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No. 15-___

Supreme Court, U.S.
FILED
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IN THE

Supreme Court of the United States

ALLERGAN PLC AND FOREST LABORATORIES, LLC,
Petitioners,

v.

STATE OF NEW YORK, BY AND THROUGH
ERIC T. SCHNEIDERMAN, ATTORNEY GENERAL,
Respondent.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Brand drug manufacturers seeking to market a new prescription drug must undergo a long and expensive process to obtain FDA approval. Under the 1984 Drug Price Competition and Patent Term Restoration Act, better known as Hatch-Waxman, generic drug manufacturers can obtain FDA approval for a "bioequivalent" generic drug more easily, by piggy-backing on the brand's approval efforts. Once the brand drug's patent and other exclusivities expire and generic versions enter the market, state drug substitution laws permit or require pharmacists to dispense lower-priced, therapeutically equivalent generic drugs in place of brand drugs, unless the prescriber directs otherwise. Under most (but not all) states' definitions of therapeutic equivalence, however, pharmacists may not substitute a generic drug that has a different dose than the prescribed brand without the physician's approval.

The Second Circuit held below that brand drug manufacturers have a federal antitrust duty to facilitate the operation of state drug substitution laws so as to maximize the future sales of their generic competitors. Petitioners are a brand drug manufacturer and its subsidiary, who sought to exercise their rights under the Patent Act to limit distribution of an outdated version of their patented Alzheimer's drug in favor of an innovative new formulation with different dosing and longer patent protection. The Second Circuit held that so doing would violate section 2 of the Sherman Antitrust Act because it would reduce the number of prescriptions most state substitution laws would automatically hand over to Petitioners' generic rivals once the old drug's exclusivities ended. The questions presented are:

1. Whether exercising rights granted by the Patent Act—in particular, not selling one patented product and selling a different patented product instead—can violate the Sherman Antitrust Act?

2. Whether drug manufacturers have a federal antitrust duty to facilitate the operation of state drug substitution laws to maximize competitors' sales?

CORPORATE DISCLOSURE STATEMENT

In accordance with Supreme Court Rule 29.6, Petitioners make the following disclosures:

Forest Laboratories, LLC is an indirect wholly owned subsidiary of Allergan plc, a public limited company incorporated in Ireland and traded on the New York Stock Exchange under the ticker symbol AGN. No publicly held company owns ten percent or more of the stock of Allergan plc.

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OPINIONS BELOW

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JURISDICTION

The Second Circuit issued its decision on May 22, 2015, App. 1a, and denied rehearing en banc on August 7, 2015, App. 146a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2, provides:

> Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

Section 154(a)(1) of the Patent Act, 35 U.S.C. § 154(a)(1), provides:

> Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others

> from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specification for the particulars thereof.

Section 271(d) of the Patent Act, 35 U.S.C. § 271(d), provides in relevant part:

> No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: ... (4) refused to license or use any rights to the patent ....

INTRODUCTION

The Second Circuit affirmed an unprecedented antitrust injunction forcing a brand drug manufacturer to continue making and selling an outdated patented drug it wanted to replace with a new and improved version. The court held that withdrawing twice-daily Namenda IR in favor of innovative once-daily Namenda XR violated section 2 of the Sherman Act because certain state pharmacy laws treat the two drugs differently. In particular, most states allow or require pharmacists to dispense a generic version of IR in place of brand IR, but not in place of brand XR. The Second Circuit held that instead of maximizing their own sales and profits, Petitioners had to keep selling IR to maximize the sales state drug laws would automatically hand over to Petitioners' generic rivals.

That ruling rests on two deeply flawed holdings that contradict decades of decisions by this Court and other courts of appeals. First, the Second Circuit held that section 2 of the Sherman Act prohibits the same conduct Congress authorized through the Patent Act—namely, unilaterally refusing to sell a patented product, and selling a different patented product instead. That counterintuitive notion directly conflicts with numerous decisions of this Court holding that patentees have the absolute right to choose whether or not to use or sell their inventions, and that the mere exercise of patent rights cannot give rise to antitrust liability. The Second Circuit also widened a recognized circuit split over the nature and scope of a patentee's immunity from antitrust scrutiny.

Second, the Second Circuit held that brand drug manufacturers have a federal antitrust duty to facilitate the operation of certain states' drug laws to maximize competitors' sales. That holding conflicts with decisions of this Court holding that there is no general antitrust duty to aid competitors, that antitrust law is not a vehicle for enforcing other regulatory regimes, and that the application of a uniform federal statute like the Sherman Act cannot turn on the vagaries of state law. The court also precipitated a split with three other circuits that hold that preventing free-riding by competitors is a legitimate business justification that precludes antitrust liability.

This Court's review is needed immediately. The Second Circuit's decision affects how drug manufacturers invest today to invent and improve treatments that won't become available for years or even decades. By penalizing drug manufacturers who seek to maximize returns on their innovations, the decision below is already chilling critical efforts to develop life-saving

medications. Respondent the State of New York has promised to use the decision below to obtain future nationwide injunctions preventing drug manufacturers from replacing out-of-date products. This Court should grant certiorari now to restore innovators' patent rights and clarify their antitrust duties.

STATEMENT

A. Regulatory Background

1. To obtain FDA approval to market a "new drug," the Federal Food, Drug, and Cosmetic Act ("FDCA") requires the drug's manufacturer to submit a new drug application ("NDA") showing that the drug is "safe" and "effective" for its intended use. 21 U.S.C. § 355(b)(1). Making that showing entails "a long, comprehensive, and costly testing process." *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013).

Under the Hatch-Waxman amendments to the FDCA, once the FDA approves a brand drug for marketing, generic manufacturers can obtain similar marketing approval far more easily. In particular, "a generic competitor [may] file an abbreviated new drug application (ANDA) piggy-backing on the brand's NDA." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). "Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Id.* (citing 21 U.S.C. § 355(j)(2)(A)(ii), (iv)).

2. Once drugs have FDA approval and enter the market, state law regulates which drugs pharmacists can dispense to fill prescriptions from physicians. Since the 1970s, states have passed laws to encourage pharmacists to fill prescriptions for brand drugs by

dispensing lower-priced generic drugs instead. "Today, all 50 states and the District of Columbia have [such] laws." App. 7a. "[D]rug substitution laws either permit or require pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug absent express direction from the prescribing physician that the prescription must be dispensed as written." App. 7a-8a.

