No. 12-416

IN THE

# Supreme Court of the United States

FEDERAL TRADE COMMISSION,

*Petitioner,*

*v.*

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

*Respondents.*

**ON 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, MICHIGAN, MINNESOTA, MISSISSIPPI, MISSOURI, NEVADA, NEW HAMPSHIRE, NEW MEXICO, NORTH CAROLINA, NORTH DAKOTA, OHIO, OREGON, PENNSYLVANIA, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, TENNESSEE, UTAH, VERMONT, WASHINGTON, AND WYOMING, THE DISTRICT OF COLUMBIA, AND THE COMMONWEALTH OF PUERTO RICO 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) (per curiam). 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, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Hampshire, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Washington, and Wyoming, the District of Columbia, and the Commonwealth of Puerto Rico.[1] The *amici* States have strong interests, both as pharmaceutical purchasers and as antitrust enforcers, in protecting fair competition in pharmaceutical markets.

Prescription drugs represent a major expenditure for the States. States purchase drugs and make reimbursements for the cost of drugs through state Medicaid and other public health programs and agencies.[2] Altogether, state and local health care programs across the country (including Medicaid and the Children's Health Insurance Program) spent approximately $8.6 billion for prescription drugs in 2011.[3] States also have a recognized

[1]The District of Columbia and the Commonwealth of Puerto Rico are not States, but possess a strong interest in this matter similar to those of the States. They are included in this brief's references to "*amici* States."

[2]The word "purchase" is sometimes used in this brief to include both the direct exchange of money for drugs and the reimbursement of purchases made by others.

[3]*See* U.S. Dep't of Health & Hum. Svcs., *National Health Expenditure Accounts: Methodology Paper, 2011*, at 4 ("Exhibit 1: National Health Expenditures by Type of Expenditure and Program: Calendar Year 2011"), http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/dsm-11.pdf.

interest in enforcing federal antitrust laws to protect their citizens' economic well-being against anticompetitive practices. Citizens of the States spend significant sums on prescription drugs; private and public expenditures for drugs nationwide total more than $260 billion annually.[4] In New York alone, private and public purchasers, including the State's Medicaid program, spent about $19 billion on prescription drugs in 2011.[5]

This case concerns "pay-for-delay" drug patent settlements—agreements that purport to settle drug patent disputes, under which patent holders pay money to potential generic competitors, and the potential competitors agree to delay their entry into the relevant markets. 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 negotiated date before the full term of the patent expires. But when a settlement agreement specifying an agreed entry date also includes a payment from the brand-name manufacturer to the potential generic competitor, that payment ordinarily represents an unlawful inducement to the generic to agree to delay entry into the market for a longer period than is warranted by the parties' evaluation of the patent's merits.

The *amici* States have a strong interest in vindicating the Federal Trade Commission's position that pay-for-delay agreements presumptively violate the federal

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[4] *See id.*

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

antitrust laws. These agreements suppress competition in the pharmaceutical markets by delaying generic entry, and thereby cause direct and substantial economic harm to the States and their residents by increasing drug prices and restricting consumer choice. 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 have standing to sue to protect their proprietary interests. *See, e.g., Massachusetts v. E.P.A.*, 549 U.S. 497, 519 (2007). The States also have statutory standing under the Sherman Act to protect their interest in the economic well-being of their residents. *See* 15 U.S.C. § 15c; *Georgia v. Pennsylvania R.R.*, 324 U.S. 439, 447 (1945); *California v. American Stores Co.*, 495 U.S. 271 (1990).[6] Acting as antitrust enforcers, the States have challenged pay-for-delay agreements to protect their consumers from the artificially high drug prices those agreements make possible. *See, e.g., New York v. Aventis S.A.*, No. 01 Civ. 71835 (E.D. Mich. 2001); *Florida v. Abbott Labs.*, No 01 Civ. 4006 (S.D. Fla. 2002).

