No. _____

In the
Supreme Court of the United States

WYETH LLC, WYETH PHARMACEUTICALS, INC., WYETH-WHITEHALL PHARMACEUTICALS LLC, WYETH PHARMACEUTICALS CO., TEVA PHARMACEUTICAL INDUSTRIES LTD., and TEVA PHARMACEUTICALS USA, INC.,
Petitioners,

v.

RITE AID CORP., RITE AID HDQTRS. CORP., MAXI DRUG INC., ECKERD CORP., JCG (PJC) USA LLC, WALGREEN CO., KROGER CO., SAFEWAY INC., SUPERVALU, INC., HEB GROCERY CO. LP, AMERICAN SALES CO. LLC, GIANT EAGLE, INC., MEIJER, INC., MEIJER DISTRIBUTION, ROCHESTER DRUG CO-OPERATIVE, INC., et al., AFL-AGC BUILDING TRADES WELFARE PLAN, et al., PAINTERS DISTRICT COUNCIL NO. 30 HEALTH & WELFARE FUND, and MEDICAL MUTUAL OF OHIO,
Respondents.

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

PETITION FOR WRIT OF CERTIORARI

ROBERT A. MILNE
WHITE & CASE LLP
1221 Sixth Avenue
New York, NY 10020
(212) 819-8200
rmilne@whitecase.com
Counsel for Wyeth LLC, et al.

JAY P. LEFKOWITZ, P.C.
Counsel of Record
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4800
lefkowitz@kirkland.com
Counsel for Teva Pharm. Indus. Ltd., et al.

(*Additional Counsel Listed on Inside Cover*)

November 20, 2017

RAJ S. GANDESHA
BRYAN D. GANT
SHERYN GEORGE
WHITE & CASE LLP
1221 Sixth Avenue
New York, NY 10020
Counsel for Wyeth LLC, et al.

JOHN C. O'QUINN
MICHAEL D. SHUMSKY
JONATHAN D. JANOW
MATTHEW D. ROWEN
KIRKLAND & ELLIS LLP
655 Fifteenth Street NW
Washington, DC 20005
Counsel for Teva Pharm. Indus. Ltd., et al.

QUESTION PRESENTED

In *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), this Court held that a patentee who settles an infringement suit by making a "large" and "unexplained" payment to an alleged infringer in exchange for the competitor's agreement to refrain from entering the market is not protected by the antitrust immunity patentees otherwise enjoy. *Actavis* made clear, however, that its holding should not be construed as impinging upon any other "right" that the patent laws grant patentees, "whether expressly or by fair implication." *Id.* at 2233.

One such right granted by the patent laws is the right to grant a competitor an exclusive license—*i.e.*, an authorization allowing the competitor to *enter* the market before patent expiry in exchange for payment *from* the competitor. *See* 35 U.S.C. §261. Despite *Actavis*' clear admonition that such rights should be respected, and notwithstanding the obvious differences between an exclusive license and the kind of "reverse payment" *Actavis* addressed, the Third Circuit held that a patentee's decision to settle patent litigation by granting an exclusive license to the alleged infringer may trigger antitrust scrutiny, even when the license allows the competitor to enter the market before patent expiry, and even when the competitor provides robust consideration in exchange for its license.

The question presented is:

Whether a patentee's grant of an exclusive license to settle a single patent dispute may give rise to antitrust liability notwithstanding 35 U.S.C. §261.

PARTIES TO THE PROCEEDING

Petitioners, the Appellees below, are Wyeth LLC, Wyeth Pharmaceuticals, Inc., Wyeth-Whitehall Pharmaceuticals LLC (now known as Pfizer Pharmaceuticals LLC), Wyeth Pharmaceuticals Company, Teva Pharmaceutical Industries Ltd., and Teva Pharmaceuticals USA, Inc.

Respondents, the Appellants below, are Rite Aid Corp., Rite Aid Hdqtrs. Corp., Maxi Drug Inc., Eckerd Corp., JCG (PJC) USA LLC, Walgreen Co., Kroger Co., Safeway Inc., Supervalu, Inc., HEB Grocery Co. LP, American Sales Co. LLC, Giant Eagle, Inc., Meijer, Inc., Meijer Distribution, Direct-Purchaser Class Plaintiffs Rochester Drug Co-Operative, Inc., et al., End-Payor Class Plaintiffs AFL-AGC Building Trades Welfare Plan, et al., Painters District Council No. 30 Health & Welfare Fund, and Medical Mutual of Ohio.

CORPORATE DISCLOSURE STATEMENT

Petitioner Teva Pharmaceuticals USA, Inc. is an indirect wholly-owned subsidiary of petitioner Teva Pharmaceutical Industries Ltd. through the following parent companies: 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.

Petitioners Wyeth LLC, Wyeth Pharmaceuticals, Inc., Wyeth-Whitehall Pharmaceuticals LLC (now known as Pfizer Pharmaceuticals LLC), and Wyeth Pharmaceuticals Company are indirect wholly-owned subsidiaries of Pfizer Inc. Pfizer Inc. has no parent corporation and no publicly held corporation owns 10% or more of Pfizer Inc.'s stock.

TABLE OF CONTENTS

APPENDIX

TABLE OF AUTHORITIES

Cases

Constitutional Provisions

Statutes

Other Authorities

PETITION FOR WRIT OF CERTIORARI

One of the oldest and most celebrated facets of the American legal system is that it rewards innovation by granting inventors a limited-duration monopoly. *See* U.S. Const. art. I, §8, cl. 8 (granting Congress "Power" "To promote the Progress of Science … by securing for limited Times to … Inventors the exclusive Right to their respective … Discoveries"). Yet from the very beginning, the patent system that evolved from that constitutional imperative has sat in tension with fundamentally American preoccupations; after all, it "was a monopoly … that sparked the Revolution." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 7 (1966). Balancing the need to reward innovation with the demands of a competitive economy thus has been a feature of the patent system for more than two centuries.

Over time, the Legislative and Judicial branches have established a stable equilibrium that fosters both innovation and competition. The decision below upends that balance and, if allowed to stand, would fundamentally alter our patent system. At its core, a patent grants its owner the right to *exclude* others from the market for a period of time. Yet that is not all a patent does. Because the option to exclude necessarily implies the right to *include*, the Patent Act explicitly grants patentees the right to let others practice the protected invention during the patent's term in exchange for royalties.

These corollary rights—to exclude all or include some—often combine in the form of an "exclusive license," through which the patentee allows one (and only one) competitor to make or sell a version of the

patented invention, usually in exchange for a fee. This Court has recognized and enforced patentees' right to grant exclusive licenses—even ones that exclude the patentee itself from practicing its own invention—for more than a century. And today, the right to grant an exclusive license remains expressly codified in the Patent Act. *See* 35 U.S.C. §261.