State drug substitution laws vary widely. Most importantly, different states define therapeutic equivalence differently. The FDA's "Orange Book" considers a generic to be "AB" rated, and therefore substitutable, if it has the same active ingredient, strength, route of administration, and dosage form as the brand drug, among other criteria. FDA, Approved Drug Products with Therapeutic Equivalence Evaluations vii–x, xiii-xiv (35th ed. 2015). Twenty-nine states and the District of Columbia have expressly adopted the FDA's AB standard. App. 32a-33a & n.33. Another sixteen states do not reference the FDA standard, but according to the Second Circuit, prohibit pharmacists from substituting a generic of a different dose than the brand without physician approval. App. 33a n.33. The five remaining states—Minnesota, North Dakota, Oklahoma, Vermont, and Washington—facially permit or require pharmacists to substitute differently-dosed generics without physician approval. App. 33a n.33.[1]

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[1] The Second Circuit stated that it "cannot determine" whether Oklahoma permits pharmacists to substitute differently-dosed generics. App. 33a n.33. But Oklahoma law plainly permits substitution of a generic selected by the pharmacist if the purchaser consents. Okla. Stat. tit. 59, § 353.13(D) (prohibiting substitution "without authority of the prescriber or purchaser"); Okla. Admin. Code § 535:15-5-7.5(4) (providing that the "[d]etermination of

B. Factual Background

Petitioner Allergan plc is one of the world's largest brand drug manufacturers, and Petitioner Forest Laboratories, LLC is its subsidiary.[2] Petitioners manufacture two pertinent drugs approved to treat moderate-to-severe Alzheimer's disease. The first is Namenda IR, a twice-daily tablet released in 2004. The second is Namenda XR, an innovative capsule released in mid-2013 with the same active ingredient as IR, but once-daily dosing. App. 11a-13a. XR's once-daily dosing can reduce errors in pill administration, ease burdens on caregivers, and improve the compliance of patients, who are by definition forgetful, often resist pills as a dignitary affront, and whose conditions often worsen as the day progresses. App. 72a, 75a. Once-daily dosing also aligns XR with other Alzheimer's treatments, all of which are administered once daily. App. 12a. Based on agreements granting early entry to certain generic manufacturers, IR's patent and other regulatory exclusivities ended on July 11, 2015. App. 12a-13a & n.16. Based on a similar agreement, XR's exclusivities currently run until January 2020.

XR supplants any market need for IR, and the FDA has approved instructions for switching from IR to XR. App. 74a. Under most states' drug substitution laws, however, once IR's exclusivities ended and generic IR entered the market, pharmacists could substitute generic IR for brand IR, but not for brand XR, due to its different dosing. Accordingly, Petitioners recognized that once

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product selection if substitution is requested or approved" must be made "by a pharmacist" and not "by supportive personnel").

[2] Below, Petitioner Allergan plc was known as Actavis plc. On March 17, 2015, Actavis plc purchased Allergan, Inc., and on June 15, 2015, it renamed itself Allergan plc.

they began selling XR, continuing to sell IR served no purpose except to provide prescriptions that state drug laws would hand over to Petitioners' generic rivals.

So in February 2014, Petitioners announced plans to cease distributing IR, and encouraged patients to switch to XR. To smooth the transition, Forest announced in November 2014 that it would continue to make IR available through a mail-order pharmacy to any patient whose doctor deemed it medically necessary. App. 14a-15a, 94a. These announcements helped ensure that patients would experience XR's once-a-day benefits, and avoided helping generics free-ride on state substitution laws. But Petitioners did nothing to prevent generics from entering the market, or from competing on the merits by pitting cheaper twice-daily generic IR against innovative, more convenient once-daily brand XR.

C. Proceedings Below

1. On September 15, 2014, Respondent the State of New York sued Petitioners, seeking declaratory relief, an injunction, disgorgement, restitution, and damages on the theory that Petitioners' announced intention to replace IR with XR violated New York's antitrust statute and sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1-2. App. 50a-52a. Respondent wanted to fill a perceived gap in its own drug substitution law, which, like most states' laws, prohibits pharmacists from filling prescriptions for XR by dispensing generic IR. App. 32a-33a. But instead of amending its law, or simply allowing the market to decide whether generic IR's lower price is worth the inconvenience and other costs that come with twice-daily dosing, Respondent asked a federal court to compel Petitioners to continue selling brand IR. App. 16a.

2. On December 11, 2014, the district court granted Respondent's motion for a preliminary injunction. The court held that replacing IR with XR would violate New York and federal antitrust law by depriving generic manufacturers of the benefit of most state substitution laws, to the detriment of their future market share. App. 46a, 127a-134a. On December 15, 2014, the court enjoined Petitioners to "continue to make Namenda IR ... available on the same terms and conditions applicable since ... Namenda XR entered the market." App. 144a. The injunction ran through August 10, 2015, "thirty days after ... generic [IR] ... [became] available." App. 145a.

3. On May 22, 2015, based on a concededly "novel" theory of antitrust liability, the Second Circuit affirmed. App. 4a. While nominally addressing the propriety of the district court's preliminary injunction, the court left no doubt about the merits under section 2 of the Sherman Act. The court acknowledged that "[a]s a general rule, courts are properly very skeptical about claims that competition has been harmed by a dominant firm's product design changes." App. 23a (quoting *United States v. Microsoft Corp.*, 253 F.3d 34, 65 (D.C. Cir. 2001) (en banc)). But the court nonetheless "conclude[d]" that

> the combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, which has the dual effect of forcing patients to switch to the new version and impeding generic competition, without a legitimate business justification, violates § 2 of the Sherman Act.

App. 37a.

The court rejected Petitioners' argument that the mere exercise of patent rights is categorically immune from antitrust scrutiny. The court recognized that a patent "grant[s] a legal monopoly," and "'is an exception to the general rule against monopolies.'" App. 22a & n.21 (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945)). But in the court's view, "the *combination* of [Petitioners]' withdrawal of IR and introduction of XR in the context of generic substitution laws ... places their conduct beyond the scope of their patent rights for IR or XR individually." App. 39a.

On August 7, 2015, the Second Circuit denied rehearing en banc. App. 146a. While the injunction gave Respondent everything it sought under federal law, Respondent's state-law claim for "restitution and damages" for "persistent fraud or illegality in the carrying on, conducting or transaction of business," N.Y. Exec. Law § 63(12); *see* App. 51a, remains pending before the district court.

REASONS FOR GRANTING THE PETITION

I. This Court Should Grant Review to Resolve Whether the Exercise of Core Patent Rights Can Violate the Antitrust Laws

A. The Decision Below Conflicts with Decisions of this Court

1. In an unbroken line of cases stretching back more than a century, this Court has held that antitrust liability cannot arise from the mere exercise of rights granted by the Patent Act.

