No. 15-1055

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 U.S. Court of Appeals for the Third Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

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 *FTC v. Actavis*, 133 S. Ct. 2223 (2013), and decades of this Court's earlier precedents.

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INTRODUCTION AND INTERESTS OF *AMICI CURIAE*

Washington Legal Foundation (WLF) is a non-profit public interest law firm and policy center with supporters in all 50 states.[1] WLF devotes a substantial portion of its resources to defending free enterprise, individual rights, a limited and accountable government, and the rule of law.

WLF has appeared before this and other courts in numerous cases involving the intersection of patent rights and antitrust law. *See, e.g., FTC v. Actavis*, 133 S. Ct. 2223 (2013); *In re K-Dur Antitrust Litigation*, 686 F.3d 2012 (3d Cir. 2012), *vacated*, 133 S. Ct. 2849 (2013). WLF also filed a brief in support of Petitioners when this case was before the Third Circuit.

The Allied Educational Foundation (AEF) is a nonprofit charitable and educational foundation based in Tenafly, New Jersey. Founded in 1964, AEF is dedicated to promoting education in diverse areas of study, such as law and public policy, and has appeared as *amicus curiae* in this Court on antitrust-related issues on a number of occasions.

The Third Circuit's decision represents a major expansion of antitrust law and directly conflicts with

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than *amici* and their counsel, made a monetary contribution intended to fund the preparation or submission of this brief. More than 10 days prior to the due date, counsel for *amici* provided counsel for Respondents with notice of their intent to file. All parties have consented to the filing; letters of consent have been lodged with the Court.

this Court's decision in *Actavis*. *Amici* are concerned that the decision will make it virtually impossible for parties to settle drug-patent disputes and will have serious negative effects on incentives for drug companies to develop and market innovative, life-saving products.

The development of innovative drugs not only saves lives but also saves consumers billions of dollars each year. Congress recognized these pro-competitive aspects of new drug development when it adopted the patent laws and the Hatch-Waxman Act, both of which offer substantial financial benefits to companies that risk the huge sums necessary to run the Food and Drug Administration (FDA) regulatory gauntlet and that eventually succeed in winning marketing approval for innovative medical products.

The decision below ignored the substantial benefits to competition derived from enforcement of the patent laws. Instead, the Third Circuit focused solely on the short-term benefits to consumers brought about by introducing generic competition before the patent on an innovative drug is set to expire. The court concluded that virtually every action by a brand-name drug company to protect its patent should be subject to searching scrutiny under the antitrust law, without ever acknowledging that such scrutiny inevitably devalues patents and thus undermines Congress's efforts to promote competition-enhancing drug development.

Such one-sided emphasis on antitrust-law enforcement runs directly counter to this Court's decision in *Actavis*. *Actavis* emphasized the need to

"balance" the antitrust and patent laws. It held that transfers of value from a brand-name drug company to a generic company in connection with a patent-litigation settlement "sometimes" should be subject to antitrust scrutiny and "sometimes" not. The district court correctly concluded that GSK's grant of a 180-day exclusive license to Teva to market a generic form of Lamictal—a license that increased competition and lowered prices in advance of the expiration of GSK's patent—was not the sort of transfer-of-value that *Actavis* had in mind when it held that large and unjustified "payments" from brand-name companies to generic companies are subject to rule-of-reason antitrust scrutiny. The appeals court's contrary conclusion cannot be squared with *Actavis* and warrants this Court's review.

STATEMENT OF THE CASE

The 2005 patent-litigation settlement agreement entered into between Petitioner SmithKline Beecham Corp., d/b/a GlaxoSmithKline ("GSK") and Petitioner Teva Pharmaceutical Industries Ltd. ("Teva") did not provide for any payment from GSK to Teva. Instead, in return for Teva's stipulation to dismiss all claims and counterclaims (including Teva's counterclaim that GSK's patents on Lamictal were invalid), GSK agreed: (1) to license Teva to begin marketing chewable forms of the drug by June 1, 2005 (more than three years in advance of expiration of the patents); (2) to license Teva to begin marketing tablet forms of the drug six

months in advance of patent expiration;[2] and (3) to include within the early-entry license for Lamictal tablets the *exclusive* right to market a generic version of the tablets (*i.e.*, GSK agreed not to market its own generic version of the drug during that six-month period or to authorize any other company to do so). Pet. App. 52a-53a.

