No. 17-752

IN THE

# Supreme Court of the United States

PFIZER, INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT CO., WARNER-LAMBERT CO. LLC, RANBAXY INC., RANBAXY PHARMACEUTICALS, INC., and RANBAXY LABORATORIES LTD.,

*Petitioners,*

v.

RITE AID CORP., *et al.*; WALGREEN CO., *et al.*; GIANT EAGLE, INC.; MEIJER INC., *et al.*; ROCHESTER DRUG CO-OPERATIVE, INC., *et al.*; and AFL-AGC BUILDING TRADES WELFARE PLAN, *et al.*;

*Respondents.*

**On Petition for a Writ of Certiorari to the U.S. Court of Appeals for the Third Circuit**

## MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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Date: December 22, 2017

**MOTION FOR LEAVE TO FILE BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF PETITIONER**

Pursuant to Rule 37.2 of the Rules of this Court, Washington Legal Foundation (WLF) and Allied Educational Foundation (AEF) respectfully move for leave to file the attached brief as *amici curiae* in support of Petitioners. Counsel for Petitioners has consented to the filing of this brief, as have counsel for Respondents Rite Aid Corp.; CVS, Inc.; and Walgreen Co., *et al.* Counsel for the remaining Respondents did not respond to a request for consent. Accordingly, this motion for leave to file is necessary.

WLF is a public interest law firm and policy center with supporters in all 50 States. 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); *SmithKline Beecham Corp. v. King Drug Co. of Florence, Inc.*, *cert. denied*, 137 S. Ct. 446 (2016); *In re K-Dur Antitrust Litigation*, 686 F.3d 2012 (3d Cir. 2012), *vacated*, 133 S. Ct. 2849 (2013).

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.

*Amici* believe that the Third Circuit's decision represents a major expansion of antitrust law and directly conflicts with 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.

*Amici* have no direct interest in the outcome of this litigation, financial or otherwise. Accordingly, *amici* can provide the Court with a perspective not shared by any of the parties.

For the foregoing reasons, Washington Legal Foundation and Allied Educational Foundation respectfully request that they be allowed to participate in this case by filing the attached brief.

Respectfully submitted,

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## QUESTION PRESENTED

Whether an antitrust complaint alleging a "large" and "unjustified" reverse-payment patent settlement agreement states a plausible claim for relief of the sort recognized by *FTC v. Actavis*, 133 S. Ct. 2223 (2013), when: (1) the complaint lacks factual allegations purporting to demonstrate that value transferred to the patentee as part of the settlement was materially less than value transferred to the alleged infringer; (2) the value allegedly transferred to the alleged infringer consists of an agreement to accept a reduced level of damages for pending infringement claims; and/or (3) the plaintiffs' reverse-payment claims cannot be adjudicated without a trial on the merits of the settled patent infringement claims.

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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); *SmithKline Beecham Corp. v. King Drug Co. of Florence, Inc.*, *cert. denied*, 137 S. Ct. 446 (2016); *In re K-Dur Antitrust Litigation*, 686 F.3d 2012 (3d Cir. 2012), *vacated*, 133 S. Ct. 2849 (2013).

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The Third Circuit's decision represents a major expansion of antitrust law and directly conflicts with this Court's decision in *Actavis*. *Amici* are concerned

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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.

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 Petitioner Pfizer, Inc.'s global settlement of its outstanding litigation with Petitioner Ranbaxy Laboratories Ltd.—a settlement that entailed the transfer of no cash or tangible assets from Pfizer to Ranbaxy—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 2008 settlement agreement entered into between Pfizer and Ranbaxy resolved scores of pending patent disputes, including Pfizer's claims that Ranbaxy infringed its Lipitor patents (by notifying FDA of an intent to market a generic version of Lipitor) and its patent on a another drug, Accupril (by marketing a generic version of Accupril from December 2004 until a federal district court preliminarily enjoined further marketing in March 2005). Ranbaxy asserted in turn that each of the patents at issue was invalid and/or not infringed and that it should recover damages for having been improperly prevented from marketing Accupril from March 2005 until June 2007 (when the Accupril patent expired).