In *Virtue v. Creamery Package Manufacturing Co.*, 227 U.S. 8 (1913), this Court rejected claims that a patentee violated the antitrust laws by licensing another company to use its patent and bring infringement claims against competitors. *Id.* at 32-33. This Court explained that, "[o]f course, patents and patent rights cannot be made a cover for a violation of law .... But patents are not so used when the rights conferred upon them by law are only exercised." *Id.*

The same principle appears in *United States v. United Shoe Machinery Co.*, 247 U.S. 32 (1918), which rejected claims that a monopolist violated section 2 by leasing patented machinery on restrictive terms. *Id.* at 35. This Court recognized that "[o]f course, there is restraint in a patent," since it confers "the right to exclude others from the use of the invention, absolutely or on the terms the patentee chooses to impose." *Id.* at 57. But that right "is the compensation which the law grants for the exercise of invention." *Id.* Because the leases were "[no]thing more than the exercise of the patent monopoly," and did not "transcend the rights given to patentees," there was no antitrust violation. *Id.* at 57, 61.

This Court has reiterated the point in case after case. *United States v. Gen. Elec. Co.*, 272 U.S. 476, 485 (1926) ("It is only when [a monopolist] ... steps out of the scope of his patent rights ... that he comes within the operation of the Anti-Trust Act."); *Simpson v. Union Oil Co. of Cal.*, 377 U.S. 13, 24 (1964) ("The patent laws ... are *in pari materia* with the antitrust laws and modify them *pro tanto*."); *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965) ("[A] patent is an exception to the general rule against monopolies ...." (quoting *Precision Instrument*, 324 U.S. at 816)).

This Court confirmed the point most recently in *FTC v. Actavis*. There, the Court held that "reverse payment settlements"—in which patentees pay alleged infringers to give up invalidity claims and stay out of the market until the patent expires—are subject to antitrust scrutiny. 133 S. Ct. at 2227. The Court reasoned that such settlements prevent adjudication of the patent's "actual preclusive scope," and therefore fall outside the "scope of the patent monopoly." *Id.* at 2231. But the Court made clear that conduct *within* the "scope of the patent monopoly"—that is, the exercise of rights granted by "any patent statute ..., whether expressly or by fair implication"—still enjoys "antitrust law immunity." *Id.* at 2231, 2233.

2. In an even longer line of cases, this Court has held that a patent owner's rights include the right to refuse to use, sell, or license the invention, while excluding competitors.

It "has been settled doctrine since at least 1896" that a patent owner "has no obligation either to use [the patented invention] or to grant its use to others." *Hartford-Empire Co. v. United States*, 323 U.S. 386, 423-33 (1945). This Court first recognized that principle in the antitrust context in *E. Bement & Sons v. National Harrow Co.*, 186 U.S. 70 (1902), which upheld a patent pooling arrangement against an antitrust challenge. *Id.* at 91. This Court explained that "[i]f [a patentee] will neither use his device nor permit others to use it, he has but suppressed his own." *Id.* at 90 (quoting *Heaton-Peninsular Button-Fastener Co. v. Eureka Specialty Co.*, 77 F. 288, 294 (6th Cir. 1896)). Similarly, in *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436 (1940), this Court affirmed an antitrust injunction because "[t]he picture [t]here revealed [wa]s *not* that of a patentee exercising its right to refuse to

sell ... the patented product." *Id.* at 457 (emphasis added). And in *Hartford-Empire*, this Court reversed an antitrust injunction that prohibited the defendants from applying for patents they did not intend to use. 323 U.S. at 431-32. The Court explained that "[a] patent owner is not in the position of a quasi-trustee for the public or under any obligation to see that the public acquires the free right to use the invention." *Id.* at 432.

Cases outside the antitrust context are equally legion. *Cont'l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 424, 429 (1908) (patented invention is patentee's "absolute property," and "it is the privilege of any owner of property to use or not use it, without question of motive"); *Crown Die & Tool Co. v. Nye Tool & Mach. Works*, 261 U.S. 24, 34-35 (1923) ("[T]he benefit which the government intended to secure [by issuing a patent] was not the making or use of the patent for the benefit of the public during ... the grant, ... but only the benefit of its public use after the grant expired."); *Woodbridge v. United States*, 263 U.S. 50, 55-56 (1923) ("[A] patentee is not obliged either to make, use, or vend his invention during the period of his monopoly."); *Special Equip. Co. v. Coe*, 324 U.S. 370, 378-79 (1945) ("[F]ailure of the patentee to make use of a patented invention does not affect the validity of the patent.").

3. The decision below cannot be reconciled with these lines of cases. Petitioners had an unqualified right under the Patent Act to refuse to sell IR, and exercising that right cannot violate the antitrust laws. Yet the Second Circuit affirmed an antitrust injunction forcing Petitioners to continue selling patent-protected IR against their will.

i. The Second Circuit relied principally on this Court's statement in *Actavis* 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." App. 38a (quoting *Actavis*, 133 S. Ct. at 2231). But this Court has *already* "determin[ed]" that "the scope of the patent monopoly" includes the right not to sell the patented product. Indeed, it "has been settled doctrine since at least 1896." *Hartford-Empire*, 323 U.S. at 432-33.

Actavis involved a question this Court had not previously addressed—whether the patent monopoly includes a right to enter into reverse payment settlements. 133 S. Ct. at 2231-32. This Court answered that question in the negative by weighing "considerations ... related to patents" and "traditional antitrust factors." *Id.* But the factors that place reverse payment settlements beyond the patent monopoly do not give lower courts carte blanche to disregard this Court's decisions and reevaluate *other* conduct this Court has previously held falls *within* the patent monopoly.

In effect, the Second Circuit held that *Actavis* silently overruled this Court's considered decisions in *Bement*, *Continental Paper Bag*, *Crown Die & Tool*, *Woodbridge*, *Ethyl Gasoline*, *Hartford-Empire*, and *Special Equipment*. But "it is this Court's prerogative alone to overrule [even] one of its precedents," *State Oil Co. v. Khan*, 522 U.S. 3, 20 (1997), let alone seven at once.

ii. The Second Circuit also relied on *United States v. Line Material*, 333 U.S. 287 (1948), for the proposition that "patent law gives [Petitioners] a temporary monopoly on individual drugs—not a right to use their patents as part of a scheme to interfere with competition 'beyond the limits of the patent monopoly.'" App. 38a (quoting *Line Material*, 333 U.S. at 308). To the

court, "the *combination* of [Petitioners]' withdrawal of IR and introduction of XR ... places their conduct beyond the scope of their patent rights for IR or XR individually." App. 39a.