[6]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 (3d Cir. 2012), *petition for cert. pending.* 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. *Accord FTC v. Motion Picture Adver. Servs. Co., Inc.*, 344 U.S. 392, 395 (1953); *Polygram Holding, Inc. v. FTC*, 416 F.3d 29, 32 (D.C. Cir. 2005). Thus, the States have an interest in the question presented here.

## 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, Paddock Laboratories, and Par Pharmaceutical Companies, to induce them to delay their entry into the market.[7]

Solvay manufactures and markets AndroGel, a gel formulation of synthetic testosterone that is used to treat low testosterone. (J.A. 36 ¶ 31.) Solvay holds a patent for AndroGel; at the time of the settlement agreements at issue, the patent was scheduled to expire in 2020.[8] (*Id*. at 39 ¶ 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 would compete with AndroGel. (Pet. App. 10a-11a.) They applied to the Food and Drug Administration (FDA) for approval of their generic products, seeking to take advantage of an abbreviated approval process created by the Drug

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

[8]The patent was later extended to February 2021. (J.A. 39 ¶ 43.)

Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the "Hatch-Waxman Act"), for a generic competitor that certifies that its proposed drug is "bioequivalent" to a brand-name drug. 21 U.S.C. § 355(j)(2)(A), (8)(B). In addition to certifying that their proposed drugs were bioequivalent to AndroGel, the generics further certified that AndroGel's patent was invalid or not infringed by their products. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). As to Watson, the first filer, this certification triggered a provision of the Hatch-Waxman Act making the first generic challenger to a brand-name patent potentially eligible for a special 180-day period of exclusivity during which the FDA may not approve other generic versions of the same drug. 21 U.S.C. § 355(j)(5)(B)(iv).

Soon after Watson and Paddock submitted their applications for approval to the FDA, Solvay sued them for patent infringement and, by doing so, obtained an automatic delay in FDA approval of their applications under another provision of Hatch-Waxman. (Pet. App. 11a.)[9] The generics responded to the suit by asserting that their drugs did not infringe Solvay's patent, and that the patent was invalid in any event. (*See* Pet. App. 12a.)

[9]Under the Hatch-Waxman Act, the FDA's approval of the proposed generic drug product must be delayed for thirty months if a patent-holder brings suit within forty-five days of receiving notice that a generic challenger has certified that it seeks approval of its generic product on the grounds that the brand's patent is invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iii). This period may be adjusted by the court if "either party to the action fail[s] to reasonably cooperate in expediting the action," or if the litigation ends with a judgment of the patent's invalidity or noninfringement. *Id.*

In 2006, 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), by which time Solvay intended to switch its marketing focus to a substitute testosterone product anyway. (J.A. 45 ¶¶ 62-63.) In exchange for this delay, Solvay agreed to pay Watson between $19 and $30 million annually, depending on Solvay's AndroGel profits for the year, and to pay Paddock and Par $10 million per year for six years, plus an additional $2 million. (Pet. App. 12a-13a.) The settlement documents 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, as confirmed by Solvay's own internal analysis, which found that the services had little or no value to the company. (J.A. 44-53 ¶¶ 60-85.)

The FTC filed suit, asserting that the agreements unlawfully extended Solvay's monopoly on AndroGel—not through the strength of its patent but through the financial incentives it offered its competitors. (*Id*. at 61 ¶ 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*. at 50-53 ¶¶ 81-85.) The complaint also alleged that Solvay was unlikely to have succeeded in its patent suit to exclude the generic competition. (*Id*. at 53-55 ¶¶ 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.)

## SUMMARY OF ARGUMENT

It serves neither the public interest nor the fundamental goals of antitrust law and patent law when brand-name drug manufacturers are allowed to immunize their patents from scrutiny by buying off their potential generic competitors with a share of their monopoly profits, thereby maintaining artificially high drug prices and restricting drug purchasers' choices. Drug patent settlement agreements under which a brand-name manufacturer extends financial consideration to a generic challenger, and the challenger agrees to delay entry into the market, carry an overwhelming tendency to perpetuate monopolies improperly, beyond any point justified by the strength of the patents held by the brand-name manufacturers.

