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

REPLY BRIEF OF PETITIONERS

BARBARA W. MATHER
Counsel of Record
ROBIN P. SUMNER
PEPPER HAMILTON LLP
Eighteenth & Arch Street
Philadelphia, PA 19103
(215) 981-4000
matherb@pepperlaw.com

Counsel for GlaxoSmithKline LLC

JAY P. LEFKOWITZ, P.C.
Counsel of Record
STEVEN J. MENASHI
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4800
lefkowitz@kirkland.com

JOHN C. O'QUINN
GREGORY L. SKIDMORE
KIRKLAND & ELLIS LLP
655 Fifteenth Street NW
Washington, DC 20005

Counsel for Teva Pharm. Indus. Ltd., et al.

May 16, 2016

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

REPLY BRIEF OF PETITIONERS

The Third Circuit squarely decided that an exclusive license, though authorized by the Patent Act, may be a suspect reverse payment under *FTC v. Actavis*, 133 S. Ct. 2233 (2013). In doing so, it distorted *Actavis*, which struck a balance between patent law and antitrust policy in part by excepting statutorily authorized settlement forms from antitrust scrutiny. This Court instructed lower courts to ask "whether 'the patent statute specifically gives a right'" to engage in the challenged conduct. *Id.* at 2231. Even the commentators on whom Respondents rely recognize that "extra antitrust deference is due to patent practices challenged under the Sherman Act when the practice is either expressly authorized by the Patent Act or is there 'by fair implication.'"[1]

Respondents' position in defense of the decision below boils down to this: Unless a patentee entirely gives up and allows immediate generic entry, any settlement terms are subject to antitrust scrutiny. That was not this Court's holding in *Actavis*, and it ignores the careful balance this Court said it was striking in that case.

---

[1] Areeda & Hovenkamp, Antitrust Law ¶ 2046d5 (2016 Supp.) (quoting *Actavis*); *id.* ¶ 2046c ("Justice Breyer's opinion … refused to subordinate antitrust concerns to those of patent law, at least in areas where *the Patent Act did not explicitly authorize the conduct in question*.") (emphasis added); *id.* ¶ 1508 ("One additional element to which the Court gave significance was that the 'reverse' payment in this case was nowhere authorized by the Patent Act."); *id.* ¶ 2046d1 ("If the Patent Act expressly authorizes a specific practice, then that practice standing alone cannot violate the more general antitrust laws.").

As evidenced by the decision below and Respondents' arguments, *Actavis*'s careful balance has been eviscerated. Many lower courts have concluded that antitrust policy overrides patent law when evaluating a patent litigation settlement—and the resulting confusion requires this Court to clarify the relationship between patent and antitrust law in this context. Unless this Court intervenes, Respondents' approach will permeate the case law and make settlement of many patent cases all but impossible.

A. This Court Must Clarify The Relationship Between Patent And Antitrust Law.

To justify the decision below, Respondents offer a policy argument based entirely on antitrust concerns. In *Actavis*, however, this Court sought "an accommodation" or "balance" between antitrust policy and patent law. *Actavis*, 133 S. Ct. at 2231. The Court followed precedents that sought "to accommodate patent and antitrust policies, finding challenged terms and conditions unlawful unless patent law policy offsets the antitrust law policy." *Id.* at 2233. One clear marker of a patent-law "offset" occurs when a "patent statute … grant[s] such a right to a patentee, whether expressly or by fair implication." *Id.* Where the patentee exercises a statutory right, antitrust policy must yield. That is because the lawful exercise of a patent right cannot be measured by its effect on competition. *Kimble v. Marvel Entm't*, 135 S. Ct. 2401, 2413 (2015) ("The patent laws—unlike the Sherman Act—do not aim to maximize competition."). Nor do patent rights wax and wane depending on the context. *Id.* ("[T]he patent term—unlike

the 'restraint of trade' standard—provides an all-encompassing bright-line rule, rather than calling for practice-specific analysis.").

It was therefore essential to the outcome in *Actavis* that the settlement there did not include the exercise of a right authorized by "any patent statute" and that making a payment not contemplated by the patent laws was "difficult to reconcile" with overall patent policy and found no support in precedent. *Actavis*, 133 S. Ct. at 2233.