That reasoning grossly distorts *Line Material* and ignores the basic distinction between concerted restraints of trade, prohibited by section 1 of the Sherman Act, and unilateral monopolization, prohibited by section 2. *Line Material* involved an *agreement* fixing the price of two firms' patented products, which this Court held unreasonably restrained trade in violation of section 1. 333 U.S. at 305, 314-15. "No issue of monopoly [under section 2] [wa]s involved." *Id.* at 304-05. Below, the Second Circuit expressly declined to address Respondents' section 1 claim, and held that Petitioners' *unilateral* conduct violated section 2. App. 39a. Nothing in *Line Material* remotely suggests that the unilateral exercise of multiple patent rights somehow provides an exception to the settled rule that patent rights don't give rise to antitrust wrongs.

Moreover, this Court's decision in *Pacific Bell Telephone Co. v. Linkline Communications, Inc.*, 555 U.S. 438 (2009), forecloses the Second Circuit's strange notion that exercising multiple patent rights separately is perfectly lawful, but doing so in combination subjects the patentee to treble damages and potential criminal liability. In *Linkline*, plaintiffs "tried to join [one] claim that cannot succeed with [another] claim that cannot succeed, and alchemize them into a new form of antitrust liability never before recognized by this Court." *Id.* at 457. This Court "decline[d] the invitation to recognize such claims," because "[t]wo wrong claims do not make one that is right." *Id.* Respondent's attempt to combine unmeritorious challenges to the

withdrawal of IR and the introduction of XR should have met the same fate.

B. The Decision Below Widens a Circuit Split

Certiorari is all the more warranted because the courts of appeal are hopelessly divided over the nature and scope of a patent owner's immunity from antitrust liability. The decision below widens that division, turning a two-way split into a three-way split.

1. Four courts of appeals have held that conduct within the scope of the patent monopoly—and in particular, the refusal to use, sell, or license the patented invention—is categorically immune from antitrust scrutiny.

The Federal Circuit so held in *In re Independent Service Organizations Antitrust Litigation* (*"ISO"*), 203 F.3d 1322 (Fed. Cir. 2000). There, a repair service brought antitrust claims against Xerox for refusing to sell the service patented replacement parts for Xerox copiers and printers. *Id.* at 1324. The court found no antitrust violation for a simple reason: "We answer the threshold question of whether Xerox's refusal to sell its patented parts exceeds the scope of the patent in the negative. Therefore, our inquiry is at an end." *Id.* at 1328 (footnote omitted).

The Third, Sixth, and D.C. Circuits agree. The Third Circuit has explained that "[t]he right to refuse to license is the essence of the patent holder's right under the patent law," and therefore rejected claims that a patentee committed an antitrust violation by charging licensing fees "so high as to preclude acceptance." *W.L. Gore & Assocs. v. Carlisle Corp.*, 529 F.2d 614, 623 (3d Cir. 1976). The Sixth Circuit similarly holds that "[a] patent holder who lawfully acquires a patent

cannot be held liable under Section 2 of the Sherman Act for maintaining the monopoly power he lawfully acquired by refusing to license the patent to others." *Miller Insituform, Inc. v. Insituform of N. Am., Inc.*, 830 F.2d 606, 609 (6th Cir. 1987). And the D.C. Circuit has rejected an antitrust challenge to a restrictive license on the simple ground that "[n]one of the[] restraints [went] beyond what the patent itself authorizes." *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1980).

2. The Ninth Circuit, by contrast, has held that the exercise of patent rights is only presumptively immune from antitrust scrutiny. In *Image Technical Services, Inc. v. Eastman Kodak Co.*, 125 F.3d 1195 (9th Cir. 1997), the Ninth Circuit addressed the same claim the Federal Circuit confronted in *ISO*—an independent repair service complained that a manufacturer refused to sell the service patented replacement parts. *Id.* at 1200. But rather than treat the patent monopoly as a threshold question, the Ninth Circuit adopted a "rebuttable presumption," whereby "a monopolist's desire to exclude others from its protected work is a presumptively valid business justification for any immediate harm to consumers." *Id.* at 1218 (quotation marks and brackets omitted). Plaintiffs can rebut this presumption by showing "that the monopolist acquired the [patent] in an unlawful manner" or by "show[ing] pretext," that is, "that the proffered business justification played no part in the decision to act." *Id.* at 1218-19.

Scholars have recognized that the Ninth Circuit's approach diverges from its sister circuits. *E.g.*, Patricia H. Moran, *The Federal and Ninth Circuits Square Off: Refusals to Deal and the Precarious Intersection Between Antitrust and Patent Law*, 87 Marq. L. Rev. 387, 387 (2003) (noting "the recent split in the circuit courts

concerning the rights of a patent holder to unilaterally refuse to deal"); Peter M. Boyle, Penelope M. Lister, & J. Clayton Everett, Jr., *Antitrust Law at the Federal Circuit: Red Light or Green Light at the IP-Antitrust Intersection?*, 69 Antitrust L.J. 739, 744, 746 (2002) ("[T]he Ninth Circuit and Federal Circuit came to diametrically different conclusions ....").

3. Below, the Second Circuit eschewed both of these approaches to a patentee's antitrust immunity, either of which would have required a ruling in Petitioners' favor. In the Federal, Third, Sixth, and D.C. Circuits, Petitioners' exercise of their patent rights would have been categorically immune from antitrust scrutiny. And in the Ninth Circuit, Petitioners' presumptively valid business justification would have remained unrebutted, as Respondent has never disputed that Petitioners' patents are valid or that patent rights played a role in Petitioners' decisions.

Before the decision below, the Second Circuit followed the majority rule, holding that "where a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws." *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981). But the decision below fashioned a novel exception to that rule for "the *combination* of [the] withdrawal of [one patented product] and introduction of [another patented product] in the context of generic substitution laws." App. 39a. In effect, the Second Circuit held that, at least "in the context of generic substitution laws," multiple patent rights exercised in combination cancel each other out, rendering patent law irrelevant to the antitrust analysis. No other court has hinted at, much less adopted, that exception. This Court's intervention is needed

to resolve the lower courts' growing confusion over patent owners' immunity from antitrust scrutiny.

C. The Decision Below Is Wrong

Congress did not prohibit through the Sherman Act the same conduct it authorized through the Patent Act. The Patent Act grants every patent owner "the right to exclude others from making, using, offering for sale or selling the invention" for a 20-year period. 35 U.S.C. § 154(a)(1). That grant necessarily gives every patentee a limited monopoly, in derogation of the Sherman Act. In determining the scope of that monopoly, "Congress ... could have provided that the grant should be conditioned upon the use of the patented invention." *Special Equip.*, 324 U.S. at 378. Indeed, Congress briefly did so in 1832, "authorizing the issue of patents to aliens conditioned upon the use of the invention." *Id.* (citing Act of 1832, 4 Stat. 577). But Congress "later repealed" that provision, *id.* (citing Act of 1836, § 21, 5 Stat. 117), and has never reinstated it. The implication is clear: A patentee who refuses to use the invention does not exceed the bounds of the patent monopoly, and therefore cannot commit an antitrust violation.

