No. 12-265

IN THE

Supreme Court of the United States

UPSHER-SMITH LABORATORIES INC.,
Petitioner,

v.

LOUISIANA WHOLESALE DRUG CO., INC., ET AL.,
Respondents.

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

BRIEF FOR THE GENERIC PHARMACEUTICAL ASSOCIATION AS AMICUS CURIAE SUPPORTING PETITIONER

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INTEREST OF THE AMICUS CURIAE

The Generic Pharmaceutical Association (GPhA) is a nonprofit, voluntary association representing nearly 100 manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. GPhA's members provide American consumers with generic drugs that are just as safe and effective as their brand-name counterparts, but substantially less expensive. GPhA members' products account for roughly 80% of all prescriptions dispensed in the United States but only 27% of the money spent on prescriptions. In this way, the products sold by GPhA members save consumers nearly $200 billion each year. GPhA's core mission is to improve the lives of consumers by providing timely access to affordable pharmaceuticals. GPhA regularly participates in litigation as *amicus curiae*, taking legal positions that are adopted by GPhA's Board of Directors and reflect the position of GPhA as an organization. *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, No. 10-844; *PLIVA, Inc. v. Mensing*, No. 09-993.[1]

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[1] All parties have consented to the filing of this brief. Letters reflecting the parties' consent have been lodged with the Clerk. No counsel for a party authored this brief in whole or in part. No party, no counsel for a party, and no person other than amicus, its members, and its counsel made a monetary contribution intended to fund the preparation or submission of this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

The decision of the court of appeals directly threatens the ability of the generic pharmaceutical industry to ensure consumers affordable access to life-saving and health-preserving medicines. The court below has staked out a novel and deeply disruptive position on a question of fundamental importance to that industry: what legal regime governs settlements of patent-infringement litigation between a brand-name manufacturer, which holds a patent and claims the right to exclude generics from the market, and a generic manufacturer, which contends that the patent is invalid or not infringed.

Over the years, settlement of such cases has brought enormous benefits to consumers by speeding the entry of generic drugs to the market. Until now, the rule governing these settlements was clear: the courts of appeals agreed that settlements of patent litigation permitting a generic drug manufacturer to start selling its product prior to patent expiry were lawful and did not violate the antitrust laws, so long as the agreement did not restrain trade beyond the scope of the patent itself. Under that rule, manufacturers of branded and generic drugs—including many GPhA members—have settled numerous patent cases in a manner that allowed generic drugs to come to market before expiry of the patents involved, providing substantial benefits to consumers.

The court of appeals' decision in this case, however, has now unsettled the legal landscape. Disagreeing with every other circuit to reach the question, the court of appeals held that such settlements are presumptively unlawful under the antitrust laws. The

court of appeals' mistaken view applies even when the settlement allows the generic to enter the market before the brand-name company's patent expires and even when the agreement does not restrain trade beyond the scope of the patent; in the court of appeals' view, an agreement is presumptively unlawful if it includes a payment from the brand-name patentholder to the generic challenger.

This Court should swiftly resolve the circuit conflict and ensure that the correct rule of law will govern. The court of appeals' decision would turn an agreement that benefits consumers—by providing them with earlier access to low-priced generic drugs than the brand-name patents would allow—into a basis for treble damages liability under the antitrust laws. If allowed to stand, the court of appeals' decision will inevitably delay the entry of new generic drugs into the marketplace, with potentially devastating costs to consumers and the Nation.

Until the split of authority is resolved, GPhA's members face an uncertain legal regime with respect to a wide range of current cases and potential future patent challenges. Because of the permissive venue provision of the antitrust laws, a host of business and litigation decisions that other circuits deem permissible are now potential targets for a nationwide class action or—as the Federal Trade Commission (FTC) has already vowed—an enforcement action, in the Third Circuit. So long as that uncertainty persists, it will chill GPhA's members from resolving litigation in a way that helps to bring cost-saving generic medicines to market and thereby *promotes* competition. This Court should end that uncertainty and take up the question now, in this case.

A. The makers and sellers of prescription drugs need to know the legal terms on which they can settle patent litigation between them without risking antitrust liability. The answer to that question will affect not only whether such settlements can be reached and how, but also whether some new generic drug applications will be filed at all.