Granting an exclusive license, by contrast, is both statutorily authorized and consistent with patent policy. As the Government acknowledged while litigating *Actavis*, an exclusive license is different from a reverse payment for (at least) two reasons. First, "an exclusive license is expressly authorized by the Patent Act, in Section 261 of Title 35."[2] Second, "an exclusive license doesn't give … the infringement defendant anything that it couldn't hope to achieve by prevailing in the lawsuit."[3] That is, by granting a license to allow the challenger to produce a generic product, the patentee does not exercise extraneous "market power" but exercises only the patent right itself. *Actavis*, 133 S. Ct. at 2236. The Court acknowledged these distinctions by emphasizing that the reverse payment at issue in *Actavis* was extraneous to the patent right and that settlements taking more "commonplace forms" are not subject to antitrust liability. *Id.* at 2233.

---

[2] Transcript of Oral Argument at 4:10-12, *FTC v. Actavis*, 133 S. Ct. 2223 (2013) (No. 12-416).

[3] *Id.* at 4:16-19.

Respondents, like the court below, ignore these distinctions and subject the exclusive license here to antitrust review even though such licenses are expressly authorized by patent law and supported by well-established precedent. *See* Pet. 20-28. Such antitrust analysis makes little sense in the context of a litigation settlement. For example, Respondents argue that 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 as an anticompetitive "agreement[] restraining trade pending a license to commence at some future date" because "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." BIO 19.

The analogy is inapt. In patent litigation, any settlement will necessarily reflect a compromise whereby the challenger agrees to respect the patent for some time but the patentee agrees to license market entry at some point "prior to the patent's expiration." *Actavis*, 133 S. Ct. at 2237. That is a compromise of what each party hopes to gain from the litigation—exactly what this Court said *was* permissible. *Id.* Respondents' approach, however, ignores the reality that the agreement resolves a dispute over legal patent rights rather than the division of an open market.[4]

---

[4] Moreover, it is not even correct that settlements short of immediate generic entry are anticompetitive. *See* Harris, Murphy, Willig & Wright, *Activating Actavis: A More Complete Story*, Antitrust, Spring 2014, at 83, 86 ("[A]ny settlement that maintains the Brand's exclusivity for even a minimal period

Contrary to Respondents' suggestion, there is no tension between respecting lawful patent rights and this Court's precedents. This Court did not hold that an "exclusive trademark license" was subject to rule-of-reason review in *American Needle v. NFL*, 560 U.S. 183 (2010). Rather, the Court concluded that the individual teams holding trademarks had engaged in "concerted action" to coordinate their licensing activities, and "[t]he legality of *that concerted action* must be judged under the Rule of Reason." *Id.* at 186 (emphasis added). Nor did the Court hold that an exclusive license to distribute copyrighted materials was "unlawful on its face" in *Palmer v. BRG of Georgia*, 498 U.S. 46 (1990). Although a licensor did grant BRG of Georgia an exclusive license to distribute materials in Georgia, the offending aspects of the parties' agreement were a bare geographic market allocation between existing competitors and a "price increase that took place immediately after the parties agreed to cease competing with each other." *Id.* at 49.

Respondents' cases demonstrate that the grant of an exclusive license does not attract antitrust scrutiny unless the parties engage in some anticompetitive conduct *beyond* the statutorily authorized licensing itself—a result consistent with *Actavis*. Here, there is no concerted action and no naked market

---

eliminates some 'risk of competition,' however small, during this period. There is no economic basis for concluding, however, that such a settlement results in anticompetitive harm if, in the alternative, Generic entry would have been expected to occur later.") (footnote omitted). The antitrust model on which Respondents and the Third Circuit rely "would condemn some procompetitive settlements." *Id.* at 87.

allocation—and there is actually a price *decrease* resulting from the *commencement* of generic competition pursuant to the license agreement.

This Court must clarify the balance between antitrust and patent law it struck in *Actavis*. Otherwise, courts will continue to extinguish lawful patent rights enacted by Congress.

B. Parties Must Be Able To Settle Patent-Infringement Litigation.

In *Actavis*, this Court emphasized that the antitrust scrutiny applied to reverse payments "does not prevent litigating parties from settling their lawsuit" because a settlement might properly "allow[] the generic manufacturer to enter the patentee's market prior to the patent's expiration." *Actavis*, 133 S. Ct. at 2237. As Respondents would have it, however, the only way for GSK and Teva to have settled their lawsuit without risking antitrust liability would have been for GSK "to permit Teva immediate entry" because antitrust law does not allow "agreements restraining trade pending a license to commence at some future date." BIO 17-19. That means no settlement is safe unless the patentee ceases enforcing its patent immediately. Given that generic companies are incentivized to challenge even strong patents,[5] requiring immediate abandonment of patent rights makes settlement unworkable.