Respondents (collectively "King Drug") are direct purchasers of Lamictal. They filed suit in February 2012, alleging that the patent-litigation settlement violated federal antitrust law.

Following this Court's *Actavis* decision, the district court affirmed an earlier decision to grant Petitioners' Rule 12(b)(6) motion to dismiss. Pet. App. 51a-74a. The court explained, "*Actavis* is clear that only certain reverse payment settlements will trigger antitrust scrutiny." *Id.* at 62a. It concluded that antitrust scrutiny is not triggered when the benefit conferred by the patentee is an early-entry license, even when that license is exclusive. *Id.* at 64a-69a.

The Third Circuit vacated and remanded, *id.* at 2a-50a, holding that the complaint adequately alleged that, by settling their patent-infringement litigation, Petitioners "acted unlawfully by seeking to prevent competition." *Id.* at 45a. The appeals court stated that it did not challenge the right of a patentee to grant an exclusive license to use its patent. But, it asserted,

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[2] Including a six-month extension granted to GSK on the basis of studies it undertook related to use of Lamictal by children, GSK's exclusive right to market Lamictal was set to expire on January 22, 2009.

"the 'right' defendants seek is not in fact a patentee's right to grant licenses, exclusive or otherwise." *Id.* at 36a. Instead, the court explained, the right that they seek:

> [I]s 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 a 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.

Pet. App. 37a.

The Third Circuit directed the district court, on remand, to subject the litigation settlement agreement

to antitrust scrutiny under a rule-of-reason analysis. *Id.* at 49a-50a.

SUMMARY OF ARGUMENT

This case presents issues of exceptional importance. *Actavis* has spawned scores of antitrust challenges to patent-litigation settlement agreements entered into between brand-name drug companies and generic drug companies. As the Petition explains at length, federal courts have reached widely disparate conclusions regarding the breadth and meaning of *Actavis* and are in need of additional guidance from the Court.[3] Review is also warranted because the Third Circuit's decision so clearly conflicts with this Court's *Actavis* decision. *Actavis* directed courts to maintain a "balance" between patent and antitrust laws, not (as the appeals court concluded) to subject to antitrust scrutiny any settlement agreement that provides any significant benefit to a generic company in return for its agreement to drop an invalidity claim.

In establishing a patent system, Congress recognized the value of temporary restraints on trade

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[3] *Amici* note that days after the filing of the Petition, the First Circuit issued a decision that adopted an approach far more cautious than the Third Circuit's, in a case involving highly similar antitrust claims. The First Circuit held that *Actavis* does not strictly limit antitrust challenges to patent-litigation settlements involving *cash* payments to the generic drug company. But in light of the novelty of the issues, it concluded that "pruden[ce]" dictated proceeding "one step at a time," and it thus put off for another day ruling on whether the grant of an exclusive license was subject to antitrust scrutiny. *In re Loestrin Fe 24 Antitrust Litig.*, __ F.3d __, 2016 WL 698077 at *12 (1st Cir., Feb. 22, 2016).

for the purpose of providing financial incentives designed to spur innovation. While such restraints cut against the normal goals of antitrust law, Congress mandated that courts should strive to maintain a balance between patent law and antitrust law, and that antitrust law should not be applied in a manner that shortchanges the rights of patent holders. *Simpson v. Union Oil Co.,* 377 U.S. 13, 14 (1964).

In *Actavis*, the Court sought to maintain that balance in the context of drug patent litigation settlements involving brand-name and generic drug companies. It sought to steer a middle ground between the "presumption of unreasonable restraint" approach adopted by the Third Circuit,[4] under which settlements involving payments from a patentee to the alleged infringer were rebuttably presumed to violate antitrust laws, and the "scope of the patent" test adopted by other federal appeals courts,[5] under which such "reverse payment" settlements were not subject to antitrust scrutiny so long as they did not extend beyond the exclusionary effects of the underlying patent. *Actavis*, 133 S. Ct. at 2237-38.

The Court held that when a generic drug company agrees, in connection with a patent litigation settlement, to drop its challenge to patent validity, the agreement is subject to antitrust scrutiny under a rule-of-reason analysis whenever the settlement also

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[4] *In re K-Dur Antitrust Litigation*, 686 F.3d 2012 (3d Cir. 2012), *vacated*, 133 S. Ct. 2849 (2013).