If section 154 were not enough, Congress amended another section of the Patent Act in 1988 to provide that "[n]o patent owner ... shall be ... deemed guilty of misuse or illegal extension of the patent right by reason of his having ... (4) refused to license or use any rights to the patent." 35 U.S.C. § 271(d); Pub. L. No. 100-703, § 201, 102 Stat. 4676 (1988). That amendment cabined the doctrine of patent misuse by creating new safe harbors for conduct Congress determined did not "hav[e] anticompetitive effects." *Princo Corp. v. Int'l Trade Comm'n*, 616 F.3d 1318, 1329-30 (Fed. Cir.

2010) (en banc). New section 271(d)(4) in particular served to "[c]odif[y]" then-"current caselaw" holding that refusing to use or license a patent is perfectly lawful. 134 Cong. Rec. H10646 & n.4 (daily ed. Oct. 20, 1988) (statement of Rep. Kastenmeier) (citing *SCM*, 695 F.2d at 1195, and *Cont'l Paper Bag*, 210 U.S. at 426-30). This Court has recognized the incongruity that would arise if conduct falling within a safe harbor from misuse under section 271(d) still qualified as an antitrust violation. "It would be absurd to assume that Congress intended to provide that the use of a patent that merited punishment as a felony [under the Sherman Act] would not constitute 'misuse.'" *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 42 (2006).

Hatch-Waxman only confirms the point. The Second Circuit effectively curtailed the term of brand drug manufacturers' exclusive rights in order to ensure that the day after those rights end, generic competitors can not only enter the market, but achieve immediate, guaranteed commercial success. The Patent Act, however, confers exclusive rights for the *entire* 20-year term. That is part of why Congress passed Hatch-Waxman. Before Hatch-Waxman, generic manufacturers often could not even begin seeking FDA approval for a generic drug until the brand drug's patents expired, since the necessary testing would constitute infringement. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 (1990). Hatch-Waxman responded by amending the Patent Act to provide that research "reasonably related to" FDA submissions "shall not be an act of infringement." 35 U.S.C. § 271(e)(1). The Second Circuit deemed that narrow statutory carve-out inadequate, and held that patentees also cannot exercise *other* patent rights that would reduce generic sales the day the patentee's exclusivities end. But amending the

Patent Act is the prerogative of Congress, not the Second Circuit.

II. This Court Should Grant Review to Resolve Whether Drug Manufacturers Have an Antitrust Duty to Facilitate State Drug Laws to Benefit their Competitors

A. The Decision Below Conflicts with Decisions of this Court

The Second Circuit also invented an expansive new antitrust duty. The court required a brand drug manufacturer to continue selling an obsolete product on past terms and conditions in order to maximize the sales certain state drug laws would hand over to its competitors. It is undisputed that, whether or not Petitioners continued to sell brand IR, once IR's exclusivities ended, generic manufacturers would be free to sell generic IR, and patients would be free to buy it. But the Second Circuit held that voluntary generic sales were not enough. Brand manufacturers must continue selling outdated drugs so that state drug laws can encourage or even force patients to buy generic substitutes.

1. That novel duty is flatly inconsistent with this Court's decisions in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004), and *Linkline*, which make clear that monopolists have no general antitrust duty to aid their competitors.

Trinko involved antitrust claims alleging that Verizon refused to give competing telephone carriers sufficient access to Verizon's local network, as required by the Telecommunications Act of 1996. 540 U.S. at 402-05. This Court rejected that claim because with only narrow exceptions, "there is no duty to aid competitors." *Id.* at 411. The claim did not fit within the exception for

"[t]he unilateral termination of a voluntary ... course of dealing" with a competitor, because Verizon's prior dealing was statutorily required, not voluntary. *Id.* at 409-10. Nor did the claim fit within the "essential facilities" doctrine recognized by some courts of appeals—the Telecommunications Act already required Verizon to open up its network, making judicially enforced sharing unnecessary. *Id.* at 410-11. Since no exception applied, the claim failed. *Id.* at 411.

In *Linkline*, independent Internet service providers asserted a so-called "price-squeeze" claim against AT&T, alleging that AT&T raised the price of wholesale inputs for Internet service while cutting the retail price, leaving an insufficient margin in between for competing Internet providers to survive. 555 U.S. at 442. This Court held that a plaintiff cannot state a price-squeeze claim "when the defendant has no obligation under the antitrust laws to deal with the plaintiff at wholesale." *Id.* at 445-46, 449. That result followed as "[a] straightforward application of ... *Trinko*," which "ma[de] clear that if a firm has no antitrust duty to deal with its competitors ..., it certainly has no duty to deal under terms and conditions that the rivals find commercially advantageous." *Id.* at 449-50.

The decision below conflicts with *Trinko* and *Linkline*. The Second Circuit did not even attempt to fit its new duty within a recognized exception to a monopolist's right to refuse to aid rivals. The court simply invented a new exception, under which replacing an obsolete product with a new one "is anticompetitive when it coerces consumers and impedes competition." App. 24a. But this Court has never suggested that monopolists must aid rivals to avoid "consumer coercion" (whatever that means). And while generic manufacturers undoubtedly prefer free-riding on state substitution laws to

competing on the merits, "the antitrust laws were passed for the protection of *competition*, not *competitors*." *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993) (quotation marks omitted). As respected commentators have explained, the decision below "is contrary to the teaching of the United States Supreme Court, which has explicitly held that the antitrust laws do not impose a general duty to aid one's rivals." Joshua D. Wright & Douglas H. Ginsburg, Comment on the Canadian Competition Bureau's Draft Updated Intellectual Property Enforcement Guidelines 3 n.7 (2015) (citing *Trinko*).

2. The decision below conflicts with *Trinko* and *Linkline* in another way. While the Second Circuit purported to vindicate the goals of Hatch-Waxman and state substitution laws, *Trinko* and *Linkline* hold that the antitrust laws are not a vehicle for enforcing other regulatory regimes.

In *Trinko*, the plaintiff alleged that Verizon breached duties to aid competitors imposed by the Telecommunications Act. This Court explained that the fact "[t]hat Congress created these duties ... does not automatically lead to the conclusion that they can be enforced by means of an antitrust claim." 540 U.S. at 406. And again in *Linkline*, this Court recognized that AT&T may have had a duty to deal with its competitors, but any such duty "arose only from FCC regulations," not from antitrust law. 555 U.S. at 448 n.2. The Court therefore held that a plaintiff cannot state a price-squeeze claim "when the defendant has no *antitrust duty* to deal with the plaintiff." *Id.* at 446 (emphasis added).