---

[5] FTC, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact, at iii n.7 (2011), http://1.usa.gov/1TiPFJx [hereinafter FTC Report] (noting that a generic manufacturer "will expect a patent challenge to be profitable" even if it has less than a 10% chance of winning).

The parties here did not invent early-entry licensing as a settlement term. In *Actavis,* the Government maintained that "parties to paragraph IV litigation have broad freedom to settle by agreeing upon a *compromise* date of generic entry."[6] This Court endorsed that view. *Actavis*, 133 S. Ct. at 2237. And courts following *Actavis* have recognized "the limiting principles set forth in the decision" that exempted "legal early-entry settlement" from antitrust scrutiny. *In re Actos End Payor Antitrust Litig.*, No. 13-CV-9244, 2015 WL 5610752, at *13-*14 (S.D.N.Y. Sept. 22, 2015).

Nor did the parties here invent the notion of a six-month exclusivity period. The main incentive for generic companies to bring Paragraph IV challenges in the first place is the promise of the six-month exclusivity period offered by the Hatch-Waxman Act. As this Court recognized, the "vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period." *Actavis*, 133 S. Ct. at 2229; *see* 21 U.S.C. § 355(j)(5)(B)(iv). It makes sense that licensing agreements settling such litigation might provide a six-month exclusivity period for the generic challenger. Such a settlement term cannot be "unexplained" because it attempts to resolve the litigation by providing an incentive like the one Congress provided to induce the litigation in the first place.

The aggressive antitrust position advocated by

---

[6] Reply Brief for the Petitioner at 8-9, *FTC v. Actavis*, 133 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 1099171 (emphasis added).

Respondents condemns settlements that compromise on the entry date and parallel the incentive structure created by Congress.[7] If such settlements are impermissible, then this Court must explain how parties may settle patent-infringement litigation without risking antitrust damages.

C. This Case Involves An Exclusive License Authorized By The Patent Act.

Respondents attempt to confuse the issues by insisting that a brand manufacturer's licensing generic production while agreeing to refrain from issuing an authorized generic is not an "exclusive license." BIO 22. Many courts have acknowledged that it is. *See, e.g.*, *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 379 (D. Mass. 2013) ("A brand manufacturer may … opt to forgo its right to market an authorized generic by entering into a 'no-authorized generic' agreement with the first-filer. Such agreements commonly take the form of an exclusive license that allows the first-filer to market a generic version of the brand manufacturer's brand-name drug during the 180-day exclusivity period.") (internal citation omitted); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 244-45 (D. Conn. 2015) (arguing that "a 'no-authorized generic' agreement" represents value that "is transferred in the form of

[7] The antitrust model on which Respondents rely has been criticized because it "does not account for key institutional features of the Hatch-Waxman Act" and ignores "the incremental private and social costs of litigation." Kobayashi, Wright, Ginsburg & Tsai, *Actavis and Multiple ANDA Entrants: Beyond the Temporary Duopoly*, Antitrust, Spring 2015, at 89, 90-91.

exclusive licenses instead of cash"). The FTC has also described such an agreement as an exclusive license.[8]

Although the Third Circuit may have questioned whether the agreement at issue included an exclusive license, it decided this case on the assumption that it did. App. 36a n.27 ("[T]he issue of whether such agreement is an exclusive license is not necessary for our decision here."). The question is thus properly presented.

Respondents characterize the license as an "agreement[] to license production at some future time." BIO 25. Yet such an agreement to transfer the right to sole practice of a patent in a particular field *is* an exclusive licensing agreement. *See Textile Prods. v. Mead Corp*., 134 F.3d 1481, 1484 (Fed. Cir. 1998) ("[A]n exclusive license is 'a license to practice the invention ... accompanied by the patent owner's promise that others shall be excluded from practicing it within the field of use wherein the licensee is given leave.'").

The Patent Act contemplates that an exclusive licensee might be limited by geography, and a patent holder may license its invention exclusively for limited uses. 35 U.S.C. § 261; *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 304 U.S. 175, 181 (1938) ("Patent owners may grant licenses extending to all uses or limited to use in a defined field."). Such limitations do not rob a license of its exclusive character.

---

[8] FTC Report, *supra* note 5, at 145 n.12 (describing "the brand company's granting the first-filer an exclusive license to a generic version of the brand").

Respondents' further insistence that the agreement cannot qualify as a license without sufficient "pro-competitive effects," BIO 23, mistakes a question of patent law for antitrust policy. *See Kimble*, 135 S. Ct. at 2413.