Before applying to introduce a new product, generic pharmaceutical companies carefully examine the expected cost. When the proposed generic would be equivalent to a brand-name drug that is claimed in a patent, the costs of seeking to introduce the generic before that patent expires inevitably include the costs of litigation. Those costs are incurred long before the new drug goes on sale and produces revenue. To carry out their mission of introducing safe, effective, and cost-effective pharmaceuticals, therefore, generic drug manufacturers need to understand what legal regime will govern that litigation. Legal rules that limit the ability to settle drive up the cost of patent challenges, meaning that fewer generic drug applications that would trigger a patent challenge will be filed.

Today, a settlement of litigation that is permissible in several circuits may nonetheless lead to antitrust liability in the Third Circuit. The uncertainty this situation creates will inevitably deter generic drug manufacturers from challenging patents to accelerate the entry of their products. And deterring the introduction of new generics hurts every health-care consumer who is deprived of access to cheaper pharmaceuticals. The national health-care marketplace needs a definitive answer to the question presented.

B. The time to answer that question is now. The circuit conflict is undeniable and entrenched. And although only one court of appeals has agreed with respondents' submission, that decision potentially affects every pharmaceutical company doing business in the United States. The antitrust laws permit plaintiffs to bring their actions in any judicial district in the country, *see* 15 U.S.C. § 22, and the decision below confirms that the Third Circuit is open to certifying a nationwide class of purchasers bringing an antitrust claim like this one. Virtually any settlement to which plaintiffs object, therefore, may potentially become the subject of an action in the Third Circuit for treble damages and may potentially be subject to that circuit's flawed decision in this case.

That decision gave insufficient weight to the patent rights at stake: a patentee does not violate the antitrust laws by exercising its patent rights, whether by bringing a patent-infringement suit or by settling one. Where, as here, the settlement does not restrain any trade beyond the scope of the patent, there can be no antitrust violation.

C. This case well illustrates the need for this Court's review: two drug companies that compete in the national marketplace have been sued by national retailers in a nationwide class action. The drug companies' settlement agreement has already been reviewed by two different courts of appeals, with extensive participation by the federal government as both a party and as amicus curiae. And the courts have split. This Court should not leave the national pharmaceutical market to be governed by the minority view of a single Third Circuit panel; it should step in now to resolve this crucially important conflict.

ARGUMENT

The circuits are now in undeniable conflict on an issue of profound importance to a multi-billion-dollar sector of the American economy. Until this Court ends the uncertainty, pharmaceutical companies will be subject to the prospect of nationwide class actions for treble damages, all governed by the minority rule laid down by the Third Circuit in this case. Only this Court can provide a final resolution, and it should speedily do so. The petition for a writ of certiorari should be granted.[2]

I. The Question Presented Is Profoundly Important To The Pharmaceutical Market And To Pharmaceutical Consumers

Generic pharmaceuticals lower prices by entering the marketplace and introducing competition. To bring a generic drug to market, manufacturers must meet the exacting standards of the Food and Drug Administration (FDA) to demonstrate that their product is safe and effective. In addition, in many instances the generic drug company must address patents that the sellers of a brand-name drug claim to cover their product—or wait until those patents have expired before marketing the generic drug. Under the system established by Congress in the Hatch-Waxman Act ("the Act," or, formally, the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585), applying for FDA approval of a new generic drug often trig-

[2] Another petition arising from the same judgment, No. 12-245, also appears to provide a suitable vehicle in the event the Court wishes to grant both petitions and consolidate the cases.

gers litigation about whether the proposed generic drug would infringe valid and enforceable patents.

Generic entry, therefore, comes at a significant cost, and much of that cost reflects the expense and risk of litigation. Settlement is a valid way of limiting that expense and managing that risk, while still allowing generic pharmaceuticals to enter the market and compete. But now, under the Third Circuit's decision, parties that settle on terms that restrain no trade beyond the scope of the patent they had been litigating would expose themselves to new risks: the threat of presumptive antitrust liability, and the enormous expense of defending antitrust litigation.

In order to make their most fundamental business decisions—whether to apply for permission to market new generic drugs, and whether to initiate a patent challenge as part of that process to accelerate the date of generic entry—GPhA's members need a single, stable, and reliable answer to the question presented: whether settlement will remain a viable alternative to litigating each and every case all the way to final judgment. That question fully merits this Court's attention.

