No. 15-1055

In the Supreme Court of the United States

SMITHKLINE BEECHAM CORPORATION,
D/B/A GLAXOSMITHKLINE, ET AL., PETITIONERS

v.

KING DRUG COMPANY OF FLORENCE, INC., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

In patent litigation, a "reverse payment" settlement agreement is one that "requires the patentee to pay the alleged infringer, rather than the other way around." *FTC* v. *Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013). "[M]ost if not all" reverse-payment settlements occur in litigation involving pharmaceutical patents, when the manufacturer of a brand-name drug pays a potential generic competitor to drop its challenges to the manufacturer's patent and stay off the market for a specified period—an arrangement that maintains the manufacturer's ability to charge monopoly prices and shares the resulting profits with the challenger. *Ibid.* In *Actavis*, this Court held that such reverse-payment agreements "can sometimes violate the antitrust laws," and that they must be assessed under the rule of reason. *Id.* at 2227, 2237. The question presented is as follows:

Whether the court of appeals correctly rejected petitioners' contention that a reverse-payment agreement is immune from antitrust scrutiny if the consideration given by the brand-name manufacturer to the generic challenger is not a cash payment, but rather a promise to restrict its competition with the challenger after the challenger enters the market.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

Cases—Continued: Page

Statutes and rule:

Statutes and rule—Continued: Page

Miscellaneous:

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This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

Like *FTC* v. *Actavis, Inc.*, 133 S. Ct. 2223 (2013), this case involves a reverse-payment settlement agreement in which a brand-name drug manufacturer allegedly shifted millions of dollars in value to a potential generic competitor in order to induce the competitor to drop its challenges to the manufacturer's patent and stay out of the market for a specified period. In *Actavis*, this Court held that a reverse-payment agreement "can bring with it the risk of significant anticompetitive effects," and that the legality of such agreements must be judged under the rule of reason.

Id. at 2237. The payments at issue in *Actavis* were, "in substance," cash transfers. *Id.* at 2231. The question presented here is whether a reverse-payment agreement is immune from antitrust scrutiny if the brand-name manufacturer's payment instead takes the form of a promise to restrict its competition with the challenger's generic drug after the challenger enters the market.

1. "[M]ost if not all reverse payment settlement agreements" occur in litigation under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly known as the Hatch-Waxman Act. *Actavis*, 133 S. Ct. at 2227-2228. As the Court in *Actavis* explained, several features of Hatch-Waxman litigation create incentives for reverse-payment agreements.

a. A manufacturer that seeks to market a new drug —known as a brand-name or pioneer drug—must submit an application to the Food and Drug Administration (FDA) showing that the drug is safe and effective. 21 U.S.C. 355. Those applications require "a long, comprehensive, and costly testing process." *Actavis*, 133 S. Ct. at 2228.

Once the FDA approves a pioneer drug, the Hatch-Waxman Act allows a potential generic competitor to "piggy-back on the pioneer's approval" by filing an Abbreviated New Drug Application (ANDA). *Actavis*, 133 S. Ct. at 2228. An ANDA need not replicate the pioneer's studies demonstrating safety and effectiveness, but rather must specify that the proposed generic drug has the same active ingredients as, and is biologically equivalent to, the pioneer. *Ibid.*; see 21 U.S.C. 355(j). The ANDA process was designed to "further[] drug competition" by "'speed[ing] the in-

troduction of low-cost generic drugs.'" *Actavis*, 133 S. Ct. at 2228 (citation omitted).

b. Pioneer drugs are often covered by one or more patents, and the Hatch-Waxman Act establishes "special procedures for identifying, and resolving, related patent disputes." *Actavis*, 133 S. Ct. at 2228. A pioneer's application for FDA approval must identify any patent that could reasonably be asserted against someone manufacturing, using, or selling the drug. *Ibid.*; see 21 U.S.C. 355(b)(1). In turn, an ANDA must "assure the FDA that the generic will not infringe the brand-name's patents." *Actavis*, 133 S. Ct. at 2228 (citation and internal quotation marks omitted); see 21 U.S.C. 355(j)(2)(A)(vii).

