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 United States Court of Appeals
for the Third Circuit

BRIEF IN OPPOSITION

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QUESTION PRESENTED

In *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), this Court held that patent litigation settlements involving large "reverse payments" from the patent holder to the patent challenger, in exchange for the challenger dropping its patent challenge and staying out of the market, are subject to antitrust scrutiny under the rule of reason.

The question presented is:

Whether, contrary to every existing lower court precedent on the question, a reverse payment must be in cash and a patent holder may evade the holding of *Actavis* by agreeing not to market its own less-expensive "authorized generic" product in competition with the challenger's generic product rather than providing the equivalent value in cash.

RULE 29.6 DISCLOSURE

Respondent King Drug Company of Florence, Inc. has no parent corporation, and no publicly held company owns ten percent or more of its stock.

Respondent Louisiana Wholesale Drug Company, Inc. is wholly owned by Lyndale Enterprises, Inc., a privately held corporation, and no publicly held company owns ten percent or more of its stock.

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STATEMENT OF THE CASE

Just two terms ago, this Court held in *FTC v. Actavis, Inc.,* 133 S. Ct. 2223 (2013), that patent litigation settlements involving large "reverse payments" from the patent holder to the challenger, in exchange for the challenger dropping its suit and staying out of the market, are subject to antitrust review under the rule of reason. Petitioners ask this Court to grant certiorari to provide drug makers an easy workaround by declaring such settlements immune from antitrust scrutiny so long as the payment takes the form of a promise by the patent holder not to compete with the challenger's generic product (the sort of promise that, in itself, ordinarily constitutes a *per se* violation of the antitrust laws) rather than an equivalent payment in cash. The petition should be denied for three basic reasons.

First, because the issue presented by the petition is only just now beginning to percolate up to the courts of appeals, Petitioners are unable to allege any circuit conflict. Instead, Petitioners seek certiorari on the basis of alleged "confusion" in the *district* courts, perhaps forgetting that it is the function of the circuit courts, not this Court, to resolve trial judges' confusion. In any event, as detailed *infra*, there is no confusion, as every district court to have considered Petitioners' position has rejected it, with the exception of the district court in this case (overruled by the Third Circuit) and a district judge in Rhode Island whose decision was vacated by the First Circuit after the filing of the petition in this case.

Second, the argument's failure to attract any support in the lower courts is hardly surprising

because, as Judge Scirica convincingly explained below, Petitioners' position cannot be squared with *Actavis* or meaningfully distinguished from the "scope of the patent" theory this Court rejected in *Actavis*.

Third, even if the question Petitioners present might warrant review by this Court at some point, this case is an especially poor vehicle for addressing it. Petitioners ask the Court to decide whether a "grant of an exclusive license" is immune from antitrust scrutiny, Petition ("Pet.") i, but neglect to mention that the court of appeals rejected the contention that the agreement in this case conferred such an exclusive license, Appendix ("App.") 36a n.27, for sound reasons. In addition, the alleged "exclusive license" in question concerning the tablet form of Lamictal began *one day* before the patent expired. App. 15a, 17a. Thus, the settlement's alleged benefit to the patent challenger was not any assignment of a right in the patent but instead a purported waiver of "pediatric exclusivity," a regulatory benefit arising from a special statutory provision with its own distinct text and purposes. Surely, if the question presented is as important and recurring as Petitioners claim, the Court will have ample opportunity in the future to address it in the context of a cleaner vehicle.

I. Factual and Regulatory Background

Lamictal (active ingredient lamotrigine) is a brand-name pharmaceutical marketed by Petitioner GlaxoSmithKline LLC ("GSK") for the treatment of epilepsy and bipolar disorder. GSK sells Lamictal in at least two forms: Tablets and Chewables, the

former being significantly more profitable than the latter. App. 51a.

GSK's patent on Lamictal (the "'017 Patent") expired on July 22, 2008. App. 53a. The Pediatric Exclusivity period expired on Feb. 22, 2009, App. 17a, although that exclusivity period was not a bar to Petitioner Teva's market launch.[1]

In 2002, Petitioner Teva[2] filed Abbreviated New Drug Applications ("ANDAs") with the FDA seeking approval to market generic versions of both Tablets and Chewables. Teva's ANDAs contained "paragraph

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[1] As detailed *infra*, GSK's pediatric exclusivity was never a bar to Teva's market entry for two reasons: (1) GSK never obtained a court determination that the '017 patent was both valid and infringed by Teva's generic Lamictal products – a determination that would be statutorily required to enable GSK's pediatric exclusivity to prevent Teva's market entry for the six month period extending from the end of the '017 patent; and (2) Teva's ANDAs for both tablet and chewable forms of generic Lamictal received final Food and Drug Administration ("FDA") approval prior to the grant of pediatric exclusivity to GSK. *See* 21 U.S.C. § 355a(c)(1)(B)(II) (requiring court determination of validity and infringement in the paragraph IV ANDA and resulting patent litigation context); and *Ranbaxy Labs., Ltd. v. Burwell,* 82 F. Supp. 3d 159, 169 (D.D.C. 2015) ("Once an ANDA has been granted final approval, the manufacturer may begin selling the drug in interstate commerce. *See* 21 U.S.C. § 355(a)."). *See also* Respondents' Complaint at ¶¶ 21, 49, 63, *available at* Case No. 2:12-cv-00995-WHW-MCA (D.N.J.)(June 25, 2012)(ECF No. 55). Not only did GSK never obtain such a court determination, it affirmatively disabled a court from ever being able to do so by virtue of entering into the settlement challenged here.