A. The Availability Of Generic Drugs Saves Consumers Money And Increases Consumer Access To Lifesaving Therapies

Generic drugs are therapeutically equivalent to their brand-name counterparts. To be approved by the FDA, a generic drug must contain the same active ingredients as a brand-name drug, in the same dosage strength and form, and the drug must be absorbed by the body in the same ways. *See* 21 U.S.C. § 355(j)(2)(A)(ii), (iv). Upon approval, FDA certifies

that a generic drug is safe and effective for its intended uses, just as FDA does for brand-name drugs. Because the generic drug is therapeutically equivalent to its counterpart in every relevant sense, it does not need to undergo the same clinical testing before approval. *See*, *e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012); FDA, *Generic Drugs: Questions and Answers*, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm (last updated Aug. 24, 2011).

Generic drugs are substantially less expensive than brand-name drugs, in part because of the efficiencies generated by this streamlined approval pathway. The average generic drug costs only about one-third as much as the average brand-name drug. GPhA, *Economic Analysis: Generic Pharmaceuticals 1999-2008: $734 Billion in Health Care Savings* 5 (May 2009). That cost saving was precisely why Congress, in adopting the Hatch-Waxman Act, sought to encourage generic-drug applications. *See*, *e.g.*, *Caraco*, 132 S. Ct. at 1676. Today, when the rising cost of health care remains one of the most pressing national issues, the ability to develop and market cost-effective generic substitutes is all the more important.

Consumers have responded overwhelmingly to the ready availability of low-cost generic drugs. About 4 billion prescriptions were written in 2011; more than 3.2 billion of them—roughly 80%—were dispensed with generics. GPhA, *Generic Drug Savings in the U.S.* 2 (4th ed. 2012). Indeed, when equivalent branded and generic drugs were both available, the generic was purchased 94% of the time. *Id.* at 3. All

told, the availability of generic drugs saved the U.S. health care system more than $1 trillion over the course of the last decade—nearly $200 billion last year alone. *Id.* at 1; *see also*, *e.g.*, Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 31 (July 1998).

B. The Process Of Bringing Generic Drugs To Market Frequently Results In Expensive, High-Stakes Litigation

In adopting the Hatch-Waxman Act, one of Congress's key goals was to ensure that generic drugs become available promptly to consumers, while still respecting legitimate patent rights. In furtherance of that goal, Congress specifically designed the Hatch-Waxman Act to create incentives for generic drug companies to bring new drugs to market, including when that new drug entails a patent challenge. That type of challenge is known as a "Paragraph IV certification," after the statutory provision that the generic drug applicant invokes when it applies for approval and asserts that the relevant patent is invalid or not infringed. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Congress also understood that such challenges require a substantial investment by the generic drug company, because under the Act a brand-name patentee may commence infringement litigation as soon as the generic drug company files an application with a Paragraph IV certification. *See* 35 U.S.C. § 271(e)(2); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); *see also* 21 U.S.C. § 355(j)(5)(B) (creating incentive for patentee to sue within 45 days). The generic drug company thus must incur

the burdens of litigation long before it has manufactured the drug or received any revenue. As a result, Congress created financial rewards for successful challengers to compensate them for their investment and to encourage future challenges. *See* 21 U.S.C. § 355(j)(5)(B)(iv); *see, e.g.*, *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1311 (D.C. Cir. 2010); *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1356 (Fed. Cir. 2008); *Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26, 33-34 (D.D.C. 2006), *aff'd summarily*, No. 06-5204, 2006 WL 2591087 (D.C. Cir. Aug. 30, 2006).

Thus, when a generic manufacturer is deciding whether to file a Paragraph IV certification to seek approval for a new generic drug that is claimed by a patent, the manufacturer must consider the cost of defending the all-but-inevitable patent-infringement action. *See, e.g.*, *Protecting Consumer Access to Generic Drugs Act of 2007: Hearing Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce*, 110th Cong. 136 (2007) (statement of Theodore Whitehouse). The ability to litigate is the price of admission. That price can be extremely high, particularly given the high stakes for the brand-name patentee seeking to protect blockbuster profits from generic competitors.

But nothing in either the Hatch-Waxman Act or the antitrust laws mandates that every single patent lawsuit under Paragraph IV must be fought to the bitter end. To the contrary, settlements of litigation are generally permissible from an antitrust perspective, *see Standard Oil Co. (Ind.) v. United States*, 283 U.S. 163, 171 (1931), and nothing in the Hatch-

Waxman Act changes that rule in the generic-drug context. Under the Act, the FDA ordinarily cannot approve an allegedly infringing generic for 30 months, but under two circumstances it may approve the generic immediately: if the generic wins a court decision (a "judgment" of a district court, or a decision of a court of appeals), *or* the parties reach a settlement (a "settlement order or consent decree") that permits the generic to go forward. 21 U.S.C. § 355(j)(5)(B)(iii)(I), (II). Thus, the Act's explicit terms condone settlements as a valid basis for terminating the patent challenge and authorizing FDA approval of a generic drug prior to patent expiry.