One way a generic applicant can provide that assurance is by certifying that a patent identified by the manufacturer "is invalid or will not be infringed by the manufacture, sale, or use" of the proposed generic. 21 U.S.C. 355(j)(2)(A)(vii)(IV). That option, known as a paragraph IV certification, "automatically counts as patent infringement" and typically prompts the brand-name manufacturer to bring an infringement suit. *Actavis*, 133 S. Ct. at 2228; see 35 U.S.C. 271(e)(2)(A). If the manufacturer sues within 45 days of the paragraph IV certification, the FDA must withhold approval of the ANDA for up to 30 months while the parties litigate the validity and scope of the patent. *Actavis*, 133 S. Ct. at 2228. "If the courts decide the matter within that period, the FDA follows that determination; if they do not, the FDA may go forward and give approval to market the generic product." *Ibid.*; see 21 U.S.C. 355(j)(5)(B)(iii).

c. To encourage challenges to invalid patents and overbroad assertions of patent rights, the Hatch-

Waxman Act creates a "special incentive" for a generic to be the first to file a paragraph IV ANDA, by establishing a 180-day period during which the FDA is not permitted to approve additional ANDAs that would allow other generics to enter the market. *Actavis*, 133 S. Ct. at 2228-2229.[1] The Generic Pharmaceutical Association has stated that the "vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period." *Id.* at 2229. (citation omitted).

Because the brand-name manufacturer already has FDA approval, the first-filer's 180-day exclusivity period does not prevent that manufacturer from marketing its own "authorized generic" version of the drug—that is, from selling the drug in generic packaging and at generic prices. *Teva Pharm. Indus. Ltd.* v. *Crawford*, 410 F.3d 51, 54-55 (D.C. Cir. 2005). In recent years, brand-name manufacturers have often chosen to market authorized generics to help offset the large loss in revenue that results from the rapid shift away from brand-name drugs when cheaper generics become available. See Federal Trade Commission (FTC), *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* 26-27, 66-69 (Aug. 2011) (*AG Report*). The entry of an authorized generic reduces the first-filer's revenues during the exclusivity period by an average of 40% to 52%. *Id.* at iii, 58-59.

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[1] Under the version of the Hatch-Waxman Act that applies in this case, the 180-day period began on the earlier of the date of a final court decision finding the patent invalid or not infringed or the first-filer's commercial marketing of the drug. Pet. App. 14a n.9. It now begins when the first-filer commercially markets the drug. 21 U.S.C. 355(j)(5)(B)(iv)(I).

2. This case arises out of paragraph IV litigation between petitioner SmithKline Beecham Corp. d/b/a GlaxoSmithKline (GSK) and petitioners Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. (collectively, Teva). GSK marketed Lamictal, a brand-name drug used to treat epilepsy and bipolar disorder. GSK sold Lamictal in both tablet and chewable form, but the market for tablets was far larger—roughly $2 billion per year, as compared to $50 million per year for chewables. GSK's patent on Lamictal's active ingredient, lamotrigine, expired on July 22, 2008. Pet. App. 15a-16a.[2]

In April 2002, Teva filed the first paragraph IV ANDAs for lamotrigine tablets and chewables. GSK sued for patent infringement, and the FDA stayed the approval of Teva's ANDAs. In January 2005, following a trial, a district court ruled that the central claim in GSK's patent was invalid. The parties then asked the court to defer further rulings so they could pursue settlement. Pet. App. 16a, 52a.

GSK and Teva settled in February 2005. Pet. App. 16a. Their agreement provided that Teva could enter the market for chewables by no later than June 1, 2005, but that its entry into the (far larger) market for tablets would be deferred for at least three years, until near the expiration of GSK's patent. *Id.* at 16a-17a. To induce Teva to agree to drop its challenge to the patent and accept a later market-entry date, GSK promised that it would not market authorized generic versions of lamotrigine tablets and chewables during Teva's six-month period of first-filer exclusivity. *Id.* at 17a. That promise, referred to as the "no-AG agree-

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[2] Because this case arises from a motion to dismiss, we describe the facts as alleged in the operative complaint. Pet. App. 15a n.11.

ment," was likely worth at least tens of millions of dollars to Teva, and it required GSK to forgo the profits it could have earned by marketing an authorized generic. *Id.* at 32a-33a.

