license, because it allowed GSK to continue to sell its drug in the branded market. At no time did GSK pull its branded product off the market, and it remained free to compete, which indeed it did by dropping the brand price substantially upon Teva's entry.

clusive licenses cannot avoid antitrust scrutiny where they are used in anticompetitive ways." App. 37a-38a. The court claimed to "make no statement about patent licensing more generally," but it ignored that an exclusive license by definition perpetuates a patent monopoly, the precise purpose for which the court stated a license could not be used. App. 38a.

Petitioners petitioned for panel rehearing and rehearing en banc, and the Third Circuit denied the petitions. App. 73a-74a.

REASONS FOR GRANTING THE PETITION

This Court's review is necessary to resolve disagreement and confusion among the lower courts about the breadth and meaning of *Actavis*, and to correct the Third Circuit's erroneous conclusion that traditional licensing arrangements that Congress authorized to promote innovation can be attacked as anticompetitive under the antitrust laws. The Third Circuit is not alone in expanding *Actavis* well beyond its intended bounds and misinterpreting the decision such that little, if anything, remains of the patentee's express power to license.

Intervention from this Court is all the more warranted because the error below strikes at the heart of patent law. The threshold question under *Actavis* is not, as the Third Circuit posited, whether a patentee is potentially using its patent rights in an anticompetitive manner. *That is the very right granted to the patentee*—to decide how, when, where, and whom to exclude without the need to justify those decisions to antitrust plaintiffs, courts, or juries.

And an indispensable part of that right is the ability to grant licenses, including those with exclusivity terms. *See* 35 U.S.C. § 261. *Actavis* preserved this bedrock of patent law when it amplified the line—already developed in this Court's doctrine—between conduct that is authorized by patent law (such as the grant of an exclusive license) and the alleged unusual, large reverse cash payments at issue there. The alleged reverse payment in *Actavis* was subject to further examination under the antitrust laws precisely because of the absence of "any patent statute that … grant[s] such a right to a patentee, whether expressly or by fair implication." *Actavis*, 133 S. Ct. at 2233. That is not the case here, where the agreement merely reflected an exercise of the patentee's express statutorily-granted right to grant an exclusive license.

If this Court does not correct the error below, the Third Circuit's decision will inflict immediate and far-reaching harm. The logic of the opinion, that any exchange of consideration to end the patent dispute is a potential improper payment for the delay of competition, calls into question the continued viability of any patent litigation settlement, as well as routine licensing agreements that are a critical part of the American economy across all industries. Plaintiffs will continue to file their suits in the Third Circuit under the Sherman Act's nationwide venue provision and parties to patent litigation will thus settle their cases only at their own peril under this new *de facto* national regime. The opportunity is therefore ripe to grant review in order to resolve the confusion among the lower courts, to prevent the

chilling of beneficial patent settlements and licensing arrangements, and to restore patent policy to its proper place.

I. LOWER COURTS ARE DIVIDED ABOUT THE MEANING OF *ACTAVIS* AND ARE LOOKING FOR GUIDANCE

As the Third Circuit's decision demonstrates, *Actavis* has spawned great uncertainty among the lower courts regarding the intersection between antitrust law and previously well-settled patent law principles. Guidance is needed so that the lower courts, which routinely confront antitrust challenges to patent litigation settlements, do not further confuse the law. The legal status of an exclusive license is a crucial and recurring issue, and resolving the question presented could meaningfully clarify the post-*Actavis* law.

In *Actavis*, the Court confronted an "unusual" kind of patent litigation settlement and indicated that its stated approach to those settlements was consistent with longstanding precedent like *United States v. Gen. Elec. Co.*, 272 U.S. 476 (1926). *See Actavis*, 133 S. Ct. at 2232-33. But the Court's reasoning was ambiguous in certain key respects, creating confusion in the lower courts and leading some courts, like the Third Circuit here, to significantly expand its scope despite the Court's assurance that its opinion was not "novel." *Id.* at 2233.

Since *Actavis* was decided, it has been applied and interpreted in more than 15 district court opinions, one jury trial, and the Third Circuit decision

below.[4] In seeking to apply *Actavis* to new cases, it is a common refrain among courts that in *Actavis*, "not a lot of guidance was provided to the trial court." *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, Docket No. 2:06-cv-01797 (E.D. Pa. July 11, 2013), Tr. 12:19-22. One court has referred to *Actavis* as a "confusing Supreme Court case, complicated by principles of law that seem at cross purposes." *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180, 194-95 (D.R.I. 2014). Another has bemoaned the "uncertain but disruptive effect" *Actavis* has had on litigation involving the intersection of antitrust and patent law. *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 233 (D. Conn. 2015). In certifying that case for appeal, the court reiterated that *Actavis* provides "limited guidance to the lower courts" and has the "clear potential for a disruptive effect on very large-scale litigation." *In re Aggrenox*, 94 F. Supp. 3d 224, *motion to certify appeal granted by* 2015 WL 4459607, at *11 (D. Conn. July 21, 2015). As a result of this uncertainty, "[s]everal district courts have already applied *Actavis,* with not entirely consistent results." *Id.* at 235-36.

In the district courts' view, *Actavis* left unanswered several important questions, including what constitutes a large and unjustified reverse payment that would trigger rule of reason review. On this question, courts have considered what effect *Actavis* has on settlement agreements that involve consideration other than a reverse payment like that in *Actavis*. The courts' answers to this question, particu-

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[4] *See* Fales & Feinstein, *Two Years and Counting Since* Actavis: *Developments in the Law*, 30 Fall Antitrust 31 (2015).

larly with respect to agreements that include an exclusive license to the generic market, are already all over the map. *See, e.g.*, *In re Actos End Payor Antitrust Litig.*, No. 13-cv-9244 (RA), 2015 WL 5610752, at *13 (S.D.N.Y. Sept. 22, 2015) (noting that "a number of district courts have reached differing conclusions as to whether a non-cash settlement may ever constitute an unlawful 'payment.'"); *In re Aggrenox*, 94 F. Supp. 3d at 242 (noting that courts have "had relatively little guidance on the question of what constitutes a 'large' and 'unjustified' reverse payment, and have diverged even on the issue of what constitutes 'payment'").

The district court below held that *Actavis* did not apply to the agreement here because under *Actavis*, only naked reverse payments of cash are subject to rule of reason review. App. 64a-65a. The District Court of Rhode Island recently agreed. Expressing some reservations about its approach, the Rhode Island court nonetheless held that only cash payments fall within the ambit of *Actavis*. *In re Loestrin*, 45 F. Supp. 3d 180. The court explained that "[i]n the end, had the Supreme Court intended for rule of reason scrutiny to apply to non-cash settlements, it could simply have said so. … But the Supreme Court said no such thing." *Id.* at 192.

Other courts have held that *Actavis* is not limited to cash payments, but an antitrust claim should be dismissed if plaintiffs fail to plead a reliable foundation for estimating the value of the alleged payment. *See In re Effexor XR Antitrust Litig.*, No. 11-5479 (PGS) (LHG), 2014 WL 4988410, at *20 (D.N.J. Oct. 6, 2014) (dismissing claim on that basis); *see also In*

re Actos, 2015 WL 5610752, at *13 ("[I]n order for the Court to find an unlawful reverse payment, it must be able to estimate the value of the term, at least to the extent of determining whether it is 'large' and 'unjustified.'")