C. Consumers Benefit From Early, Definite Resolution Of Paragraph IV Litigation

The availability of settlements helps broaden the gains consumers get from the Hatch-Waxman framework. Litigants under that framework (like litigants everywhere) settle cases to manage risk and to save money on litigation costs. Because the cost, length, and uncertainty of litigation represent the chief obstacles to entering the market with a Paragraph IV certification, settlements are a key way of overcoming those obstacles and bringing cheaper pharmaceuticals to market sooner—the Act's goal. Indeed, settlement can yield earlier or better access to the market than litigation to final judgment. In the Act, Congress treated settlement and final judgment as equally valid ways to end litigation and permit approval of a generic. Congress did not want to require parties to litigate to the death, particularly at a time when the branded manufacturer will often have a resource advantage because the generic manufacturer is not yet able to enter the market.

Branded and generic drug manufacturers have entered into hundreds of patent settlements over the past several years. *See* Bureau of Competition, 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 2011,* http://www.ftc.gov/os/2011/10/1110mmaagree.pdf (last visited Sept. 27, 2012). In case after case, settlement has brought a low-cost generic drug into the marketplace *sooner* than the brand-name drug's patent would have permitted. One of GPhA's members estimated in 2009 that its settlements had "removed 138 years of monopoly protection" and thereby provided $128 billion in savings to consumers through early generic entry. *See* Teva Pharms. USA, Press Release, *Teva Pharmaceuticals Issues Statement in Response to Federal Trade Commission Claims on Patent Settlements* (June 24, 2009), http://tinyurl.com/TevaStatement.

One recent example involves Lipitor®, the best-selling drug of all time. The manufacturer of Lipitor® claimed that it was entitled to exclude generic equivalents from the market until as late as 2017; a generic manufacturer filed Paragraph IV certifications and, after settling the ensuing patent litigation, brought a generic equivalent to market in late 2011. Introducing a lower-cost alternative, more than five years early, to the world's best-selling drug is projected to save consumers $2 billion this year, and as much as $4.5 billion per year by 2014.[3]

Other cases illustrate how settlements can give consumers access to generic equivalents that they

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[3] *See* Cynthia A. Jackevicius et al., *Generic Atorvastatin and Health Care Costs*, 366 New Eng. J. Med. 201 (2012).

otherwise would not have. For example, four different generic manufacturers filed Paragraph IV certifications seeking to manufacture generic tamoxifen citrate, a breast-cancer treatment that was then the world's most widely prescribed anticancer medication. The brand-name manufacturer sued all four to enforce its patent. The first generic manufacturer to file its certification, Barr Laboratories, ultimately reached a settlement allowing it to market tamoxifen under its own label, nine years before the patent expired, in return for dropping its patent-invalidity claim. The three other generic manufacturers litigated their cases, but were unsuccessful. "In each case, the court . . . upheld the validity of [the branded manufacturer's] tamoxifen patent." *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 195 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007); *see id.* at 190, 193-95.

The unsuccessful court challenges to the tamoxifen patent illustrate the tangible consumer benefit from Barr's settlement. Nine years before the patent expired, Barr was able to bring a cheaper version of tamoxifen to market. *See id.* at 194 & n.9. If Barr had instead litigated to final judgment and lost as the other companies did, the brand-name manufacturer would have faced no generic competition for nine more years.

Even setting aside the immediate, bargained-for benefit to consumers, settlements support competition on a more general level. Money not spent litigating a patent challenge to one generic drug can be spent developing and bringing to market a new generic drug. Conversely, a rule that restricts settlement options—even when the settlement does not

restrain trade beyond the scope of the patent—will only increase the cost of Paragraph IV litigation and decrease the number of such cases generic drug companies will be willing to undertake. That result does nothing to promote competition.

Since the Act was enacted, therefore, generic drug manufacturers have understood that settlement is just as valid a means of obtaining a favorable resolution—and potentially a much cheaper, faster, and more certain one. Generic companies have acted on that understanding and have created tremendous savings for consumers through agreements allowing for accelerated generic entry. The question presented by this case is whether that understanding will now be turned upside down.