Consequently, this Court should adopt a presumption that pay-for-delay drug patent settlements are anticompetitive and unlawful. Such a settlement should be treated as an unreasonable restraint of trade, unless the settling parties can show that the agreement has procompetitive benefits or that the payment does not represent an inducement to delay entry. *See In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (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).[10] This approach serves basic principles of antitrust law and patent law, and it promotes the public's especially strong interest in seeing that the validity and scope of pharmaceutical patents are tested, as reflected in the Hatch-Waxman Act. Applying a presumption of illegality also accords with the realities of drug patent practice, because pay-for-delay agreements are usually anticompetitive, and the presumption appropriately permits the parties to those agreements to rebut that conclusion in those limited cases where it may be untrue.

By contrast, the approach adopted by the Eleventh Circuit below would disable antitrust law from policing these drug patent settlements and would permit brand-name drug manufacturers systematically to extend their monopolies, all the way up to patent expiration dates, whenever doing so would enable them to earn more in surplus monopoly profits than they would have to pay competitors to induce them to stay out of the market. The court below held that pay-for-delay agreements are immune from antitrust scrutiny so long as they do not exclude competition beyond "the scope of the exclusionary potential of the patent." (Pet. App. 28a.)[11] This approach,

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[10]The Sixth and D.C. Circuits have also concluded that pay-for-delay settlements raise serious antitrust concerns. *See In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908 (6th Cir. 2003); *Andrx Pharmaceuticals v. Biovail Corp. Int'l*, 256 F.3d 799, 806-815 (D.C. Cir. 2001).

[11]*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*

which has become known as the "scope of the patent" test, would allow brand-name drug manufacturers to exclude competition up to the extent allowed by the patent on its face, even though the questions whether the patent is valid and whether it is infringed remain unresolved. This rule would allow brand-name drug makers to maintain a monopoly, not by virtue of a defensible legal right to exclude competition, but simply by paying generic competitors a share of their monopoly profits. The resulting restraint on competition would come at enormous cost to drug purchasers and the public at large. The Court accordingly should reject the "scope of the patent" test and ensure that pay-for-delay settlements of drug patent disputes are subject to meaningful antitrust scrutiny.

## ARGUMENT

### I. Pay-for-delay settlements contravene basic principles of antitrust law and patent law.

The issue presented by pay-for-delay drug settlements involves the relationship between 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. This scrutiny will promote the objectives of patent law and not—as the court of appeals held—disserve them.

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*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).

A. Antitrust law protects the public from anti-competitive practices. One 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. Monopolists are typically able to earn surplus monopoly profits at the public's expense by keeping prices artificially high and restricting output. These surplus profits available to the monopolist usually exceed the combined profits that multiple firms would be able to earn in a competitive market. For this reason, settled law holds that an agreement in which an incumbent firm splits "monopoly rents" with a would-be competitor to preserve the incumbent's monopoly constitutes a per se antitrust violation. *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 alleges that payments under the settlement agreements from Solvay to its potential generic competitors made economic sense only as a mechanism for delaying the generics' competition with Solvay. (J.A. 50-53 ¶¶ 81-85.) And it alleges 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. (J.A. 43-44 ¶¶ 57-59.) Solvay also concluded that without such a payment, the parties would settle on an earlier entry date, based solely on their views of the validity of the patent and the likelihood that it was infringed by the generics. (*Id.* at 43-44 ¶¶ 58-60.) Solvay estimated that if its generic competitors entered the market, it would lose $125 million a year in profits. (*Id.* at 41 ¶ 49.) Accordingly, Solvay could expect to earn large surplus profits by making very substantial annual payments to its potential competitors—roughly $30 to 40 million per year—to keep generic equivalents to AndroGel off the market. (*Id.* at 46 ¶ 66, 49 ¶ 77.)