Still other courts to consider this issue have espoused the approach adopted by the Third Circuit here, that an exclusive license to the generic market can constitute an unlawful reverse payment under *Actavis*. *See In re Aggrenox*, 94 F. Supp. 3d 224 (plaintiffs adequately alleged that an agreement in which patentee gave an exclusive license to market a generic, and thus agreed not to launch a competing authorized generic, was an unlawful reverse payment); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014) (similar); *In re Opana ER Antitrust Litig.*, No. 14 C 10150, 2016 WL 521005 (N.D. Ill. Feb. 10, 2016) (similar); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 382 (D. Mass. 2013) (denying summary judgment to defendants on basis that a similar agreement could constitute an unlawful reverse payment); *United Food and Commercial Workers Local 1776 & Participating Emp'rs Health and Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1068 (N.D. Cal. 2014) (plaintiffs plausibly pleaded antitrust claim based in part on a similar agreement).

By broadening *Actavis* to include licensing arrangements, these courts have essentially held that any exchange of consideration can be characterized as a "reverse payment" in an antitrust challenge and exposes the settling parties to possible treble damages under the rule of reason—an "elaborate in-

quiry" that "produces notoriously high litigation costs and unpredictable results." *Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2411 (2015) (quotation marks omitted). The decision in *In re Aggrenox* exemplifies this reading of *Actavis*. Addressing the role that authorized licensing plays in the analysis of what constitutes a suspect reverse payment, the court opined that "licenses can be worth money, and granting them can thus be the equivalent of transferring money." 94 F. Supp. 3d at 245. Accordingly, the court wrote,

> The statutory authority to grant exclusive licenses no more immunizes reverse-payment settlements that include them from antitrust scrutiny under *Actavis* than the statutory authority to use cash as a legal tender immunizes reverse-payment settlements made in cash from such scrutiny. The issue is not whether the *form* of the payment was legal, but whether the *purpose* of the payment was legal.
>
> *Id.* (emphasis in original).

This reasoning, which permeates many of the lower courts decisions trying to apply *Actavis*, profoundly distorts the role a patent and patent licensing play. It goes without saying that "statutory authority to use cash as a legal tender" is not, in any way, an authorization to use cash in ways that otherwise violate the antitrust laws. It should go equally without saying, though, that "statutory authority to grant exclusive licenses" *does* reflect Congress's determination that innovation and competition are best served in the long run by granting property rights that should not be second-guessed on a case-

by-case basis under the antitrust laws. *See, e.g.*, *Kimble*, 135 S. Ct. at 2413 (describing the Patent Act as setting forth "all-encompassing bright-line rule[s]" that foster competition and innovation over the long run).

The *Actavis* decision has unwittingly set the lower courts on a path that is unfaithful to core patent law principles. This problem will not remedy itself. Only this Court can step in to resolve this specific and frequently recurring issue and to clarify that it was not drastically shifting course in *Actavis*. Rather, *Actavis* preserved the bright line that protects a patentee's conduct, like exclusive licensing, that is expressly authorized by Congress. Congress made the *ex ante* judgment that this category of conduct is beneficial to innovation and competition in the long term. The Third Circuit's decision improperly overrides Congress's judgment that case-by-case antitrust review of patent licenses would harm competition by reducing incentives to innovate.

II. THE DECISION BELOW IMPROPERLY CHILLS STATUTORILY-AUTHORIZED PATENT LICENSING

A. The Holding that Granting an Exclusive Patent License is a Potential Antitrust Violation Cannot be Reconciled with *Actavis* and Decades of Precedent

This Court in *Actavis* announced that "there is *nothing* novel about our approach." *Actavis*, 133 S. Ct. at 2233 (emphasis added). Proving the point, the Court in *Actavis* relied on decades of patent law, in-

cluding cases holding that patent law grants a patentee the ability to license its monopoly to others without risking potential antitrust liability, even if the license includes certain conditions that (in the absence of a patent) could be characterized as anticompetitive. In *General Electric*, for example, the Court recognized that a patentee may engage in price fixing of its patented product by granting a license with price conditions. *Gen. Elec. Co.*, 272 U.S. 476. The Court was elaborating on *E. Bement & Sons v. National Harlow Co.*, which held that an exclusive license did not violate the antitrust laws because it was "nothing more in effect than an assignment or sale of the exclusive right to manufacture and vend the [patented] article." 186 U.S. 70, 94 (1902). Thus, the Court has long emphasized that licenses are an "old" and "common practice" whose "legality has never been questioned." *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124, 127 (1938).

Actavis adopted and reconfirmed the fundamental conclusion expressed in *United States v. Line Material Co.*, 333 U.S. 287 (1948), that licensing agreements should not be second-guessed case-by-case under the antitrust laws because, to the extent the license restrains trade, that "*reasonable* restraint … *accords with the patent monopoly granted by the patent law*." 133 S. Ct. at 2232 (quoting *Line Material*, 333 U.S. at 311-12) (emphasis added). The Court recognized that the relevant question, asked in *Line Material*, was "whether 'the patent statute *specifically gives a right*' to restrain competition in the manner challenged,'" *Id*, at 2231 (quoting *Line Material*,

333 U.S. at 311) (emphasis added). The answer was no in *Actavis*, but the answer here is plainly *yes*. Section 261 of Title 35 explicitly authorizes the patentee to "grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States." 35 U.S.C. § 261. As the FTC represented to this Court at oral argument in *Actavis*, reverse payments are meaningfully different from traditional exclusive licenses, which are "expressly authorized by the Patent Act." *Actavis* Oral Arg. at 4.

The Third Circuit's holding flies in the face of this well-settled precedent. The court accepted the "fact that the Patent Act expressly authorizes licensing." App. 38a. Nonetheless, the court held that arrangements like the licensing agreement here are subject to antitrust scrutiny. There is no basis for the court's holding.

Nothing in *Actavis* upended the bedrock of patent law that a patentee's licensing power is part of the bundle of rights Congress granted the patentee in order to spur and incentivize innovation. On the contrary, the Court sought to delineate the true "'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent," 133 S. Ct. at 2231, and it did so by amplifying existing doctrine about the proper harmony between antitrust and patent law.

In *Actavis*, plaintiffs brought an antitrust challenge against a patent litigation settlement between a brand and generic manufacturer. The agreement included an early-entry license for the generic, but unlike here, plaintiffs also alleged that the brand

company made a "reverse" payment of tens of millions of dollars to its potential generic competitors as further consideration to drop their patent invalidity claims. Relying on then-existing Eleventh Circuit precedent, the drug manufacturers defended their settlement on the grounds that the alleged agreement was within the "scope of the patent." They posited that as long as the settlement "'fall[s] within' the legitimate 'scope' of the patent's '*exclusionary potential*,'" that sufficed to confer immunity from the antitrust laws even when non-patent related resources (such as cash) were conferred. *Id.* (emphasis added).

This Court determined that the Eleventh Circuit had improperly defined the "'scope of the patent monopoly'—and consequently [the scope of] antitrust law immunity—that is conferred by a patent." *Id.* Drawing on decades of precedent that delineated the scope of the patent monopoly, *Actavis* applied two clear limits on the patentee's immunity from antitrust suit; an immunity the Court recognized "is conferred by a patent." *Id.* In particular, actions may run afoul of the antitrust laws when they fall into one of two categories: (a) those that use the patent toward an *end* other than securing value from the patented discovery itself; and (b) those that use a *means* other than the patent to promote the monopoly of the patent. The settlement in *Actavis* fell into the second category; the settlement here falls into neither.

A. On the question of proper *ends*, the Court reiterated that the patentee has a right to exclude competition, but only vis-à-vis the products covered

by the patent itself. This principle was nothing new. Numerous Supreme Court cases, including several cited by the Court in *Actavis*, already had made clear that where a patentee enters an arrangement that enlarges the monopoly *beyond* what the patent itself provides, that agreement (even if it includes a license) will merit antitrust review. *See, e.g.*, *United States v. United States Gypsum Co.*, 333 U.S. 364 (1948) (monopolization of entire industry through price control and regulation of distribution among all licensees).

