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 OTHER SIMILARLY SITUATED,
Respondents.

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

SUPPLEMENTAL BRIEF OF PETITIONERS

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SUPPLEMENTAL BRIEF OF PETITIONERS

In *Actavis*, the Government assured this Court that permitting antitrust review of an unusual type of patent settlement would not impose any obstacles to "a wide range of ordinary settlement practices" and would allow patent owners to continue to exercise rights granted by Congress, such as the ability to enter exclusive licenses.[1] This Court's decision reflects those commitments. *See* Pet. 20-28. But the Government has a new message about the limits that it previously endorsed: never mind.

The Government suggests in its amicus brief that whenever an exclusive patent license poses a danger of "anticompetitive effects," it ought to be subject to antitrust scrutiny under the rule of reason despite the explicit statutory authorization. That is no test at all, leaving parties settling patent litigation no guidance other than the near certainty of expensive antitrust litigation—and the threat of treble damages. But worse, it is fundamentally inconsistent with the premise of having patent rights in the first place: The exercise of patent rights, by definition, can *always* be said to limit competition. And an exclusive license to a patent will always restrict competition more than a hypothesized non-exclusive license.

The Third Circuit's decision means *all* exclusive patent licenses between potential competitors are at risk—whether the licenses arise from litigation settlements or otherwise. Yet such licenses are at the

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[1] *See* Reply Brief for the Petitioner at 10, *FTC v. Actavis*, 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 1099171; Transcript of Oral Argument at 4:3-21, *FTC v. Actavis*, 133 S. Ct. 2223 (2013) (No. 12-416).

heart of a patentee's statutory rights, and exclusive licenses are granted routinely in fields across the American economy.

The Government's endorsement of the Third Circuit's boundless approach to *Actavis* is unsurprising because the FTC is actively litigating *Actavis* cases in the Third Circuit and has consistently pushed for broad readings of this Court's decision (including as an amicus below). But lower courts that have attempted to honor this Court's effort in *Actavis* to balance patent law and antitrust policy (rather than override the former with the latter) have struggled to identify limiting principles that would allow parties to settle patent litigation without risking antitrust liability. This case offers an opportunity to provide much-needed guidance by establishing an essential (but narrow) limiting principle: When a patentee offers a challenger consideration that is intrinsic to the patent itself—such as a license authorized by the patent laws—that, without more, cannot subject the patentee to the risk of treble damages under the antitrust laws.

Downplaying both the Third Circuit's actual holding and its own flip-flop in endorsing it, the Government suggests that this case is a suboptimal vehicle for establishing that principle because the settlement terms involved not *just* exclusive patent licenses but also an exclusive waiver of the brand manufacturer's statutory pediatric-exclusivity rights. Yet that fact played no role in the decision below, and it would not affect this Court's review. The undisputed presence of patent licenses in this case would allow

the Court to reach the question presented without even addressing the pediatric-exclusivity issue. Moreover, the Government offers no reason why a waiver of statutory exclusivity rights that have the effect of extending a patentee's exclusivity should be treated differently for antitrust purposes than licensure of patent rights themselves. Courts routinely treat them the same way, and properly so.

The Third Circuit is already the epicenter of *Actavis* litigation (because it is home to many of the nation's pharmaceutical companies and the antitrust laws permit nationwide venue, 15 U.S.C. § 22), and forum-shopping plaintiffs undoubtedly will bring future claims there to take advantage of the Circuit's new anti-patent rule. *See* Pet. 32. This Court should grant the petition to ensure that the Third Circuit's rule does not become the *de facto* national standard.[2]

A. *Actavis* Must Be Subject To Some Limiting Principle.

The Government devotes the initial portion of its brief (at 9-11) to an argument that was *not* the basis for the Third Circuit's decision and was *not* raised in the petition here, contending that *Actavis* should not be limited to cash payments. But the fact that a "cash-only" rule may not be viable does not suggest (as the Third Circuit and the Government would

[2] The Government speculates (at 22) that pending actions in other Circuits might someday raise the issue presented here, but the Government completely fails to address the *in terrorem* effect that the Third Circuit's decision will exert on patent owners throughout the country.

