No. 12-416

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

WATSON PHARMACEUTICALS, INC., *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE STATES OF NEW YORK, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, HAWAII, IDAHO, ILLINOIS, IOWA, KENTUCKY, LOUISIANA, MAINE, MARYLAND, MASSACHUSETTS, MINNESOTA, MISSISSIPPI, NEVADA, NEW HAMPSHIRE, NEW MEXICO, OHIO, OREGON, PENNSYLVANIA, RHODE ISLAND, TENNESSEE, UTAH, VERMONT, WASHINGTON, WEST VIRGINIA, AND WYOMING AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Federal competition law generally prohibits an incumbent firm from agreeing to pay a potential competitor to stay out of the market. *See Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990). This case concerns agreements between (1) the manufacturer of a brand-name drug on which the manufacturer assertedly holds a patent, and (2) potential generic competitors who, in response to patent-infringement litigation brought against them by the manufacturer, defended on the grounds that their products would not infringe the patent and that the patent was invalid. The patent litigation culminated in a settlement through which the seller of the brand-name drug agreed to pay its would-be generic competitors tens of millions of dollars annually, and those competitors agreed not to sell competing generic drugs for a number of years. Settlements containing that combination of terms are commonly known as "reverse payment" agreements. The question presented is as follows:

Whether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud (as the court below held) or instead are presumptively anticompetitive and unlawful (as the Third Circuit has held).

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INTEREST OF THE *AMICI*

Amici are the States of New York, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Hawaii, Idaho, Illinois, Iowa, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Nevada, New Hampshire, New Mexico, Ohio, Oregon, Pennsylvania, Rhode Island, Tennessee, Utah, Vermont, Washington, West Virginia and Wyoming.[1] The *Amici* States have strong interests, both as purchasers and as regulators, in protecting fair competition in pharmaceutical markets. Prescription drugs represent a major expenditure for the States, which purchase drugs and make reimbursements for the cost of drugs through state Medicaid and other public health programs and agencies.[2] State Medicaid and local health care programs spent $6.5 billion on prescription drugs in 2010. States also have a recognized interest in enforcing federal antitrust laws, through *parens patriae* standing, to protect their citizens' economic well-being against anticompetitive practices that raise prices and restrict consumer choice.

This case concerns agreements that purport to settle patent disputes, under which a drug patent holder pays money to a would-be generic competitor, and the would-be competitor agrees to delay its entry into the market—described here as "pay-for-delay" agreements. A dispute over the validity or scope of a patent may be appropriately compromised by an agreement that the competitor will enter the market on a date prior to the full term of the

[1] Counsel of record received timely notice of the States' intent to file this brief, as required by Supreme Court Rule 37.2(a).

[2] The word "purchase" is used in this brief to include purchases and reimbursements.

patent. But when the patent holder pays to delay the entry date of the competitor, monopoly prices prevail for a longer period than is warranted by the uncertain outcome of the patent litigation.

The *Amici* States have a strong interest in vindicating the Federal Trade Commission's position that such agreements presumptively violate the federal antitrust laws.[3] The delay in the entry date of the generic competitor that results from such agreements causes direct and substantial harm to the States and their residents. A recent study shows that pay-for-delay agreements cause drug purchasers nationwide to pay $3.5 billion per year more than they would pay if drug litigation settlements did not include pay-for-delay provisions. As major drug purchasers, the *Amici* States have a strong interest in avoiding those additional costs. And as antitrust enforcers,