Far from rejecting decades of settled practice, *Actavis* embraced *Line Material*'s distinction between a practice that "accords with the patent monopoly granted by the patent law," and an agreement that is "outside the patent monopoly." 133 S. Ct. at 2232 (quoting *United States v. Line Material Co.*, 333 U.S. 287, 312 (1948)). On the permissible side of the line, *Actavis* pointed to the vertical license in *General Electric*, where the Supreme Court "permitted a single patentee to grant to a single licensee a license containing a minimum resale price requirement," *id.* at 2232. On the other side, *Actavis* referred to *Line Material*, where two patentees had cross-licensed their related patents, subject to resale price restrictions and other limitations. The Court held that this arrangement, unlike a vertical licensing arrangement, could find no shelter in the patent laws because "[w]here two or more patentees with competitive, non-infringing patents combine them and fix prices on all devices produced under any of the patents, competition is *impeded to a greater degree than where a single patentee fixes prices for his licen-*

sees." *Line Material*, 333 U.S. at 311 (emphasis added).

B. *Actavis* further recognized that pursuing the proper ends is a necessary, but not a sufficient, condition for the patent law to confer complete antitrust immunity. Confronted with the unusual reverse payment at issue in *Actavis*, the Court considered whether a patentee has carte blanche to use *means* other than the patent and its express concomitant rights to promote its patent monopoly.

The Court explained that the settlement in *Actavis* was not entirely immune from antitrust review because no one could "identify any patent statute that it understands to grant such a right [to make a reverse cash payment to stay off the market], whether expressly or by fair implication." 133 S. Ct. at 2233. To be sure, the patentee was acting toward the end of enhancing the value of its patent-based monopoly—but the means it was using were not overtly blessed in patent law, which expressly entitles the patentee only to use the patent itself as a means to exclude competition, not necessarily to use cash or any other resource extraneous to the patent to accomplish that goal.

The Third Circuit ignored all of this when it mistakenly reasoned that the circumstances of this case were not meaningfully different from the alleged reverse payment in *Actavis*. The court concluded that rule of reason review was warranted because: "It seems to us that no-AG agreements are likely to present the same types of problems as reverse payments of cash;" "The anticompetitive consequences of this pay-for-delay may be as harmful as those resulting

from reverse payments of cash"; and "we think, a no-AG agreement could likewise 'prevent the risk of competition.'" App. 34a-35a (quoting *Actavis*, 133 S. Ct. at 2236).

In extending *Actavis* to the licensing agreement here, the Third Circuit ignored the core issue of the case: the power of the patent rights. The only agreement at issue in this case involves an early-entry licensing arrangement between two parties (1) for the valid end of protecting the patent, and (2) by means that do not share any anticompetitive features surpassing those authorized by patent law and its concomitant statutory rights of exclusivity.

The exclusivity term was as much part and parcel of the license as any other commonplace condition associated with a license, whether it be duration, geographic scope, or a royalty rate. *Actavis* took care to emphasize that such conditions, so long as they are not accompanied by the use of cash or other patent-extraneous resources to achieve anticompetitive ends, remain wholly permissible: parties may continue to "settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration." 133 S. Ct. at 2237. *Actavis* thus expressly endorsed early-entry licenses. This is just such a license, and there is no basis in *Actavis* to pick apart standard licensing terms that are expressly authorized by the Patent Act on the theory that the terms are too favorable to the generic company.

The Third Circuit, however, attempted to justify its departure from precedent by insisting that the case did not concern a patentee's unquestionable

right to license its patent, but rather the potentially impermissible "use [of] valuable licensing in such a way as to induce a patent challenger's delay." App. 37a. That is a distinction without a difference, for it overlooks that the fundamental purpose and function of a patent and its licenses are to enable the short-term delay of competition to foster long-term innovation. By expressly allowing patent holders to grant exclusive and restricted licenses, 35 U.S.C. § 261, Congress created a regime in which perfectly legal licensing agreements may temporarily restrict competition. *See Kimble*, 135 S. Ct. at 2413 ("The patent laws—unlike the Sherman Act—do not aim to maximize competition (to a large extent, the opposite).")

Of course, here, the early-entry license accelerated competition to begin before the expiration of the patent and its related exclusivities. The Third Circuit curiously suggested that the exclusivity arrangement raised antitrust concerns because if the brand had the option to introduce an authorized generic, there was a possibility of even *more* generic competition with the brand, a "generic duopoly" instead of a "generic monopoly." App. 33a. But *any* generic entry results in a more competitive environment, and it is well established that a settlement is not invalid merely because a party can hypothesize a variation that would have been *more* procompetitive. *See Verizon Commc'ns Inc. v. Law Offices of Curtis v. Trinko, LLP*, 540 U.S. 398, 415-16 (2004) (court may not "insist that a monopolist alter its way of doing business," simply because "some other approach might yield greater competition").

The Third Circuit was flatly incorrect to suggest that "[i]n 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." App. 37a (internal quotation marks omitted). The Third Circuit's disregard for settled patent law is apparent from its reliance on *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990), for the sweeping proposition that exclusive licenses "cannot avoid antitrust scrutiny where they are used in anticompetitive ways." App. 37a-38a. *Actavis* cited *Palmer* only as indirect support for the uncontroversial proposition that sometimes agreements may violate the antitrust laws. *Actavis*, 133 S. Ct. at 2227. *Palmer* had nothing to do with patent law; it was a per curiam decision that summarily invalidated a naked market division and horizontal price fixing agreement in the context of a copyright license.

Under *Actavis*, unlike the Third Circuit decision, patent law continues to play an indispensable role. *Actavis* explained that cases like *General Electric* and *Line Material* "seek to accommodate patent and antitrust policies, finding challenged terms and conditions unlawful *unless patent law policy offsets the antitrust law*." 133 S. Ct. at 2233 (emphasis added). This Court and Congress have established categorical rules about when patent law rights are not subject to antitrust attack. It would be nonsensical to measure conduct that is, by express legal design, monopolistic, against antitrust standards that police anticompetitive behavior. This case, therefore, is within the heartland of circumstances where "patent law policy offsets the antitrust law." *Id.*

B. The Decision Threatens All Patent Licensing, Not Only the Licensing of Pharmaceutical Patents

Importantly, there is nothing about the Third Circuit's holding that would be limited to the pharmaceutical context. The court's opinion thus calls into question the continued viability of exclusive licenses in all industries, despite their express authorization in the Patent Act. And rather than enhancing competition, the Third Circuit's holding would in fact harm competition by reducing incentives to innovate and raising the costs for generic companies to challenge pharmaceutical patents.

Actavis was clear that its holding should "not prevent litigating parties from settling their lawsuit," including with early-entry licenses. *Actavis*, 133 S. Ct. at 2237. But under the Third Circuit's reasoning, every settlement of any patent litigation would be subject to antitrust review, as would any deal struck to avoid patent litigation entirely. Selectively quoting *Actavis*, the court stated that "eliminating 'the risk of patent invalidation or a finding of noninfringement' by 'paying the challenger to stay out' of the market" is what "'constitutes the relevant anticompetitive harm,' which must then be analyzed under the rule of reason." App. 31a-32a (quoting *Actavis*, 133 S. Ct. at 2236-37). By definition, however, a settlement eliminates the risk of patent invalidation and the accused infringer gains something in return, otherwise it would not settle. A patent holder in particular will only enter a settlement that offers an assurance of some delay to immediate competition. Likewise, any exclusive license, which by def-

inition is more valuable to a patent challenger than a non-exclusive license, could always be recharacterized as having been offered in exchange for limitations on the license's term, territory, or scope.