The principal terms of the complex settlement were as follows: (1) both parties agreed to drop their

competing claims for damages with respect to Accupril; (2) Ranbaxy agreed to pay $1 million to Pfizer in connection with the competing Accupril claims; (3) Ranbaxy agreed to drop its claims that the Lipitor patents were invalid and/or not infringed; and (4) Pfizer granted Ranbaxy a non-exclusive license to market a generic form of Lipitor in the United States beginning in November 2011—a date three-and-a-half years after the settlement agreement but more than five years before the expiration of the last of Pfizer's seven Lipitor patents. Pfizer transferred no cash or tangible assets to Ranbaxy.

Respondents (collectively, "Rite Aid") are a putative class of direct purchasers of Lipitor, a putative class of end payors, and several individual retailers asserting direct-purchaser claims. Their lawsuits, filed beginning in 2011, allege *inter alia* that the Pfizer-Ranbaxy settlement violated federal antitrust laws. They allege that Pfizer made, in effect, a "large" and "unjustified" payment to Ranbaxy in exchange for the latter's agreement to delay its marketing of a generic form of Lipitor. The alleged "payment" consisted of Pfizer's agreement to settle the Accupril litigation for an amount far less than it could have recovered at a patent-infringement trial. Rite Aid alleges that an antitrust trial would demonstrate that: (1) the Accupril patent was both valid and infringed; (2) Ranbaxy's infringing sales from December 2004 to March 2005 caused Pfizer to lose over $100 million in Accupril sales; and (3) Pfizer conferred this huge settlement benefit on Ranbaxy for the sole purpose of delaying the onset of generic competition to Lipitor.

After carefully examining this Court's *Actavis*

decision, the district court dismissed the antitrust complaints for failure to state a claim. Pet. App-122 to App-177. The court agreed with the plaintiffs that a patent settlement can constitute a reverse-payment patent settlement (of the sort that *Actavis* deemed subject to antitrust scrutiny) even when the "payment" does not consist of cash. It concluded, however, that the pleadings in such claims "must show some reliable foundation for estimating the alleged reverse payment." App-163. It held that the plaintiffs failed to meet that pleadings standard, stating, "Plaintiffs have failed to delineate any type of methodology to connect the claim to its monetary value." App-176.

The Third Circuit reversed. Pet. App-1 to App-79. The appeals court held that the complaint sufficiently alleged an actionable reverse-payment settlement agreement by alleging that "Pfizer released its claim worth 'hundreds of millions of dollars.' ... [A]dvanced calculations related to those allegations may come later." App-38. It stated, "The alleged reverse payment here was large enough to permit a plausible inference that Pfizer possessed the power to bring about an unjustified anticompetitive harm through its patents and had serious doubts about the ability of those patents to lawfully prevent competition." App-37 to App-38.

The appeals court did not dispute that the settlement followed a "commonplace form"—with the patent holder agreeing to settle for payment of a less-than-initially-claimed level of damages. Rather, it focused solely on the allegedly large disparity between the amount accepted in settlement and the potential recovery. Nor did the appeals court discuss how, at a

trial, Rite Aid could attempt to prove that the Accupril damages claims released by Pfizer were worth far more than the $1 million paid by Ranbaxy. By omitting such a discussion, the appeals court avoided providing the obvious answer: Rite Aid's burden of proving its antitrust claim would include proving the validity of the Accupril patent and Ranbaxy's infringement of that patent.

The Third Circuit directed the district court, on remand, to subject the litigation settlement agreement to antitrust scrutiny under a rule-of-reason analysis. Pet. App-44a.

## 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. Review is 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. The Third Circuit for many years has been a magnet for plaintiffs' lawyers seeking to file antitrust claims against pharmaceutical companies. The decision below will significantly exacerbate that trend and is likely to reduce competition and slow development of life-saving products.

In establishing a patent system, Congress recognized the value of temporary restraints on trade 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,[2] 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,[3] 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

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

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

agreement is subject to antitrust scrutiny under a rule-of-reason analysis whenever the settlement also 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. 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.