Despite this robust and previously unquestioned authority, the court below concluded that a patentee's decision to grant an exclusive license as part of a litigation settlement can give rise to antitrust scrutiny—and thus potential treble damages—under the Sherman Act. The Third Circuit was convinced that its holding followed from this Court's recent decision in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). But a review of *Actavis* reveals the Third Circuit's error.

While lower courts have described *Actavis* as opaque,[1] two key principles are clear. On the one hand, *Actavis* held that a patentee who settles an

---

[1] *See, e.g.*, *In re Aggrenox Antitrust Litig.*, No. 3:14-md-2516 (SRU), 2015 WL 4459607, at *11 (D. Conn. July 21, 2015) (lamenting that *Actavis* provides "limited guidance" on numerous core issues, thus creating the "clear potential for a disruptive effect on very large-scale litigation"); *In re Loestrin 24 FE Antitrust Litig.*, 45 F. Supp. 3d 180, 194-95 (D.R.I. 2014) (referring to *Actavis* as a "confusing Supreme Court case, complicated by principles of law that seem at cross purposes"), *vacated*, 814 F.3d 538 (1st Cir. 2016); *see also* Kevin D. McDonald, *Because I Said So: On the Competitive Rationale of* FTC v. Actavis, 28 Antitrust 36, 37 (2013) ("Except for telling us that the FTC won and that the rule of reason must govern, [*Actavis*] neither addresses the hard questions necessary to its conclusion, nor provides useful guidance going forward.").

infringement dispute by making a "large" and "unexplained" payment *to* an alleged infringer is not protected by the antitrust immunity patent holders generally enjoy. *Id.* at 2230-37. On the other hand, *Actavis* made clear that this carefully circumscribed holding was not intended to expose all patent-related activity to rule-of-reason review. Indeed, *Actavis* took pains to limit its holding to conduct which, like a large and unexplained monetary payment to "a party with no claim for damages," is *not* authorized by any "patent statute" either "expressly or by fair implication." *Id.* at 2233.

That line of demarcation is entirely consistent with the equilibrium Congress and the courts have crafted over generations. Because the Patent Act does *not* authorize patentees to pay would-be competitors simply to stay off the market, *Actavis* held that a patent's mere existence does not foreclose the ordinary operation of the antitrust laws when a patentee engages in such conduct. But granting an exclusive license is totally different from the conduct addressed in *Actavis*, because the Patent Act expressly protects that right. Indeed, *Actavis* held that the kind of "reverse payments" it addressed could be subject to antitrust attack only after the United States assured the Court that such payments were entirely *unlike* "an exclusive license," which "is expressly authorized by the Patent Act, in Section 261 of Title 35." Oral Arg. Tr. at 3-4, *FTC v. Actavis, Inc.*, No. 12-416 (U.S. Mar. 25, 2013) ("*Actavis* Oral Arg.") (Malcolm L. Stewart, Deputy Solicitor General).

The decision below cannot be squared with the government's assurances or this Court's reasoning in

Actavis. In contrast to *Actavis*' allegation that a patentee effectively had bribed a competitor *to stay off the market*, the only allegation here is that the patent holder granted its competitor exclusive licenses *to enter the market* before patent expiry in exchange for robust consideration from the competitor (namely, and as in virtually all patent-licensing scenarios, a significant royalty stream from sales of the licensed product). Given the express Congressional grant of authority to offer such exclusive licenses, 35 U.S.C. §261, this type of licensing agreement to settle patent cases is routine—and, until recently, its lawfulness had "never been questioned." *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124, 127 (1938). Put simply, the Third Circuit's contrary conclusion conflicts directly with decades of patent law and this Court's jurisprudence.

It is also destabilizing. As this Court recently emphasized, rule-of-reason review is an "elaborate inquiry" that "produces notoriously high litigation costs and unpredictable results." *Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2411 (2015). The Third Circuit's holding, however, subjects licensing agreements premised on rights *expressly conferred* by the Patent Act to precisely that elaborate and costly unpredictability. In addition to contradicting basic principles of patent law, that conclusion is also plainly inconsistent with *Actavis*, which disavowed any "inten[tion] to alter th[e] understanding" that "commonplace," "familiar," and "traditional" patent settlement terms are immune from "antitrust liability." *Actavis*, 133 S. Ct. at 2233.

This problem is not confined to pharmaceutical settlements or the Third Circuit. The Third Circuit's holding would apply with equal force to any other patent infringement settlement, whether involving pharmaceuticals, automobiles, electronics, or consumer goods. And in light of the Sherman Act's nationwide venue provision, antitrust plaintiffs will flock to the Third Circuit, which also happens to be the home of many of the Nation's leading pharmaceutical and biotechnology companies.

This Court's intervention is imperative.

OPINIONS BELOW

The Third Circuit's opinion is reported at 868 F.3d 231 and reproduced at Appendix ("Pet.App.") 1-79. An earlier opinion of the Third Circuit finding appellate jurisdiction is reported at 855 F.3d 126 and reproduced at Pet.App.80-121. The district court's opinion, which is unreported, is reproduced at Pet.App.122-81.

JURISDICTION

The Third Circuit issued its opinion on August 21, 2017. Pet.App.1-79. This Court has jurisdiction under 28 U.S.C. §1254(1).

CONSTITUTIONAL AND 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."

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. Statutory and Factual Background

"The point of patent law is to grant limited monopolies as a way of encouraging innovation." *Actavis*, 133 S. Ct. at 2238 (Roberts, C.J., dissenting). Innovation is not always, or even generally, the result of a spark; more often it is the outgrowth of tremendous investment. That is particularly true in the pharmaceutical industry, where the cost of innovation is staggering. Indeed, developing a new FDA-approved medicine costs several *billion* dollars on average. *See* Matthew Herper, *The Cost of Creating A New Drug Now $5 Billion, Pushing Big Pharma To Change*, Forbes (Aug. 11, 2013), https://tinyurl.com/yc9jkjdj.

The reward for successful innovation—and the incentive to continue to invest the substantial time, effort, and money underlying it—is a patent, including the right to protect and enforce that patent by excluding all others from profiting from the invention during the patent's life. Of course, nothing in the patent laws requires patentees to bar every would-be competitor from practicing the protected art; to the contrary, a patentee may license its patent to prospective competitors and thereby permit others to manufacture or sell otherwise-potentially infringing

products, sometimes in exchange for a fee. Specifically, a patentee "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 Petitioner Wyeth. Wyeth sells Effexor IR and Effexor XR, the immediate-release and extended-release forms of the compound venlafaxine hydrochloride, which the FDA has approved to treat depression. Wyeth's patent covering the active ingredient in venlafaxine hydrochloride expired on June 13, 2008. Each of Wyeth's three patents protecting the extended-release form expired on March 20, 2017. Pet.App.18.