[5] *See, e.g.*, *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006).

includes an "unusual," "large," and "unexplained" "payment" from the brand-name drug company to the generic company. *Id.* at 2231, 2237. On the other hand, it held that an agreement to abandon an invalidity claim (and to delay entry) is *not* subject to antitrust scrutiny when the benefits that flow to the generic company take "traditional" and "familiar settlement forms"—such as the brand-name company's willingness to abandon substantial damages claims, *id.* at 2233, or to grant a license permitting the generic to enter the market prior to expiration of the patent. *Id.* at 2237. Such non-cash benefits may be of *immense* value to a generic company, but the Court—in its effort to maintain a proper "balance" between patent law and antitrust law—could not have been clearer that such benefits were exempt from antitrust scrutiny without regard to their magnitude.

The Third Circuit's decision conflicts with *Actavis*'s balanced approach. It held that the exclusive license granted by GSK to Teva was subject to antitrust scrutiny simply because GSK is alleged to have granted the license in order to induce Teva to settle the lawsuit, *i.e.,* in order to induce Teva to abandon its invalidity claim. Pet. App. 37a. But that standard would, contrary to *Actavis*'s teaching, subject all patent settlements to antitrust scrutiny, because generic companies only ever agree to abandon their litigation claims if they have been granted something of value in return.

The likely result of the Third Circuit's approach: settlements of drug patent litigation will become a practical impossibility. That result is also inconsistent with *Actavis*, which recognized the pro-competitive

desirability of such settlements and sought to preserve the ability of drug-patent litigants to settle their disputes.

The full-scale antitrust scrutiny dictated by the Third Circuit is particularly inappropriate in the context, as here, of a brand-name drug company granting an exclusive license to market generic versions of its products. The grant of an exclusive license, an action whose purpose is to restrict competition as compared to a non-exclusive license, is explicitly sanctioned by federal patent law, *see* 35 U.S.C. § 261, and has long been upheld by the Supreme Court as an integral part of a patent holder's right to employ (and thereby profit from) its patent. Any rule calling for application of antitrust scrutiny to the grant of an exclusive license under these circumstances would erroneously call into question the legality of this long-sanctioned method of utilizing one's patent.

REASONS FOR GRANTING THE PETITION

I. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW EFFECTS AN UNWARRANTED EXPANSION OF THE LIMITED ANTITRUST SCRUTINY CONTEMPLATED BY *ACTAVIS*

The Third Circuit in essence held that any patent-litigation settlement—other than one in which the sole benefit granted to the generic drug company as a settlement inducement is a non-exclusive license to enter the market prior to patent expiration—is subject to antitrust scrutiny. Review is warranted because that holding sharply conflicts with this Court's *Actavis*

decision. There is simply no principled basis for distinguishing the exclusive licensing agreements that the Third Circuit held were subject to antitrust scrutiny from the early-entry agreements that *Actavis* held did not trigger antitrust scrutiny. Both types of agreements involve commonly used patent-licensing arrangements that are explicitly sanctioned by federal statute. In both instances, the agreements can provide large non-cash benefits to the generic company. Yet, the Third Circuit held that the licensing agreement at issue here is subject to antitrust scrutiny without providing any explanation regarding why it should be treated differently from the early-entry agreements that *Actavis* deemed exempt from antitrust scrutiny.

A. *Actavis* Held that Federal Courts Reviewing Challenges to Patent Settlement Agreements Must Maintain a "Balance" Between Antitrust Law and Patent Law

Actavis addressed a Federal Trade Commission antitrust challenge to a patent-litigation settlement under which the patent holder, Solvay Pharmaceuticals, allegedly had agreed to make hundreds of millions of dollars in cash payments to several generic drug companies in return for those companies' agreeing not to market generic versions of the patented drug for another nine years. The drug companies argued that the settlement should be immune from antitrust scrutiny because the settlement was within the scope of the patent; *i.e.*, the patent at issue was not scheduled to expire until 2021, while the agreement permitted the generic companies to begin

marketing in August 2015—65 months sooner. The FTC argued, on the other hand, that the "large and unjustified" cash payments from Solvay indicated that Solvay was paying potential competitors not to enter the market, and therefore that the agreement should be *presumed* to constitute an illegal conspiracy in restraint of trade, subject to the defendants' right to attempt to demonstrate that the agreement actually promoted competition.