[2] Herein, "Teva" is Petitioner Teva Pharmaceuticals USA, Inc. and Petitioner Teva Pharmaceutical Industries Ltd.

IV" certifications that the '017 Patent was invalid, unenforceable and/or not infringed by Teva's proposed generic products. App. 16a. As the first generic manufacturer to make such an application, Teva was statutorily entitled to 180 days of marketing exclusivity. During this 180 day period, the FDA was not permitted to approve any other ANDAs for generic versions of Lamictal Tablets and Chewables, placing Teva in the highly-profitable position of being the only generic manufacturer on the market. App. 52a.

Significantly, a first-filing generic's 180 day exclusivity does not prevent the brand manufacturer (GSK, here) from marketing an "authorized generic" ("AG") version of its brand product during the 180 day exclusivity period.[3]

In response to the paragraph IV certifications in Teva's ANDAs, GSK sued Teva for alleged infringement of the '017 Patent. The infringement litigation culminated in a bench trial that took place in January 2005. App. 52a. On the final day of trial, the judge ruled from the bench that Teva had established by clear and convincing evidence that claim 1 of the patent (which covered the active

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[3] "Authorized generic" is a term of art in the pharmaceutical industry. An AG product is simply the brand product sold under generic trade dress at a lower price than the brand, and is often launched by a brand manufacturer once a generic product enters the market in order to recoup some of the profits the brand would otherwise lose to the generic. App. 53a. GSK has launched AGs in at least ten instances during the 1999-2012 time period. *See* Complaint at ¶ 24.

ingredient in Lamictal) was invalid and that a ruling on the remaining claims would be forthcoming. App. 52a. Rulings on the remaining claims placed both GSK and Teva at risk. GSK stood to lose patent protection from generic competition, and Teva stood to lose its 180 day exclusivity period since its ANDAs were not otherwise ready for final approval from FDA immediately upon conclusion of trial.[4]

On February 2, 2005, GSK and Teva requested that the court refrain from issuing any further rulings. App. 52a. On February 16, 2005, GSK and Teva entered into a settlement agreement resolving the infringement litigation (the "Settlement"). App. 52a. Although Teva had already succeeded in invalidating claim 1 of the patent and was therefore well-poised to succeed on the remaining claims (all of which depended from claim 1), the Settlement contained the following terms:

- Teva agreed not to market a generic version of Lamictal Tablets until: (i) March 1, 2008 if GSK did not receive pediatric exclusivity; or (2) 5:00 PM (Pacific) on July 21, 2008 – the day before the '017 patent expired – in the event

[4] A final decision in Teva's favor from which no appeal could be or had been taken would trigger the running of Teva's 180-day exclusivity period, meaning that the period could expire before Teva actually marketed its product, leading it to lose the valuable opportunity of being the only generic (other than an AG) on the market for six months. App. 17a.

GSK did receive pediatric exclusivity, which GSK agreed to waive[5]; and

- GSK agreed not to launch an AG version of Lamictal Tablets during the first six months Teva was on the market.

App. 16a-17a.[6]

Thus, through this "no-AG" agreement, GSK promised not to compete with Teva's generic during its six months of Hatch-Waxman exclusivity, thereby removing the only source of generic competition Teva could face during that period. This no-compete agreement was "worth hundreds of millions of dollars to Teva." App. 33a.

But GSK could expect to make up those lost revenues and more through Teva's agreement to stay out of the market for at least three more years, during which time GSK could continue to charge monopoly prices for its brand name Lamictal drugs. In addition to removing Teva as a potential competitor, GSK would also eliminate the very real prospect of patent invalidation, which would have promptly opened the doors to competition by other generic manufacturers as well.

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[5] As stated in note 1 *supra*, because the pediatric exclusivity period could not prevent launch of Teva's product, GSK had nothing to waive as concerns Teva.

[6] The agreement also covered chewable forms of the drug, but the tablets were the far more important product. *See* App. 9a (noting that tablet market was "alleged to be annually worth $2 billion" compared to "$50 million" for the chewable form).

The deal was thus designed to ensure that consumers would continue to pay supracompetitive prices for lamotrigine for three-and-a-half years, with GSK and Teva dividing the surplus.[7]

II. Proceedings Below

1. Respondents are direct purchasers of Lamictal from GSK and filed their initial antitrust complaint in February 2012. App. 8a. In December 2012, the district court granted Petitioners' motions to dismiss Respondents' complaint, concluding that the Third Circuit's decision in *In re K-Dur Antitrust Litig.*, 686 F. 3d 197 (3d Cir. 2012), which held that "quick look" rule of reason was the appropriate standard for antitrust review of reverse-payment settlements, was only "directed towards settlements when a generic manufacturer is paid off with money, which is not the case here." App. 55a.