The Third Circuit's analysis thus makes commonplace licensing exchanges potential antitrust violations. This is cause for alarm. The Supreme Court emphasized in *Actavis* that it did not intend to disturb "commonplace," "familiar," or "traditional" settlement forms. *Actavis*, 133 S. Ct. at 2233. And in *Kimble*, the Court reminded that it "prefer[s] not to unsettle stable law," especially law regarding patents and licensing agreements, because "parties are especially likely to rely on such precedents when ordering their affairs." 135 S. Ct. at 2410. Patent holders grant exclusive licenses routinely, and such licenses have become the backbone of economic relationships in fields across the American economy. Exclusive licenses represent 84 percent of patent licenses in the life sciences sector, 66 percent of patent licenses issued by commercial licensors, and 94 percent of patent licenses issued by universities. *See* Thomas R. Varner, *An Economic Perspective on Patent Licensing Structure and Provisions*, 46 BUS. ECON. 229, 237 (Oct. 2011); *see also* Licensing Executives Society (USA and Canada), Inc., *Global BioPharmaceutical Royalty Rates & Deal Terms Survey*, 7 (Sept. 2010) (finding that 82 percent of the licensing deals of surveyed members of the biotech and pharmaceutical industries were exclusive). Not surprisingly, for more than a century, courts have repeatedly and routinely upheld them. *See, e.g., Bement*, 186 U.S. at 94; *Genentech, Inc. v. Eli Lilly &*

Co., 998 F.2d 931, 949 (Fed. Cir. 1993), *cert. denied Regents of Univ. of Cal. v. Genentech, Inc.*, 510 U.S. 1140 (1994); *Rail-Trailer Co. v. ACF Indus., Inc.*, 358 F.2d 15, 16-17 (7th Cir. 1966); *Brownell v. Ketcham Wire & Mfg. Co.*, 211 F.2d 121, 128-29 (9th Cir. 1954).

Since the Third Circuit decision was issued, the Supreme Court has reaffirmed that patent holders have broad latitude to set licensing terms that are confined to the monopoly of the patent grant. *See Kimble*, 135 S. Ct. at 2408. In *Kimble*, the Court declined to overrule *Brulotte v. Thys Co.*, 379 U.S. 29 (1964), which held that a patentee cannot continue to receive royalties for sales made *after* its patent expires. 135 S. Ct. at 2405. But the Court went out of its way to note that parties "can often find ways around *Brulotte*" and enter arrangements "to share the risks and rewards of commercializing an invention." *Id.* at 2404, 2408. Specifically, the Court endorsed licensing arrangements, including ones that are designed to benefit the licensee (such as an amortized royalty payment scheme) so long as the license terms are cabined within the patent term. *See id.*

The decision here disserves both patent and antitrust policy—and runs contrary to Supreme Court precedent—by exposing routine and familiar licenses to potential treble damages under the antitrust laws. It leaves every exclusive license vulnerable to antitrust challenge on the grounds that the license conveys value and is an impermissible agreement not to compete because the parties could instead have settled on a longer term or broader scope. That annuls

the Patent Act's express endorsement of exclusive licensing and extends the reach of antitrust law far beyond any precedents cited in the opinion.

C. Absent This Court's Intervention, the Decision Below Will be the *De Facto* National Standard

This is a case that calls for speedy intervention. No patentee can be certain today about its rights to use and protect its patent. And the series of decisions that have emerged condemning settlements in which any value is transferred are poised to have a crippling effect on the ability of parties in patent suits to settle cases. As the Supreme Court recognized last Term, rule of reason litigation is an "elaborate inquiry" that "produces notoriously high litigation costs and unpredictable results." *See Kimble*, 135 S. Ct. at 2411. Parties will thus undertake settlement only at their own peril, if at all.

There is reason to believe that the situation will not resolve itself and, indeed, will only get worse. Many of the challenges to patent litigation settlements are already brought within the Third Circuit —which is home to a large percentage of the nation's pharmaceutical companies—and will thus be governed by the decision below absent this Court's review. In light of the decision below, this trend is likely to accelerate. The ordinary venue rules do not apply in antitrust cases: antitrust plaintiffs can bring a Sherman Act case in any one of the 94 federal judicial districts. *See* 15 U.S.C. § 22. As a result, the Third Circuit's rule will become the *de facto* national standard as plaintiffs engage in forum-shopping to take advantage of the circuit's misguid-

ed precedent. At a minimum, settling parties will understand that they are always at risk of facing a challenge under the Third Circuit's new regime, and as a result will not enter traditional settlements that now subject them to expensive antitrust litigation and possible treble damages.

This new status quo will have unfortunate consequences far beyond the pharmaceutical context, with the certainty of review and the risk of invalidation deterring parties from agreeing to settlements that may ultimately be beneficial to consumers and competition. Without the prospect of settlement, parties are also less likely to challenge patents in the first place, given the complexity and notoriously high cost of litigating patent disputes to completion. The public, in turn, will lose the benefits those cases and settlements have in bringing generic products to the market before patent expiration. *See, e.g., Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 334-35 (1971) (noting the "staggering" expense of infringement litigation and the benefit to a potential infringer of "accepting a license from a patentee who was threatening him with a suit" and "avoiding the necessity of defending an expensive infringement action"). The upshot here is that generic competition is more likely to be delayed until patent expiration.

This, too, is contrary to *Actavis*, which cautioned that its limited holding should "not prevent litigating parties from settling their lawsuit," 133 S. Ct. at 2237. The Supreme Court has never sought to chill patent litigation settlements, but has instead recognized that it is good policy to encourage them. *See Standard Oil Co. (Ind.) v. United States*, 283 U.S.

163, 171 (1931) ("Where there are legitimately conflicting claims or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by [antitrust law].").

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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February 19, 2016

APPENDIX

Table of Contents

Appendix A

PRECEDENTIAL

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 14-1243

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

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[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.

litigation of the validity or infringement of the patent ("reverse payment") "can 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 litigation, Teva had challenged the validity and enforceability of GSK's patents on lamotrigine,

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[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.

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 verification, in its *Orange Book*.[5] *Caraco*, 132

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[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.

[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. §

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 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

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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").

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] This exclusivity

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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. § 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).

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]

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

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

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."

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

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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

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 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

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holder completes certain studies "relating to the use of [the] drug in the pediatric population").

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.

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]

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[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.

[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

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 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

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reason standard that the Supreme Court subsequently decided is proper for reverse payment settlement agreements, *see Actavis*, 133 S. Ct. at 2237-38.

[16] *See supra* note 15.

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.

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 *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

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[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).

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]

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

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[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 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)).

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 "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.*

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

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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)).

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 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

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

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 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

[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* 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)).

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]

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

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[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/ ploads/Tufts_CSDD_ briefing_on_ RD_cost_ study_-_Nov_18,_2014..pdf.

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

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[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.

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 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]

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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

2.

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

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.'").

[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 that the no-AG agreement was in fact an "exclusive" license. However, since the issue of whether such

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 "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

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agreement is an exclusive license is not necessary for our decision here, we will leave its determination for another day.

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

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[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.

[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)).

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 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

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[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 . . . .").

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 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

[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

do 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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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-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

4.

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

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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 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.").

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 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]

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

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[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 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.").

unlawfully by seeking to prevent competition. Plaintiffs have sufficiently pleaded as much.[35]

C.

1.

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 its antitrust claim" under the rule of reason, 133 S. Ct. at 2234, as a redefinition of the "rule of reason" itself. But the

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

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]

On remand, we invite the District Court to proceed with the litigation under the traditional rule

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[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).

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.