The Court rejected both arguments and instead adopted a compromise position that attempted to balance the competing demands of antitrust law and patent law. It concluded that litigation settlements in which the brand-name company transfers something of value to the generic company can "sometimes" be subject to antitrust scrutiny and can "sometimes" violate the antitrust laws. *Actavis*, 133 S.Ct. at 2227. The Court repeatedly stated that courts hearing antitrust challenges to patent settlement agreements must seek to "balance" the often-conflicting principles of antitrust and patent law. *See, e.g., id.* at 2231 (describing decision in *United States v. Line Material Co.*, 333 U.S. 287 (1948), as an effort to "strike [a] balance" between "the lawful restraint of trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act."); *ibid* (stating that "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust immunity—that is conferred by a patent.").

The Court held that "a reverse payment, where large and unjustified, can bring with it the risk of

significant anticompetitive effects" and thus subject a patent settlement to antitrust scrutiny under a rule-of-reason analysis—particularly when "parties may well find ways to settle patent disputes without use of reverse payments." *Id.* at 2237.[6] In contrast, the Court held that *no* antitrust scrutiny is warranted if the generic company drops its patent invalidity claim in return for a license to market its product in advance of the patent's expiration—even if, as will often be the case, the early-entry license is worth many millions of dollars to the generic company. *Ibid.* The Court did not define precisely what sort of value transfers it intended to include within the term "reverse payment."

But the Court unarguably did *not* intend that the term should apply (as the Third Circuit held) to any and all contractual terms that confer value on the generic company. The Court would not have characterized early-entry licenses as instances in which a brand-name company permits entry prior to patent expiration "*without paying* the challenger to stay out prior to that point," *ibid* (emphasis added), if it thought the word "paying" included the immense value transferred to challengers by virtue of such licenses. While *Actavis* clearly intended the term "reverse payment" to encompass large *cash* payments, the Court said nothing to indicate what, if any, non-cash payments are included.

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[6] The Court rejected the FTC's contention that "reverse payment settlement agreements are presumptively unlawful and that courts reviewing such agreements should proceed via a 'quick look' approach, rather than applying a 'rule of reason.'" *Actavis*, 133 S. Ct. at 2237.

B. *Actavis* Contemplated that "Familiar Settlement Forms" Such as Exclusive Licenses Would Not Be Subject to Antitrust Scrutiny

Actavis noted that it is highly unusual for a plaintiff not facing damages claims (particularly a plaintiff alleging patent infringement) to pay cash to settle pending litigation. The highly unusual nature of the multi-million-dollar cash payments made by Solvay Pharmaceuticals (the patentee in *Actavis*) played a major role in the Court's decision to subject the patent-infringement litigation settlement to antitrust scrutiny. Conversely, given the Court's recognition that settlements of patent disputes are to be encouraged, 133 S. Ct. at 2234, the fact that exclusive licenses are commonly used as a means of settling disputes strongly suggests that such settlements do not warrant antitrust scrutiny.

Indeed, the FTC itself for many years singled out large cash payments as *the* forbidden form of consideration in reverse-payment patent settlements. "A settlement agreement is not illegal simply because it delays generic entry until some date before expiration of the pioneer's patent. . . . [T]he *payment of money* by Schering . . . is what makes this case different." *In re Schering-Plough Corp.*, 136 F.T.C. 956, 987 (F.T.C. 2003) (emphasis added), *rev'd sub nom., Schering-Plough Corp. v. FTC*, 402 F.2d 1056 (11th Cir. 2005). Only following the *Actavis* decision did the FTC begin broadening its horizons and asserting that virtually any transfers of value from the

patentee to the challenger warrant antitrust scrutiny.

The Third Circuit recognized that *Actavis* expressly exempted from antitrust scrutiny the first two forms of consideration provided by GSK to Teva—the license to begin marketing chewable forms of Lamictal by June 1, 2005 and the license to begin marketing tablet forms of the drug six months in advance of patent expiration. It held, however, that the third form of consideration—GSK's agreement to grant Teva exclusive generic rights during the first 180 days of marketing—should be subject to the same antitrust scrutiny that *Actavis* applied to cash payments. Pet. App. 30a.

The appeals court held that antitrust scrutiny applies not just to payments but also to *any* "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." *Id.* at 10a. In particular, it applies to any use of "valuable licensing in such a way as to induce a patent challenger's delay." *Id.* at 37a. The court held that the exclusive license had considerable value to Teva and thus was subject to antitrust scrutiny. *Id.* at 30a-32a.