Petitioner Teva, a generic drug manufacturer, wished to manufacture generic versions of venlafaxine hydrochloride. 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 preemptive patent challenges before receiving final FDA approval or marketing a generic drug.

To do so, the generic company files an Abbreviated New Drug Application ("ANDA") with what is known as a "Paragraph IV" certification. The "Paragraph IV" certification alleges that the brand-name drug's "patent is invalid or will not be infringed" by the generic version, and applicants who make such certifications must notify the patentee of any such 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), so the brand company often sues for infringement immediately upon receiving the challenger's notification. In the ensuing litigation, the generic company may 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 an ANDA with Paragraph IV certifications for generic venlafaxine hydrochloride with the FDA in or around December 2002. Pet.App.19. Wyeth then filed suit for patent infringement against Teva in the U.S. District Court for the District of New Jersey. *Id.* Teva, in turn, asserted noninfringement and challenged the validity of the patents covering Effexor XR. *Id.*

Wyeth and Teva ultimately settled in October 2005. Pet.App.19-20. Unlike in *Actavis*, the patentee (Wyeth) did not pay one penny to the alleged infringer (Teva). Instead, the parties negotiated two early-entry patent licenses permitting Teva to market generic versions of Effexor before the relevant patents were scheduled to expire. Specifically:

- Wyeth granted Teva an exclusive license to market a generic version of Effexor XR by July 1, 2010, nearly *seven years* before the relevant patents expired. Pet.App.19-20.

- Wyeth further agreed that the generic Effexor XR license would be exclusive even as against Wyeth itself during Teva's 180-day first-filer period. Under this term, Wyeth could continue to market its *branded* product during the 180-day period, but it could not market an "authorized generic" version of Effexor XR—*i.e.*, a product sold under the brand's original new drug application, but marketed as a generic—during Teva's 180-day exclusivity period. Pet.App.20.
- Wyeth also granted Teva an exclusive license to market a generic version of Effexor IR two years before the end of Wyeth's lawful period of patent exclusivity for the instant-release formulation of the drug. Wyeth further agreed not to launch an "authorized generic" version to compete with Teva's instant-release generic during that two-year period. Pet.App.20, 97.
- In return for these exclusive licenses, Teva agreed to pay Wyeth substantial royalties. With regard to the extended-release generic, Teva would pay Wyeth 15% royalties during its 180-day exclusivity period. If Wyeth chose not to introduce an authorized generic after 180 days and no other generic entered the market, Teva would pay Wyeth 50% royalties for the next 180 days and 65% royalties thereafter for up to 80 months. With regard to the instant-release generic, Teva agreed to pay Wyeth 28% royalties during the first year and 20% during the next year. Pet.App.20.

Wyeth submitted the agreement to the Federal Trade Commission ("FTC") and the U.S. Department of Justice ("DOJ"), as required by an earlier consent

decree and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified at 21 U.S.C. §355). Pet.App.20-21. Neither DOJ nor the FTC—the latter of which has challenged a number of patent settlement agreements through internal actions, lawsuits in federal court, or both—filed any action objecting to the settlement, though the FTC did reserve its right to take later action should circumstances warrant it. *Id.*

Over the next few years, Wyeth initiated patent-infringement actions against several other companies that sought to market generic versions of Effexor XR. None of these suits resulted in an order invalidating the Effexor XR patents, and several resulted in *Markman* rulings favorable to Wyeth before the cases settled.[2] Pet.App.21.

B. Proceedings Below

Beginning in May 2011, several alleged direct purchasers of Effexor XR (*i.e.*, companies that allegedly purchased the drugs directly from Wyeth for the purpose of reselling them at wholesale prices to indirect purchasers) filed class-action antitrust actions in the U.S. District Court for the Southern District of Mississippi. Those cases were ultimately consolidated and transferred to the District of New Jersey. *Id.*

---

[2] One of the defendants in those subsequent cases, Apotex, pursued its Effexor XR patent case through the bulk of a trial on infringement *and* inequitable conduct, but settled for no payment as well. Plaintiffs do not allege the Wyeth-Apotex settlement contains a reverse payment.

Following consolidation and transfer, the alleged direct purchasers filed an amended consolidated class-action complaint.[3] In addition, a group of alleged end payors (*i.e.*, parties claiming to be last in the drug's distribution chain, who allegedly paid for or purchased Effexor from a retailer, not Wyeth) filed their own class-action complaint; several alleged individual retailers brought suit as well, as did two individual alleged third-party payors. Pet.App.22. Each complaint raised two broad types of claims. First, Plaintiffs brought monopolization claims against Wyeth alone under Section 2 of the Sherman Act, 15 U.S.C. §2, and state law. These claims broadly alleged that Wyeth fraudulently obtained and improperly enforced the three patents covering Effexor XR. Pet.App.22. Second, Plaintiffs brought claims against both Wyeth and Teva under Section 1 of the Sherman Act, 15 U.S.C. §1, and state law, alleging that the settlement agreement that ended the Effexor infringement litigation constituted an unlawful restraint of trade. Pet.App.22.

As to these latter claims, Plaintiffs alleged that Wyeth's agreement not to introduce its own authorized generic during Teva's statutory exclusivity period "constituted a substantial, net payment by Wyeth to Teva in exchange for Teva agreeing to delay generic entry much later than it otherwise would have," because the license did not permit Teva to enter the generic market immediately. Pet.App.45.

---

[3] The consolidated Effexor litigation was decided together with a separate set of consolidated cases raising *Actavis* claims against the brand-name manufacturer of Lipitor, a patented statin, and a generic challenger to the underlying patents. *See* Pet.App.7-18.

Focusing on the value of the exclusivity provision to the alleged infringer, Plaintiffs claimed the license "amount[ed] to over $500 million in value." *Id.* They made no additional factual allegations to support these claims.