[3] The FTC's claims in this case were brought under the Federal Trade Commission Act, 15 U.S.C. § 45(a); other challenges to similar settlements have been brought under the Sherman Act, 15 U.S.C. § 1. *See, e.g.*, *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 208 (3d Cir. 2012), *petitions for cert. filed*, 81 U.S.L.W. 3090 (Aug. 24, 2012) (No. 12-245); 81 U.S.L.W. 3090 (Aug. 29, 2012) (No. 12-265). The court below decided the case on the assumption that the relevant standards are the same under the FTC Act and the Sherman Act. *See* Pet. App. 17a n.5. *See also Polygram Holding, Inc. v. FTC*, 416 F.3d 29, 32 (D.C. Cir. 2005) ("[T]he . . . analysis under § 5 of the FTC Act is the same . . . as it would be under § 1 of the Sherman Act."); *FTC v. Motion Picture Adver. Servs. Co., Inc.*, 344 U.S. 392, 395 (1953) (holding that conduct prohibited by Sherman Act automatically violates section 5 of the FTC Act). Thus, the States, which have used the Sherman Act to bring antitrust enforcement actions, *see, e.g., New York v. Aventis S.A.*, No. 01 Civ. 71835 (E.D. Mich. 2001), have an interest in the question presented here.

the *Amici* States have a strong interest in bringing cases that would redress and prevent these harms for the benefit of their residents. *See, e.g., New York v. Aventis S.A.*, No. 01 Civ. 71835 (E.D. Mich. 2001) (state plaintiffs challenging pay-for-delay agreement); *Florida v. Abbott Labs.*, No 01 Civ. 4006 (S.D. Fla. 2002) (same).

STATEMENT

In this antitrust enforcement action, the Federal Trade Commission alleges that the defendants violated federal antitrust law by settling a patent dispute with agreements under which the manufacturer of a brand-name drug, Solvay Pharmaceuticals, paid money to would-be generic competitors, Watson Pharmaceuticals and Paddock Pharmaceuticals, to induce them to agree to delay their entry into the market.

Solvay manufactures and markets AndroGel, a gel formulation of synthetic testosterone that is used to treat low testosterone. (2d Am. Compl. ¶ 31.) Solvay holds a patent for AndroGel; at the time of the settlement agreements at issue, the patent was scheduled to expire in 2020.[4] (*Id.* ¶ 43.) Solvay's patent does not cover the drug's active ingredient: testosterone was first synthesized in 1935 and lost patent protection decades ago. (Pet. App. 10a.) Rather, Solvay's patent relates to a particular gel formulation of the drug. (Pet. App. 10a.)

In 2003, Watson and Paddock separately announced plans to market generic testosterone products that

[4] The patent was later extended to February 2021. (2d Am. Compl. ¶ 43.)

would compete with AndroGel. (Pet. App. 10a-11a.) They each applied to the FDA for approval of their generic products under a provision of the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585, that affords the first generic challenger of a brand-name drug the right, under certain circumstances, to a 180-day period during which the FDA will not approve other generic versions of the same drug. 21 U.S.C. § 355(j)(5)(B)(iv). Soon after Watson and Paddock filed their applications with the FDA, Solvay sued them for patent infringement. (Pet. App. 11a.) The generics responded that their drugs did not infringe Solvay's patent, and that the patent was invalid in any event. (*See* Pet. App. 12a.)

The parties settled the case. Watson and Paddock agreed to delay their entry until 2015, five years before the patent was scheduled to expire in 2020. (Pet. App. 10a.) Solvay already planned to switch its marketing focus to a substitute testosterone product by 2015 in any event. (2d Am. Compl. ¶¶ 62-63.) In exchange for the generic manufacturers' agreement to delay entry, Solvay agreed to pay Watson between $19 and 30 million annually—calculated based on Solvay's AndroGel profits for the year—and to pay Paddock $10 million per year for six years, and Paddock's affiliate Par Pharmaceuticals an additional $2 million per year. (Pet. App. 12a-13a.) The agreement portrayed these payments as compensation for manufacturing or marketing services provided by Watson and Paddock to Solvay. But Solvay had no need for manufacturing or marketing services from its would-be competitors and did not expect to use them. Indeed, Solvay acknowledged internally that the services had little or no value. (2d Am. Compl. ¶¶ 60-85.)