2. After Respondents filed a timely notice of appeal, the Third Circuit stayed proceedings pending the issuance of this Court's then-upcoming decision in *Actavis*. App. 55a. After *Actavis* issued, the Third Circuit remanded the litigation back to the district court for further proceedings. App. 55a. Respondents moved the district court for reconsideration of the district court's previous grant of the motions to dismiss, and the district court affirmed its previous

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[7] The Third Circuit noted that: "The no-AG agreement transfers the profits the patentee would have made from its authorized generic to the settling generic – plus potentially more, in the form of higher prices, because there will now be a generic monopoly instead of a generic duopoly." App. 33a.

dismissal, concluding that *Actavis* had "not change[d] this Court's earlier decision" because *Actavis* only applied to reverse payments "of money." App. 51a-72a.

In June 2015, the Third Circuit vacated the decision of the district court dismissing Respondents' complaint, concluding that *Actavis* was not limited to reverse payments of only cash, and that no-AG agreements that convey unexplained large transfers of value can constitute reverse payments. App. 2a-50a. Noting that what *Actavis* found problematic with reverse payments was not the specific form they took, but rather, their potential to harm competition, the Third Circuit correctly recognized that the same anticompetitive harm caused by reverse payments of cash is equally accomplished through a brand company's valuable agreement not to compete by refraining from launching its own less-expensive authorized generic product. *Id.* 31a-35a.

In so holding, the Third Circuit rejected Petitioners' argument that no-AG agreements are merely "exclusive licenses" permitted under principles of patent law that should be exempt from antitrust scrutiny. The Third Circuit recognized that what Petitioners truly sought sanction of, under the guise of an "exclusive license" label, was "***not in fact*** a patentee's right to grant licenses, exclusive or otherwise," but rather, the "right to use valuable licensing in such a way as to induce a patent challenger's delay." App. 36a-37a (emphasis added). Reiterating *Actavis's* concern about a patentee improperly leveraging its patent for the purpose of causing anticompetitive harm, as well as *Actavis*'s recognition that even *bona fide* exclusive licenses are

not exempt from antitrust scrutiny when utilized in anticompetitive ways, the Third Circuit concluded "that the Patent Act expressly authorizes licensing does not necessarily mean it also authorizes reverse payments to prevent generic competition." *Id*. 37a-38a.

The court therefore remanded the case for application of the rule of reason and resolution of any other defenses Petitioners might have. App. 45 n.35, 50a.

3. In September 2015, the Third Circuit denied Petitioners' request for rehearing and rehearing *en banc* without any recorded dissent. App. 73a-74a. Petitioners' writ followed.

REASONS FOR DENYING THE WRIT

Impatient Petitioners, unwilling to await either a final judgment in this case or the development of a circuit conflict, insist that this Court must grant interlocutory review to decide a question about the scope of *Actavis*, decided just two terms ago. That extraordinary request should be denied. Every court to have considered Petitioners' novel argument has rejected it (or been overruled). That uniform rejection is well founded. Petitioners' obvious attempt to evade *Actavis* by paying off patent challengers through valuable consideration other than cash is flatly incompatible with this Court's decision, antitrust law, and the Patent Act. And even if the Court believed Petitioners' arguments worthy of consideration at some point, this case presents a particularly poor vehicle for doing so.

I. There Is No Division In The Lower Courts Over Whether Patent Law Immunizes No-AG Agreements From Antitrust Scrutiny.

Petitioners do not even pretend that there is a circuit conflict over the antitrust treatment of no-AG agreements. Instead, they claim that this case presents the Court an opportunity to "resolve disagreement and confusion among the lower courts" (by which they mean *district* courts) "about the breadth and meaning of *Actavis*" (including issues other than the one presented by the petition). *See* Pet. 16-18. Even if this Court were in the business of resolving "confusion" among the district courts, review would still be unwarranted because no relevant disagreement or confusion exists.

To their credit, Petitioners are fairly forthright in acknowledging the lack of any circuit conflict. They emphasize, instead, that *Actavis* "has been applied and interpreted in more than 15 district court opinions, one jury trial, and the Third Circuit decision below," Pet. 15-16, and say that "*Actavis* left unanswered several important questions." *Id*. 16. Petitioners then proceed to list only two: (1) whether plaintiffs must "plead a reliable foundation for estimating the value of the alleged payment," *id.* 17, a question that would not be answered by granting certiorari here; and (2) the question presented here, *see id*. 17, 18-19.

With respect to the question presented here, Petitioners identify only two district court decisions accepting their view that "only naked reverse payments of cash are subject to rule of reason review": the district court's decision here and *In re*

Loestrin 24 Fe Antitrust Litig., 45 F. Supp. 3d (D.R.I. 2014). *See* Pet. 17. However, both decisions were subsequently reversed in unanimous panel decisions. *See* App. 50a; *In re Loestrin 24 Fe Antitrust Litig.,* 2016 U.S. App. LEXIS 3049, *25-26 (1st Cir. Feb. 22, 2016) ("Antitrust scrutiny attaches not only to pure cash reverse payments, but to other forms of payment that induce the generic to abandon a patent challenge….").