In April 2012, Wyeth and Teva each moved to dismiss under Federal Rule of Civil Procedure 12(b)(6). Pet.App.22. The district court initially stayed proceedings pending this Court's decision in *Actavis*. After *Actavis* was decided in June 2013, the district court vacated the stay, reopened the case, and requested supplemental briefing on the pending motions to dismiss. The alleged direct purchasers filed an amended complaint, which Wyeth and Teva again sought to dismiss under Rule 12(b)(6). *Id.*

On October 6, 2014, the district court granted in part and denied in part Defendants' motions to dismiss. The district court denied Wyeth's motion to dismiss the monopolization claims against it. But the district court granted—with prejudice—Defendants' motions to dismiss Plaintiffs' antitrust challenges to the Effexor settlement. Pet.App.23. Plaintiffs appealed that latter decision to the Third Circuit. *Id.*

While the appeal was pending, the Third Circuit decided *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015), *cert. denied*, 137 S. Ct. 446 (2016) (mem.). The plaintiffs in *King Drug* were direct purchasers of Lamictal, a drug used to treat bipolar disorder. As part of an earlier patent-litigation settlement, Lamictal's manufacturer GlaxoSmithKline (GSK) agreed not to compete with Teva in the market for generic Lamictal during the 180-day statutory exclusivity period for the first-filed

generic. *Id.* at 397; *see* 21 U.S.C. §355(j)(5)(B)(iv).[4] In other words, GSK settled its dispute with Teva by doing what the Patent Act expressly authorizes: It granted an early-entry license to use its patent and made that license exclusive by precluding all other manufacturers—including GSK itself—from launching their own generic version of Lamictal during the license period. The *King Drug* plaintiffs nonetheless alleged that the Lamictal settlement "worked to maintain supracompetitive prices in the Lamictal market," Pet.App.31, and thus constituted an actionable reverse payment under Sections 1 and 2 of the Sherman Act within the meaning of *Actavis*. *King Drug*, 791 F.3d at 397-98.

The Third Circuit agreed. It held in *King Drug* that a brand manufacturer's agreement not to introduce its own generic "may be subject to antitrust scrutiny under the rule of reason" in cases where "it represents an unexplained large transfer of value from the patent holder to the alleged infringer." *Id.* at 403. The court also held that the plaintiffs—who alleged only that (1) the Lamictal settlement provided the generic manufacturer with "many millions of dollars of additional revenue" and (2) GSK otherwise had "an incentive to launch its own authorized generic"—plausibly alleged that the license term constituted a "large and unjustified" reverse payment within the meaning of *Actavis*. *Id.* at 409-10.

The *King Drug* defendants petitioned this Court for certiorari. *See* Pet. for Cert., *SmithKline Beecham*

---

[4] The generic Lamictal license in *King Drug* also extended into GSK's FDA-granted period of pediatric exclusivity. 791 F.3d at 397; *see* 21 U.S.C. §355a.

Corp. v. King Drug Co. of Florence, No. 15-1055 (U.S. Feb. 19, 2016). The Court then called for the views of the Solicitor General, who conceded that the patent laws expressly permit patentees to grant exclusive licenses but argued principally that the "no-AG agreement" there could not "be characterized as an exclusive patent license because it extended beyond the term of GSK's patent" into GSK's period of pediatric exclusivity—a six-month period that bars the FDA from approving a generic version of the brand-name drug, but which does not begin until the patent has expired and therefore extends beyond the scope of the patent's protection (and that of the Patent Act). Br. for the United States as Amicus Curiae at 12, *SmithKline Beecham Corp. v. King Drug Co. of Florence*, No. 15-1055 (U.S. Oct. 3, 2016). Consistent with the Solicitor General's assertion that *King Drug* therefore did not present any conflict between the Patent Act's authorization for exclusive licenses and the Third Circuit's rule-of-reason approach, the Court denied certiorari. 137 S. Ct. 446 (Nov. 7, 2016) (mem.).

Relying on *King Drug*, the court below held that the exclusive licensing arrangement between Wyeth and Teva could be subject to antitrust attack notwithstanding the patent statute's explicit authorization for exclusive licenses like the one granted here, and even though the agreement between Wyeth and Teva (unlike the agreement in *King Drug*) did not extend beyond the life of the patent. Pet.App.46-49.[5] The court below likewise held that

[5] Before reaching the merits, the Third Circuit concluded that it, not the Federal Circuit, was the proper forum to hear the appeal. Pet.App.80-121; *see* 28 U.S.C. §§1295(a)(1), 1338(a).

Plaintiffs plausibly alleged that the Effexor settlement constituted a "large and unjustified" reverse payment within the meaning of *Actavis* even though, in stark contrast to *Actavis*, the only transfer of funds contemplated by the settlement here was a customary payment of royalties by a licensee (Teva) to the patentee (Wyeth). Pet.App.49-52.

REASONS FOR GRANTING THE PETITION

The decision below conflicts with more than a century of settled patent law. Since the Founding, patentees have held the power to unilaterally decide how, when, where, and whom to exclude from the market. And because the right to exclude necessarily includes the right to include, the patent laws long have granted patentees plenary authority to grant licenses—including exclusive licenses—to make, use, or sell the patented invention.

Actavis preserved this longstanding feature of the patent laws by drawing a sharp line between conduct that is authorized by patent law (*e.g.*, the grant of an exclusive license in exchange for royalty payments) and therefore immune from antitrust challenges, and conduct that is not so authorized (*e.g.*, an "unexplained" and "large" payment *from* a patent holder *to* an alleged infringer, which inverts the ordinary flow of payments in both customary patent settlements and traditional patent-licensing agreements). *See* 133 S. Ct. at 2231. The reverse payment in *Actavis* thus was subject to rule-of-reason review because there was not "any patent statute that … grant[s] such a right to a patentee, whether expressly or by fair implication." *Id.* at 2233.

The opposite is true here. In contrast to the reverse-payment settlement in *Actavis*, the patentee here exercised its *expressly conferred* statutory right to grant an exclusive license—a right that, until recently, had "never been questioned," *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124, 127 (1938)—and received hefty royalties in return. To be sure, the licenses here could have been even *more* procompetitive—the alleged infringer could have been allowed to go to market immediately, or the patentee could have insisted on retaining its ability to introduce its own authorized generic whenever it wanted. But that the patentee chose not to do so does not transform an otherwise immune patent settlement into a suspect reverse payment. As an initial matter, patentees have always been understood to possess the statutory authority to grant licenses that are exclusive even as to themselves. *See, e.g.*, *Waterman v. Mackenzie*, 138 U.S. 252, 256 (1891). And there is no requirement that an exclusive license must be as procompetitive as possible to escape antitrust scrutiny. *See Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, Inc.*, 540 U.S. 398, 415-16 (2004). To the contrary, the Patent Act grants patentees the right to decide when (and on what terms) to allow competitors to enter the market, just like they may decide when (and on what terms) to exclude competitors. If the straightforward exclusive licenses at issue here can be subjected to antitrust attack, then every patent license is vulnerable.