The FTC filed suit in the United States District Court for the Central District of California to challenge

these agreements under Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. The case was later transferred to the Northern District of Georgia on defendants' motion. *See* Def. Joint Motion to Transfer Venue, ECF No. 44-1 (N.D. Ga. Feb. 27, 2009.)[5]

The FTC asserted that the agreements unlawfully extended Solvay's monopoly on AndroGel—not through the strength of Solvay's patent but through the financial incentives it offered its competitors. (2d Am. Compl. ¶ 111.) The complaint specifically alleged that the payments to the generics made economic sense only as a mechanism for delaying the generics' competition with Solvay. (*Id.* ¶¶ 81-85.) The complaint also alleged that Solvay was unlikely to have succeeded in its patent suit to exclude the generic competition. (*Id.* ¶¶ 86-92.)

The district court dismissed the FTC's complaint for failure to state a claim (Pet. App. 37a), holding that there was no antitrust violation because the settlement agreements excluded only competition that could already have been excluded by the patent itself—if the patent were determined valid and the competing generic products were held to infringe it. (Pet. App. 47a-52a.) The United States Court of Appeals for the Eleventh Circuit affirmed (Pet. App. 1a), holding that in the absence of sham litigation or fraud, a settlement of drug patent litigation does not violate antitrust law as long as "its anticompetitive effects fall within the scope of the exclusionary potential of the patent." (Pet. App. 28a.) The court denied a petition for rehearing or rehearing en banc. (Pet. App. 62a-63a.)

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[5] The State of California originally brought this suit jointly with the FTC in California, but California dismissed its claims after the suit was transferred to Georgia over California's jurisdictional objections.

SUMMARY OF ARGUMENT

This Court should grant the petition for certiorari because it squarely presents a legal question of exceptional nationwide importance on which the courts of appeals are sharply divided: whether antitrust law is violated when drug patent litigation is settled by agreements in which drug patent holders pay their generic competitors to stay out of the market. The Court should grant certiorari to resolve the split and lift the uncertainty that currently hangs over drug purchasers and drug manufacturers alike on this issue. And the Court should hold that pay-for-delay settlements are presumptively anticompetitive and unlawful. It serves neither the public interest nor the fundamental goals of antitrust law and patent law when brand-name manufacturers are allowed to immunize their patents from scrutiny by buying off their competitors with a share of their monopoly profits.

ARGUMENT

I. There is a well-developed circuit split as to whether pay-for-delay settlements of drug patent disputes should receive scrutiny under federal antitrust laws.

Over the last decade, the courts of appeals have divided over how federal competition laws apply to "pay-for-delay" or "reverse-payment" settlement agreements. Six circuits have addressed the question, and two major and diametrically opposed approaches have developed.

The first approach, adopted by the Third Circuit, regards a payment "from a patent-holder to a generic

patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade." *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 208 (3d Cir. 2012), *petitions for cert. filed*, 81 U.S.L.W. 3090 (Aug. 24, 2012) (No. 12-245); 81 U.S.L.W. 3090 (Aug. 29, 2012) (No. 12-265). Under this approach, pay-for-delay settlements of drug patent litigation presumptively violate antitrust law, and the parties to the settlement may attempt to rebut this presumption by proving that the settlement has procompetitive benefits, or that the payment was not made to induce delayed entry. *Id*. The Sixth and D.C. Circuits—although they have not specifically adopted the exact approach followed by the Third Circuit—have also concluded that pay-for-delay settlements raise serious antitrust concerns.[6]

The other approach, taken by the Eleventh Circuit below and by the Second and Federal Circuits, holds, in sharp contrast, that payments for delayed market entry as part of a drug-patent settlement are essentially immune from antitrust scrutiny, as long as the settlement agreement does not exclude competition beyond the term