Under the parties' agreement, the exact date of Teva's entry into the market for lamotrigine tablets depended on whether GSK received "pediatric exclusivity." Pet. App. 16a-17a. Pediatric exclusivity is a non-patent form of exclusivity created to encourage studies on the use of pioneer drugs in children. If a manufacturer completes pediatric studies on one of its drugs after being asked to do so by the FDA, and the FDA accepts the results, the FDA generally may not approve an ANDA for the drug until six months after the manufacturer's patent expires. 21 U.S.C. 355a(c)(1)(B); see *AstraZeneca AB* v. *Apotex Corp.*, 782 F.3d 1324, 1341 (Fed. Cir. 2015).

The parties agreed that, if GSK did not receive pediatric exclusivity, Teva would be allowed to enter the market for tablets on March 1, 2008. Pet. App. 16a-17a. If GSK received pediatric exclusivity, then Teva would defer market entry until July 21, 2008—the day before GSK's patent expired. *Id.* at 16a, 53a. In that scenario (which ultimately came to pass), all but one day of the period during which GSK agreed not to market an authorized generic lamotrigine tablet occurred after GSK's patent expired, during the subsequent period of pediatric exclusivity. *Id.* at 53a.

3. Respondents are purchasers of Lamictal. In 2012, they filed this suit on behalf of a putative class, alleging that petitioners' agreement violated Sections 1 and 2 of the Sherman Act, 15 U.S.C. 1 and 2. The district court dismissed the complaint for failure to state a claim, but the court of appeals remanded for

further consideration after this Court held in *Actavis* that reverse-payment agreements must be judged under the rule of reason. Pet. App. 18a-20a.

On remand, the district court again dismissed the complaint, holding that "*Actavis* applies only to 'reverse payments' of money." Pet. App. 65a (capitalization altered). The court also stated that petitioners' agreement would "most likely" survive scrutiny under the rule of reason. *Id.* at 70a-72a.

4. The court of appeals vacated and remanded. Pet. App. 2a-50a. The court held that *Actavis* cannot "be limited to reverse payments of cash," and that "a no-AG agreement, when it represents an unexplained large transfer of value from the patent holder to the alleged infringer, may be subject to antitrust scrutiny under the rule of reason." *Id.* at 30a-31a. The court explained that, like a cash payment, a no-AG agreement can be of "great monetary value" to a generic challenger. *Id.* at 31a. The court further explained that using a valuable no-AG agreement "to induce the generic to abandon the patent fight" has the same anticompetitive consequences as a cash payment: "[T]he chance of dissolving a questionable patent vanishes," and "the generic also presumably agrees to an early entry date that is later than it would have otherwise accepted." *Id.* at 34a.

The court of appeals rejected petitioners' contention that no-AG agreements are immune from antitrust scrutiny "because they are in essence 'exclusive licenses'" authorized by the Patent Act, 35 U.S.C. 1 *et seq.* Pet. App. 36a. The court explained that "the 'right' [petitioners] seek is not in fact a patentee's right to grant licenses, exclusive or otherwise. Instead, it is a right to use valuable licensing in such a way as to in-

duce a patent challenger's delay" through a transaction with the same anticompetitive effect as a reverse payment of cash. *Id.* at 36a-37a (footnote omitted). Accordingly, while the court made "no statement about patent licensing more generally," it held that the presence of a patent license does not confer antitrust immunity on agreements that are in substance "reverse payments to prevent generic competition." *Id.* at 38a.

Finally, the court of appeals held that respondents' complaint adequately pleaded a rule-of-reason claim, and it remanded to allow litigation to proceed "under the traditional rule of reason, tailored, as necessary, to the circumstances of this case." Pet. App. 49a-50a.

5. The court of appeals denied rehearing en banc without recorded dissent. Pet. App. 73a-74a.

DISCUSSION

Petitioners contend (Pet. 13-34) that, notwithstanding this Court's decision in *FTC* v. *Actavis, Inc.*, 133 S. Ct. 2223 (2013), a reverse-payment agreement is categorically immune from antitrust scrutiny so long as the brand-name manufacturer uses a no-AG agreement rather than a cash payment to induce its would-be generic competitor to agree to abandon its patent challenge and accept a later date of market entry than it would otherwise insist upon. The court of appeals correctly rejected that argument, and its interlocutory decision does not conflict with any decision of this Court or another court of appeals.