*Actavis* was also mindful that sometimes the high cost of antitrust litigation can dwarf whatever benefits to competition might be derived from permitting antitrust claims to go to trial. Accordingly, the Court permitted the antitrust claims at issue in *Actavis* to go forward only after assuring itself that they could be tried without also litigating the validity of the underlying patent. *Id.* at 2236 (stating that "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself").

The Third Circuit's decision conflicts with *Actavis*'s balanced approach. It held that the Pfizer-Ranbaxy settlement agreement was subject to antitrust scrutiny simply because Pfizer is alleged to have

provided Ranbaxy with something of value in order to induce Ranbaxy to settle the lawsuit, *i.e.,* in order to induce Ranbaxy to abandon claims that one or more Lipitor patents were invalid. 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. Moreover, the Third Circuit's standard will—contrary to *Actavis*—lead to full-scale litigation over patent validity when, as here, a determination of whether the "payment" by the patentee is "large" depends entirely on the strength of the patentee's compromised infringement claims.

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.

## 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 settlement agreements of the sort at issue here (which the Third Circuit held were subject to antitrust scrutiny) from the "commonplace forms" of settlement that *Actavis* held did *not* trigger antitrust scrutiny. Indeed, the Third Circuit made no effort to distinguish them. It held that antitrust scrutiny is warranted *whenever* a plaintiff plausibly alleges that a patentee has conveyed something of large value to a potential competitor to induce the competitor to delay entry. Pet. App-32 to App-33.

### 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.[4] 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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[4] 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 the Compromise of Damages Claims 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 the compromise of damages claims is a commonly used 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 previously recognized that *Actavis* expressly exempted from antitrust scrutiny one of the forms of consideration provided by Pfizer to Ranbaxy—the early-entry license to begin marketing Lipitor in November 2011, five years before the expiration of the last of Pfizer's seven Lipitor patents. *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 403 (3d Cir. 2015), *cert. denied*, 137 S. Ct. 446 (2016). The appeals court held below, however, that another benefit that flowed to Ranbaxy in connection with the settlement—Pfizer's agreement to compromise its damages claims arising from infringement of the Accupril patent—should be subject to the same antitrust scrutiny that *Actavis* applied to cash payments. Pet. App-30a.

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.[5] 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

[5] The Third Circuit holds that antitrust scrutiny applies not just to cash or in-kind 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." *King Drug*, 791 F.3d at 394.

"transfers" anything of "considerable value" to the generic company.

Moreover, the appeals court did not reconcile its adoption of a "considerable value" criterion with the explicit exemption from antitrust liability that *Actavis* provided to "commonplace forms" of litigation settlement, such as when "a party with a claim (or counterclaim) for damages receives a sum equal to or less than the value of its claim." *Actavis*, 133 S. Ct. at 2233. The Court said that "settlement taking these commonplace forms have not been thought for that reason alone subject to antitrust liability." *Ibid.*[6]

The Third Circuit sought to distinguish *Actavis*'s exemption for "commonplace" settlement forms, asserting that Rite Aid plausibly alleged that Pfizer

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[6] In explaining what it meant by compromise settlements that take "commonplace forms," the Court cited antitrust authorities describing the following types of settlements:

> When Company A sues Company B for patent infringement and demands, say, $100 million in damages, it is not uncommon for B (the defendant) to pay A (the plaintiff) some amount less than the full demand as part of the settlement—$40 million, for example. ... The cited authorities also indicate that if B has a counterclaim for damages against A, the original infringement plaintiff, A might end up paying B to settle B's counterclaim.