[6] The Sixth and D.C. Circuit decisions analyzed the same agreement—an interim agreement reached during the course of patent litigation, rather than a final settlement agreement—in which the generic competitor agreed not to enter the market during the pendency of the patent litigation. The D.C. Circuit held that an antitrust challenge to the agreement survived a motion to dismiss. *Andrx Pharmaceuticals v. Biovail Corp. Int'l*, 256 F.3d 799, 806-815 (D.C. Cir. 2001). The Sixth Circuit found that the agreement was *per se* illegal under federal antitrust law because it represented "a horizontal agreement to eliminate competition." *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908 (6th Cir. 2003).

and extent of the patent on its face. This approach is sometimes known as the "scope-of-the-patent" test. On this approach, "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary *potential* of the patent." (Pet. App. 28a (emphasis added).) *See also In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006). *But see Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 604 F.3d 98 (2d Cir. 2010) (per curiam) (expressing serious concerns about the scope-of-the-patent approach); *rehearing en banc denied*, 625 F.3d 779 (2d Cir. 2010) (Pooler, J., dissenting); *cert. denied*, 31 S. Ct. 1606 (2011).

The persistence of this circuit split about the correct treatment of pay-for-delay settlements under federal antitrust law has serious adverse consequences. First and most important, agreements between brand-name drug manufacturers and would-be generic competitors affect consumers in every State. It makes no sense for the same nationwide agreement to be viewed as unlawful in some circuits and not in others under a single federal scheme. And that is precisely the situation right now; two circuit courts have reached different conclusions about the legality under federal antitrust law of the very same nationwide settlement agreement. *Compare K-Dur*, 686 F.3d at 218, *with Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1068 (11th Cir. 2005).

The interests of all parties affected by pay-for-delay settlements—the companies that are parties to the agreements, the government agencies that challenge

those agreements, and the governments and members of the public that purchase drugs whose prices are affected by those agreements—would be served by resolution of the current conflict over their lawfulness. Parties on both sides of the issue have urged this Court to resolve the split: the petition in this case was filed by the FTC, as the federal antitrust enforcer seeking to preserve fair competition and protect the interests of drug purchasers, and petitions were also filed in the *K-Dur* case by pharmaceutical companies seeking to defend their pay-for-delay settlements. *See* Pet. for Certiorari, *Merck v. Louisiana Wholesale Drug Co.*, No. 12-245 (challenging the Third Circuit's decision in *K-Dur*); Pet. for Certiorari, *Upsher-Smith Laboratories v. Louisiana Wholesale Drug Co.*, No. 12-265 (same).

The *Amici* States in particular seek a prompt resolution of the circuit split. The States have standing under federal antitrust law to protect their own proprietary interests. *See, e.g., Massachusetts v. E.P.A.*, 549 U.S. 497, 519 (2007). They also have *parens patriae* standing to protect their quasi-sovereign interest in the economic well-being of their residents. *See* 15 U.S.C. § 15c (affording state attorneys general *parens patriae* standing under the Sherman Act); *Georgia v. Pennsylvania R.R.*, 324 U.S. 439, 447 (1945); *California v. American Stores Co.*, 495 U.S. 271 (1990). States have brought a series of cases challenging conduct that delayed a generic drug's entry, including pay-for-delay settlements. *See, e.g., New York v. Aventis S.A.*, No. 01 Civ. 71835 (E.D. Mich. 2001) (state plaintiffs challenging pay-for-delay agreement); *Florida v. Abbott Labs.*, No. 01 Civ. 4006 (S.D. Fla. 2002) (same). The *Amici* States seek a single rule to govern such cases under federal antitrust law.

II. Pay-for-delay settlements should be presumptively unlawful because they are almost always anticompetitive.

The Court should adopt a presumption that pay-for-delay settlements are anticompetitive and unlawful. The issue presented by these settlements involves the intersection of two bodies of law—antitrust law and patent law—each of which exists to protect the public good, and each of which is fundamentally undermined by pay-for-delay drug settlements. Consequently, such settlements should be given serious antitrust scrutiny, as the rule adopted by the Third Circuit requires.