The distinction between antitrust law and other regulatory regimes should have applied with particular force here. Replacing IR with XR undisputedly would not violate Hatch-Waxman or any state substitution

law. If antitrust claims cannot enforce other laws that *prohibit* the conduct at issue, *a fortiori* they cannot enforce other laws that *permit* that conduct.

The Second Circuit rejected Petitioner's argument "that antitrust law is not a vehicle for enforcing the 'spirit' of drug laws" on the ground that "'antitrust law must always be attuned to the particular structure and circumstances of the industry at issue.'" App. 34a (quoting *Trinko*, 540 U.S. at 411). But *Trinko* relied on regulatory context to *reject* an antitrust claim. And this Court has rejected special antitrust rules for the "health care industry." *Arizona v. Maricopa Cnty. Med. Soc'y*, 457 U.S. 332, 349-50 (1982). Anyway, sensitivity to context is no excuse for transforming the Sherman Act into a roving commission to enforce the supposed "spirit" of federal and state drug regulations.

3. There is more. This Court has repeatedly held that "federal statutes are generally intended to have uniform nationwide application." *Miss. Band of Choctaw Indians v. Holyfield*, 490 U.S. 30, 43 (1989). Courts therefore "start ... with the general assumption that in the absence of a plain indication to the contrary, ... Congress when it enacts a statute is not making the application of the federal act dependent upon state law." *Id.* (quotation marks omitted). This Court has applied that rule in numerous contexts. *E.g.*, *id.* (Indian Child Welfare Act); *Dickerson v. New Banner Inst., Inc.*, 460 U.S. 103, 119 (1983) (Gun Control Act); *NLRB v. Natural Gas Util. Dist. of Hawkins Cnty.*, 402 U.S. 600, 603-04 (1971) (Wagner Act); *Jerome v. United States*, 318 U.S. 101, 104 (1943) (Bank Robbery Act); *United States v. Pelzer*, 312 U.S. 399, 402-03 (1941) (tax code).

The Sherman Act obviously is a uniform federal statute "intended to solve a national problem on a national scale." *Natural Gas Util. Dist.*, 402 U.S. at 603-04

(quotation marks omitted). Nothing in the statute suggests that Congress intended its application to differ from state to state based on "varying local conceptions, either statutory or judicial." *Id.* at 604 (quotation marks omitted). Conduct that violates the Sherman Act in New York must violate the Sherman Act in Minneapolis as well.

But the Second Circuit's new antitrust duty does not apply in Minneapolis. The court acknowledged that the laws of four states, including Minnesota, facially "allow substitution of generic IR for Namenda XR." App. 33a n.33.[3] Replacing IR with XR would not prevent generics from entering the market or competing on the merits anywhere, but in those states, it would not even alter the application of generic substitution laws. Those states may "account for less than 6% of the U.S. population," App. 33a n.33, but the Sherman Act contains no exception for small states. And even if all 50 states' laws happened to be the same, the decision below still "mak[es] the application of the federal act dependent upon state law." *Holyfield*, 490 U.S. at 43.

B. The Decision Below Precipitates a Circuit Split

The Second Circuit's new antitrust duty conflicts with the decisions of three other circuits, which all hold that preventing competitors from free-riding on a monopolist's advertising or other investments is a legitimate business purpose that enhances rather than impedes competition.

1. In *Olympia Equipment Leasing Co. v. Western Union Telegraph Co.*, 797 F.2d 370 (7th Cir. 1986), the Seventh Circuit confronted antitrust claims against a

[3] *Five* states clearly allow such substitution. *Supra* n.1.

monopolist that had previously provided free advertising for its competitors, but then stopped in order to boost its own sales. *Id.* at 372-73. The court overturned a jury verdict for the plaintiff, holding that "a firm with lawful monopoly power has no general duty to help its competitors, whether by holding a price umbrella over their heads or by otherwise pulling its competitive punches." *Id.* at 375. "You cannot conscript your competitor's salesmen to sell your product even if the competitor has monopoly power and you are a struggling new entrant." *Id.* at 378. The plaintiff therefore "had no right under antitrust law to take a free ride on its competitor's sales force." *Id.* at 377-78.

The Fourth Circuit held similarly in *Abcor Corp. v. AM International, Inc.*, 916 F.2d 924 (4th Cir. 1990). There, an independent repair service brought antitrust claims against a manufacturer that barred the service from buying replacement parts at the manufacturer's local repair center, "inhibit[ing] [the service]'s ability to handle emergencies." *Id.* at 929. The Fourth Circuit held that the manufacturer legitimately determined that the plaintiff "should bear its own inventory costs." *Id.* "If [the plaintiff] wants to ensure emergency access to a supply of parts, it may do so by maintaining its own stockpile rather than 'free riding' on the inventory costs incurred by [the manufacturer]." *Id.* Because the manufacturer "only eliminated [a] 'free ride' by shifting the inventory cost to the plaintiff," the "parts policy simply d[id] not rise to the ... level of anticompetitive activity." *Id.* at 929-30.

The Eleventh Circuit too has held that "[t]he prevention of free-riding ... provides a valid business justification" that precludes antitrust liability. *Morris Commc'ns Corp. v. PGA Tour, Inc.*, 364 F.3d 1288, 1298 (11th Cir. 2004). *Morris* concerned an antitrust

claim challenging restrictions the PGA Tour imposed on the media's right to sell real-time golf scores the PGA compiled through proprietary technology. *Id.* at 1290-92. The court rejected that claim because the PGA "met its business justification burden by showing that it seeks to prevent Morris from 'free-riding' on PGA's [scoring] technology." *Id.* at 1295.

2. Like the defendants in *Olympia Equipment*, *Abcor*, and *Morris*, Petitioners also sought to prevent competitors from free-riding on their considerable business investments. Petitioners spent hundreds of millions of dollars developing and promoting a blockbuster drug to treat a horrifying disease. But once IR's exclusivities ended, state substitution laws were poised to hand Petitioners' hard-won sales over to their generic competitors. Rather than recognizing that preventing such free-riding is a legitimate business purpose, the Second Circuit held that "what [Petitioners] call 'free riding' ... is authorized by law; is the explicit goal of state substitution laws; and furthers the goals of the Hatch–Waxman Act by promoting drug competition." App. 33a-34a. The Fourth, Seventh, and Eleventh Circuits disagree: "Advertising a competitor's products free of charge ... is the antithesis of competition." *Olympia Equip.*, 797 F.2d at 378; *see Abcor*, 916 F.2d at 929; *Morris*, 364 F.3d at 1298.