The agreements here were thus a textbook example of a monopoly improperly preserved through anticompetitive payments, at the public's expense. Indeed, Solvay agreed to pay one of its competitors, Watson, a percentage of its profits from AndroGel, allowing the competitor to share directly in the surplus profits from the monopoly preserved by the settlement. (*Id.* at 44 ¶¶ 60-61, 46 ¶ 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. Patent law creates

limited monopolies to encourage innovation for the public good. But it is a basic principle of patent law that the limits on those monopolies must be carefully evaluated and strictly enforced to ensure that competition is restrained only in accordance with the congressional judgments underlying the patent system.

Congress has determined that patents do not reward innovation and do not promote the public interest when they are claimed for products or processes that are not genuinely new, *see* 35 U.S.C. §§ 101, 102 (requirement of novelty); or that can reasonably be derived from existing products or processes, *see id.* § 103 (bar on patentability if subject matter is obvious). *See also id.* §§ 101, 112 (setting forth additional requirements for patentability). Such invalid patents, unless exposed, create improper monopolies that impose higher prices on consumers without conferring any public benefit in return. The same is true when patent holders preserve their monopolies by claiming that patents are infringed by competing products when this is not actually so.

Therefore, this Court has stressed that important public interests 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"). These principles would be undermined if brand-name manufacturers were permitted to shield their patents from scrutiny by paying off their challengers with a share of their monopoly rents, and thereby preserve an exclusive market position that may well be unjustified under the patent system.

Allowing drug patents to escape challenge in this way would not only undermine the basic goals of patent law, but also subvert the particularly strong public policy favoring the testing of patents in the pharmaceutical industry, where unwarranted restraints on competition increase the cost of and diminish access to health care. Congress has enacted provisions under the Hatch-Waxman Act specifically to encourage the testing of drug patents through litigation. The Act gives generic manufacturers a significant incentive to challenge weak patents, so that consumers can benefit from lower drug prices when patents are revealed to be invalid or narrower than claimed. *See* S. Rep. No. 107–167, at 4 (2002); H.R. Rep. No. 98–857, pt. 1, at 14, reprinted in 1984 U.S.C.C.A.N. 2647 at 2647.

The Act aims to promote the policy of testing drug patents' strength with several provisions that make litigation more attractive to potential generic competitors. Most importantly, the first generic manufacturer who challenges a brand-name drug's patent receives a valuable benefit: a period of 180 days, beginning when the generic drug is first marketed, during which the FDA will not approve other generic versions of the same drug. 21 U.S.C.

§ 355(j)(5)(B)(iv). Generic challengers also receive the benefit of a streamlined application process for seeking approval of generic equivalents to an existing drug, which is less costly and time-consuming than the ordinary application for approval of a new drug. *See* 21 U.S.C. § 355(j)(2)(A), (8)(B). These incentives are not meant to provide a windfall for generic manufacturers, but rather are created to serve the public interest by facilitating the testing of brand-name drug patents, so that the public can benefit from generic competition if the patent proves to be invalid or to be less expansive than the patent holder claims.

The Hatch-Waxman policy favoring the testing of drug patents is critically important to the States and their residents. Total expenditures on prescription drugs in 2011 were more than $260 billion.[12] The States are major participants in this market, because they expend funds for prescription drugs through Medicaid and other public health programs. In New York, for example, private and public purchasers, including the Medicaid program, spent about $19 billion on prescription drugs in 2011.[13] Altogether, state and local health care programs across the country (including Medicaid and the Children's Health Insurance Program) spent $8.6 billion for prescription drugs in 2011.[14] 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. (J.A. 35 ¶ 28.) When generic competitors successfully challenge a brand-name patent, the benefits

[12]*See* U.S. Dep't of Health & Hum. Svcs., *supra* note 3, at 4.

[13]*See* Kaiser Family Foundation, *supra* note 5.