A. Antitrust law protects the public from anticompetitive practices. A classic form of antitrust violation occurs when one firm preserves a profitable monopoly by paying potential competitors to stay out of the market. *See Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990). The law forbids this practice because it will often be in a monopolist's economic interests to pay a competitor to stay out of the market, thereby allowing the monopolist to earn surplus monopoly profits at the public's expense by keeping prices artificially high and restricting consumer choice. For this reason, settled law holds that agreements in which an incumbent firm splits "monopoly rents" with a would-be competitor to preserve the incumbent's monopoly constitute per se antitrust violations. *Id.*

The facts of this case—as alleged in the amended complaint and accepted as true on the motion to dismiss—illustrate the way that pay-for-delay settlements of drug patent litigation present just this classic antitrust problem.

The FTC's complaint alleged that payments under the settlement agreements from Solvay to its would-be generic competitors made economic sense only as a mechanism for delaying the generics' competition with Solvay. (2d Am. Compl. ¶¶ 81-85.) And it alleged that Solvay understood and intended this result. The company sought to preserve its AndroGel monopoly until 2015, when it planned to shift its marketing focus to a substitute testosterone product. An internal analysis by Solvay, known as "Project Tulip," concluded that it was worth a substantial payment to keep the generic competition out of the market until 2015—that the expected profits during that period from Solvay's sales of AndroGel at the high prices made possible by the absence of generic competition would exceed, by far more than the payment, the expected profits from sales at the lower volume and competitive price that would be required if the competitors entered the market sooner. (*Id.* ¶¶ 57-59.) Solvay also concluded that without such a payment, the parties would settle on an earlier entry date, based solely on their competing views of the validity of the patent, and the likelihood that it was infringed by the generics. (*Id.* ¶¶ 58-60.) Solvay estimated that if its generic competitors entered the market, it would lose $125 million a year in profits (*id.* ¶ 49)—a figure that greatly exceeded the roughly $30 to 40 million per year Solvay would pay the competitors under the settlements.[7]

Thus, the agreements that kept Solvay's competitors out of the market here were a classic example of a

[7] Under the agreements, Watson received $19-30 million per year as its share of the profits from AndroGel; Par received $10 million per year, and Paddock received $2 million per year. (2d Am. Compl. ¶¶ 66, 77.)

monopoly improperly preserved through anticompetitive payments, at the expense of the public. Indeed, Solvay agreed to pay one of its competitors, Watson, a percentage of its profits from AndroGel, allowing the competitor to directly share in the profits from the monopoly preserved by the settlement. (*Id.* ¶¶ 60-61, 66.) The approach taken by the court below effectively prevents the antitrust laws from regulating such anticompetitive agreements and would permit drug companies, systematically and in case after case, to pay competitors to preserve their monopolies beyond what their patents themselves would allow them to achieve.

B. In addition to violating basic antitrust principles, pay-for-delay settlements of drug patent litigation subvert fundamental principles of patent law. It is a mistake to conclude, as the court below did (Pet. App. 18a), that the purposes of patent law are served by immunizing pay-for-delay drug-patent settlements from antitrust scrutiny. Patent law creates limited monopolies, under carefully delineated circumstances, to encourage innovation for the public good. But patents on products that are not genuinely new, can reasonably be derived from existing products, or otherwise are not legitimately patented, do not reward innovation and do not promote the public interest. Instead, those patents, unless exposed as invalid, lead to an improper monopoly that imposes higher prices on consumers and limits consumer choice, without conferring any public benefit in return. The same is true when a patent holder preserves its monopoly by claiming that the patent is infringed by a competing product when this is not actually so.