Thus, there is no conflict among the courts of appeals, and the district courts are now uniform in holding that *Actavis* is not limited to cash payments only.[8] Many of those decisions have involved no-AG

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[8] *See In re Opana ER Antitrust Litig.*, 2016 U.S. Dist. LEXIS 16700, *23-25 (N.D. Ill. Feb. 10, 2016) (deeming various forms of non-cash consideration as sufficient); *In re Actos End Payor Antitrust Litig.,* 2015 U.S. Dist. LEXIS 127748, *42 (S.D.N.Y. Sept. 22, 2015) ("This Court shares the majority view that *Actavis's* holding is not limited to payments made in cash"); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 242 (D. Conn. 2015) ("To read [*Actavis*] [as requiring cash] is to cabin its reasoning to the point of meaninglessness"); *United Food & Commercial Workers v. Teikoku Pharma USA*, 74 F. Supp. 3d 1052, 1069 (N.D. Cal. 2014) (agreeing with the "bulk of the recent decisions holding that courts need not restrict the definition of 'payments' under *Actavis* to cash"); *In re Effexor XR Antitrust Litig.,* 2014 U.S. Dist. LEXIS 142206, *62 (D.N.J. Oct. 6, 2014) ("*Actavis* never indicated that a reverse payment had to be a cash payment"); *Time Ins. Co. v. Astrazeneca AB*, 52 F. Supp. 3d 705, 709-10 (E.D. Pa. 2014) ("[R]everse payments deemed anti-competitive pursuant to *Actavis* may take forms other than cash payments"); *In re Lipitor Antitrust Litig.,* 46 F. Supp. 3d 523, 543 (D.N.J. 2014) (*Actavis* does not require cash); *In re Niaspan Antitrust Litig.,* 42 F. Supp. 3d 735, 751 (D.N.J. 2014) ("To read *Actavis* as [] limited [to cash] would be

agreements.[9] And several have specifically rejected Petitioners' argument that a no-AG agreement is nothing more than an "exclusive license" sanctioned by patent law and exempt from antitrust review.[10]

Petitioners' request to bypass and short-circuit the ordinary process of percolation in the courts of appeals is unwarranted. Petitioners imply that no circuit split could ever develop because forum shopping plaintiffs will abandon all other circuits and file suit only in the Third. Pet. 32. But Petitioners' own citations belie that speculation. *See id*. 18 (citing cases addressing question presented in the First, Second, Third, Seventh, and Ninth Circuits). Given the widespread rejection of Petitioners' theory by nearly every district court to have considered it, there is little reason to believe that plaintiffs will feel the

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particularly anomalous in the context of antitrust law, in which 'economic realities rather than a formalistic approach must govern'") (internal citation omitted); *In re Nexium (Esomeprazole) Antitrust Litig.,* 968 F. Supp. 2d 367, 392 (D. Mass. 2013) ("This Court does not see fit to read into [*Actavis*] a strict limitation of its principles to monetary-based arrangements alone").

[9] *See In re Loestrin*; *In re Opana*; *In re Aggrenox*; *United Food and Commercial Workers*; *In re Effexor*; *Time Ins. Co. v. Astrazeneca AB; In re Niaspan*; *In re Nexium*.

[10] *See, e.g., In re Aggrenox*, 94 F. Supp. 3d at 244 (rejecting defendants' argument that "an authorized generic should not be considered part of a reverse payment because exclusive licenses are authorized by the Patent Act and are the kind of traditional form of settlement *Actavis* permits"); *In re Niaspan*, 42 F. Supp. 3d at 751 ("[T]he Court rejects defendants' argument that a no-AG provision has the same economic effect as the grant of an exclusive license…").

need to flock to Third Circuit venues, even if they could.[11] Moreover, plaintiffs must also consider other consequences of venue selection, including their ability to subpoena witnesses. *See* Fed. R. Civ. P. 45. And defendants also may move for transfer of venue due to *forum non conveniens* or seek alternative venues by making application to the Judicial Panel on Multidistrict Litigation. *See, e.g.*, 28 U.S.C. § 1404(a) and 1407; *United States v. Nat'l City Lines, Inc.*, 337 U.S. 78 (1949).

II. The Decision Below Is Correct.

Certiorari is also unwarranted because the Third Circuit's decision is consistent with the decisions of this Court as well as long held understandings of patent and antitrust law.

A. *Actavis* Applies To No-AG Agreements As Well As Cash Payments.

As Judge Scirica convincingly explained below, there is no merit to Petitioners' insistence that no-AG agreements are excluded from the rule of reason analysis required by *Actavis*. *See* App. 21a-41a. While the inducement in *Actavis* was cash (disguised

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[11] Although 15 U.S.C. § 22 provides liberal venue for antitrust cases, plaintiffs still must satisfy statutory and constitutional requirements for personal jurisdiction over the defendant. *See KM Enters., Inc. v. Global Traffic Techs, Inc.*, 725 F.3d 718, 723 (7th Cir. 2013). Petitioners note that many pharmaceutical companies are headquartered in the Third Circuit, Pet. 32, but then emphasize that the question presented here could arise outside the context of pharmaceutical patents, *see id*. 29-31.

as payments for alleged legitimate services), nothing in *Actavis's* holding or rationale limits the rule to cash payments or excludes cases in which the alleged infringer is induced to drop its patent challenge through a valuable promise not to compete with the challenger's generic. To the contrary, as the Federal Trade Commission explained in its brief supporting Respondents below, Petitioners' "narrow reading of *Actavis* would undermine the Supreme Court's decision in that case and encourage parties to structure potentially anticompetitive reverse-payment settlements simply by avoiding the use of cash."[12]

1. Petitioners cite nothing in *Actavis* that expressly limits its holding to cash payments. To the contrary, the Court described the issue it confronted in terms that transcend the specific form of consideration paid by the patent holder. *See, e.g.*, *Actavis*, 133 S. Ct. at 2232 ("[T]his Court's precedents make clear that patent-related settlement agreements can sometimes violate the antitrust laws."); *id*. at 2332 ("Similarly, both within the settlement context and without, the Court has struck down overly restrictive patent licensing agreements.").