Appendix B

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IN RE LAMICTAL DIRECT PURCHASER ANTITRUST LITIGATION

THIS DOCUMENT RELATES TO:

ALL DIRECT PURCHASER ACTIONS

OPINION

No. 12-cv-995 (WHW)

Walls, Senior District Judge

This Court dismissed the complaint of Direct Purchaser Plaintiffs Louisiana Wholesale Drug Company, Inc. and King Drug Company of Florence, Inc. for failure to state a claim upon which relief could be granted. Plaintiffs appealed, and the Third Circuit remanded the case to this Court in light of the Supreme Court's decision in *FTC v. Actavis*, 133 S. Ct. 2223 (June 17, 2013). The Court affirms its order of dismissal.

FACTUAL AND PROCEDURAL BACKGROUND

GlaxoSmithKline LLC ("GSK") sells Lamictal Tablets and Lamictal Chewables, which treat epilepsy and bipolar disorder. Am. Compl. ¶ 46 (ECF No. 55). These products are very profitable. As example, from March 2007 to March 2008, GSK's domestic sales of Lamictal Tablets exceeded $2 billion. *Id.* The lower-dosage Lamictal Chewable products had domestic sales of about $50 million from 2004 to 2005. *Id.* The active ingredient in Lamictal products is lamotrigine, covered by U.S. Patent No. 4,602,017 ("the '017 patent"). *Id.* ¶ 11.

GSK's patent for lamotrigine expired in July 2008. *Id.*

In 2002, Defendants Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals ("Teva") sought to produce generic versions of lamotrigine and filed Abbreviated New Drug Applications ("ANDAs") with the Food and Drug Administration ("FDA"). *Id.* ¶ 50. As the first generic manufacturer to file an ANDA for lamotrigine, Teva would be entitled to a 180-day period during which it would be the only generic manufacturer authorized to market the drug (the "first-filer exclusivity period"). *Id.* ¶ 12. In response to Teva's ANDA, GSK sued Teva for patent infringement. *Id.* ¶ 54. On January 27, 2005, Judge Bissell ruled from the bench that claim 1 of the '017 patent was invalid as anticipated by prior art. *Id.* ¶ 56. On February 2, 2005, the parties had a conference before Judge Bissell to announce that they were in settlement negotiations and asked the court to refrain from any further rulings. *Id.* ¶¶ 68-69. There are three key terms of the resulting settlement, which the Court paraphrases:

1) **Chewables**: Teva was permitted to sell generic lamotrigine chewables by June 1, 2005. *Id.* ¶ 70. This "early entry" period was approximately 37 months before the expiration of the '017 patent, and also before the FDA approved Teva's ANDA for lamotrigine chewables. *Id.* GSK supplied the chewables to Teva and Teva began selling them on May 25, 2005. *Id.*

2) **Tablets**: Teva was permitted to sell generic lamotrigine tablets during an "early entry" period of about six months before the expiration date of the '017 patent. *Id.* ¶ 71; GSK Mot. Dis., Ex. A ("License

and Supply Agreement" ("Settlement")) at 11-12 (ECF No. 72-2). At the time, GSK did not know if it would receive "pediatric exclusivity" from the FDA which, if awarded, adds an additional six months of protection to the existing patent term. If GSK did not receive pediatric exclusivity, Teva would have been allowed to enter the tablet market on March 1, 2008. Settlement at 12. If GSK did receive pediatric exclusivity, Teva would have been allowed to enter July 21, 2008—the date the '017 patent was originally due to expire—via an exclusive waiver from the pediatric exclusivity extension. *Id.* ¶ 71; Settlement §§ 2.2(b) (regarding chewables), 2.3(b) (regarding tablets). In 2007, GSK received pediatric exclusivity and thus an extra six months of patent protection, so the latter date applied. *Id.* ¶ 49.

3) **The "No-AG Agreement"**: GSK agreed not to launch its own generic versions of Lamictal products (or "authorized generics," the common name for products manufactured by the brand name manufacturer but without the brand name) during Teva's first-filer exclusivity period—i.e., the 180 days after Teva first marketed the generic version of the drug. Am. Compl. ¶¶ 76,

81. Because GSK received pediatric exclusivity, extending its patent protection from July 2008 to January 2009, Teva enjoyed its first-filer exclusivity period at the same time. This agreement arises from the exclusive license provisions, which specifically made the license exclusive "including as to GSK and its Affiliates and Third Parties with respect to Generic Equivalents." Settlement §§ 2.2(a), 2.2(b) (regarding chewables), 2.3(a),

2.3(b) (regarding tablets); Pls.' Opp'n Br. at 21-22, 22 n.17 (ECF No. 86).

In sum, in exchange for dropping its challenge to GSK's patents, the settlement allowed Teva to market generic lamotrigine before the relevant patent expired and ensured that once it did so, its generic tablets and chewables would not face competition from GSK's own "authorized generic" for a certain period of time. *Id.* ¶¶ 76, 81, 86.

Plaintiffs allege that the settlement violates federal antitrust laws. Id. ¶¶ 108-50. Defendants filed a motion to dismiss the complaint on August 15, 2012, ECF Nos. 72-73, which this Court granted. Op. of Dismissal (ECF No. 105), *In re: Lamictal*, No. 12-cv-995 (WHW), 2012 WL 6725580 (Dec. 6, 2012).

At the time, the circuits were split about when and under what standard district courts should scrutinize "reverse payment settlements" between a brand name and generic drug manufacturer under the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, as amended, commonly known as the Hatch-Waxman Act. In 2012, the Third Circuit announced that the appropriate test was a "quick look": if a patent holder makes a reverse payment to a generic patent challenger, that payment is "*prima facie* evidence of an unreasonable restraint of trade." *Id.* at *4, citing *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012). Other circuits, including the Federal Circuit, applied the "scope of the patent" test, according to which reverse payment settlements are immune from antitrust scrutiny as long as the settlement falls within the scope of the patent. *Id.* at *5. Under "quick look," most reverse payment

settlements get antitrust scrutiny, and under "scope of the patent" most do not. *See Actavis*, 133 S. Ct. at 2230 (describing the "quick look" standard as "settlements presumptively unlawful" and the "scope of the patent" standard as "settlements generally immune from antitrust attack").

Applying *K-Dur* (the standard more lenient to plaintiffs), this Court found that its decision rested on a preliminary question: whether the settlement at issue contained a "reverse payment." Defendants argued that it did not because there was no transfer of money; Plaintiffs argued that it did because Teva had received "significant consideration, incentives, and benefits." *Lamictal*, 2012 WL 6725580, at *6. The Court sided with Defendants, finding that because the settlement did not involve a transfer of money, it "[was] not subject to antitrust scrutiny": "The Third Circuit's *K-Dur* opinion is directed towards settlements when a generic manufacturer is paid off with money, which is not the case here." *Id*. The Court concluded that Plaintiffs had failed to state a claim for which relief could be granted. *Id*. at 7.

Plaintiffs appealed. ECF No. 107. On February 26, 2013, the Third Circuit stayed proceedings pending the Supreme Court's decision in *FTC v. Actavis*.[1] Third Circuit Do. No. 12-4584, Doc. No. 003111176912. The Supreme Court issued its opinion on June 17, 2013. 133 S. Ct. 2223. Two days later, the Third Circuit lifted the stay and Defendant-Appellees promptly moved to remand the case to this Court in light of *Actavis*. Defs.-

[1] Then known as *FTC v. Watson Pharmaceuticals, Inc.*

Appellees' Mot. for Remand, Third Circuit Do. No. 12-4584, Doc. No. 003111300341. Plaintiff-Appellants opposed the move to remand, arguing that even if *Actavis* changed the antitrust standard for review, this Court's opinion granting Defendants' motion to dismiss was based not on the antitrust standard but on the insufficiency of Plaintiffs' pleadings. Pls.-Appellants' Opp'n to Mot. for Remand at 6, Do. No. 12-4584, Doc. No. 003111305434. On July 2, 2013, the Third Circuit remanded the case to this Court ". . . for further proceedings." Do. No. 12-4584, Doc. No. 003111312528.