C. The Decision Below Is Wrong

"To safeguard the incentive to innovate, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive *conduct*." *Trinko*, 540 U.S. at 407. Petitioners allegedly showed insufficient solicitude for their competitors when choosing which products to sell on what terms. That is not anticompetitive.

Before IR's exclusivities ended, replacing IR with XR had no effect on competition whatsoever, because Petitioners possessed a lawful monopoly. Limiting competition within "the same company" raises no antitrust concerns, because it does not "deprive[] the marketplace of the independent centers of decisionmaking that competition assumes and demands." *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 769 (1984). And after IR's exclusivities ended, generic competitors have been perfectly free to distribute, market, price, and sell their drugs as they please. True, generic manufacturers less able to rely on state substitution laws might have made fewer sales, but only if they failed to make offsetting efforts to make generic IR more attractive to doctors and patients. "[T]o the extent [Petitioners' conduct] obligated [generics] to increase [their] own advertising, competition was only enhanced." *Covad Commc'ns Co. v. Bell Atl. Corp.*, 398 F.3d 666, 674 (D.C. Cir. 2005) (citing Robert H. Bork, The Antitrust Paradox 314 (2d ed. 1993)).

The Second Circuit reasoned that judicial intervention was necessary because the patients and doctors who choose drugs do not pay their full costs. App. 10a, 34a & n.34. But numerous market forces push patients and doctors towards lower-priced drugs. Third-party payors encourage the use of generics through "[f]ormularies, tiered-drug structures, step programs, and prior-authorization requirements." App. 29a & n.29. "[P]harmacies typically realize higher profit margins on generic drugs due to health plan incentives." App. 10a n.11. Various stakeholders mount "counter-detailing" campaigns "to promote the use of generic pharmaceuticals." *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2661 (2011). And generic manufacturers themselves can and do advertise. *See Mylan Pharm., Inc. v.*

Warner Chilcott Pub. Ltd. Co., No. Civ. 12-3824, 2015 WL 1736957, at *14 (E.D. Pa. Apr. 16, 2015).

At bottom, the decision below posits that courts and antitrust enforcers know better than markets which new products are worth higher prices. The Second Circuit purported to balance the supposed "anticompetitive harms" from blunting the effect of state substitution laws against the "procompetitive benefits" of allowing brand drug manufacturers to maximize returns on their innovations. App. 36a-37a. But that kind of balancing inquiry "is not just unwise, it is unadministrable. There are no criteria that courts can use to calculate the 'right' amount of innovation, which would maximize social gains and minimize competitive injury." *Allied Orthopedic Appliances, Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 1000 (9th Cir. 2010). And if drug manufacturers guess wrong about that balancing inquiry, the consequences are dire—they can face crippling injunctions, treble damages, even criminal penalties.

III. The Questions Presented Are of Critical and Recurring Importance to Pharmaceutical Manufacturers and Patients

1. The scope of patent owners' immunity from antitrust liability and the existence of an antitrust duty to facilitate competitors' sales will profoundly affect the course of innovation in the pharmaceutical industry.

Pharmaceutical innovation is critical to the U.S. healthcare system. "There are roughly 7,000 known diseases; about 500 have a treatment." Amy Dockser Marcus, *Trials: A Desperate Fight to Save Kids & Change Science*, Wall Street Journal, Nov. 18, 2013, http://projects.wsj.com/trials/#chapter=1. New drug treatments not only improve patients' lives, but also reduce healthcare spending. According to one study,

using newer drugs "reduces non-drug expenditure 7.2 times as much as it increases drug expenditure." Frank Lichtenberg, *Benefits and Costs of Newer Drugs: An Update*, Nat'l Bureau of Econ. Research 9 (2002). In other words, "the replacement of older by newer drugs results in reductions in mortality, morbidity, *and* total medical spending." Frank R. Lichtenberg, *Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS*, 20 Health Affairs 241, 250 (2001) (emphasis added).

Innovation often proceeds by small steps. "[R]epeated incremental improvement is the predominant mechanism of innovation and product development within most manufacturing and high-technology industries," and "[t]he pharmaceutical industry is no exception." Albert Wertheimer et al., *Too Many Drugs? The Clinical and Economic Value of Incremental Innovations*, 14 Investing in Health: The Social & Economic Benefits of Health Care Innovation 77, 78 (2001). HIV treatment, for example, once consisted of a complex "cocktail" of drugs that was difficult to administer and prone to error, but incremental innovation has now simplified it to a single pill. Joshua Cohen & Kenneth Kaitin, *Follow-On Drugs and Indications: The Importance of Incremental Innovation to Medical Practice*, 15 Am. J. Therapeutics 89, 90 (2008). Two-thirds of all new drugs approved by the FDA contain an active ingredient already on the market. Nat'l Inst. for Health Care Mgmt. Research & Educ. Found., Changing Patterns of Pharmaceutical Innovation 3 (2002). Almost two-third of the drugs on the World Health Organization's Essential Drug List—which compiles the drugs necessary for a basic national healthcare system—are incremental innovations. Joshua P. Cohen et al., *The Role of Follow-on Drugs and Indications on the WHO*

Essential Drug List, 31 J. Clinical Pharmacy & Therapeutics 6 (2006).

Incremental drug innovations have numerous benefits. More drugs enable physicians to tailor treatments to patient needs, provide backups if other drugs are unavailable, and facilitate competition on both price and quality. Wertheimer, *supra*, at 78-79. In addition, alternative dosing and delivery mechanisms can help patients take their medications more easily and consistently. *Id.* XR's once-daily dosing illustrates the point—studies confirm that patient compliance is "higher with once than multiple daily dosing regimens." Matthew Falagas et al., *Compliance with Once-Daily versus Twice or Thrice-Daily Administration of Antibiotic Regimens: A Meta-Analysis of Randomized Controlled Trials*, PLoS One (Jan. 5, 2015). And patients' failure to take their pills as prescribed "is a major barrier to realizing the benefits of medications." Robbie Nieuwlaat et al., *Interventions for Enhancing Medication Adherence*, Cochrane Database of Systematic Reviews 3 (Nov. 2014).