Even if the question presented otherwise warranted this Court's review, this case would be an unsuitable vehicle in which to consider it. Petitioners' core argument, which they incorporate into their question presented (Pet. i), is that no-AG agreements are immune from antitrust scrutiny because they are exclu-

sive patent licenses "specifically permitted under the patent laws." In this case, however, GSK's promise not to market an authorized generic version of lamotrigine tablets extended for six months *past* the expiration of its patent. Such a promise cannot even arguably be characterized as a patent license or as conduct "expressly authorized by the Patent Act" (Pet. 4). Further review is not warranted.

A. The Rule Set Forth In *Actavis* Is Not Limited To Reverse Payments Of Cash

1. In *Actavis*, this Court rejected the so-called "scope of the patent" test, a rule applied by some lower courts under which a reverse-payment settlement generally was immune from antitrust scrutiny so long as the generic challenger's "promise not to enter the patentee's market expired before the patent's term ended." 133 S. Ct. at 2225, 2227. The Court found the "scope of the patent" test deficient because that approach, in assessing the competitive effects of a reverse-payment agreement, effectively assumes that the brand-name manufacturer's patent is valid and infringed. See *id.* at 2230-2231. The Court explained that "[t]he paragraph IV litigation" between the parties in *Actavis* "put the patent's validity at issue, as well as its actual preclusive scope." *Id.* at 2231. The parties' reverse-payment agreement "ended that litigation"—and eliminated the possibility of a finding that the patent was invalid or not infringed—through an "unusual" settlement in which "the plaintiff agreed to pay the defendants many millions of dollars to stay out of its market, even though the defendants did not have any claim that the plaintiff was liable to them for damages." *Ibid.*

The Court found "reason for concern that settlements taking this form tend to have significant adverse effects on competition." *Actavis*, 133 S. Ct. at 2231. When a potential generic competitor successfully challenges the validity or scope of a patent in paragraph IV litigation, it deprives the brand-name manufacturer of the "supracompetitive profits" made possible by the patent. *Id.* at 2234. The revenues lost by the manufacturer instead "flow in large part to consumers in the form of lower prices." *Ibid.* But when the manufacturer pays the challenger to drop its challenge and stay out of the market, the agreement "keeps prices at patentee-set levels," maintaining the "patent-related * * * monopoly return while dividing that return between the challenged patentee and the patent challenger. The patentee and the challenger gain; the consumer loses." *Id.* at 2234-2235.

In light of that significant potential for anticompetitive effects, and after taking into account a number of other relevant considerations, the Court held that reverse-payment agreements must be evaluated under the rule of reason. *Actavis*, 133 S. Ct. at 2237; see *id.* at 2234-2237. The Court emphasized that its conclusion was consistent with past decisions holding that the antitrust laws sometimes limit the ways in which litigants may settle patent disputes. *Id.* at 2231-2234.

2. The court of appeals correctly rejected the district court's conclusion that the rule set forth in *Actavis* is limited to cash payments. Reverse-payment agreements warrant antitrust scrutiny because they raise a "concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement" by "induc[ing] the generic challenger to abandon its claim with a share of [the]

monopoly profits that would otherwise be lost in the competitive market." *Actavis*, 133 S. Ct. at 2235-2236. That concern, and the corresponding risk of serious anticompetitive harms, is the same whether the manufacturer agrees to share its profits in cash or instead through some non-cash consideration, such as stock, real property, product inventory, or (as here) a reciprocal agreement not to compete.

There is thus no sound reason to limit *Actavis* to cash payments. To the contrary, adopting that distinction would "give drug manufacturers carte blanche to negotiate anticompetitive settlements so long as they involve non-cash reverse payments." *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 550 (1st Cir. 2016) (*Loestrin*). Such a rule would fly in the face of this Court's repeated admonitions that the antitrust laws are "aimed at substance rather than form." *American Needle, Inc.* v. *National Football League*, 560 U.S. 183, 193 (2010) (quoting *United States* v. *Yellow Cab Co.*, 332 U.S. 218, 227 (1947)).