*Ibid.* The Court said that such settlements would not by themselves subject Companies A and B to antitrust liability, even though it recognized that, in the first example, A's compromise of its damages claim might be characterized as "an implicit net payment from A to B of $60 million." *Ibid.*

released its Accupril claims "in exchange for Ranbaxy's agreement to delay its launch of (and not to authorize another ANDA filer to launch) generic Lipitor until November 30, 2011)." Pet. App-43 to App-44. But if such allegations were sufficient to distinguish *Actavis*, nothing would be left of the antitrust exemption for commonplace forms of settlement. The sole reason that the issue of compromised patent-damages claims *ever* arises in the antitrust context is that the plaintiff alleges that the patentee agreed to compromise his damages claims in order to disguise his true motivation: to pay the alleged infringer to desist from future competition. *Actavis* made clear that such settlements are not subject to antitrust scrutiny without regard to what the antitrust plaintiff may believe about the patentee's true motivation.

Nor can *Actavis* be distinguished based on allegations that Pfizer's alleged "payment" was very large. *Actavis* stated that antitrust scrutiny is inappropriate in cases in which the patentee agrees to forgo damages claims totaling $60 million as part of the settlement. 133 S. Ct. at 2233. Rite Aid contends that Pfizer agreed to forgo considerably more than $60 million in damages claims. But nothing in *Actavis* indicates that the antitrust exemption for "commonplace forms" of settlement is dependent on the compromised damages claims not being *too* large. *Actavis* premised antitrust scrutiny of a patent litigation settlement on findings that the settlement is "unusual," 133 S. Ct. at 2231, (such as a cash payment from a patentee to an alleged infringer who has asserted no claim for damages) as well as "large."

Indeed, the decision below makes no mention of

the fact that, as part of the settlement, Ranbaxy also compromised its substantial claim for damages. Pfizer obtained a preliminary injunction that prevented Ranbaxy from marketing its generic Accupril from March 2005 until expiration of the Accupril patent in June 2007. Ranbaxy sought millions of dollars in damages caused by this allegedly wrongful injunction. In connection with the settlement, Ranbaxy not only waived those claims entirely but also paid money to Pfizer. As the Petition explains at length, review is particularly warranted in light of the Third Circuit's failure to take Ranbaxy's compromised counterclaim into account when determining that Pfizer's alleged "payment" was subject to antitrust scrutiny. Pet. 24-27.

Nor did the appeals court make any effort to reconcile adoption of its "considerable value" criterion with the explicit exemption from antitrust liability that *Actavis* provides to licensing agreements that "allow the generic manufacturer to enter the patentee's market prior to patent expiration." *Id.* at 2237. *Actavis* endorsed 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*.

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 another factor: whether the settlement employs "traditional settlement forms," such as a compromise of competing claims for damages. 133 S. Ct. at 2233. Review is warranted to resolve the conflict between *Actavis* and the decision below, which sanctioned antitrust scrutiny of patent settlements without regard to the form they take.

### C. *Actavis* Counseled Against Antitrust Scrutiny When, as Here, Resolution of Antitrust Claims Would Require a Trial Regarding the Validity of Underlying Patent Infringement Claims

*Actavis* was mindful that sometimes the high cost of antitrust litigation can dwarf whatever benefits to competition might be derived from permitting antitrust claims to go to trial. Accordingly, the Court permitted the antitrust claims at issue in *Actavis* to go forward only after assuring itself that they could be tried without also litigating the validity of the underlying patent. *Id.* at 2236 (stating that "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself").

In disregard of that admonition, the Third Circuit reinstated Rite Aid's antitrust claims even though it will be impossible to adjudicate those claims without conducting a trial regarding the validity of the

Accupril patent, whether Ranbaxy infringed it, and the extent of damages suffered by Pfizer and Ranbaxy at the hands of each other. A trial on those issues would be necessary because a determination of whether the "payment" by Pfizer to Ranbaxy was "large" depends entirely on the strength of the Accupril infringement claims that Pfizer agreed to compromise. Review is warranted to resolve the conflict between *Actavis* and the decision below regarding whether antitrust scrutiny of patent-litigation settlement agreements is permissible under those circumstances.