Respondents also suggest that the statutory "pediatric exclusivity" period complicates this case. It does not. As the district court explained, pediatric exclusivity "adds an additional six months of protection to the existing patent term." App. 53a.[9] When the parties negotiated the settlement agreement, they anticipated that pediatric exclusivity would do just that. The addition of those six months by statute does not alter the issues in the case. The court below decided this case on the ground that a statutorily authorized exclusive license may be a reverse payment under *Actavis*.[10] That Respondents now press a theory of liability not addressed by the Third Circuit is

---

[9] The appellate court noted that "[w]ith a pediatric exclusivity extension … the FDA would have been foreclosed from approving ANDAs filed by competing generics until" six months after the patent expired. App. 17a.

[10] Following the settlement, Teva received ANDA approval before GSK received pediatric exclusivity. If there were no settlement waiving pediatric exclusivity, the FDA would have proceeded differently. If litigation had continued and GSK prevailed, the patent-infringement court could have reset the effective ANDA date to the end of the pediatric exclusivity period and reset final FDA approval to tentative approval. *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1368-69 (Fed. Cir. 2008) (concluding a court may reset the effective date of an ANDA to reflect the grant of pediatric exclusivity); *Mylan Labs. v. Thompson*, 389 F.3d 1272, 1281-82 (D.C. Cir. 2004) (concluding a court may consider an ANDA with final approval as only tentatively approved once a showing of infringement is made).

no reason to let stand an erroneous decision based on a flawed application of this Court's precedent.

D. Only This Court Can Clarify What It Meant In *Actavis*.

Respondents argue certiorari is unwarranted because courts agree that *Actavis* is not limited to cash payments. BIO 11. That is not the question presented by this petition. Rather, it is clear from *Actavis* that *some* basis for settlement must be available without risking antitrust damages. Yet many courts, like the Third Circuit, read *Actavis* to hold that any transfer of *anything of value* from the patentee to the challenger invites antitrust scrutiny. That understanding makes settlement impossible. *Cf. Actos*, 2015 WL 5610752, at *14 ("[*A*]*ny* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement.").

This petition asks the Court to clarify that a patentee may at least exercise rights specifically authorized by Congress in the Patent Act without risking antitrust liability or the "notoriously high litigation costs and unpredictable results" of a rule-of-reason inquiry. *Kimble*, 135 S. Ct. at 2411.

That conclusion follows from this Court's insistence that *Actavis* did not disturb longstanding precedent holding that the exercise of traditional patent rights does not subject a patentee to antitrust scrutiny. *See* Pet. 20-28. Yet this Court's ambiguity in holding that reverse "payments" must be subjected to scrutiny where "large" and "unjustified" has led to judicial confusion and conflict. *See Aggrenox*, 94

F. Supp. 3d at 242 ("[C]ourts applying *Actavis* have thus had relatively little guidance on the question of what constitutes a 'large' and 'unjustified' reverse payment, and have diverged even on the issue of what constitutes 'payment.'").

This Court has granted certiorari where ambiguities in its decisions have prompted confusion in the lower courts. *E.g.*, *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288-89 (1995) (clarifying statement in *Cipollone v. Liggett Group* that spawned confusion about availability of preemption defense); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352-53 (2001) (clarifying scope of holding in *Medtronic v. Lohr*). That clarification is especially necessary here, where the Court overturned the majority approach among the lower courts—the scope-of-the-patent test—but did not explain the test courts are to apply instead. That ambiguity has left an "uncertain but disruptive effect" on patent litigation, *Aggrenox*, 94 F. Supp. 3d at 233, and created results that this Court specifically disclaimed: new judicial scrutiny of traditional patent rights, and the inability of parties to settle patent-infringement litigation without risking antitrust liability.

Whether *Actavis* properly leads to such results is a question of exceptional importance this Court should answer.

CONCLUSION

The petition should be granted.

Respectfully submitted,

BARBARA W. MATHER
Counsel of Record
ROBIN P. SUMNER
PEPPER HAMILTON LLP
Eighteenth & Arch Street
Philadelphia, PA 19103
(215) 981-4000

Counsel for
GlaxoSmithKline LLC

JAY P. LEFKOWITZ, P.C.
Counsel of Record
STEVEN J. MENASHI
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4800

JOHN C. O'QUINN
GREGORY L. SKIDMORE
KIRKLAND & ELLIS LLP
655 Fifteenth Street NW
Washington, DC 20005

Counsel for Teva Pharm.
Indus. Ltd., et al.

May 16, 2016