The Third Circuit's fundamental assumption—that any exchange of consideration to end a patent-infringement suit may be unlawfully anticompetitive, regardless of which direction the consideration flows,

focusing principally on the unremarkable fact that an exclusive license may be valuable to the licensee, and notwithstanding the fact that the Patent Act expressly authorizes the very type of conduct at issue—casts doubt on the viability not only of patent settlements but of licensing arrangements generally. Routine patent-licensing activity is a critical part of the American economy; indeed, it is impossible to imagine any industry that does not depend on patent licenses (exclusive or otherwise) to use otherwise-patented technology. The Third Circuit's sweeping decision to subject such common, previously-unchallenged arrangements to antitrust review threatens to make these routine arrangements a thing of the past. And while the Third Circuit may have believed its approach was uniquely applicable to the Hatch-Waxman context, there is nothing specific to the pharmaceutical area that would stop the Third Circuit's rule from affecting other industries.

This is not a problem that can tolerate further percolation in the circuit courts. The Third Circuit is home to the highest concentration of the Nation's leading pharmaceutical companies and, given its consistently broad interpretations of the antitrust laws in drug-related cases, it stands poised to become ground zero for the plaintiffs' bar's assault on the industry. Nor will the usual happenstance that dictates the venue of federal litigation pose any barrier to Third Circuit predominance. Because antitrust plaintiffs may select any district court in the Nation in which to file suit, 15 U.S.C. §22, and in light of the Third Circuit's increasingly strident rulings, plaintiffs asserting *Actavis* claims will flock there to file suit. Rather than allow the Third Circuit to

override a century of settled law, this Court should intervene now to prevent the chilling of beneficial patent settlements and licensing arrangements and to restore patent policy to its proper place.

I. The Decision Below Conflicts With Foundational Principles Of Patent Law.

A. Patent law is an "exception to the general rule against monopolies and to the right to access to a free and open market." *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). Virtually every patent-law question therefore implicates a tug-of-war between our Nation's belief in robust competition and the constitutional imperative to spur continued innovation by ensuring that inventors reap the benefits of their creative endeavors. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

Our law resolves this tension through a carefully calibrated equilibrium. *See, e.g.*, *Actavis*, 133 S. Ct. at 2231 (cataloging cases recognizing need to "balance" antitrust policy and patent law). First, patents are not granted lightly. To ensure that the "rights and welfare of the community [are] fairly dealt with and effectually guarded," *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328 (1858), the standards for patentability are exacting, and these "prerequisites to obtaining a patent are strictly observed." *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230 (1964).

Yet for those inventors who manage to clear the high bar to patentability, certain legal "superpowers" await. *Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2406-07 (2015). "The grant of a patent is the grant of

a statutory monopoly,"[6] *Sears, Roebuck*, 376 U.S. at 229, so once a patent is granted, "the general rule is absolute freedom in the use or sale of rights under the patent laws of the United States." *E. Bement & Sons v. Nat'l Harlow Co.*, 186 U.S. 70, 91 (1902). That not only means patentees have the right to *prevent* would-be competitors from practicing the protected invention, *see Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980); it means patentees have an unfettered right to *permit* competitors to enter the market if they so choose. *Kimble*, 135 S. Ct. at 2407; *see also Gen. Talking Pictures*, 305 U.S. at 127 ("The practice of granting licenses for a restricted use is an old one, [and] its legality has never been questioned." (internal citations omitted)). In other words, patent rights—like virtually all other rights—are alienable at the sole election of the patentee.

Consistent with that understanding, this Court long has held that traditional patent-licensing agreements are immune from antitrust review so long as the license otherwise falls within the four corners of the patent. The decision in *United States v. General Electric Co.*, 272 U.S. 476 (1926), is particularly instructive. In *General Electric*, the patentee granted its would-be competitor a license that was subject to a minimum resale price requirement, with the intended effect of allowing the patentee to maintain higher prices for its original product—a type of price-fixing constituting a *per se* violation of the antitrust laws under then-current law. *Id.* at 478-79. Like Plaintiffs

---

[6] Of course, a patent "monopoly" is not the same as an *economic* monopoly. *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 31, 45 (2006).

here, the government in *General Electric* argued that the Patent Act could not absolve a license term which, outside the patent context, plainly would violate antitrust law.

This Court, however, rejected that contention. "[T]he patentee may grant a license to make, use, and vend articles under the specifications of his patent *for any royalty, or upon any condition the performance of which is reasonably within the reward which the patentee by the grant of the patent is entitled to secure*." *Id.* at 489 (emphasis added); *see also United States v. Line Material Co.*, 333 U.S. 287, 311-12 (1948) ("If the objection is made that a price agreement between a patentee and a licensee equally restrains trade, the answer is not that there is no restraint in such an arrangement but … that [the] restraint *accords with the patent monopoly granted by the patent law*." (emphasis added)).

More recent cases reaffirm this well-established rule. *See, e.g.*, *Simpson v. Union Oil Co. of Cal.*, 377 U.S. 13, 24 (1964) ("The patent laws which give a … monopoly on 'making, using, or selling the invention' are in pari materia with the antitrust laws *and modify them pro tanto*." (emphasis added)); *cf. Credit Suisse Sec. (USA) LLC v. Billing*, 551 U.S. 264, 275 (2007) (antitrust laws must yield where there is a "clear repugnancy" with another law or the two are "clearly incompatible"). And this Court acknowledged such authority in *Actavis*, noting that *General Electric* "permitted a single patentee to grant to a single licensee a license" despite the presence of a "minimum resale price requirement." *Actavis*, 133 S. Ct. at 2232. Nearly a century of precedent thus makes clear that,

where a right expressly conferred by the Patent Act otherwise would conflict with general antitrust principles, the former controls.

B. The Third Circuit's decision directly conflicts with this settled law. The challenged feature of the Effexor settlement is a so-called "no-AG agreement," Pet.App.47-48, under which Wyeth granted Teva exclusive licenses to market generic versions of Effexor IR and XR (that were exclusive even as against Wyeth itself) in exchange for Teva's agreement to pay Wyeth significant royalties from the sale of the licensed products. Pet.App.19-20. These are classic exclusive licenses in which ample consideration (in the form of royalties) flows from the licensee to the patent holder in exchange for the antecedent license to enter the market before the patent's expiration. *See, e.g.*, *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." (emphasis added)); *Textile Prods. v. Mead Corp.*, 134 F.3d 1481, 1484 (Fed. Cir. 1998) ("[A]n exclusive license is 'a license to practice the invention … accompanied by the patent owner's promise that others shall be excluded from practicing it within the field of use wherein the licensee is given leave.'").