2. By penalizing brand drug manufacturers that seek to maximize returns on new drug formulations, the decision below decimates incentives to innovate. As the head of the Department of Justice's Antitrust Division recently explained, "[c]ompanies that know they may easily gain access to the patents or other intellectual property of their competitors have less incentive to undertake the risky and expensive research necessary to be innovators themselves. Likewise, innovative companies have less incentive to continue their efforts." Bill Baer, Assistant Att'y Gen., Remarks at 19th Annual Int'l Bar Ass'n Competition Conf. (Sept. 11, 2015), http://www.justice.gov/opa/speech/assistant-attorney-general-bill-baer-delivers-remarks-19th-annual-

international-bar. Moreover, "[n]o mature industry can sustain itself on income from breakthrough innovation alone. The pharmaceutical industry must generate revenue based predominantly on incremental innovations." Wertheimer, *supra*, at 108-09. Restricting revenue from incremental improvements thus will make R&D riskier and will reduce the resources for research into incremental and breakthrough innovations alike. *Id.* at 109-10.

The Second Circuit asserted that its new antitrust rule will discourage only "trivial or minor product reformulations" and not "riskier, but medically significant innovations." App. 37a. As explained, however, XR's once-daily dosing *is* a "medically significant innovation." And courts are ill-equipped to sort significant innovations from insignificant ones. *Trinko*, 540 U.S. at 407-08. Moreover, the limits of the Second Circuit's new rule are anyone's guess. When in the patent term does ceasing sales become unlawful? If distributing IR to patients whose doctors deemed it medically necessary was not enough, how much distribution would suffice? What if a patentee continued to sell an old product but raised its price, or stopped advertising? Deterring innovation is bad enough, but doing so under a nebulous rule is even worse.

Precisely because the decision below will dampen innovation, Federal Trade Commissioner Joshua Wright and the Hon. Douglas H. Ginsburg of the D.C. Circuit have urged foreign antitrust authorities not to follow it. "[E]ven small changes in product design[] can generate significant consumer benefits," and "[c]ompetition law is not a suitable instrument for micromanaging product design and innovation." Wright & Ginsburg, *supra*, at 2. Wright and Ginsburg therefore advised the Canadian Competition Bureau "against imposing

a competition law sanction on product switching absent clear and convincing objective evidence that [the new product] represents a sham innovation with zero or negative consumer welfare benefits." *Id.* at 1. Instead, they urged Canadian authorities to "treat product substitution as falling within the exemption for 'mere exercise' of a patent right." *Id.*; *see also* Baer, *supra* ("If there is no bad conduct by the patent holder ..., but rather an assertion of lawful patent rights, competition enforcers need to stand down. Otherwise we are penalizing lawful innovation.").

These issues urgently require this Court's attention. Developing a new drug takes at least a decade. PhRMA, 2015 Biopharmaceutical Research Industry Profile 13 (2015). Investment decisions made today will determine whether innovative new treatments will become available 10 or 20 years from now. Patients counting on those treatments cannot wait for further percolation in the lower courts. This Court has not hesitated to grant certiorari in pharmaceutical and antitrust cases of similar national importance. *E.g.*, *Wyeth v. Levine*, 555 U.S. 555, 563 (2009); *Texaco Inc. v. Dagher*, 547 U.S. 1, 5 (2006); *PhRMA v. Walsh*, 538 U.S. 644, 650 (2003); *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 456 (1992).

3. The nominally interlocutory posture of this case is no impediment to this Court's review. While the district court's preliminary injunction has now expired, the decision below is not moot, for two independent reasons.

i. First, the Second Circuit reached the merits of Respondent's section 2 claim, and Respondent seeks damages based on that claim.

The propriety of a preliminary injunction is usually distinct from the final merits, but here, the two issues

merged. Generally, "whether [a] preliminary injunction should have issued depend[s] on [a] balance of factors," including the "likelihood of success on the merits." *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 393-94 (1981). This Court has warned against "improperly equat[ing] 'likelihood of success' with 'success.'" *Id.* at 394. But the distinction between a preliminary injunction and the final merits "is a rule of orderly judicial administration, not a limit on judicial power," and thus "is not inflexible." *Thornburgh v. Am. Coll. of Obstetricians & Gynecologists*, 476 U.S. 747, 756-57 (1986), *overruled on other grounds by Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992). Accordingly, where "the facts are established or of no controlling relevance," an appellate court reviewing a preliminary injunction may "proceed[] to plenary review" and reach the ultimate merits. *Id.* at 757.

That is precisely what the Second Circuit did below. The opinion's language is unequivocal: "In sum, we conclude that the combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, ... violates § 2 of the Sherman Act." App. 37a.

That ruling in turn affects a pending claim for relief. Respondent cannot seek any further relief under federal law, but Respondent continues to seek damages under a New York statute that authorizes "restitution and damages" for "persistent ... illegality." N.Y. Exec. Law § 63(12). If this Court overturns the Second Circuit's holding that product replacement violates section 2, that pending damages claim must fail.

ii. Second, the district court's preliminary injunction is capable of repetition, yet evading review. That "established exception to mootness" applies where "(1) the challenged action is in its duration too short to

be fully litigated prior to cessation or expiration, and (2) there is a reasonable expectation that the same complaining party will be subject to the same action again." *Fed. Election Comm'n v. Wisc. Right to Life, Inc.*, 551 U.S. 449, 462 (2007).

Both requirements plainly are met here. Given how long it takes to develop new drug formulations and obtain FDA approval, brand drug manufacturers often replace old drugs with new versions only shortly before the old version's exclusivities expire. And Petitioners have numerous drugs they intend to replace with innovative new versions in coming years. But if Petitioners were to announce a replacement, Respondent could simply file suit within the Second Circuit and immediately obtain a nationwide injunction based on the decision below. Indeed, that is apparently Respondent's intention—Respondent's counsel describes the decision below as "a very useful framework ... for future enforcement." Melissa Lipman, *Namenda Isn't End of NY AG's Pharma Work: Antitrust Chief*, Law360, May 29, 2015, http://www.law360.com/articles/661685/namenda-isn-t-end-of-ny-ag-s-pharma-work-antitrust-chief.

iii. In any event, even if the decision below were fully moot, the proper course would be for this Court to grant, vacate, and remand. Under *United States v. Munsingwear, Inc.*, 340 U.S. 36 (1950), "[w]hen a civil case becomes moot pending appellate adjudication, the established practice in the federal system is to reverse or vacate the judgment below and remand with a direction to dismiss." *Arizonans for Official English v. Arizona*, 520 U.S. 43, 71 (1997) (quotation marks and alterations omitted). This practice "prevent[s] an unreviewable decision from spawning any legal consequences" through its preclusive or precedential effect

on future cases. *Camreta v. Greene*, 131 S. Ct. 2020, 2035 (2011) (quotation marks omitted). Here, the decision below is a "legally consequential decision," *id.*, that Respondent and other enforcement agencies may use to challenge Petitioners' conduct in the future. If the "happenstance" of timing has rendered that decision moot, *id.*, vacatur is appropriate.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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