This Court has stressed that important public objectives are served when the invalidity or limited scope of a patent is revealed: "It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly." *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892). The Court has likewise recognized "the broad public interest in freeing our competitive economy from the trade restraints which might be imposed by price-fixing agreements stemming from narrow or invalid patents." *Edward Katzinger Co. v. Chicago Metallic Manufacturing Co.*, 329 U.S. 394, 400 (1947); *see also Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100–01 (1993) (noting the "importance to the public at large of resolving questions of patent validity").

The public policy favoring the testing of patents is particularly strong in the area of pharmaceuticals, where Congress has enacted a special statutory scheme, as part of the Hatch-Waxman Act, to encourage would-be generic competitors to challenge patents on brand-name drugs. H.R. Rep. No. 98–857, pt. 1, at 14, reprinted in 1984 U.S.C.C.A.N. 2647 at 2647. The Hatch-Waxman Act gives generic manufacturers a significant incentive to challenge weak patents, so that consumers can benefit from lower drug prices when patents are weak or invalid. *See* S. Rep. No. 107–167, at 4 (2002). The first manufacturer who challenges a brand-name drug's patent by applying to the FDA for approval of a generic version of the drug can benefit from a 180-day period during which the FDA will not approve other generic versions of the same drug. 21 U.S.C. § 355(j)(5)(B)(iv). Congress sought to encourage challenges to drug patents because it understood that the public interest is strongly served when those patents are

tested in litigation. By contrast, the public interest is not served at all when brand-name manufacturers holding weak or invalid patents are allowed to immunize their patents from scrutiny by buying off their competitors with a share of their monopoly profits.

In this very case, the complaint alleges facts suggesting that Solvay's AndroGel patent may well be invalid, and therefore not a patent that serves the purposes of patent law or promotes the public interest. The patent does not cover the active ingredient in AndroGel, synthetic testosterone, which lost patent protection decades ago. (Pet. App. 10a.) Solvay's AndroGel patent applies primarily to the gel formulation the product uses to deliver synthetic testosterone, and Solvay's generic competitors argued, before they settled the patent litigation, that the gel formulation was an obvious variation on existing methods or formulations and accordingly not patentable. (2d Am. Compl. ¶ 88.) *See* 35 U.S.C. § 103 (an invention is not patentable if the subject matter is obvious). The competitors also argued that their generic drugs would not infringe Solvay's patent because their drugs contained ingredients the patent did not cover, and contained amounts different from what Solvay had patented. (2d Am. Compl. ¶ 88.) And the FTC's complaint in this case alleges that if the underlying patent case had been litigated to conclusion, Solvay's patent would likely have been held not to prohibit competition from the generic drugs. (*Id*. ¶¶ 86-92.)

Despite these allegations, the court below held that the payments for delay embodied in the AndroGel settlement agreements were permitted as a matter of law, because "the patent holder had a 'lawful right to exclude others'

from the market." (Pet. App. 17a, quoting *Valley Drug Co. v. Geneva Pharmaceuticals*, 344 F.3d 1294, 1304 (11th Cir. 2003).) The court's statement, however, assumes a conclusion that may well be false. The court essentially assumed that the patent was valid and that the competing products would have infringed the patent—assumptions that the FTC alleged were incorrect on the facts of this case, and assumptions that are unwarranted as a general rule because challenged patents are frequently found to be invalid or not infringed. According to a study by the FTC, generic competitors that challenge drug patents prevail seventy-three percent of the time. *See* FTC, Generic Drug Entry Prior to Patent Expiration 16 (2002).[8] And empirical research has shown that challenges are more likely when a patent is weak. C. Scott Hemphill and Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. Empirical Legal Stud. 613, 643 (2011). Many of the patents that are the subject of pay-for-delay agreements therefore could not succeed in excluding competition to the full extent that the patents on their faces claim. Yet the approach of the court below—which allows payments that exclude competition to the same extent that is allowed on the face of the patent—enables brand-name drug manufacturers in the aggregate to exclude far more generic competition than their patents themselves, if legitimately tested, could legally exclude.