B. Petitioners' Contention That No-AG Agreements Are Immune From Antitrust Scrutiny Because They Are Exclusive Patent Licenses Does Not Apply In This Case And Lacks Merit In Any Event

Petitioners do not defend the district court's holding that *Actavis* is limited to cash payments. Instead, they advance the narrower contention (Pet. 4) that a reverse-payment settlement involving a no-AG agreement is immune from antitrust scrutiny because no-AG agreements are "exclusive licenses" that are "expressly authorized by the Patent Act" in 35 U.S.C. 261. The premise that a no-AG agreement is "expressly authorized" by Section 261 pervades the petition and

is the basis for virtually all of petitioners' arguments on the merits. See, *e.g.*, Pet. i, 1, 4 11-12, 14, 18-22, 27.

Petitioners' reliance on Section 261 is misplaced for two reasons. Because GSK's promise not to launch an authorized generic extended for six months *after* the expiration of its patent, that promise cannot plausibly be characterized as a patent license. And in any event, the court of appeals correctly held that even a no-AG agreement that fell entirely within the patent term would not be immune from antitrust scrutiny.

1. Petitioners' no-AG agreement cannot be characterized as an exclusive patent license because it extended beyond the term of GSK's patent

Petitioners' agreement provided that, if GSK received pediatric exclusivity for Lamictal, Teva would delay its entry into the market for lamotrigine tablets until 5 p.m. on July 21, 2008—the day before GSK's patent expired. Pet. App. 16a-17a; C.A. App. 116. In exchange, GSK promised that it would not sell a competing authorized generic until January 2009. Pet. App. 16a-17a. Except for a few hours on July 21, that promise did not grant Teva any license, exclusive or otherwise, to practice the patent. Instead, GSK agreed to waive its pediatric exclusivity as to Teva, and further agreed to refrain from selling an authorized generic for a six-month period beginning the day before the patent expired.[3]

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[3] GSK had not yet received pediatric exclusivity when petitioners settled. Their agreement provided that, if GSK did not receive pediatric exclusivity, Teva could enter the market for tablets in March 2008, 4.5 months before GSK's patent expired. Pet. App. 16a-17a. It is unclear whether, in that scenario, the no-AG agreement for tablets would have extended beyond the patent term. See *id.* at 17a (stating unconditionally that the no-AG agreement ran

That distinction matters because "[a] pediatric exclusivity period is not an extension of the term of the patent." *AstraZeneca AB* v. *Apotex Corp.*, 782 F.3d 1324, 1343 (Fed. Cir. 2015). Pediatric exclusivity protects a brand-name manufacturer from generic competition by prohibiting the FDA from approving an ANDA for six months after its patent expires. *Id.* at 1341; see 21 U.S.C. 355a(b)-(c). During that period, however, the manufacturer's rights "[a]re not attributable to its patents." *AstraZeneca*, 782 F.3d at 1344. Instead, consistent with the "categorical principle that all patents, and all benefits from them, must end when their terms expire," *Kimble* v. *Marvel Entm't, LLC*, 135 S. Ct. 2401, 2413 (2015), a manufacturer's rights during a period of pediatric exclusivity are limited to those provided by 21 U.S.C. 355a and related provisions of the Hatch-Waxman Act. See, *e.g.*, *AstraZeneca*, 782 F.3d at 1343-1345 (holding that a manufacturer may not sue for patent infringement or recover Patent Act damages based on "sales during the post-expiration period of pediatric exclusivity").

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until January 2009, but without expressly addressing the no-pediatric-exclusivity scenario); C.A. App. 74 (complaint) (same). But the agreement recited that the FDA had asked GSK to perform pediatric studies on Lamictal, that GSK intended to perform the studies, and that GSK was "not aware of any information that call[ed] into question" its eligibility for pediatric exclusivity. C.A. App. 113. The parties thus expected their agreement to result in a no-AG commitment for tablets that extended beyond the patent term. The same appears to be true for chewables. Teva was allowed to enter that (far smaller) market well before the patent expired, but respondents allege that the no-AG agreement for both forms of the drug extended until January 2009. Pet. App. 16a-17a; C.A. App. 74 (complaint).

GSK's promise not to market an authorized generic during its pediatric-exclusivity period thus was not even arguably part of an exclusive patent license. The Patent Act authorizes a patent holder to grant "exclusive" rights "under his * * * patents." 35 U.S.C. 261. But neither Section 261 nor any other provision of the Patent Act authorizes agreements extending beyond a patent's expiration.