On July 26, 2013, Plaintiffs filed a motion for reconsideration of the opinion and order granting Defendants' motion to dismiss. ECF No. 113. After Defendants opposed the motion and Plaintiffs replied, ECF Nos. 119-20, 122, there followed a flurry of letters regarding additional authority Plaintiffs wanted the Court to consider: an amicus brief the Federal Trade Commission ("FTC") filed in *In re Effexor Antitrust Litigation*, Do. No. 11-cv-5479, a case in this district before Judge Sheridan, ECF No. 117; an opinion from a different case before Judge Sheridan, *In Re: Lipitor Antitrust Litigation*, No. 3:12-cv-2389 (PGS), 2013 WL 4780496 (D.N.J. Sept. 5, 2013), ECF No. 123; and an opinion from the District of Massachusetts, *In Re: Nexium (Esomeprazole) Antitrust Litigation*, No. 12-md-02409 (WGY), 2013 WL 4832176 (D. Mass. Sept. 11, 2013), ECF No. 125. Defendants asked this Court to ignore these submissions or, in the alternative, find them unpersuasive. ECF Nos. 121, 127.

STANDARD OF REVIEW

I. Reconsideration

"The first question to be decided is the nature of the reconsideration which the Third Circuit mandated." *Rolo v. City Investing Co. Liquidating Trust*, 897 F. Supp. 826, 830 (D.N.J. 1995) *aff'd*, 155 F.3d 644 (3d Cir. 1998). In *Rolo*, the Third Circuit vacated a dismissal Judge Debevoise had ordered and remanded for reconsideration in light of intervening Third Circuit authority. Judge Debevoise ultimately concluded that, "even if [the intervening authority] had been decided in December 1993 and applied in this case, the plaintiffs' [] claims would have been dismissed . . . ." *Id.* at 833. The Third Circuit affirmed. 155 F.3d 644. *See also In re Mazzocone*, 183 B.R. 402, 409 (Bankr. E.D. Pa. 1995) *aff'd*, 200 B.R. 568 (E.D. Pa. 1996) (explaining that, on remand generally, "a trial court should attempt to put the parties back to the place where the error identified on appeal occurred").

When a party moves for reconsideration under Federal Rule of Civil Procedure 59(e), the scope will be determined by the basis for the motion, such as a claim that reconsideration is "justified by an intervening change in controlling law." 11 Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice and Procedure* § 2810.1 at 158-62 (3d ed. April 2013) (listing four possible rationales); *see North River Ins. Co. v. CIGNA Reinsurance Co.*, 52 F.3d 1194, 1218 (3d Cir. 1995). But, "[t]he Rule 59(e) motion may not be used to relitigate old matters . . . ." 11 Wright & Miller § 2810.1 at 163-64. *See Gutierrez v. Ashcroft*, 289 F. Supp. 2d 555, 561 (D.N.J. 2003) ("A party seeking reconsideration must

show more than a disagreement with the Court's decision, and recapitulation of the cases and arguments considered by the court before rendering its original decision fails to carry the moving party's burden." (citation and quotation omitted)).

Here, it is obvious that the Court's task is to reconsider, in light of *Actavis*, its December 2012 opinion and order dismissing the case. Plaintiffs have submitted what they call a motion for reconsideration,[2] though their brief veers widely from the Court's narrow mandate. The Plaintiffs spend most of their brief "relitigating old matters" in a manner that would be patently inappropriate under Rule 59(e); had Plaintiffs submitted their motion absent a mandate from the Third Circuit to consider *Actavis*, the Court would summarily have denied it for failure to "show more than a disagreement with the Court's decision." Indeed, as even they concede, "Plaintiffs believe this Court's position would not be altered by *Actavis*." *See* Pls.' Recon. Reply at 4 (ECF 122). Simply, what follows is this Court's reconsideration of Defendant's motion to dismiss in the presence of *Actavis's* authority.

II. *Actavis*

What did the Supreme Court do in *Actavis*? The opinion clearly did at least one thing. In deciding the appropriate level of antitrust scrutiny for reverse payments, the Supreme Court explicitly rejected both current circuit tests: "scope of the patent," 133

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[2] The full name is "Direct Purchaser Plaintiffs' Opening Brief in Support of Motion to Reconsider Dismissal of Action for Failure to State an Antitrust Cause of Action in Light of Recent Supreme Court Precedent." ECF No. 113-1.

S. Ct. at 2231 (describing its holding as "contrary to the [Eleventh] Circuit's view that the only pertinent question is whether 'the settlement agreement . . . fall[s] within' the legitimate 'scope' of the patent's 'exclusionary potential'") and "quick look," *id*. at 2237 (explaining that this approach is only appropriate when the "anticompetitive effect on customers and markets" is clear to "an observer with even a rudimentary understanding of economics"). Instead, it adopted the "rule of reason" analysis generally applied in antitrust matters. *Id*. The Court summarized its holding:

> In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments.

133 S. Ct. at 2237. To this Court, that looks like a three-part test: two steps to determine *when* to apply this rule of reason, followed by an application of the rule of reason to the scenario. In Step One, a district court must ask, is there a reverse payment? As the Court discusses below, the answer hinges on what the parties exchanged in the settlement and must include money. In Step Two, a district court

must ask, is that reverse payment large and unjustified? As the Supreme Court explained, only *certain* reverse payments will actually warrant scrutiny. *See, e.g., Actavis*, 133 S. Ct. at 2237 (explaining that "the likelihood of a reverse payment bringing about anticompetitive effects" is not presumed but "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").

Step Three is the rule of reason. Under that analysis, long a standard tool of antitrust law, a court asks whether the parties to an agreement creating a restraint of trade had market power and exercised it, whether the restraint had anti-competitive consequences and whether those consequences are otherwise justified. *See United States v. Brown Univ.*, 5 F.3d 658, 679 (3d Cir. 1993) (describing the three steps of traditional rule of reason analysis). The *Actavis* opinion lays out "five considerations" to guide district courts in applying the rule of reason in this context. See 133 S. Ct. at 2234-37. Put as questions, those considerations are: First, Does the payment have the "potential for genuine adverse effects on competition"? *Id*. at 2234. Second, Is the payment justified in some way, perhaps because it approximates "litigation expenses saved through the settlement" or compensates the patent challenger for "other services . . . such as distributing the patented item or helping to develop a market for that item"? *Id*. at 2235-36. Third, Does the brand name manufacturer have the market power needed to bring about anticompetitive harm? *Id*. at 2236. Fourth, Does the size of the settlement

suggest that it is intended to maintain supracompetitive prices and serve as a "workable surrogate for a patent's weakness"? *Id.* at 2236-37. Fifth, Could the parties have settled in some way that did not involve the use of reverse payments? *Id.* at 2237. Under this fifth consideration, the Court explicitly created a carve out for early entry provisions:

> [T]he fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit. 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.

Id. These five considerations track onto traditional rule of reason analysis fairly cleanly: District courts must ask whether the parties to a settlement had market power, a factor which appears here as the third consideration, whether the trade restraint at issue had anti-competitive consequences, the first and fourth considerations, and whether those consequences are justified, the second and fifth considerations.

There is some overlap in the steps as this Court describes them. As example, the Supreme Court's concern about a settlement's size appears both in Step Two and in Step Three. This could suggest to some that Steps One and Two are not preliminary steps, but rather part of a broad, open-ended balancing of the "five considerations" in Step Three.

As discussed further, this Court does not so conclude. *Actavis* is clear that only certain reverse payment settlements will trigger antitrust scrutiny; the framework established here provides a direct way for district courts to make that inquiry in the manner *Actavis* demands.