Nor do Petitioners seriously contest that no-AG agreements are materially indistinguishable from cash payments with respect to each of the five factors that led the Court to conclude that rule-of-reason

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[12] *See* Brief of Federal Trade Commission as *Amicus Curiae* ("FTC Br.") at 11, *available at* 2014 WL 1745072, Case No. 14-1243 (3d Cir.)(Apr. 28, 2014)(Document No. 003111601297).

review should be applied to the settlement before it. *See Actavis*, 133 S. Ct. at 2234-37; App. 28a-30a; FTC Br. 22 ("A No-AG commitment raises all the same concerns that the *Actavis* Court identified as a basis for antitrust review.").

Thus, in *Actavis* this Court first concluded that reverse payments of cash had "the potential for genuine adverse effects on competition." *Actavis*, 133 S. Ct. at 2234. That potential comes not from the form of payment, but from *what* the payment buys – namely, an end to the challenge of a potentially invalid patent and a delay in the challenger's entry into the market. *Id*. at 2234-35. That this delay in competition to the brand name drug is secured through an *additional* promise by the brand not to compete with its authorized generic only amplifies the anticompetitive effect of such agreements and the need for antitrust review. *See* FTC Br. 28 ("If anything, No-AG agreements raise even further antitrust concerns because they embody a *second, additional* agreement not to compete.")(emphasis in original).[13]

Second, the Court believed that "these anticompetitive consequences will at least sometimes

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[13] *See also* Areeda & Hovenkamp, Antitrust Law ¶ 2046d6 (2015 Supp.) ("'No authorized generic' agreements in fact place a second market exclusion agreement (i.e., generic versus generic, for 180 days following generic entry) on top of the first one, which was at issue in *Actavis* itself (pioneer versus generic for the term of the settlement). The outcome is *more anticompetitive* than a large cash payment for delay.") (emphasis added).

prove unjustified." *Actavis*, 133 S. Ct. at 2235-36. For example, the Court explained, the harm to competition is not justified when the payment is used "to prevent the risk of competition" by eliminating "the risk of patent invalidation or a finding of noninfringement." *Id*. at 2236. That same prospect arises when, as here, the defendant avoids competition by eliminating a patent challenge through a lucrative promise not to compete rather than direct cash payment.

Third, the Court regarded large payments to a patent challenger as showing that "the patentee likely possesses the power to bring that [competitive] harm about." *Actavis*, 133 S. Ct. at 2236. Here, the FTC estimated "GSK's agreement not to launch an AG version of Lamictal tablets during Teva's exclusivity period may have increased Teva's revenues by *hundreds of millions of dollars*." FTC Br. 13 (emphasis added). As in *Actavis*, GSK's willingness to cede hundreds of millions of dollars in revenue to Teva illustrates its ability to recoup those losses from consumers by charging supracompetitive prices during the several year period in which Teva agreed not to challenge its monopoly position. *See id*. 9-13.

Fourth, the Court believed that applying the rule of reason to reverse payments would not prove administratively infeasible. *Actavis*, 133 S. Ct. at 2236-27. Specifically, the Court rejected the claim that antitrust scrutiny would require courts to decide the validity of the relevant patent, explaining that "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness." *Id*. at 2236. Petitioners do not argue

that applying the rule of reason would be any less administrable in this case simply because the consideration paid was in the form of a non-compete agreement rather than cash.

Finally, the Court concluded that applying the rule of reason to large unjustified reverse payments would not "prevent litigating parties from settling their lawsuit." *Actavis*,133 S. Ct. at 2237. The Court noted that nothing in its holding precluded a patent holder from settling by "allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Id*. The same is true here. That GSK was unwilling to permit Teva immediate entry, and was willing to give it a concession worth hundreds of millions of dollars to stay out, suggests an illegitimate "desire to maintain and share patent-generated monopoly profits," *id.*, just as strongly as any cash payment would.

2. Instead of arguing that no-AG settlements pose a lesser competitive harm than cash payments, Petitioners simply insist that the public must suffer these harms because the arrangement does not exceed the scope of a patent holder's traditional right to issue exclusive licenses, even when they have anticompetitive consequences. Pet. 20-22. But as the Third Circuit observed (App. 38a n.29), this argument is hardly distinguishable from the "scope of the patent" theory this Court rejected in *Actavis*. *See Actavis*,133 S. Ct. at 2230-34.

At base, both the argument this Court rejected and the one Petitioners now propose are premised on the claim that antitrust principles cannot limit the

scope of the rights conferred by a patent. Pet. 20-22; *Actavis,* 133 S. Ct. at 2230. Yet this Court unambiguously rejected that claim in *Actavis* as fundamentally question-begging. The Court explained that "patent *and antitrust* policies are *both* relevant in determining the 'scope of the patent monopoly' – and consequently antitrust law immunity – that is conferred by a patent." *Actavis*,133 S. Ct. at 2231 (emphasis added). And the Court concluded that neither patent nor antitrust law conferred on patent holders a right to "simply pay a competitor to respect its patent and quit its invalidity or noninfringement claim without any antitrust scrutiny whatever." *Id*. at 2233 (quotation marks, brackets, and citation omitted).