Petitioners assert (Pet. 11 n.2) that a period of pediatric exclusivity should be treated as "equivalent to a patent extension." But patents and pediatric exclusivity are governed by very different statutory schemes. Pediatric exclusivity simply bars the FDA from approving generic applicants through the abbreviated ANDA process; it does not confer any other exclusionary rights or remedies comparable to those afforded by the Patent Act. 21 U.S.C. 355a; see *AstraZeneca*, 782 F.3d at 1344-1345. Most importantly, petitioners' fundamental contention (*e.g.*, Pet. 4) is that *Actavis* should not apply to exclusive licenses because such arrangements are "expressly authorized by the Patent Act." By contrast, neither the Patent Act nor the Hatch-Waxman Act authorizes a brand-name manufacturer to grant an exclusive license of (*i.e.*, convey to another party the prerogatives associated with) its pediatric exclusivity.[4] This case there-

[4] The FDA does permit brand-name manufacturers to selectively waive pediatric exclusivity, allowing the agency to approve ANDAs filed by some generic applicants but not others. *AstraZeneca*, 782 F.3d at 1341. That sort of selective waiver, however, differs from a traditional exclusive patent license, since it does not limit in any respect the brand-name manufacturer's own ability to market the drug (for which that manufacturer already has FDA approval).

fore would be an inappropriate vehicle in which to decide a question that petitioners themselves have framed and argued (Pet. i) as an inquiry into the application of *Actavis* to conduct "specifically permitted under the patent laws."

2. In any event, no-AG agreements that fall within the term of a patent are not immune from antitrust scrutiny

a. Even when a no-AG agreement covers a period within the term of an existing patent, "[t]he anticompetitive consequences" of such agreements "may be as harmful as those resulting from reverse payments of cash." Pet. App. 34a. Like a cash payment, a no-AG agreement effectively allows the brand-name manufacturer to offer the generic challenger a share of its monopoly profits in order to induce the challenger to accept a later market entry date as a settlement term in paragraph IV litigation.

From the challenger's perspective, the 180-day exclusivity period can be worth "several hundred million dollars" and accounts for the "vast majority" of a generic's total potential profits from a drug. *Actavis*, 133 S. Ct. at 2229 (citations omitted). But if the brand-name manufacturer launches an authorized generic—something that generic firms "routinely assume" will occur when forecasting their "sales and profitability" —the first-filer's revenues during the exclusivity period are cut roughly in half. *AG Report* 81; see *id.* at iii, 58-59. The brand-name manufacturer's offer not to introduce an authorized generic can thus provide a very substantial financial incentive for the challenger to agree to stay off the market longer than it otherwise would. Here, for example, the court of appeals found "plausible indicia" that GSK's no-AG agreement

was worth tens or even hundreds of millions of dollars to Teva. Pet. App. 32a-33a.

For the brand-name manufacturer as well, a reverse-payment settlement with a no-AG agreement shares the key features of a settlement with a reverse payment of cash. The manufacturer maintains its patent monopoly, but then effectively shifts a portion of the resulting profits to the generic challenger by "giv-[ing] up the valuable right to capture profits" through an authorized generic. Pet. App. 33a. And like a manufacturer who agrees to make a cash payment to a party with no claim for damages, a manufacturer who enters into a no-AG agreement gives the challenger something it could not have obtained even if it had prevailed in the underlying paragraph IV litigation: a generic monopoly for the duration of its first-filer exclusivity period. See *Actavis*, 133 S. Ct. at 2233, 2235.

Accordingly, like a reverse payment of cash, a no-AG agreement can have "significant adverse effects on competition," *Actavis*, 133 S. Ct. at 2231, because it may not reflect "traditional settlement considerations" and may instead be an effort "to maintain supracompetitive prices to be shared among the patentee and the challenger," *id.* at 2236. Respondents allege that, but for the no-AG agreement, Teva would have entered the market for lamotrigine tablets far earlier than it actually did, either because the courts would have held the relevant claims of GSK's patent invalid, or because Teva would have launched "at risk" as soon as it secured FDA approval. Pet. App. 17a.[5] If GSK

[5] Teva's own representations lend credence to that allegation. In a suit filed against GSK for allegedly breaching the no-AG agreement, Teva asserted that GSK's promise not to market an authorized generic was "an important component of the settlement" that

had not agreed to the no-AG term, Teva might also have insisted on an earlier entry date as a condition of settling the paragraph IV suit.