DISCUSSION

The settlement allowed Teva to enter the market for lamotrigine chewables 37 months early and the market for lamotrigine tablets 6 months early. Am. Compl. ¶¶ 70-71. GSK agreed not to produce an authorized generic lamotrigine, in either chewable or tablet form, during Teva's first-filer exclusivity period from July 2008 to January 2009. *Id*. at 76. Teva, in return, dropped its challenge to the Lamictal patents. Plaintiffs alleged that this settlement violated federal antitrust laws. This Court found that, under *K-Dur*, the settlement did not trigger antitrust scrutiny because there was no transfer of money and therefore the amended complaint failed to state a claim.

The only question before the Court is whether *Actavis* and its adoption of a "rule of reason" standard for antitrust scrutiny of reverse payment settlements renders Plaintiffs' amended complaint sufficient. This would be the case if one of two things were true: if *Actavis* does not require a preliminary finding of a "reverse payment," but instead requires scrutiny of every patent settlement for anticompetitive concerns, or if *Actavis* defines "payment" in a way that includes non-monetary transfers of value.

Neither of these readings of *Actavis* is supportable. It follows that *Actavis* does not change

the outcome of Defendants' motion to dismiss and the earlier opinion stands. The Court has also considered how the settlement would fare under the rule of reason analysis if a reverse payment of money was absent and finds that the settlement would most likely survive.

I. *Actavis* Scrutiny Applies Only to Patent Settlements that Contain Reverse Payments

The Court has considered the possibility that *Actavis* requires district courts to apply the rule of reason not only to reverse payment settlements but to *all* patent settlements with any anticompetitive potential. *See* FTC Amicus, *In re: Effexor XR Antitrust Litigation*, No. 3:11-cv-05479, ECF No. 236-2 (No. 12-cv-995 (WHW) ECF No. 117) at 9 ("The Supreme Court's rejection of the scope-of-the-patent test and its directive to consider traditional antitrust factors is not a special rule limited to 'reverse payment' cases.").[3] But *Actavis* just does not go that far.

Actavis certainly looks more skeptically at patent settlements than did courts applying the "scope of the patent" test and there is some very broad language in the opinion regarding patent settlements of all kinds. *See, e.g.*, 133 S. Ct. at 2232 ("[T]his Court's precedents make clear that patent-related settlement agreements can sometimes violate the antitrust laws."); *id*. at 2238 (describing the "basic question" as "that of the presence of significant unjustified anticompetitive consequences"); *id*. at

[3] The Court has decided, in its discretion, to consider this submission.

2233 (describing how earlier cases in this area of law "seek to accommodate patent and antitrust policies, finding *challenged terms and conditions* unlawful unless patent law policy offsets the antitrust law policy strongly favoring competition" (emphasis added)). It is possible to read the Court's statement about "challenged terms and conditions" to mean that any term or condition of a patent settlement can trigger antitrust scrutiny, without regard to whether the settlement contains a reverse payment.

But that argument does not persuade. *Actavis* requires scrutiny only of patent settlements that contain reverse payments. The Court's focus is on reverse payments from the very first words of the opinion. *See* Section II, below. It explains that there is "something quite different" about reverse payment settlements, as opposed to "traditional" and "commonplace forms" of settlement, which is why only the former are subject to antitrust scrutiny. *Id.* at 2233. Other types of settlement are explicitly exempt: though "a large, unjustified reverse payment risks antitrust liability," the Court provides that parties may "settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration" without also paying the generic. 133 S. Ct. at 2237. At the very least, then, one kind of settlement may be free from antitrust scrutiny: one consisting *solely* of an early entry provision.[4]

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[4] Plaintiffs and the FTC would likely argue that this carve out extends only that far and no further. *See* FTC, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact (2011) ("2011 FTC Report"), 140, http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf.

Finding that a settlement contains a reverse payment is a necessary prerequisite to undertaking the broader *Actavis* rule of reason analysis. Any language suggesting otherwise is too vague and too far removed from the Supreme Court's holding to be anything other than dicta.

II. *Actavis* Applies Only to "Reverse Payments" of Money

Whether a "reverse payment" is required is one question and how to define that term is another.

Plaintiffs argue that the settlement amounted to a "reverse payment" because it "conferred substantial financial benefits on Teva"—namely, through the No-AG Agreement. Pls.' Mot. Recon. at 1 (ECF No. 113-1). But nothing in *Actavis* says that a settlement contains a reverse payment when it confers substantial financial benefits or that a no-AG agreement is a "payment."

Both the majority and the dissenting opinions reek with discussion of payment of money. Writing for the majority, Justice Breyer immediately begins his opinion by saying:

> 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*

("These types of simple settlements, with no other provisions, generally do not raise competition concerns."). But such a reading would far too greatly constrict parties' power to settle, a power the *Actavis* court clearly meant to keep intact.

> *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.*

133 S. Ct. at 2227 (emphasis this Court's). This is the factual foundation of the resulting opinion and decision. Later on, the Justice repeats: "In reverse payment settlements . . . a party with no claim for damages . . . walks away with money simply so it will stay away from the patentee's market." *Id*. at 2233.

The referenced language reasonably means that the Supreme Court considered a reverse payment to involve an exchange of money. *See also id*. at 2231 ("The FTC alleges that in substance, the plaintiff agreed to pay the defendants many millions of dollars . . . there is reason for concern that settlements *taking this form* tend to have significant adverse effects on competition" (emphasis added)); *id*. at 2233 (plaintiff "pays money" to defendant); *id*. at 2234 ("multimillion dollar payoffs"); *id*. at 2235 ("patentees sometimes pay a generic challenger a sum even larger than what the generic would gain in profits").

Granted, there is an argument that a "reverse payment" need not consist of money. Black's Law Dictionary defines "payment" as the "[p]erformance of an obligation by the delivery of money *or some other valuable thing* accepted in partial or full discharge of an obligation." Black's Law Dictionary (9th ed. 2010) (emphasis added). *See* 60 Am. Jur. 2d Payment § 30 ("A payment may refer to the transfer of value other than money"). But in *Actavis*, support for this broadened reading of "payment" is thin.

There is a concern about patent settlements in general, see Section I above, but there are only a few scattered indications that the Supreme Court intended its holding to apply to non-monetary "payments." As example, the Court wrote, "reverse payment settlements—*e.g.*, in which A, the plaintiff, *pays money* to defendant B." Id. at 2233 (emphasis added). There, the Supreme Court's use of "e.g." suggests that this scenario is nothing more than an example of a reverse payment settlement and there are others. But that one Latin abbreviation is hardly enough to counter the overwhelming evidence that when the Supreme Court said "payment" it meant a payment of money.

The *Actavis* dissent critiques the majority precisely *because* it drew a line between monetary and non-monetary payments. Taking for granted that the majority uses the phrase "reverse-payment settlements" to refer only to money, Chief Justice Roberts argues that the Court's logic "cannot possibly be limited to reverse-payment agreements, or those that are 'large,'" suggesting that it must also sweep in "'other consideration' and 'alternative arrangements'" as well as even "the Court's own solution of negotiated early entry." *Id.* at 2245 (C.J. Roberts, dissenting). *See also id.* at 2243 (calling the distinction between money and other transfers of value "a distinction without a difference"). Chief Justice Roberts and Plaintiffs here agree: the scrutiny should be the same irrespective of what kind of consideration the settlement contains.

Plaintiff expends much effort trying to persuade this Court that the parties to the settlement each received something of value. *See, e.g.*, Pls.' Recon.