3. In any case, Petitioners' arguments fail on their own terms. Petitioners are willing to concede that exclusive licensing agreements "may run afoul of the antitrust laws" if they "use the patent toward an *end"* that is illegitimate. Pet. 23 (emphasis in original). While Petitioners insist that no-AG agreements further "the valid end of protecting the patent," this Court made abundantly clear in *Actavis* that "avoid[ing] the risk of patent invalidation or a finding of noninfringement" is *not* a valid use of a patent or the monopoly profits it generates, *Actavis*, 133 S. Ct. at 2236, given the "patent-related policy of eliminating unwarranted patent grants," *id*. at 2233, and the antitrust policy of preventing agreements whose "objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market," *id*. at 2236.

B. Calling No-AG Agreements A Form Of "Exclusive License" Does Not Change The Analysis.

Simply recharacterizing the transaction as an "exclusive licensing" arrangement, Pet. 22, does nothing to alter the underlying economic reality or this legal conclusion. The antitrust objection is not that GSK licensed Teva to practice its patent, but that it *also* paid Teva not to do so until the patent was set to expire (thereby delaying competition for years) *and* bought Teva's acquiescence to a patent that very likely would have been invalidated (thereby preventing competition from other generics as well).

As Professor Hovenkamp has explained, it is *these* non-licensing aspects of the agreement that give rise to special antitrust concerns that warrant rule-of-reason scrutiny. That is, "[u]ntil generic production commences . . . the agreement is simply a horizontal market division." Areeda & Hovenkamp, Antitrust Law ¶ 2046d6 (2015 Supp.). After all,

> antitrust law does not ordinarily permit firms to agree to merge several years in the future but to fix prices or divide markets in the meantime. Pending the actual union, these agreements are simply naked restraints on trade. Justice Breyer's opinion for the *Actavis* court assumed as much when he concluded that payments for delay are not authorized by the Patent Act. The Patent Act does in fact authorize licenses but not agreements restraining trade pending a license to commence at some future date. A no-authorized-generic agreement that takes

> effect immediately but is part of an agreement that contemplates generic production several years in the future should be treated in the same way.

Id.

Accordingly, Petitioners' lengthy discourse on the established tradition of exclusive patent licenses, Pet. 20-22, is entirely beside the point. Even if no-AG agreements were properly called exclusive licensing arrangements – which they are not, *see infra* § II.C – Petitioners can point to no history of antitrust immunity for the practice of *using* exclusive licenses as a means of preventing competition in the manner alleged here. Quite to the contrary, while "the Patent Act contemplates licensing and actual production by others, it nowhere justifies reverse payments to keep others out." Areeda & Hovenkamp, Antitrust Law ¶ 2046d1 (Supp. 2015). *See also* 35 U.S.C. § 261 (stating only that patents "shall be assignable" and patent holders may "grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States").[14]

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[14] Even territorial divisions accomplished by exclusive licensing — the particular (and here, inapposite) subject of § 261 — receive scrutiny under the rule of reason, though some such territorial divisions have been upheld. *See* Areeda & Hovenkamp, Antitrust Law ¶ 2044a1 (Supp. 2015); Areeda & Hovenkamp, Antitrust Law ¶ 2046b3 (3d ed. 2012) ("Assuming the patent is valid, the Patent Act expressly permits exclusive licenses, but this fact alone does not render them immune from antitrust scrutiny.").

Moreover, contrary to Petitioners' assertion, this Court has consistently scrutinized exclusive and non-exclusive licenses at the very least under the antitrust rule of reason, and has sometimes applied even higher levels of scrutiny. *See Am. Needle, Inc. v. NFL*, 560 U.S. 183, 187, 203-04 (2010) (exclusive trademark license between NFL and Reebok "must be judged according to the flexible Rule of Reason"); *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 47, 50 (1990) ("agreement that gave BRG an exclusive license" to copyrighted materials and trademarks, such that "HBJ would not compete with BRG in Georgia and that BRG would not compete with HBJ outside of Georgia," was "unlawful on its face"); *Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 7, 10, 15-16, 19, 24 (1979) (despite provisions in Copyright Act expressly permitting blanket licenses, blanket license would be judged under antitrust Rule of Reason); *Timken Roller Bearing Co. v. United States*, 341 U.S. 593, 598 (1951) (allocation of territories incidental to trademark licensing contracts was subject to antitrust scrutiny). In *Actavis*, this Court cited *United States v. Line Material Co.*, 333 U.S. 287 (1948), which had condemned a patent licensing scheme despite the dissent's citation of § 261 (then codified as § 47). 333 U.S. at 333-34 (Burton, J. dissenting).[15]

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[15] Petitioners' cited decisions are not to the contrary. Petitioners cite *United States v. Gen. Elec.*, 272 U.S. 476 (1912), but characterize the license there as vertical, Pet. 24, and as controlling the licensee's minimum resale prices, neither of which characteristic is present here. *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 394 U.S. 175 (1938) merely restates that a

C. No-AG Agreements Are Not Exclusive Patent Licenses.

Even if Petitioners were right that exclusive patent licenses are generally immune from antitrust scrutiny, that would make no difference here because no-AG agreements are not the equivalent of traditional exclusive patent licenses.