Rather than engage with more than a century of precedents that, without exception, have shielded such licenses from antitrust review, the Third Circuit instead held that this Court's decision in *Actavis* (as interpreted by the appellate court's earlier decision in

King Drug) effectively tied its hands. *See* Pet.App.46-47; *see also King Drug*, 791 F.3d 388, *cert. denied*, 137 S. Ct. 446 (2016) (mem.). Even a cursory review of *Actavis* reveals the Third Circuit's error.

Though *Actavis* has been criticized as opaque, *see supra* note 1, the Court at least made clear that its decision was not intended to disrupt the preceding century-plus of established patent-law rules. *Actavis* took pains to emphasize that "there is nothing novel about our approach," 133 S. Ct. at 2233, and consistent with that admonition, it explained that the central inquiry in these cases is "whether 'the patent statute specifically gives a right' to restrain competition in the manner challenged." *Id.* at 2231. In *Actavis* itself, the answer to that question was no. No "patent statute" authorizes a patentee to make a monetary payment to a potential competitor in exchange for an agreement to stay off the market, "whether expressly or by fair implication." *Id.* at 2233.

The opposite is true here. In contrast to the statutorily unauthorized patentee-to-infringer monetary payment in *Actavis*, the Patent Act specifically authorizes patentees to "grant and convey an exclusive right under [their] patent, or patents, to the whole or any specified part of the United States," 35 U.S.C. §261, and the entirely normal payment in such cases consists of royalties from the potential infringer to the patentee. *Gen. Elec.*, 272 U.S. at 489. Indeed, *Actavis* held that the reverse payment at issue in that case could be subject to antitrust scrutiny only after the Executive Branch assured this Court that such reverse payments were wholly distinct from "an exclusive license" which "is expressly authorized by

the Patent Act, in Section 261 of Title 35," *Actavis* Oral Arg. Tr. at 3-4, and pursuant to which the alleged infringer often pays the patentee for its license to practice the patented art (rather than *vice versa*). *See also id.* at 27.[7] It therefore should come as no surprise that this Court has *never* held that a patent holder violated the antitrust laws simply by granting an exclusive license to practice the patent at issue.

Given this Court's longstanding recognition that the Patent Act expressly authorizes exclusive licenses (and that exclusive licenses may be exclusive even as to the patentee itself, *see Waterman*, 138 U.S. at 256), *Actavis*' clear statement that it was not intended to disrupt settled rights under the patent laws should have been the end of the matter. The Third Circuit nonetheless ignored all of this by declaring that the challenged settlement was effectively identical to the reverse payment in *Actavis*, purportedly because the grant of an exclusive license transferred value from the patentee to the alleged infringer that would limit competition during the license term. Pet.App.46-47; *see also King Drug*, 791 F.3d at 409-10. The simple

---

[7] "Mr. Weinberger: [I]f someone was entering into a license agreement with … someone who had a product that they claimed did not infringe the patent, they sat down, negotiated a license and resolved it—

Justice Sotomayor: But there, you know that they're not sharing the profits.

Mr. Weinberger: Yes.

Justice Sotomayor: Meaning there you know that a—a product's been licensed and the—that's normal. The infringer is now paying the other side money to sell that product…. A reverse payment suggests something different, that they're sharing profits."

answer is: Of course it did. *Every* license granted as part of a settlement agreement, whether exclusive or not, transfers value from the patentee to the alleged infringer by allowing it to enter the market. But as this Court made clear in *Actavis*, the mere transfer of value from a patentee to an alleged infringer does not convert a valid license into an invalid reverse payment. *See, e.g.*, *Actavis*, 133 S. Ct. at 2236 (noting that "fair value"—not "no value"—agreements do not raise the same competitive concerns as do large reverse payments).

The Third Circuit's twin observations that an exclusive license to practice a patent (a) is valuable and (b) restricts competition thus missed *Actavis*' point completely. Whenever a patentee issues one party a license but not others, there is less competition than there otherwise might have been had the patentee licensed everybody under the sun or dedicated its patent to the public. *See* 35 U.S.C. §253(b). In short, there is always a better deal to be had—but that's not the test for whether the deal struck by the parties violates the antitrust laws. *See Trinko*, 540 U.S. at 415-16 (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").

Rather, as this Court emphasized in *Actavis*, the relevant question is not merely whether there is a "payment" in some abstract sense of the word or whether an agreement has supposedly "anticompetitive" potential, Pet.App.54, but instead whether the conduct contemplated by the agreement is *within the powers Congress granted patentees in the*

Patent Act. *See Actavis*, 133 S. Ct. at 2232 (distinguishing a practice that "accords with the patent monopoly granted by the patent law" from an agreement that is "outside the patent monopoly"); *see also, e.g.*, *United States v. U.S. Gypsum Co.*, 333 U.S. 364 (1948) (defendants' monopolization of an entire industry through price control and regulation of distribution among all licensees was subject to antitrust scrutiny, because not within patent rights); *Line Material*, 333 U.S. at 311 (two patentees' cross-licensing their related patents, subject to resale price restrictions and other limitations, was subject to antitrust scrutiny, because the resulting combination "impeded [competition] to a greater degree than where a single patentee fixes prices for his licensees").

The challenged settlement term here is thus totally unlike the settlement in *Actavis*. By granting a license—even an exclusive license—that allows a competitor to practice the patent by producing and selling a generic version of the product, a patentee exercises no "market power" beyond what the Patent Act expressly authorizes her to exercise. *Actavis*, 133 S. Ct. at 2236. And indeed, the exclusive licensing arrangement here is *pro*competitive: As *Actavis* itself recognized, "settlement on terms permitting the patent challenger to enter the market before the patent expires would … bring about competition … to the consumer's benefit." *Id.* at 2234.[8] The licenses

[8] *See also* U.S. Dep't of Justice & Fed. Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* 5 (Apr. 6, 1995), https://tinyurl.com/yd6dm6mt (exclusive licenses "give a licensee an incentive to invest in the commercialization and distribution of products embodying the licensed intellectual

here plainly fit that bill: Exercising its explicit rights under the Patent Act, a patentee allowed a competitor to enter the market nearly *seven years* (in the case of Effexor XR) and *two years* (in the case of Effexor IR) *before* the end of the patent terms, thus resulting in a far more competitive market environment—and all the consumer benefits that come with it.