The Third Circuit's expansion of antitrust scrutiny to cover any "reverse transfer[s] of considerable value" conflicts with *Actavis*'s directive that courts seek to "balance" the competing interests of antitrust and patent law. Instead of seeking such a balance, the appeals court has simply applied full-bore antitrust scrutiny to all patent-litigation settlements.

While this Court limited the scope of antitrust scrutiny to settlement agreements that include "reverse payments," the appeals court has substituted its own, far broader criterion: antitrust scrutiny is now deemed applicable whenever the brand-name company "transfers" anything of "considerable value" to the generic company.

More importantly, the appeals court made no effort to reconcile its adoption of a "considerable value" criterion with the explicit exemption from antitrust liability that *Actavis* provided to licensing agreements that allow "the generic manufacturer to enter the patentee's market prior to patent expiration." *Id.* at 2237. *Actavis* provided that exemption even though such early-entry licenses are often of considerable value to generic drug companies—indeed, in some cases they can be worth many millions of dollars. Accordingly, under the Third Circuit's "reverse transfer of considerable value" criterion, such early-entry licenses should be subject to antitrust scrutiny too. Yet we know from *Actavis* that such licenses are *not* subject to antitrust scrutiny—a clear indication that the appeals court has misconstrued *Actavis*.

Nor does the Third Circuit's standard account for other transfers of "considerable value" that *Actavis* held were not subject to antitrust scrutiny. *Actavis* held that no antitrust scrutiny is warranted when, as part of the settlement, the brand-name company agrees to drop some or all of its claims for damages for patent infringement. *Actavis*, 133 S. Ct. at 2233. In the example cited by the Court, the value effectively transferred to the alleged infringer by virtue of the

patentee's abandoning its damages claim was $60 million, yet the Court concluded that maintaining the balance between patent law and antitrust law required that such transfers be exempt from antitrust scrutiny. *Ibid.*[7] The only credible explanation for that exemption is that an agreement to drop damages claims does not constitute a "reverse payment" within the meaning of *Actavis*.

In determining whether a patent-litigation settlement agreement should be subject to antitrust scrutiny, the magnitude of the transfer to the generic company is only one of several factors that *Actavis* deemed relevant. *Actavis* focused at least as much if not more so on other factors: whether the settlement employs "traditional settlement forms," 133 S. Ct. at 2233, and whether a "patent statute" grants the patentee a right to offer such terms, "whether expressly or by fair implication." *Ibid.*

GSK and Teva have identified a statute that expressly provides a patentee the right to grant

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[7] King Drug has repeatedly asserted that even 180 days of marketing a generic drug without competition from a second generic company can be immensely valuable to a generic company, and that losses a brand-name company incurs due to the onset of generic competition far outstrip the profits earned by the generic company. Accordingly, when a generic company decides to market a generic product "at risk" for even a few months, the brand-name company likely can demonstrate potential infringement damages amounting to hundreds of millions of dollars. *Actavis* nonetheless held that no antitrust scrutiny is warranted if the brand-name company waives those damages claims in return for the generic company's agreement to cease competition. *Ibid.*

exclusive licenses to its patent: 35 U.S.C. § 261. The grant of an exclusive license, an action whose purpose is to restrict competition as compared to a non-exclusive license, has long been upheld by the Court as an integral part of a patent holder's right to utilize its patent so as to maximize profits. *See, e.g., E. Bement & Sons v. Nat'l Harrow* Co., 186 U.S. 70, 82 (1902); Kimble *v. Marvel Entertainment, LLC*, 135 S. Ct. 2401, 2408, 2413 (2015) (broadly endorsing right of patentees to enter into licensing agreements while acknowledging, "The patent laws—unlike the Sherman Act—do not aim to maximize competition (to a large extent, the opposite)."). Given the well-established pedigree of exclusive licenses, their use in connection with settlement agreements easily qualifies as the type of "traditional settlement form" that *Actavis* deemed protected by patent law against antitrust scrutiny.