In a traditional exclusive license, the patent holder turns over its patent rights to the licensee, and the licensee alone practices the patented invention, receiving rights to enforce the patent. *See e.g.*, *Waterman v. Mackenzie*, 138 U.S. 252, 256 (1891) (an exclusive license "excludes all other persons, even the patentee"); *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1553 (Fed. Cir. 1995) (en banc) (licensees held to be not exclusive licensees because licensee "had no right under the agreements to exclude anyone from making, using, or selling the claimed invention"); United States Dep't of Justice and Fed. Trade Comm'n, Antitrust Guidelines for the Licensing of Intellectual Property ("DOJ Guidelines") § 5.7 (1995) ("[A]n exclusive license for intellectual property" is "a license that precludes all other persons, including the licensor, from using the licensed intellectual property"). In this case, by contrast, Teva did not receive any rights to enforce GSK's patent (under the challenged agreement GSK specifically retained those rights). And GSK was not

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patentee may issue licenses to a patent containing field of use restrictions. Neither decision purports to construe § 261; neither involved a territorial division.

required to (and concedes it did not) stop selling branded Lamictal at any time. *See* Pet. 12 n.3.

Second, no-AG agreements do not function as traditional exclusive patent licenses in any relevant respect. Ordinary exclusive licenses may have procompetitive effects, permitting a patent holder to create incentives in the licensee to more efficiently exploit the patent, "benefiting consumers through the reduction of costs and the introduction of new products." DOJ Guidelines § 2.3.[16] "These various forms of exclusivity can be used to give a licensee an incentive to invest in the commercialization and distribution of products embodying the licensed intellectual property and to develop additional applications for the licensed property. The restrictions may do so, for example, by protecting the licensee against free-riding on the licensee's investments by other licensees or by the licensor." *Id.*

Here, Petitioners do not argue that the absence of GSK's authorized generic created incentives in Teva to help GSK reduce costs, introduce new products, or benefit consumers. Instead, as Professor Hovenkamp has noted, the point of such a "no-AG" agreement generally is not to authorize the generic to practice a patent, but to induce a potential competitor

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[16] In briefing before the court of appeals, GSK, echoing this principle, argued that exclusive licenses "have been upheld repeatedly for more than a century where they create more competition than existed before." *See* Brief of Defendant-Appellee GlaxoSmithKline LLC at 18, *available at* Case No. 14-1243 (3d Cir.)(May 27, 2014)(Document No. 003111630881).

to *delay* production of the patented drug, here until after the patent has expired:

> "No authorized generic" agreements sometimes take the form of an "exclusive license" given to the generic to commence production at some future date. One defense thus offered for them is that the Patent Act itself authorizes exclusive licenses. ***Given the delay, however, such agreements appear not to constitute a "license" at all. At most they are agreements to license production at some future time.*** Until generic production commences, however, the agreement is simply a horizontal market division.

Areeda & Hovenkamp, Antitrust Law ¶ 2046d6 (2015 Supp.) (emphasis added).

The "no authorized generic" agreement here is precisely what Professor Hovenkamp describes. Petitioners allege that Teva would have launched generic lamotrigine tablets in or around August of 2006 after receipt of final approval from FDA, App. 17a, but instead agreed to delay entry into the market until March or July of 2008, *id*. 16a-17a, in exchange for GSK's admitted agreement, Pet. 11, not to launch a competing authorized generic until January 2009, 6 months after Teva had been on the market. App. 17a.[17] Teva would not have delayed its

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[17] The "no authorized generic" provision was thus effective for months *after* the expiration of GSK's patent. *Id*. 16a-17a.

launch if not for the large "inducement" that the "no authorized generic" agreement represented. *Id.* 17a-18a; 33a ("hundreds of millions of dollars to Teva"). In subsequent litigation between GSK and Teva, Teva admitted that "GSK's no-AG agreement was 'an important component of the settlement between the parties and formed part of the inducement to Teva to relinquish the rights and defenses it was asserting against GSK in the Patent Litigation.'" *Id*. 17a-18a. GSK and Teva's no-authorized-generic agreement took effect immediately, but was part of an agreement that contemplated generic production almost two years in the future.

As Professor Hovenkamp describes, the "no authorized generic" agreement was thus not a license, but was "[a]t most [an] agreement[] to license production at some future time." Areeda & Hovenkamp, Antitrust Law ¶ 2046d6 (2015 Supp.). Neither GSK nor Teva could point the court of appeals to a single example of an agreement containing these features that was classified by a court as an exclusive license, much less one held immune from antitrust scrutiny. The petition likewise lacks any such citation.

III. This Case Is A Poor Vehicle For Addressing The Question Presented.

Even if the question presented by the petition warranted review, this would be a poor case for answering it.

A. Because Petitioners' No-AG Agreement Is Not An Exclusive Patent License, The Question Presented Does Not Arise On The Facts Of This Case.