have it) that reverse-payment claims should have no limiting principle *at all*. To the contrary, other lower courts have correctly recognized that "limiting principles" are needed to avoid "subject[ing] virtually *any* settlement to antitrust scrutiny—a result [this] Court could not have intended." *In re Actos End Payor Antitrust Litig.*, No. 13-9244, 2015 WL 5610752, at *14 (S.D.N.Y. Sept. 22, 2015). As the district court observed in this case, a "law student learns in the first semester that consideration is an essential element of any enforceable contract. In this sense, there is 'payment' in every settlement." App. 68a. If anything that may be characterized as a "payment" or "compensation" were subject to antitrust scrutiny, there would be no way to settle patent-infringement litigation without risking liability for damages. As this Court has acknowledged, the rule-of-reason inquiry entails "notoriously high litigation costs and unpredictable results." *Kimble v. Marvel Entm't*, 135 S. Ct. 2401, 2411 (2015).

That problem is illustrated by this very case, where Respondents maintain that any settlement term beyond unconditional "immediate entry" by the generic competitor should trigger antitrust scrutiny. BIO 17. That is not a settlement but a surrender, and settlements are unlikely where surrender is the only option. Accordingly, courts have concluded that "not *all* non-cash settlement terms fall within the purview of *Actavis*," *Actos*, 2015 WL 5610752, at *13. And they have tried to develop a way to distinguish suspect reverse payments from permissible settlement consideration in order to "preserv[e] for liti-

gants a viable path to resolve their disputes." *In re Loestrin 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180, 192 (D.R.I. 2014). But courts have struggled over the limiting principle to be applied.

The Government offers no help. Its approach (at 15-20) treats all valuable settlement consideration as a potentially illicit reverse payment, subjecting all settlements to antitrust scrutiny and potential treble damages. Instead, the Government merely wishes the problem away, suggesting with unjustifiable confidence that settlements without consideration somehow remain possible.[3]

Petitioners propose a straightforward limiting principle that is rooted in *Actavis* and the laws enacted by Congress: Where a patentee offers a challenger consideration that is intrinsic to the patent—such as a license or exclusive license—that, without more, cannot invite antitrust scrutiny.

An otherwise permissible, statutorily authorized license should not become impermissible simply be-

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[3] The Government relies (at 19) on its own FTC report that purportedly supports this conclusion. That report considered 53 settlements that "involve 'first-filer' generics," such as the settlement at issue in this case. Of those, only one "does not restrict the generic manufacturer's ability to market its product." FTC, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2014*, at 2 (Jan. 2016). Even taking the FTC's self-interested characterizations at face value, only one analogous settlement appears to meet Respondents' test for a permissible settlement agreement.

cause it is given in the context of settling a case. *Actavis* itself recognizes that the mere exercise of rights granted to a patentee under the patent statute should not be subject to antitrust scrutiny.[4] Even the Government itself told this Court when litigating *Actavis* that conduct "authorized by the Patent Act" would not risk antitrust scrutiny,[5] though it has now reversed its position without any meaningful effort to reconcile its current view with its prior representations to the Court. *See* U.S. Br. 18-19 n.7. If this Court is serious about striking a "balance" between antitrust policy and patent law—rather than subordinating the latter to the former—it ought to reaffirm this basic principle. *Actavis*, 133 S. Ct. at 2231; *see* Pet. 20-28.

B. Evaluating Patent Licenses On A Case-By-Case Basis Is Unworkable And Contrary To The Patent Laws.

The Government argues that an exclusive license—even one falling entirely within the patent term—should be subjected to full-scale rule-of-reason review when it is granted pursuant to an agreement settling Hatch-Waxman litigation because, under those circumstances, it may have "anticompetitive effects." U.S. Br. 20. Those effects, the Government asserts, distinguish this case from ones involving so-

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[4] *FTC v. Actavis*, 133 S. Ct. 2223, 2233 (2013) (asking whether "any patent statute … grant[s] such a right to a patentee, whether expressly or by fair implication").