This Court in *Actavis* was reviewing an Eleventh Circuit decision—*FTC v. Actavis*, 677 F.3d 1298 (11th Cir. 2012)—that had barred antitrust scrutiny of the patent-litigation settlement agreement at issue based largely on practical considerations. As summarized by this Court, the Eleventh Circuit feared that permitting antitrust scrutiny would require litigation of patent validity and would "prove time consuming, complex, and expensive. The antitrust game, the Circuit may believe, would not be worth that litigation candle." *Actavis*, 133 S. Ct. at 2234. This Court acknowledged, "We recognize the value of settlements and the patent litigation problem." *Ibid.* It ultimately ruled, however, that the claim should be allowed to go forward, but only after satisfying itself that the claim could be adjudicated without the necessity of conducting two trials in one (*i.e.*, both a patent validity/infringement trial and an antitrust trial). *Id.* at 2236.

The Court concluded, "An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival," and that under those circumstances a full-

fledged patent invalidity trial would be unnecessary to determine whether the litigation settlement had anticompetitive effects. *Ibid.* But of course, a determination that a settlement includes "an unexplained large reverse payment" first requires a determination that the payment is "large." In this case, that would require a determination that the *actual value* of Pfizer's damages claims (less the value of Ranbaxy's counterclaims) vastly exceeded the amount Pfizer ultimately received. A trial court could make that determination only after determining the validity of the Accupril patent and examining Pfizer's claims for infringement damages. Under those circumstances, there is serious reason to believe that "the antitrust game ... would not be worth the litigation candle."

This Court has frequently restricted the scope of private antitrust enforcement, in recognition of the tremendous burdens that antitrust litigation often imposes on both parties and the courts. For example, the Court limits antitrust standing to "direct purchasers"—those who are the immediate victims of the alleged anticompetitive conduct. *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977). The Court recognized that indirect purchasers may well suffer injuries when manufacturers raise their prices in violation of the antitrust laws and the direct purchasers then manage to pass along those price increases to purchasers further down the distribution chain. The Court nonetheless concluded that concerns for litigation efficiency required imposing a direct-purchaser standing limitation, in light of "the costs to the judicial system and the efficient enforcement of the antitrust laws" if courts were required to allocate damages

among all possible victims. 431 U.S. at 732.

For similar reasons, the Court denies antitrust standing to States seeking to sue in their *parens patriae* capacities for damages to their "general economy" caused by antitrust violations. *Hawaii v. Standard Oil Co.*, 405 U.S. 251 (1972). The Court explained that apportioning damages awards in connection with such claims would be far too burdensome: "Even the most lengthy and expensive trial could not in the final analysis, cope with the problems of double recovery inherent in allowing damages for harm both to the economic interests of individuals and for the quasi-sovereign interests of the State." *Id.* at 264. *See also Assoc. General Contractors of Calif., Inc. v. California State Council of Carpenters*, 459 U.S. 519, 543 (1983) (unions lack antitrust standing to sue for injuries arising from contractors' alleged group boycott of companies that did not direct business to nonunion firms; barring such claims furthers "the strong interest, identified in our prior cases, in keeping the scope of complex antitrust trials within judicially manageable limits.").

As the Court has recognized, "The administrative efficiency interests in antitrust regulation are unusually compelling." *FTC v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411, 430 (1990). It is, of course, theoretically possible that a patent-infringement litigation settlement might have anti-competitive effects if it includes: (1) an agreement by the alleged infringer to delay market entry, but not past the end of the patent term; (2) no cash payments from the patentee to the alleged infringer; and (3) a compromise of existing damages claims whereby the

patentee agrees to receipt of a reduced award. But when, as here, a determination of whether such anti-competitive effects exists would require a trial regarding the validity of the underlying patent, *Actavis* counsels that antitrust scrutiny is not warranted. The Third Circuits conflicting determination merits review.

## II. 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.[7] Of course, no litigant will agree to a settlement unless he 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 only rarely are potential damages that a patentee could offer to forgo (or that are permissibly forgone without incurring antitrust scrutiny), 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

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[7] 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.

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 the only permissible settlement tool is an early-entry agreement along the lines endorsed by the Third Circuit. 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 the right to compromise damages claims) must remain 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*.

## CONCLUSION

The Court should grant the Petition.

Respectfully submitted,

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