An exclusive license's tendency to reduce competition is not a reason to question its validity under antitrust laws; indeed, reducing competition (as compared to competition present under a non-exclusive license) is precisely its purpose. It is nonetheless undeniable that the early-entry license granted by GSK to Teva (a license that included the exclusive right to market a generic product for 180 days) *promoted* competition and reduced prices by granting consumers earlier access to generic Lamictal than they would have had in the absence of the license. *Actavis*, 133 S. Ct. at 2234 ("[S]ettlement on terms permitting the patent challenger to enter the market before the patent expires would . . . bring about competition . . . to the consumer's benefit."). While other license terms might have produced even more short-term competition, this

Court has explained that a pro-competitive agreement is not subject to antitrust challenge simply because of the possibility that an even more pro-competitive agreement could have been crafted. *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, Inc.*, 540 U.S. 398, 415-16 (2004).

The appeals court concluded that "even exclusive licenses cannot avoid antitrust scrutiny where they are used in anticompetitive ways," and that "the question is not one of patent law, but of antitrust law, the latter of which invalidates 'the improper use of [a patent] monopoly.'" Pet. App. 37a-38a (quoting *Actavis*, 133 S. Ct. at 2231; and *Line Material*, 333 U.S. at 310). But this Court has never ruled that a patentee "improper[ly] use[s]" its patent simply by licensing rights to others, even when the license imposes restrictions that could be deemed anticompetitive in the absence of a patent. Indeed, the Court held in *United States v. General Electric Co*, 272 U.S. 476, 485 (1926)—a case cited approvingly by *Actavis*—that a patentee may use its monopoly power to fix the prices at which its licensees sell the patented product, provided only that the patentee does not conspire with other patent holders to restrain trade.[8]

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[8] Each of the cases cited by *Actavis* in which the Court ruled that patent rights had been used improperly involved *multiple* patent holders who, using their patent monopoly power, conspired with one another either to fix prices or to drive competitors from the market. *See, e.g., Line Materials*, 333 U.S. at 308; *United States v. New Wrinkle, Inc.*, 342 U.S. 371 (1952); *United States v. Singer Mfg. Co.*, 374 U.S. 174 (1963).

C. Patent Litigation Settlements Will Be Virtually Impossible If Granting an Early-Entry License of the Sort Contemplated by the Third Circuit Is the Only Permissible Settlement Tool

Actavis was decided based on the assumption that it would still be possible for litigants to settle pharmaceutical patent-infringement litigation even without "reverse payment" settlements. *Id.* at 2237 (stating that "parties may well find ways to settle patent disputes without use of reverse payments."). Yet, under the Third Circuit's' expansive definition of what constitutes a "reverse payment," it is doubtful that a drug-patent lawsuit would *ever* settle.

The impossibility of settlement under the appeals court's antitrust standards is the result of unique litigation dynamics created by the Hatch-Waxman Act, Pub. L. No. 98-417. Unlike the defendants in patent-infringement litigation that arises in other contexts, a generic drug company that initiates infringement litigation (by filing a "Paragraph IV certification" with FDA and thereby essentially forcing a brand-name company to file an infringement lawsuit) cannot be held liable for damages because it has not marketed any infringing products.[9] Of course, no litigant will agree to a settlement unless he

[9] In contrast, patent-infringement litigation arising in other contexts generally involves defendants who are alleged to be committing more concrete infringing acts. Such defendants face severe, potentially-bankrupting damages awards if the trial court sustains the infringement claim.

perceives that it is advantageous. Accordingly, if a patentee cannot transfer anything of "considerable value" to a generic drug company without facing antitrust scrutiny, and if there are no potential damages that a patentee could offer to forgo, there may never again be a settlement of any drug-patent litigation because a patentee will be unable to offer lawful settlement terms that a generic drug company would find sufficiently attractive to induce it to abandon the huge financial rewards that Hatch-Waxman offers to drug-patent challengers.

As Judge Posner has cogently observed:

> [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. If any settlement agreement is thus to be classified as involving a forbidden "reverse payment," we shall have no more patent settlements.

Asahi Glass Co. v. Pentech Pharms., Inc., 289 F.Supp. 2d 986, 994 (N.D. Ill. 2003). The Third Circuit's advocacy of antitrust criteria that would halt all future drug-patent litigation settlements cannot be squared with *Actavis*, given that decision's stated intent to create a standard under which settlements could still flourish. *Actavis* recognized "a general legal policy favoring the settlement of disputes" and "the value of settlements." *Actavis*, 133 S. Ct. at 2234.

There exist potential settlement terms that make it attractive for any party to settle litigation.