[5] *See* Transcript of Oral Argument at 4:3-21, *FTC v. Actavis*, 133 S. Ct. 2223 (2013) (No. 12-416).

called "typical patent licenses" and so, in the Government's view, the Third Circuit's decision does not undermine the patent laws.

The problem with the Government's approach is there is no such thing as a "typical" patent license that does not involve terms which could theoretically be more or less restrictive. Short of complete capitulation by the patent owner, the exercise of patent rights *always* limits competition (and could always persuade an actual or potential challenger to give up a patent fight), so in principle patent licensing could raise antitrust concerns under a wide range of circumstances—unless the statutory authorization is understood to exempt the exercise of patent rights from the antitrust laws.

A patent is "an exception to the general rule against monopolies and to the right to access to a free and open market." *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). This Court has recently said that "[t]he patent laws—unlike the Sherman Act—do not aim to maximize competition (to a large extent, the opposite). And the patent term—unlike the 'restraint of trade' standard—provides an all-encompassing bright-line rule, rather than calling for practice-specific analysis." *Kimble*, 135 S. Ct. at 2413.

Abandoning the bright-line rule of the Patent Act would lead to incoherence because it would require case-by-case determinations about whether exercises of patent rights under certain circumstances restrained competition *even more* than the permissible

exercise of those rights under other circumstances. There is no principled way to conduct that analysis, and it contradicts the well-established rule that the Sherman Act does not authorize judges "to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition." *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 415-16 (2004).

The Third Circuit's approach (which the Government endorses) does just that, and its analysis cannot be confined to the Hatch-Waxman context. Exclusive licenses *always* restrict competition more than a hypothesized non-exclusive license. So each and every patent litigation settlement that involves an exclusive license—and indeed each and every licensing agreement, even if not executed as part of a litigation settlement—might be subjected to antitrust scrutiny on the theory that the patentee is sharing its monopoly profits with the exclusive licensee. That would always be true—because that's precisely what a patent monopoly and license do.

The Government relies on Respondents' allegation 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." U.S. Br. 16. One might ask the Government to identify the principle limiting a plaintiffs' ability to allege a hypothetically more competitive alternative to an exclusive licensing arrangement. Are exclusive licenses suspect only

when offered in the context of a litigation settlement agreement? What about an agreement in anticipation of litigation? What about an agreement where litigation is a theoretical possibility? What if plaintiffs allege that litigation and patent invalidity would have happened absent the agreement? Or even for non-exclusive licensees, what if entry could be earlier? What if there were no conditions on early entry?

There is no stopping point, and the result is to subject routine agreements to antitrust scrutiny. Exclusive licenses represent 84 percent of patent licenses in the life sciences sector, 66 percent of patent licenses issued by commercial licensors, and 94 percent of patent licenses issued by universities.[6] The threat to these arrangements is apparent from the fact that amici both within *and outside* the pharmaceutical industry have filed briefs here in support of certiorari.

C. There Is No Vehicle Problem.

The Government argues that this case is a poor occasion to clarify the relationship of patent to antitrust law because it involves a waiver of statutory exclusivity in addition to exclusive patent licenses. That is no reason to avoid the question presented.

As an initial matter, the settlement agreement indisputably involved exclusive patent licenses. GSK

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[6] Thomas R. Varner, *An Economic Perspective on Patent Licensing Structure and Provisions*, 46 Bus. Econ. 229, 237 (Oct. 2011).

granted Teva an exclusive license allowing Teva to sell lamotrigine chewables supplied by GSK by June 1, 2005—more than three years before the patent expired. App. 52a.[7] In addition, GSK promised that if it did not receive pediatric exclusivity, it would grant Teva an exclusive license for tablets beginning on March 1, 2008. App. 53a. Because GSK did receive pediatric exclusivity, it granted Teva an exclusive license for tablets that ran from July 21 to July 22, 2008, and an exclusive waiver of its pediatric-exclusivity rights that ran for six months thereafter. *Id.*[8] The Government even concedes (at 12) that the settlement agreement included a patent license for July 21. So the question of patent licensing would be presented even if the Government were correct about pediatric-exclusivity waivers.