D. The Legal Status Of Settlements Needs Resolution

During the period when a brand-name pharmaceutical is claimed by a patent, generic pharmaceutical manufacturers' key business decision boils down to one question: whether it makes economic sense to challenge that patent. The Third Circuit's decision has introduced significant uncertainty into that process.

In short, the decision to start the process with a new generic drug will be a profoundly different one if the challenge can take only one form: a protracted fight all the way to final judgment. Pharmaceutical companies urgently need to know whether they can settle Paragraph IV cases, and if so, on what sort of terms. If the ability to bargain for settlement becomes so restricted that, in many cases, there will be no ability to settle at all, generic drug companies will

bring fewer patent challenges and consumers will have to wait longer to obtain lower-cost medicines. The Third Circuit's decision threatens precisely that outcome. Until the circuit conflict is resolved, therefore, the chilling effect on generic drug companies will continue.

II. The Question Presented Urgently Requires A Nationwide Resolution By This Court

A. The Issue Has Produced A Deep And Entrenched Circuit Conflict

1. The courts of appeals are intractably divided over the correct answer to the question presented. As petitioner Upsher explains (Pet. 13-15), the Second, Eleventh, and Federal Circuits have squarely held that settlements within the scope of a patent are not unlawfully anticompetitive, absent fraud or sham litigation. *See Tamoxifen Citrate*, 466 F.3d at 212-13 (Second Circuit); *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1067-68 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008), *cert. denied*, 557 U.S. 920 (2009). The Third Circuit in this case reached precisely the opposite conclusion and held that such settlements are presumptively anticompetitive.

The circuit split extends not only to the same question of law, but even to the same *settlement agreement*. This case involves agreements Schering-Plough made with Upsher and ESI-Lederle in 1997 and 1998. The FTC challenged those same agree-

ments in administrative proceedings, and the Eleventh Circuit in *Schering-Plough* rejected the FTC's analysis and held that the agreements survive antitrust review. Now private plaintiffs—supported by the FTC as amicus curiae—have persuaded the Third Circuit that the very same agreements presumptively *fail* antitrust review.[4]

2. That conflict will not dissipate without review by this Court. All three of the circuits with which the court below disagreed have denied petitions for rehearing en banc requesting that they reconsider their precedent—including petitions by, or supported by, the FTC and a host of other amici. *See*, *e.g.*, *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, *reh'g denied*, 625 F.3d 779 (2d Cir. 2010), *cert. denied*, 131 S. Ct. 1606 (2011); FTC Amicus Br. in Supp. of Reh'g En Banc, *Ark. Carpenters*, *supra* (No. 05-2851-CV); FTC Pet. for Reh'g En Banc, *Watson Pharms.*, *supra* (No. 10-12729).

Indeed, several of the respondents in this case were also plaintiffs in the litigation resolved by the Second Circuit's *Arkansas Carpenters* case.[5] After that decision, those same respondents sought review in this Court of the same question presented here. At that time, however, there was no circuit conflict, and two Members of the Court were recused from the case. *See Louisiana Wholesale Drug Co.* v. *Bayer AG*,

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[4] In *Schering-Plough* the FTC invoked the Federal Trade Commission Act as well as the Sherman Act, but identical legal standards apply under the two statutes. *See, e.g.*, *Watson Pharms.*, 677 F.3d at 1307 n.5.

[5] Compare Pet. ii (listing Louisiana Wholesale Drug Co., CVS Pharmacy, Inc., and Rite Aid Corp. as plaintiffs) with Pet. ii, *Louisiana Wholesale Drug Co. v. Bayer AG* (No. 10-762) (same).

131 S. Ct. 1606 (2011) (denying certiorari). With the circuits now in conflict, the case for this Court's review has become incontrovertible.

B. Postponing Review Will Produce Only Forum-Shopping, Not Meaningful Further Percolation

If the Third Circuit's decision stands undisturbed, an unusual feature of the antitrust laws will allow plaintiffs nationwide to rush to courts in that circuit, rather than take their chances anywhere else. Further percolation, therefore, will be substantially cut off.