Reply at 6-7 (ECF 122). Employing boldface type to express some combination of outrage, disbelief and condescension, Plaintiffs write, "the challenger (the alleged infringer) **is being paid by the patent holder** for something." *Id*. at 6 (emphasis original). As this Court wrote in its original dismissal opinion, "Without doubt Teva received consideration in the settlement. Otherwise, there would be no incentive to settle. A law student learns in the first semester that consideration is an essential element of any enforceable contract. In this sense, there is 'payment' in every settlement." Op. of Dismissal (ECF No. 105), *In re: Lamictal*, No. 12-cv-995 (WHW), 2012 WL 6725580, at *6 (Dec. 6, 2012). Plaintiffs have failed to explain how *Actavis* changes this; in fact, they concede that it has not. *See* Pls.' Recon. Reply at 4.

Moving on from the words of the opinion, Plaintiffs argue that applying *Actavis* scrutiny only to reverse payments of money "would be directly inconsistent with the overall holding and tenor of *Actavis*." Pls.' Mot. Recon. at 11 (ECF 113-1). Of course, an opinion's overall tenor is a less reliable measuring stick than its actual words. But the settlement is within the gestalt of *Actavis*. That Teva was allowed early entry, that there was no payment of money and that the duration of the No-AG Agreement was relatively brief all serve to persuade this Court that the settlement was reasonable and not of the sort that requires *Actavis* scrutiny.

Context matters. The facts before the *Actavis* court involved a payment by a brand name manufacturer of hundreds of millions of dollars to

generic manufacturers, *id*. at 2229, as did the cases decided under the "quick look" and "scope of the patent" tests, *see* Teva Opp'n to Recon. at 9, n. 2 (ECF 119). It is good jurisprudence that the result flows from the factual source; this Court will not extend the holding of *Actavis* to the non-monetary facts before it.

A. In re Lipitor and In re Nexium

Other district courts have found that *Actavis* applies to non-monetary patent settlements. This Court finds their readings of *Actavis* unpersuasive.

Plaintiffs have found friendly language in a recent decision from this district, *In re Lipitor*. There, Judge Sheridan addressed a motion by Plaintiffs to amend their complaint in light of *Actavis*. 2013 WL 4780496, at *1. He allowed the amendments because "nothing in *Actavis* strictly requires that the payment be in the form of money." *Id*. at *26. As Defendants correctly point out, this is more like a request for further briefing than a decision. *See* Letter from Michael Patunas, Sept. 19, 2013 (ECF 127). In fact, Judge Sheridan explicitly tabled that question. 2013 WL 4780496, at *26.

In re Nexium was, as here, a reconsideration in light of *Actavis*. 2011 WL 4832176, at *1. The facts and allegations in that case and this one are similar, with one crucial distinction: the plaintiffs alleged that the brand name manufacturer not only entered a no-AG agreement but also paid the first-filing generic millions of dollars. *Id*. at *6-9. So even though the *Nexium* court read *Actavis* to sweep in non-monetary payments—"[n]owhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction," *id*. at *15—the allegation of

cash payment made this statement dictum. In any event, it is unpersuasive to this Court.

The *Nexium* decision is distinguishable for another reason. The court interpreted the *Actavis* decision's call for scrutiny of "large and unjustified" reverse payments to sweep in "only those reverse payment agreements whose anticompetitive consequences are sufficiently great and sufficiently unrelated to the settlement of a particular patent dispute." *Id*. It found that *Actavis* scrutiny was appropriate because each of the three settlements was either "outsize" or "entirely disconnected" from the dispute over the Nexium patents. *Id*. Here, every element of the settlement is directly related to the dispute over the Lamictal patents.

In sum, the *Lipitor* and *Nexium* decisions reflect interpretations of *Actavis* which—to this Court's thinking—are unsupported by the words of *Actavis* or are inapposite. This Court does not find them persuasive.

III. The Rule of Reason Analysis

Because it is plausible that *Actavis* does not require finding a large, unjustified reverse payment of money, this Court has considered the settlement under the "five considerations" of *Actavis*. It finds that the settlement would most likely survive.

First, the Court believes that the settlement does not have the potential for genuine adverse effects on competition. The Supreme Court explained that "the likelihood of a reverse payment bringing about anticompetitive effects" is not presumed but "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." *Actavis*, 133 S. Ct. at 2237. This Court finds that the potential for adverse effects on competition is minimal. That Teva was allowed six months of early entry, that there was no payment of money and that the duration of the No-AG Agreement was a relatively brief six months all serve to persuade this Court that the settlement was reasonable and not anti- competitive as forbidden by *Actavis*. While there may be instances in which a settlement without a monetary payment provision would raise antitrust concerns, this is not one.

Second, the payment is justified. Though the value to Teva of the No-AG Agreement likely exceeds what the parties would have spent litigating the patent dispute, the consideration which the parties exchanged in the settlement is reasonably related to the removal of the uncertainty created by the dispute. GSK may also have derived some ancillary benefit from Teva's licensed sales of lamotrigine in terms of distribution and marketing.

Third, the Court cannot conclude whether the brand name manufacturer has the market power needed to bring about anticompetitive harm, but finds that this would not be dispositive.

Fourth, the sweep of the settlement does not suggest that it is intended to maintain supracompetitive prices and serve as a "workable surrogate for a patent's weakness." Though the parties settled soon after Judge Bissell ruled that claim 1 of the '017 patent was invalid, the provision for early entry within the life of the patent and the relatively brief period of the No-AG Agreement

persuade the Court that the settlement is not of undue size.

Fifth, the parties settled in a way that did not involve monetary reverse payments. *Actavis* provides an explicit carve out for parties to "settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration." 133 S. Ct. at 2237. Here, the settlement gave Teva the right to early generic entry along with a promise that it could do so without competition from an authorized generic for a limited time of six months. The Supreme Court made clear its intent to give patent litigants latitude to settle without triggering the antitrust scrutiny that large, unjustified reverse payments bring. GSK and Teva did just that.

It follows then that the settlement would survive *Actavis* scrutiny and is reasonable.

CONCLUSION

The Court concludes that *Actavis* applies to patent settlements that contain an unjustified reverse payment of money. Such conclusion does not change this Court's earlier decision. The Court affirms its grant of Defendants' motion to dismiss.

Date: January 24, 2014

/s/ William H. Walls

United States Senior District Judge

Appendix C

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 14-1243

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

(D.C. Civil Action No. 2-12-cv-00995)

SUR PETITION FOR REHEARING

Present: AMBRO, FUENTES, SMITH, FISHER, CHAGARES, JORDAN, GREENAWAY, JR., VANASKIE, SHWARTZ, SCIRICA *, and ROTH,* Circuit Judges

The petitions for rehearing filed by Appellees Smithkline Beecham Corporation and Appellees Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals in the above-entitled case having

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* Pursuant to Third Circuit I.O.P. 9.5.3, the votes by Judges Scirica and roth are limited to panel rehearing.

been submitted to the judges who participated in the decision of this Court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the judges of the circuit in regular service not having voted for rehearing, the petition for rehearing by the panel and the Court en banc, is denied.

BY THE COURT,

s/ Anthony J. Scirica
Circuit Judge

Dated: September 23, 2015
tmm/cc: all counsel of record

Appendix D

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 14-1243

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

Before: AMBRO, SCIRICA, and ROTH, Circuit Judges

ORDER AMENDING OPINION

The Precedential Opinion which was filed on June 26, 2015 shall be amended with respect to footnote 27 which appears on page 37 of the opinion. The footnote as amended shall read in its entirety:

> 27. We do not believe that the no-AG agreement was in fact an "exclusive"

> license. However, since the issue of whether such agreement is an exclusive license is not necessary for our decision here, we will leave its determination for another day.

This amendment does not alter the original filing date of the opinion and the Court's judgment.

By the Court,

/s/ Anthony J. Scirica
Circuit Judge

Date: September 23, 2015