Thus, the Eleventh Circuit's approach, which effectively immunizes settlements from antitrust scrutiny even where the brand-name drug manufacturer's right to exclude has never been established, fits badly with the

[8] Available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

realities of drug patent practice. Indeed, the rule would allow every brand-name drug manufacturer to preserve its monopoly, all the way up to the expiration date on the face of the patent, whenever the monopoly profits it would earn from doing so exceed the amount that would be required to pay the generic competitor to go away. In case after case, if this approach were adopted, federal antitrust law will provide no bar to the monopolist's ability to preserve the monopoly for as long as is in its economic interests to preserve it, up to the expiration of the patent.

The Eleventh Circuit ignored the reality that many challenged patents are weak, because it believed that taking this into account would involve a cumbersome inquiry into the merits of the specific underlying patent litigation—that is, into whether the particular patent at issue was valid or infringed. (Pet. App. 33a-36a.) But the Third Circuit's approach does not require "mining through mountains of evidence." (Pet. App. 33a.) The approach simply applies a well-grounded presumption that payments to generic competitors in settlement agreements calling for delayed generic entry are made to induce a delay in competition beyond what the patent—whether strong or weak—would support on its own. *K-Dur*, 686 F.3d at 218. Defendants can rebut the presumption by showing that the payment was not made to induce delay in market entry or resulted in a procompetitive benefit of some kind. *Id*. This analysis does not require the court in the antitrust suit "to make a judgment about the merits of a patent infringement claim." (Pet. App. 35a.)

Drug patent disputes should not generally be settled with payments for delay, because such settlements conflict with basic tenets of both antitrust and patent law and

frustrate a key objective of the Hatch-Waxman Act. This principle leaves ample room for settling drug patent litigation in ways that do not facilitate anticompetitive behavior. No antitrust problem arises when the parties to a drug patent dispute resolve the dispute by negotiating a date on which the would-be generic competitor is permitted to enter the market, without a payment made by the brand-name drug manufacturer to the generic to induce the generic to push the entry date back further than the strength of the patent itself would support. In such a settlement, the interests of the antitrust plaintiff and of the general public are aligned. The generic competitor's incentive is to seek the earliest possible date of entry onto the market, and that is precisely what serves the public interest as well, by maximizing competition and reducing consumers' costs. Consequently, settlements with agreed entry dates, without payments for delay, by their nature carry with them public benefits that are similar to those achieved when drug patent disputes are litigated to decision.

Pay-for-delay settlements are a different story. Pay-for-delay settlements allow the brand-name drug manufacturer to purchase more delay in market competition than would result from a negotiation based on the merits of the patent alone. Contrary to the Eleventh Circuit's reasoning (Pet. App. 17a), pay-for-delay settlements do not merely bar competition that is already barred by the patent—the court's position wrongly assumes the validity of the patent and assumes that the generic product infringes the patent, both of which are in dispute in the litigation that is the subject of the settlement.

By allowing brand-name drug manufacturers to buy exclusion of competition—and to do so all the way up to patent expiration dates when it serves their economic interests—such settlements result in greater monopoly protection than the patents alone could have supported. Because that result leads to exactly the kind of anticompetitive harms that antitrust law seeks to prevent, and also thwarts Congress's policy of promoting challenges to invalid drug patents, this Court should grant certiorari to review and reverse the Eleventh's Circuit's decision.

III. Pay-for-delay settlements cause real and substantial harm to the States and to the public

The question presented by this case has enormous practical significance for consumers of pharmaceutical products, for the national economy, and for the States. Total expenditures on prescription drugs in the United States in 2010 were about $259 billion.[9] In New York alone, about $19 billion was spent on prescription drugs in 2011.[10] The States are major participants in the pharmaceutical market, because they expend funds for prescription drugs through Medicaid and other public

[9] *See* U.S. Dep't of Health & Hum. Svcs., *National Health Expenditure Accounts: Methodology Paper, 2010*, at 4 (Exhibit 1: National Health Expenditures by Type of Expenditure and Program: Calendar Year 2010), available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/dsm-10.pdf.