Before this Court's decision in *Actavis*, no-AG agreements had become a common feature of reverse-payment settlements and served as "a recognized mode for a brand to provide compensation to generics." *AG Report* 152; see *id.* at 152-153. Antitrust immunity for such arrangements would thus provide a ready means of circumventing *Actavis*.

b. Petitioners do not appear to dispute that no-AG agreements can have the same anticompetitive effects as reverse payments of cash. Petitioners assert, however, that the court of appeals' analysis is inconsistent with the Patent Act's express authorization of exclusive licenses in 35 U.S.C. 261. See, *e.g.*, Pet. 4, 14, 22, 27. Petitioners are mistaken.

Exclusive patent licenses are authorized by Section 261, and they are often procompetitive. But neither Section 261 nor any decision of this Court suggests that exclusive licenses, or larger agreements containing exclusive licenses among their terms, are immune from antitrust scrutiny. More generally, although antitrust analysis of patent-related agreements must take account of congressional policy judgments reflected in the patent laws, the presence of a patent does not render the antitrust laws inoperative. To the contrary, "both within the settlement context and without, th[is] Court has struck down overly restrictive patent licensing agreements" as violations of the antitrust laws. *Actavis*, 133 S. Ct. at 2232-2233 (discussing cases); see, *e.g.*, *United States* v. *New Wrinkle, Inc.*,

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"formed part of the inducement to Teva to relinquish" its challenge to GSK's patent. Pet. App. 17a-18a (citation omitted).

342 U.S. 371, 378 (1952) ("Patents give no protection from the prohibitions of the Sherman Act * * * when the licenses are used, as here, in the scheme to restrain.").[6]

Although petitioners concede (Reply Br. 5) that an agreement that includes a patent license may violate the antitrust laws, they maintain that such an agreement warrants scrutiny only if "the parties engage in some anticompetitive conduct *beyond* the statutorily authorized license itself." But that accurately describes a reverse-payment settlement that relies on a no-AG agreement. The brand-name manufacturer does not simply confer an exclusive license on the generic challenger in return for a form of consideration, such as a payment of cash, that by itself has no anticompetitive effect. Instead, by agreeing to share its monopoly profits through the mechanism of a no-AG commitment, the brand-name manufacturer induces the potential generic competitor to agree to drop its patent challenge and to accept a later market entry date than it would otherwise find acceptable. The court of appeals correctly held that such an arrangement does not acquire the antitrust immunity that was found lacking in *Actavis* simply because the manufacturer uses an exclusive license rather than cash as the consideration to secure the challenger's agreement not to compete. Pet. App. 37a-38a.[7]

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[6] The federal antitrust agencies' longstanding guidance on the application of the antitrust laws to intellectual-property licensing likewise confirms that licenses are not immune from antitrust scrutiny. U.S. Dep't of Justice & FTC, *Antitrust Guidelines for the Licensing of Intellectual Property* § 2.1 (Apr. 6, 1995).

[7] Petitioners assert that the government in *Actavis* drew a distinction between a "reverse payment" and a "traditional exclusive

c. Petitioners also contend (Pet. 33) that treating no-AG agreements as reverse payments will impede settlement of patent cases. But parties' preference for a particular settlement term—which may be motivated "by a desire to maintain and to share patent-generated monopoly profits"—does not trump the antitrust laws. *Actavis*, 133 S. Ct. at 2237. Moreover, petitioners offer no evidence to support their assertion that parties will have difficulty settling without no-AG agreements, and the FTC's review of Hatch-Waxman Act settlements suggests otherwise.[8] The number of no-AG commitments fell significantly in 2013 and 2014, the first full year following *Actavis*. FTC, *Agreements Filed with the FTC Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed In Fiscal Year 2014* (Jan. 2016). But the total number of Hatch-Waxman Act settlements has not declined. Indeed, the 160 settlements in 2014 is the most of any year since the FTC began comprehensively tracking such settlements in 2004. *Id.* Ex. 1.