To be sure, the generic Effexor licenses did not take effect immediately, and they were exclusive even as to Wyeth for a narrow period, so they could have been even more procompetitive. But again, this Court has made clear that a procompetitive agreement (like one allowing a competitor to enter the market long before patent expiry) is not subject to antitrust challenge simply because an even more procompetitive agreement could have been crafted. *See Trinko*, 540 U.S. at 415-16. Moreover, *Actavis* itself emphasized that parties to an infringement dispute may settle in "traditional" ways—"for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration," 133 S. Ct. at 2236-37—and there is hardly a patent settlement more "traditional" than one granting exclusive licenses permitting early market entry on a negotiated date in exchange for royalties.

Complaining, as Plaintiffs do here, that the Effexor license was not as favorable to potential purchasers as it could have been (because it was exclusive even as to Wyeth and did not go into effect as soon as the ink dried on the settlement) thus

---

property," and thus "allow[] the licensor to exploit its property as efficiently and effectively as possible").

fundamentally misunderstands a century of this Court's antitrust law up to and including *Actavis*. That robust authority makes clear that where, as here, the only agreement (1) was undertaken for the express purpose of protecting (not expanding) the patent, and (2) takes the form of an early-entry licensing arrangement *explicitly authorized by the Patent Act* and long recognized as valid by this Court, the antitrust laws pose no barrier.

* * *

Even the most bullish defenders of the prerogatives of antitrust law have recognized that at least "one clear exception" exists to the application of antitrust law to patentee conduct: "if the Patent Act expressly authorizes a specific practice, then that practice standing alone cannot violate the more general antitrust laws." Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court's* Actavis *Decision*, 15 Minn. J.L. Sci. & Tech. 3, 17 (2014); *see also id.* at 19 (advocating for "[c]loser antitrust scrutiny of practices that threaten competitive harm *but are not expressly authorized by the Patent Act*" (emphasis added)).

This petition asks nothing other than for the Court to clarify that basic point, *i.e.*, that a patentee may exercise at least those rights specifically authorized in the Patent Act without risking antitrust liability or the "notoriously high litigation costs and unpredictable results" of rule-of-reason inquiry. *Kimble*, 135 S. Ct. at 2411. Such clarification is all the more needed given the confusion the lower courts have already expressed about this Court's *Actavis* decision. *See supra* note 1. Lest the "all-encompassing bright-

line rule[s]" of patent law be swallowed whole by case-by-case second-guessing under the rule of reason, *see Kimble*, 135 S. Ct. at 2413, this Court's intervention is imperative.

II. The Third Circuit's Decision Will Profoundly Destabilize Patent Settlements And Licensing Agreements If Left Intact.

This Court has long recognized the "value" and "desirability" of settlements. *E.g.*, *Actavis*, 133 S. Ct. at 2234, 2237. That value is particularly apparent in patent litigation, "which is often inordinately complex and time consuming." *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976). By expeditiously removing complex and resource-intensive cases from overcrowded dockets, patent settlements ease the burden on scarce judicial resources. At the same time, settlements provide the parties another scarce resource—certainty—thus allowing the engines of our economy to focus more on innovation and less on litigation. *See Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1309 (11th Cir. 2003).

The decision below strikes a body blow against these long-settled principles. The Third Circuit held that because it eliminates the risk of patent invalidation, granting a valuable license to an alleged infringer "by way of [a] no-AG agreement" presents "the very anticompetitive harm that the Supreme Court identified in *Actavis*." Pet.App.26-29, 52. But a patent settlement *by definition* eliminates the risk of patent invalidation; otherwise, no patentee ever would settle an infringement suit. The Third Circuit's approach thus risks subjecting all patent settlements to antitrust scrutiny so long as they transfer *any*

"value" from the patentee to the alleged infringer, which many (if not most) "traditional" and "commonplace" settlement forms undoubtedly do. *See Actavis*, 133 S. Ct. at 2233 (compromise of damages not suspect under antitrust laws).

That radical outcome is precisely the opposite of what *Actavis* intended. *Actavis* emphatically declared that it should not be read to "prevent litigating parties from settling their lawsuit." 133 S. Ct. at 2237. Even as it held that reverse-payment settlements could be reviewed under the antitrust laws, *Actavis* thus made clear that "commonplace," "familiar," and "traditional" settlement forms—*e.g.*, a settlement "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," which amply describes the settlement here—should not be subjected to the black box of rule-of-reason review. *Id.* at 2233, 2237.

That is no small concern. As this Court recently explained, it "would prefer not to unsettle stable law," especially law regarding property and contract rights, because "parties are especially likely to rely on such precedents when ordering their affairs." *Kimble*, 135 S. Ct. at 2410-11. Yet the decision below effectively authorizes courts to impose retroactive antitrust liability *at pain of treble damages* for exercising a right this Court has long recognized and Congress specifically granted in the Patent Act. The Third Circuit's decision thus undermines patentees' ability to rely on the word of the courts, the legislature, and their patent grant in ordering their affairs. *See Walker Process Equip., Inc. v. Food Mach. & Chem.*

Corp., 382 U.S. 172, 180 (1965) (Harlan, J., concurring) ("[T]o hold, as we do not, that private antitrust suits might also reach monopolies practiced under patents … might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits.").

After all, there is hardly a more "commonplace" settlement form in the patent context than exclusive licensing agreements. According to a recent study, 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. Thomas R. Varner, *An Economic Perspective on Patent Licensing Structure and Provisions*, 46 Bus. Econ. 229, 237 (Oct. 2011). And in light of the settled law protecting the right of patentees to grant exclusive licenses, *see supra* 18-21; 35 U.S.C. §261, courts have repeatedly and routinely upheld such provisions. *See, e.g.*, *E. Bement & Sons*, 186 U.S. at 94; *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 949 (Fed. Cir. 1993), *cert. denied sub nom. Regents of the Univ. of Cal. v. Genentech, Inc.*, 510 U.S. 1140 (1994) (mem.); *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). The decision below thus threatens to render one of the most "familiar" and "traditional" forms of settling patent disputes a relic of the past, and to thrust patent holders into potentially crippling uncertainty about whether decisions already made will soon be met with copycat antitrust lawsuits seeking massive damage awards.

Nor is the particular license at issue here some sort of outlier. *Actavis* makes that clear. The Government in *Actavis* maintained that "parties to paragraph IV litigation have broad freedom to settle by agreeing upon a compromise date of generic entry," Reply Br. for Pet'r at 8-9, *FTC v. Actavis, Inc.*, No. 12-416 (U.S. Mar. 18, 2013), and the Court expressly adopted that position. *Actavis* accordingly cautioned that parties should still be able to settle infringement disputes and specifically singled out agreements that "allow[] the generic manufacturer to enter the patentee's market prior to the patent's expiration" as one approved form—which, of course, would be effectuated by way of a license. 133 S. Ct. at 2237. That is *precisely* what the Effexor settlement did: It allowed Teva "to enter the patentee's market" nearly *seven years* before the expiration of Wyeth's patents for Effexor XR and *two years* before the expiration of Wyeth's patents for Effexor IR via exclusive licenses matched by licensee-paid royalties. *See* Pet.App.19-20.