1. An antitrust plaintiff can choose to bring a Sherman Act case in any one of the 94 federal judicial districts. The usual venue rules do not apply. *See* 15 U.S.C. § 22. Furthermore, the Third Circuit has held that an antitrust defendant need not even have the usual degree of "minimum contacts" with the forum State. Rather, in antitrust cases the Third Circuit will find personal jurisdiction over any defendant that has minimum contacts with the United States as a whole, whether or not it has any contacts with New Jersey, Delaware, or Pennsylvania. *See In re Auto. Refinishing Paint Antitrust Litig.*, 358 F.3d 288, 298 (3d Cir. 2004) ("[P]ersonal jurisdiction in federal antitrust litigation is assessed on the basis of a defendant's aggregate contacts with the United States as a whole," not with the forum state).

2. Moreover, even under the ordinary rules, venue would be proper in the Third Circuit in a host of cases. The Third Circuit is home to a large percentage of the nation's pharmaceutical companies, and many of the largest pharmaceutical manufacturers have

their principal places of business there, are incorporated there, or both. New Jersey, for instance, touts itself "as the global epicenter of the pharmaceutical industry, [with] 15 of the world's 25 largest pharmaceutical companies having major facilities in New Jersey." State of N.J. Bus. Portal, *Pharmaceutical Industry*, http://www.state.nj.us/njbusiness/industry/pharmaceutical/ (last visited Sept. 19, 2012). Other large manufacturers of branded and generic drugs have headquarters or major facilities in Pennsylvania or Delaware. *See* Pa. Dep't of Cmty. & Econ. Dev., *Why PA?*, http://www.newpa.com/business/whypa (last visited Sept. 19, 2012); Del. Econ. Dev. Office, *Biotechnology & Life Sciences*, http://dedo.delaware.gov/DelawareIndustries/Delaware Industries_Biotech.shtml?Biotech (last visited Sept. 19, 2012).

Indeed, for those reasons, New Jersey and Delaware are already the epicenter of Paragraph IV litigation—the cases that, when settled, lead to antitrust claims like respondents'. Between 2000 and 2009, the five districts within the Third Circuit hosted more Paragraph IV litigation than all other districts combined. *See* RBC Capital Mkts., *Pharmaceuticals: Analyzing Litigation Success Rates* 6 Ex. 6 (Jan. 15, 2010), http://amlawdaily.typepad.com/pharmareport.pdf.

Since the Third Circuit handed down the decision in this case, the FTC Chairman has declared that if this Court does not review the issue, "we'll simply be forced to bring pay-for-delay cases in the Third Circuit for years to come."[6] Indeed, private plaintiffs

[6] Fed. News Serv., *Prepared Remarks of Federal Trade Commission (FTC) Chairman Jon Leibowitz at the Sixth Annual*

are not waiting for this Court. At least one new lawsuit has been filed in the Third Circuit to challenge a settlement of Paragraph IV litigation. *See Rochester Drug Co-Operative, Inc. v. AstraZeneca AB*, No. 12-cv-04911-LDD (E.D. Pa. filed Aug. 27, 2012). And multidistrict litigations already pending in the Third Circuit continue to attract new cases. *See*, *e.g.*, *Meijer, Inc. v. Pfizer Inc.*, No. 3:12-cv-4537-PGS-DEA (D.N.J. filed July 19, 2012) (consolidated into *In re Lipitor Antitrust Litig.*, MDL No. 2332).

3. The split between the Third Circuit and three other circuits is particularly significant. Because these claims can be litigated on a nationwide basis in the Third Circuit, *see* Pet. App. 42a-53a (affirming the certification of a nationwide class of direct purchasers), percolation in federal court may well have come to an end. Indeed, even in cases pending outside the Third Circuit, the litigants are awaiting a decision by this Court in this case. *See* Order, *In re Cipro Cases I & II*, No. S198616 (Cal. Sept. 12, 2012) ("On its own motion, the court stays further briefing in this matter pending action by the United States Supreme Court in [this case and No. 12-245].").

The split is especially pernicious because it involves the intersection of patent law with another body of law, and therefore implicates the somewhat blurry jurisdictional line between the Federal Circuit and the regional circuits. Some antitrust claims involving patent settlements have gone to the Federal Circuit, *e.g.*, because the plaintiffs pleaded both antitrust and patent claims. Other antitrust claims, like those here, have gone to the regional circuit. *See*

Georgetown Law Global Antitrust Enforcement Symposium (Sept. 19, 2012), *available in* WL FDNUS Database.