Under *Actavis*, parties remain free to "settle in other ways," such as by "allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the

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license." Pet. 2 (citing Tr. of Oral Arg. 3-4, *Actavis*, *supra* (No. 12-416)); see Reply Br. 3. But the government did not suggest that exclusive licenses enjoy antitrust immunity. And as the foregoing discussion makes clear, this case does not involve a "traditional exclusive license." Instead, it involves a transaction with the same economic substance as the reverse payment of cash at issue in *Actavis*.

[8] Since 2004, drug manufacturers have been required to file certain infringement-litigation settlement agreements with the FTC and the Department of Justice. See 21 U.S.C. 355 note.

challenger to stay out prior to that point." 133 S. Ct. at 2237. Nothing in the decision below casts doubt on such settlements. Indeed, the court of appeals specifically distinguished the no-AG agreement at issue here from an ordinary early-entry settlement. Pet. App. 39a; see *id.* at 33a-34a.

d. Finally, petitioners contend (Pet. 29-32) that the decision below threatens all patent licensing, not merely reverse-payment settlements between branded and generic drug manufacturers. But the antitrust objection here focused not on the grant of a patent license per se, but rather than on the use of a no-AG agreement as consideration in a transaction with the same anticompetitive effects as the cash transfers at issue in *Actavis*. Because typical patent licenses do not share those features, the decision below makes "no statement about patent licensing more generally." Pet. App. 38a.

C. The Decision Below Does Not Conflict With Any Decision Of Another Court Of Appeals Or Otherwise Warrant This Court's Review

The only other court of appeals to consider the issue has likewise "declined to limit *Actavis* to cash payments." *Loestrin*, 814 F.3d at 550. The First Circuit in *Loestrin* remanded the case to allow the district court to decide in the first instance whether the particular non-monetary commitments there at issue, which included a no-AG agreement, "warranted antitrust scrutiny as unlawful reverse payments." *Id.* at 552-553. Petitioners do not dispute that some forms of consideration other than cash can trigger antitrust scrutiny under *Actavis*.

Petitioners assert (Pet. 16-17) that this Court's guidance is urgently needed because district courts

considering the application of *Actavis* to different forms of non-cash consideration are "all over the map." Even if that characterization were accurate, disagreements among district courts do not warrant this Court's review because they can and should be resolved in the first instance by the courts of appeals. Sup. Ct. R. 10. In any event, petitioners' claim that district courts have reached conflicting results on the question presented here is based entirely on two district court decisions (in this case and in *Loestrin*) that (1) have been reversed on appeal and (2) adopted a legal rule (*i.e.*, that antitrust scrutiny under *Actavis* is limited to patent-infringement settlements that involve reverse payments of cash) that petitioners themselves do not defend.

Petitioners recognize that antitrust scrutiny under *Actavis* applies to *some* forms of non-cash consideration, while arguing that it does not apply to no-AG agreements. But petitioners do not cite a single district court decision, and we are aware of none, that has adopted that view of the law. Other than in this case and in *Loestrin*, the district courts that have considered the question have uniformly held that "a no-authorized-generic term can constitute a payment" subject to antitrust scrutiny under *Actavis*. *United Food & Commercial Workers Local 1776* v. *Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1070 (N.D. Cal. 2014).[9]

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[9] See, *e.g.*, *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 716-717 (N.D. Ill. 2016); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 245 (D. Conn. 2015); *In re Effexor XR Antitrust Litig.*, No. 11-5479, 2014 WL 4988410, at *22 (D.N.J. Oct. 6, 2014); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 752 (E.D. Pa.

Finally, petitioners imply (Pet. 32-33) that this Court should overlook the absence of a circuit split because future antitrust plaintiffs will simply file suit in the Third Circuit to take advantage of the rule adopted below. But cases currently pending in district courts in at least four other circuits—the First, Second, Seventh, and Ninth—likewise present the question whether a no-AG agreement can be a reverse payment within the ambit of *Actavis*. See p. 21 & note 9, *supra*. Petitioners thus provide no sound reason for this Court to abandon its usual practice by taking up a question that is just beginning to percolate in the courts of appeals. And, as explained in Part B.1, *supra*, a departure from that usual practice would be particularly unwarranted in a case where the brand-name manufacturer's no-AG commitment extended well beyond the expiration of the relevant patent.

2014); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 391-392 (D. Mass. 2013).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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