Of course, the license terms here theoretically could have been even *more* procompetitive if, for instance, the licenses had each gone into effect immediately or included no period of exclusivity under the patent. But as this Court repeatedly has emphasized, a procompetitive agreement (like one conferring an exclusive license to enter a market) is not subject to antitrust challenge simply because an even better deal (from the perspective of potential antitrust plaintiffs) could have been crafted. *See Trinko*, 540 U.S. at 415-16. That the Third Circuit was willing to override even a settlement form so "traditional" and "commonplace" as royalty-bearing

exclusive licenses sends an unmistakable message: No patent settlement is safe.

The stakes could hardly be higher. A recent study found that "more than 90% of [patent] lawsuits settle before the court resolves summary judgment or tries the case." John R. Allison, et al., *Understanding the Realities of Modern Patent Litigation*, 92 Tex. L. Rev. 1769, 1780 (2014). At best, parties to patent disputes will see the writing on the wall and internalize the lesson that they are always at risk of facing an antitrust challenge to a patent settlement under the Third Circuit's regime. Or perhaps rule-of-reason skittishness will cause infringement suits across the country to go all the way to judgment simply to avoid the prospect of treble damages. Either way, everyone (except the plaintiffs' bar) will be worse off. And in addition to those negative externalities, the Third Circuit's rule of *caveat settlor* will inevitably diminish competition and impede the free flow of information—exactly the opposite of what both the patent system and the antitrust laws are designed to achieve. *See* Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1049 (2004).

These consequences will not be limited to Paragraph IV litigation under the Hatch-Waxman Act or the pharmaceutical context more generally. The basic logic of the decision below is that any exclusive license is potentially unlawfully "anticompetitive" because it necessarily conveys value in the form of a patentee's promise not to compete for a set time. *E.g.*, Pet.App.52; *see also Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003)

(Posner, J.) ("*[A]ny* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement."). In short, if "any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements." *Asahi Glass*, F. Supp. 2d at 994. That prospect is particularly troubling given that a disproportionate share of leading businesses (which own patents in various fields) are incorporated in Delaware and are thus at home in the Third Circuit.

Nor will the usual happenstance that dictates the venue of federal litigation pose any barrier to Third Circuit predominance. Unlike the mine run of cases, the ordinary venue rules do not apply in antitrust litigation. Under the Clayton Act, antitrust plaintiffs may file suit in any judicial district. 15 U.S.C. §22. Making matters worse, the Third Circuit is home to a particularly large percentage of the nation's pharmaceutical companies (many of which are headquartered in New Jersey or Pennsylvania), and most challenges to patent litigation settlements already are brought within its borders—in no small part due to the Third Circuit's open hostility to pharmaceutical patent settlements. Absent this Court's intervention, then, the Third Circuit's anti-patent, anti-settlement rule will soon become the *de facto* national standard. *See, e.g.*, Pet. for Cert. at 10, 23, *SAS Inst. Inc. v. Matal*, No. 16-969 (U.S. Jan. 1, 2017) (arguing that the decision below "is contrary to" federal law and is "critically important," and thus warrants plenary review even absent a circuit split), *cert. granted*, 137 S. Ct. 2160 (2017) (mem.); Pet. for Cert. at 12, 17, *Kindred Nursing Ctrs. Ltd. P'ship v.*

Clark, No. 16-32 (U.S. Jul. 1, 2016) (similar), *cert. granted*, 137 S. Ct. 368 (2016) (mem.).

III. This Case Is An Ideal Vehicle To Resolve The Question Presented.

This issue came to the Court once before. In *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015), the brand-name manufacturer of Lamictal agreed not to compete with Teva in the market for a generic version of the drug during both the 180-day first-filer period and the brand's FDA-granted period of pediatric exclusivity. *Id.* at 397; *see* 21 U.S.C. §355a. After the Third Circuit held that the patentee's agreement not to introduce its own authorized generic "may be subject to antitrust scrutiny under the rule of reason," *King Drug*, 791 F.3d at 403, the defendants sought this Court's review, *see* Pet. for Cert., *SmithKline Beecham Corp. v. King Drug Co. of Florence, Inc.*, No. 15-1055 (U.S. Feb. 19, 2016).

In response to a call for the views of the Solicitor General, the Government's principal objection to plenary review was that the exclusive license in *King Drug* went beyond what the relevant patent itself conferred. According to the Government, the "no-AG agreement" in *King Drug* could not "be characterized as an exclusive patent license because it extended beyond the term of [the] patent" into the patentee's period of pediatric exclusivity, which "'is not an extension of the term of the patent.'" Br. for the United States as Amicus Curiae at 12-13, *King Drug*, No. 15-1055 (U.S. Oct. 3, 2016) (citation omitted)). Consistent with the Government's recommendation,

the Court denied certiorari. 137 S. Ct. 446 (Nov. 7, 2016) (mem.).

The present case contains no such impediment to this Court's intervention. The only "anticompetitive" conduct alleged here is Wyeth's grant of an exclusive license to Teva during the latter's 180-day first-filer period, which all agree occurred during the term of Wyeth's Effexor XR patents, and the grant of an exclusive license to Teva two years prior to the expiration of the Effexor IR patents. *See* Pet.App.19-20. This case thus presents a paradigmatic exclusive license, *see Waterman*, 138 U.S. at 256—and unlike *King Drug*, contains no obstacle to plenary review.

CONCLUSION

For the foregoing reasons, this Court should grant the petition for certiorari.

Respectfully submitted,

ROBERT A. MILNE
WHITE & CASE LLP
1221 Sixth Avenue
New York, NY 10020
(212) 819-8200
rmilne@whitecase.com

RAJ S. GANDESHA
BRYAN D. GANT
SHERYN GEORGE
WHITE & CASE LLP
1221 Sixth Avenue
New York, NY 10020

Counsel for Wyeth LLC, et al.

JAY P. LEFKOWITZ, P.C.
Counsel of Record
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4800
lefkowitz@kirkland.com

JOHN C. O'QUINN
MICHAEL D. SHUMSKY
JONATHAN D. JANOW
MATTHEW D. ROWEN
KIRKLAND & ELLIS LLP
655 Fifteenth Street NW
Washington, DC 20005

Counsel for Teva Pharm. Indus. Ltd., et al.

November 20, 2017