Nothing in the Third Circuit's decision turned on a supposed distinction between an exclusive patent license and a statutory-exclusivity waiver. The Third Circuit treated the settlement as an exclusive licensing agreement, and its opinion applies to all patent licensing arrangements, including those that involve a patent license alone. This Court has no reason to address a distinction on which the Third Circuit did not rely; if the Court believes the distinction is significant, it could decide the exclusive-license issue

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[7] GSK also granted Teva an exclusive license allowing Teva to sell its own lamotrigine chewables by June 1, 2006. 3d Cir. Appx. JA117-18 (§ 2.2 of License and Supply Agreement).

[8] Respondents claim that each of these exclusive licenses induced Teva to delay its generic launch. 3d Cir. Appx. JA52, 80 (Amended Compl. ¶¶ 23, 93).

and then remand for the lower court to consider whether the presence of a pediatric-exclusivity waiver was relevant.

Nevertheless, the exclusivity waiver does not affect the analysis. Courts routinely treat pediatric exclusivity as equivalent to an extension of the patent term.[9] And it functions in a materially identical way. A patentee that succeeds in establishing infringement is entitled to an order barring the infringer from marketing its product prior to the end of any pediatric exclusivity. *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1367-69 (Fed. Cir. 2008). Pediatric exclusivity, like a patent, provides a right to exclude, as do many other congressionally granted statutory exclusivities. And because pediatric exclusivity does not apply until the end of a patent term, the effect of pediatric exclusivity is to extend the patent term, as courts have recognized.

The Government relies heavily (at 14) on the Federal Circuit's recent decision holding that a patentee cannot recover damages for patent infringement based on royalties that would have been due during the pediatric exclusivity period. *See AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324 (Fed. Cir. 2015). But the Government over-reads that decision, which also recognized that pediatric exclusivity functions like a

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[9] *See, e.g.*, *Merck & Co. v. FDA*, 148 F. Supp. 2d 27, 29 (D.D.C. 2001) (describing company's pediatric exclusivity as "a six-month extension of its patent rights"); *In re Omeprazole Patent Litig.*, 258 F. Supp. 2d 221, 224 n.1 (S.D.N.Y. 2001) ("The FDA granted Astra a six-month pediatric exclusivity extension of the patent term pursuant to 21 U.S.C. § 355a.").

patent extension in other respects. The Federal Circuit emphasized that the licensing of production during the exclusivity period, and the payment of royalties during the exclusivity period, was entirely proper and akin to a patent license. *Id.* at 1342.

Although this Court has held that a royalty agreement cannot project beyond the expiration date of the patent, *see Brulotte v. Thys Co.*, 379 U.S. 29 (1964), the Federal Circuit explained that "[t]he Court's analysis in *Brulotte* … does not apply to a situation … in which Congress, by creating the pediatric exclusivity period, *explicitly authorized additional market exclusivity to be granted to the patent owner beyond the life of the patent*" and therefore the patentee's "demand for royalty payments for post-expiration sales does not rest on its patent monopoly; the demand is based on the fact of [its] *legal entitlement to a pediatric exclusivity period*." *AstraZeneca*, 782 F.3d at 1342 (emphasis added). A prospective licensee under those circumstances "would have agreed to a license covering both the patent term and the pediatric exclusivity period" because both would be necessary in order to produce the product. *Id.* at 1344.

Thus, for licensing purposes, the rights conferred by a patent and those conferred by a statutory exclusivity are indistinguishable. In both cases, Congress has granted the patentee a market exclusivity that may be licensed at the patentee's discretion. Indeed, "the FDA allows [a brand manufacturer] to monetize its exclusivity right by waiving it in favor of a generic drug manufacturer, much as a patentee may li-

cense the right to use its patent for a payment of royalty." *Id.* at 1343.

The Government provides no compelling reason to treat the "exclusive waiver" of a statutory exclusivity, App. 53a, differently from the "exclusive license" under the patent laws for antitrust purposes.

CONCLUSION

The petition should be granted.

Respectfully submitted,

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