Ark. Carpenters, 604 F.3d at 103 n.10 (explaining that part of the case was transferred to the Federal Circuit and part remained in the Second Circuit). And because the Third Circuit and Federal Circuit have answered the question presented in diametrically opposite ways, the jurisdictional line becomes outcome-determinative. *Cf. Holmes Group, Inc.* v. *Vornado Air Circulation Sys.*, 535 U.S. 826, 835 (2002) (Stevens, J., concurring in part and concurring in the judgment) (explaining how a plaintiff with both patent and antitrust claims may be able to manipulate the case to determine which appellate court will hear it). One district judge in the Third Circuit, who is considering several cases presenting this question, has noted that he may need to conduct two trials applying different legal standards: one governed by Federal Circuit precedent, which goes one way, and the other by Third Circuit precedent, which goes the opposite way. Order at 4, *King Drug Co. of Florence v. Cephalon, Inc.*, No. 2:06-cv-1797 (E.D. Pa. Aug. 29, 2012). That situation is untenable for courts and litigants alike.

Even before the square circuit conflict arose, the issue had already led to gamesmanship and forum-shopping in an attempt to find a court that would break from the appellate consensus. *See FTC v. Cephalon, Inc.*, 551 F. Supp. 2d 21, 30 & n.5 (D.D.C. 2008) (criticizing the FTC's choice of a venue with no connection to the facts of the case and noting that "the Commission is rather openly shopping for a circuit split on the issue of reverse-payment Hatch-Waxman settlements") (footnote omitted); *see also FTC v. Watson Pharms., Inc.*, 611 F. Supp. 2d 1081 (C.D. Cal. 2009) (transferring the FTC's suit from a district court in the Ninth Circuit to one in the Elev-

enth Circuit). Although respondents and the FTC have now persuaded a single circuit to decide the issue their way, that should not be the last word on the matter. The last word properly belongs to this Court.

C. The Decision Below Is Wrong

The fact that the decision below effectively sets nationwide competition policy from Philadelphia, rejecting the rule in other circuits, is enough by itself to justify this Court's review. But the Third Circuit also got the law wrong, which only strengthens the case for certiorari here.

Patents restrict competition for a specified time, but they are not unlawful restraints of trade. Rather, they represent a determination by Congress that the incentive to innovate justifies granting "Inventors the exclusive Right to their . . . Discoveries" for a "limited Time[]." U.S. Const. art. I, § 8, cl. 8. The court of appeals concluded that the rule of law applied in its sister circuits must be wrong because no antitrust plaintiff has yet prevailed under it. *See* Pet. App. 32a-33a ("[N]o court applying the scope of the patent test has ever permitted a reverse payment antitrust case to go to trial."). But the reason why plaintiffs do not prevail under that rule is simply that they have not stated an unlawful restraint on competition: a patentee has a *statutory* right to exclude its competitors from the market,[7] or to license its patent to competitors if it wishes. Where, as here, the agreement does not restrain any trade beyond

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[7] *See* 35 U.S.C. § 154(a)(1); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392, 394 (2006) (right is subject to background principles of equity).

the scope of the patent, there simply cannot be an antitrust violation.

The court of appeals emphasized that patents often are held invalid, and it accordingly concluded that settlements of Paragraph IV litigation are presumptively anticompetitive absent some "assurance that the underlying patent is valid." Pet. App. 37a. But there can be no such "assurance" until an invalidity claim is litigated to final judgment through the federal system—precisely the sort of "fight to the death" that settlements avoid. Rather, a properly issued patent is presumed valid. 35 U.S.C. § 282; *see Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238 (2011). The court of appeals objected that the presumption of validity "is not a substantive right of the patent holder." Pet. App. 33a. But the right to exclude certainly is such a substantive right. The settlement in this case simply bargained away that right. The court of appeals thus had no warrant to treat a settlement of patent rights as presumptively unlawful.

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The question presented is a frequently recurring issue of nationwide importance on which the law is now profoundly unsettled. The answer to that question will determine how an entire industry does business, because it will dramatically affect the economics of each decision to introduce a new generic drug. Here, the question arises in the context of a dispute between multinational manufacturers and a nationwide class of retailers, who themselves do business nationwide and have litigated this same issue in multiple circuits, with divergent results. The specific dispute concerns settlement agreements that, for the past fifteen years, have been subject to

discovery before an administrative law judge and a district judge; to administrative scrutiny before the FTC; and to judicial review by two different federal courts of appeals—again, with divergent results. This Court should provide the definitive answer.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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