[10] Kaiser Family Foundation, *Total Retail Sales for Prescription Drugs Filled at Pharmacies, 2011*, available at http://www.statehealthfacts.org/comparemaptable.jsp?typ=4&ind=266&cat=5&sub=66&sortc=1&o=a

health programs. Altogether, state Medicaid programs and local health programs across the country spent $6.5 billion for prescription drugs in 2010.[11]

Pay-for-delay settlements harm drug purchasers, both government health-care programs and consumers alike: such settlements delay the availability of generic drugs and keep drug prices artificially high. A 2010 analysis by the FTC found that pay-for-delay settlements cost drug purchasers $3.5 billion annually. FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 2 (2010).[12] Another empirical study conducted in 2009 estimated that pay-for-delay settlements had cost consumers at least $16 billion since 1993. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Competition*, 109 Colum. L. Rev. 629, 645, 661 & n.130 (2009). And decisions by the courts of appeals that immunize pay-for-delay settlements from antitrust scrutiny have made pay-for-delay settlements more popular, as the Second Circuit has noted. *Arkansas Carpenters*, 604 F.3d at 109 (noting that pay-for-delay settlements appeared to have become more common after the *Tamoxifen* decision). Thus, judicial protection of pay-for-delay settlements has caused significant and direct harms to consumers, and these harms will continue until meaningful antitrust scrutiny of these agreements is restored on a nationwide basis.

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[11] *See* U.S. Dep't of Health & Hum. Svcs., *National Health Expenditure Accounts, supra,* note 9, at 4.

[12] Available at http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

When generic competitors successfully challenge a brand-name patent, the benefits for consumers and governments that participate in the health-care market are substantial. In general, the availability of a generic substitute for a popular drug has immediate and significant consequences for drug consumers; the average retail price for a brand-name drug in 2007 was $119, while the average price for a generic was about $34, just over one-fourth of the average brand-name price. (2d Am. Compl. ¶ 28.) A successful challenge to the patent for Prozac, for example, resulted in entry of a generic two and a half years before the patent would have expired, saving consumers about $2.5 billion. (*Id.* ¶ 30.)

Litigation that challenges patents is an important check on aggressive patent practices, and patent practices are growing only more aggressive. *See* Hemphill and Sampat, *supra*, at 640-643 (discussing empirical evidence of a rise in weaker patents). Immunizing pay-for-delay settlements will result in the use of patents to maintain improper monopolies at serious cost to consumers, even when those patents are invalid or not infringed by the generic product that the settlement keeps off the market. As noted above, a significant majority of challenges to drug patents that are litigated to conclusion—about seventy-three percent—result in a victory by the generic. *See* FTC, *Generic Drug Entry Prior to Patent Expiration* 16 (2002).[13] Empirical research has also demonstrated that challenges to drug patents are more likely to occur when a patent is legally weak and the case against its validity or infringement is therefore strong. Hemphill and Sampat,

[13] Available at http://www.ftc.gov/os/2002/07/genericdrug study.pdf.

supra, at 643. For example, drug patents are more likely to be challenged under Hatch-Waxman when they, like the AndroGel patent at issue here, do not cover the active ingredient in a drug, but rather cover its formulation in a particular product or aspects of the way the product delivers the active ingredient. *Id.*

Therefore, drug patents that draw Hatch-Waxman challenges are less likely to represent major innovations of the kind that patent law seeks to reward, and are more likely to represent aggressive claims of rights to exclude competition that are legally tenuous. It is thus especially important not to bar antitrust scrutiny of settlements in which brand-name drug-makers terminate such patent challenges through payments to would-be competitors—settlements that will systematically perpetuate improper monopolies to the detriment of the public.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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