Petitioners ask this Court to decide whether "a patentee's grant of an exclusive license" is immune from antitrust scrutiny. Pet. i. They insist that the question warrants review in the absence of a circuit conflict because the proper treatment of exclusive licensing agreements is an important issue affecting "all patent licensing, not only the licensing of pharmaceutical patents." *Id*. 29. Petitioners thus do not argue that the proper antitrust treatment of no-AG agreements in pharmaceutical settlements is a question independently worthy of the Court's attention. They consciously chose to seek review solely on the broader question of whether exclusive licenses in general are immune from antitrust scrutiny. And they have made no attempt to document how common, or explain how important, no-AG settlement terms are standing alone. *Cf.* Pet. 30 (providing statistics regarding the number of exclusive licenses generally).

Accordingly, Petitioners' assertion that no-AG agreements are exclusive licenses is essential not only to their merits argument, but also to their claim that the petition presents a question of sufficiently broad and recurring significance to warrant review.

But as discussed, the premise of both arguments – that no-AG agreements are exclusive licenses – is incorrect. Having considered the specific agreement in this case, the court of appeals did "not believe that the no-AG agreement was in fact an 'exclusive

license.'" Pet. 36a n.27. And, while it declined to rest its decision on that conclusion, *id*., the court was clearly correct. *See supra* at pp. 22-25. As a consequence, the question presented by the petition does not arise in this case.

B. This Case Presents An Atypical No-AG Agreement.

Even if the proper treatment of no-AG agreements was, in itself, a question worthy of this Court's attention at this time, this case would still present a poor vehicle because the particular no-AG agreement between Petitioners is atypical in ways that would substantially complicate the Court's analysis and limit any decision's usefulness for providing guidance in future cases.

First, Petitioners claim that no-AG agreements are immune from antitrust scrutiny because they merely exercise a right (to give an exclusive license) long recognized to be inherent in the patent itself. *See, e.g.*, Pet. 1 ("This Court has long recognized that express patent rights include a right to grant a license to practice the patent."). But, as noted, the agreement in this case gave Teva permission to practice the tablet patent for exactly one day – the day before the patent expired. *See supra* at pp. 3, 5-6. After that, GSK did not purport to license the expired patent to Teva, but instead to "waive" a

regulatory period of "pediatric exclusivity." Pet. 11 & n.2.[18]

Petitioners insist in passing that this is a distinction that makes no difference, Pet. 11 n. 2, but that is incorrect. As recently explained by the Federal Circuit, the "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) (citing 21 U.S.C. § 355a(o)(1)) (distinguishing patent exclusivity from non-patent exclusivity). *See also* FDA, *Guidance for Industry Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act* (Sept. 1999), at 13 ("Pediatric exclusivity . . . is not a patent term extension under 35 U.S.C. § 156.") (internal citations omitted). Whether Congress would have intended to allow recipients of pediatric exclusivity to leverage such receipt to delay competition is a distinct question that turns on an interpretation of a separate statutory provision with its own language, history, and purposes. *See* 21 U.S.C. § 355a(o)(1).

Second, even if waiver of a period of pediatric exclusivity received the same treatment under antitrust law as a patent license, here the purported waiver is simply meaningless window dressing on a naked restraint of trade. Teva did not need a "waiver" of GSK's pediatric exclusivity period in order to market generic Lamictal tablets. Because

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[18] Any attempt to license an expired patent is invalid. *See, e.g., Brulotte v. Thys Co.*, 379 U.S. 29, 30, 33 (1964); *Kimble v. Marvel Entertainment, LLC*, 135 S. Ct. 2401, 2407 (2015).

Teva filed and maintained a paragraph IV certification to the '017 Patent and obtained final FDA approval on August 30, 2006, GSK's later-awarded pediatric exclusivity period could not prevent the market launch of Teva's generic Lamictal tablet upon expiration of the '017 Patent or during earlier periods of time.[19] Thus, the August 2006 final FDA approval for Teva's generic Lamictal tablets, and Teva's associated right to enter the market, could not have been hindered in any way by GSK's later receipt of pediatric exclusivity.

Accordingly, the arrangement between GSK and Teva involved neither a meaningful patent license (the patent having expired) nor even a genuine waiver of pediatric exclusivity. The essence of the agreement, instead, was simply that Teva would drop its challenge to GSK's patent and stay out of the market for three or more years, in return for GSK agreeing not to compete with Teva's generic for six months. That is simply a naked restraint of trade. *See* FTC Br. 28-29; Areeda & Hovenkamp, Antitrust Law ¶ 2046d6 (2015 Supp.). For that reason, GSK would lose this case even if the Court granted

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[19] Upon receipt of final FDA approval, an applicant is free to begin commercially marketing its generic drug in the United States. *See Ranbaxy Labs., Ltd. v. Burwell*, 82 F. Supp. 3d 159, 169 (D.D.C. 2015) ("Once an ANDA has been granted final approval, the manufacturer may begin selling the drug in interstate commerce. See 21 U.S.C. § 355(a).").

certiorari and answered the Question Presented in the affirmative.[20]

CONCLUSION

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

Respectfully submitted,

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May 2, 2016

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[20] Given the case's interlocutory posture, answering the Question Presented might not affect the result in this case for other reasons as well. *See, e.g.*, App. 45a n.25 (leaving "the question of antitrust injury" for the district court on remand).