Moreover, there are numerous disadvantages to any decision to continue with patent litigation—its outcome is always uncertain, and its costs (both in terms of dollars and the diversion of executives' attention away from competitive, money-making activities) are enormous. But settlements can occur only if patent litigants are given the tools required to reach a point at which both parties are satisfied by the settlement terms.

Arriving at terms that satisfy both parties will often be impossible if, as the Third Circuit held, the only settlement tool is an early-entry agreement along the lines advocated by King Drug. For example, let us assume that the sole item being negotiated in settlement talks is the precise early-entry date and that parties are six month apart in terms of what each party considers an acceptable date. The virtual impossibility of bridging that gap and arriving at a settlement arises because for every day that the early-entry date moves backward in time, the potential losses to the brand-name company are many times larger than the potential gains to the generic company. Under those circumstances, even huge financial concessions by the brand-name company (concessions it is unlikely to be willing to make) will not achieve a settlement because they will confer very little financial benefit on the generic. *See* Kevin McDonald, "Because I Said So: On the Competitive Rationale of *FTC v. Actavis*," 28 ANTITRUST 36, 37 (2013). If, as *Actavis* indicated, parties should be provided the means to settle patent litigation, alternative non-cash tools (such as exclusive-licensing agreements) must be made available.

Review is warranted to resolve the conflict between *Actavis* and the decision below, which precludes use of the tools necessary to achieve the settlements contemplated by *Actavis*.

II. REVIEW IS WARRANTED TO PROTECT THE SUBSTANTIAL BENEFITS TO COMPETITION DERIVED FROM ENFORCEMENT OF THE PATENT LAWS

Throughout the Third Circuit's decision, the discussion of competition myopically focuses on the short-term benefits to consumers brought about by introducing generic competition before the patent on an innovative drug is set to expire. The court totally ignored the substantial benefits to competition derived from enforcement of the patent laws, benefits that Congress sought to nurture when it enacted them.

Both the patent laws and the Hatch-Waxman Act promote the development of life-saving, money-saving drugs by providing substantial financial benefits (in the form of temporary monopolies) to companies that risk the huge sums necessary to run the FDA regulatory gauntlet and that eventually succeed in winning marketing approval for their medical products. Quite obviously, any antitrust rules that inhibit the ability of patentees to protect their patent rights reduce the value of the financial incentives otherwise available to those contemplating devoting the vast sums necessary to develop new drugs.

Numerous studies demonstrate the pro-

competitive value of new drug development. For example, one recent study determined that use within the United States of new, brand-name drugs (in place of older drugs already on the market) increases overall drug expenditures somewhat. The study determined, however, that the *reduction* in overall non-drug health care expenditures attributable to the use of new drugs is *7.2 times greater* than the increase in overall drug expenditures. Frank Lichtenberg, *Benefits and Costs of Newer Drugs: An Update* (Nat'l Bureau of Economic Research, 2002). The study found that the reduction was largely attributable to reduced hospital costs. In other words, the effects of a policy that encourages development and use of new (and generally higher-priced) drugs are to improve health care, reduce costs, and enhance competition.

Another comprehensive study concluded that if patent protection were immediately eliminated for all current and future prescription drugs, consumers would benefit in the short term from reduced prices. But for every dollar that current consumers would save in the short term, future consumers would lose three dollars (in present value terms) because of decreases in future pharmaceutical innovation. James M. Hughes, Michael J. Moore, Edward A. Snyder, *"Napsterizing" Pharmaceuticals: Access, Innovation, and Consumer Welfare* (Nat'l Bureau of Economic Research 2002). Other studies have demonstrated how development of new medications has improved productivity in the workplace through reduced absenteeism or disability leave. *See* PhRMA, "Economic Development: The Biopharmaceutical Industry Helps Strengthen the U.S. Economy" (available at www.phrma.org/print/51).

WLF urges the Court to grant review in order to restore the necessary balance between antitrust and patent law, a balance required in order to protect the numerous pro-competitive benefits derived from the nation's patent laws. *Actavis* cautioned that resolution of antitrust claims of litigants who object to patent settlement agreements requires a careful balancing of antitrust law and patent law. *Actavis*, 133 S.Ct. at 2231. The Court should overturn the Third Circuit's efforts to write patent law out of the balancing analysis.

CONCLUSION

The Court should grant the Petition.

Respectfully submitted,

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