[14]*See* U.S. Dep't of Health & Hum. Svcs., *supra* note 3, at 4.

for consumers and governments that participate in the health-care market are substantial, because the availability of a generic substitute for a popular drug has immediate and significant price consequences for drug consumers. 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.* at 36 ¶ 30.)

By facilitating the approval of generic drugs and encouraging generics to bring challenges that test the strength of patents on brand-name drugs, Hatch-Waxman has been quite successful overall in increasing the availability of generic drugs. When the statute was passed in 1984, about one-fifth of prescriptions were filled with generic drugs; by 2002, nearly half of all prescriptions were.[15] Before the Act (in 1983), only 35 percent of the top-selling drugs that were no longer under patent had generic versions available; by 1998, nearly all of them did.[16]

But the ability of Hatch-Waxman to serve its objectives is seriously impaired by pay-for-delay settlements. Congress sought to encourage challenges to drug patents

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[15]*See* FTC, Generic Drug Entry Prior To Patent Expiration: An FTC Study at i (2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf ("Beyond any doubt, Hatch-Waxman has increased generic drug entry. Generic drugs now comprise more than 47 percent of the prescriptions filled for pharmaceutical products – up from 19 percent in 1984, when Hatch-Waxman was enacted.")

[16]Cong. Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry 37 (1998), http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/6xx/doc655/pharm.pdf.

because it understood that the public interest is strongly served when those patents are tested. By contrast, that public interest is undermined when brand-name manufacturers are allowed to immunize their patents from challenge by buying off their competitors with a share of their monopoly profits.

C. The Court should adopt a presumption that drug patent settlements featuring both a payment from the brand-name manufacturer to the generic challenger and a delay in generic entry violate the antitrust laws. Contrary to the view of the court of appeals below, adopting this presumption would not require courts to "min[e] through mountains of evidence" to examine the merits of the underlying patent litigation. (Pet. App. 33a-36a.) A prime virtue of the presumption is that it does *not* require courts to assess whether the terms of the settlement are fair as between the parties or to evaluate the likelihood that the patent would have been upheld if litigated to judgment. If financial consideration from the brand-name manufacturer to the generic competitor is part of a settlement featuring a negotiated entry date, it is reasonable to presume that the generic has agreed to delay entry by some increment in exchange for that additional consideration. The presumption merely acknowledges that the exclusion of competition is the most likely explanation for a Hatch-Waxman settlement having these features. *Cf. California Dental Ass'n v. FTC*, 526 U.S. 756, 770 (1999) (recognizing that a presumption of illegality is appropriate in antitrust cases when "the great likelihood of anticompetitive effects can be easily ascertained" as to a challenged practice). The settling parties may rebut this presumption by showing that the payment is not part of the parties' bargain about the date of generic entry, but

rather addresses some other matter, such as allocation of litigation costs avoided by the settlement, or by proving that the payment serves some procompetitive purpose.

The principle that drug patent disputes should not generally be settled with payments for delay leaves ample room for settling drug patent litigation in ways that are not anticompetitive. For example, no antitrust problem usually 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 from the brand-name drug manufacturer to the generic manufacturer. When such settlements occur without a payment, the interests of the generic manufacturer and 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, because it maximizes competition and reduces consumers' costs. Consequently, settlements with agreed entry dates, without a payment 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, because they 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. It also assumes that the generic product infringes the patent. But these are the very propositions

that are disputed in the litigation that is the subject of the settlement. By allowing brand-name drug manufacturers to buy exclusion of competition—all the way up to patents' expiration dates if it serves their financial interests—such settlements result in greater monopoly protection than the patents alone could have supported. That result leads to exactly the kind of anticompetitive harm that antitrust law seeks to prevent, and thwarts Congress's policy of promoting challenges to invalid drug patents.

## II. Adopting the "scope of the patent" rule would allow brand-name drug manufacturers to exclude competition systematically, unchecked by antitrust law, whenever doing so is profitable.

The court below held that the disguised 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).) But this begs the question whether the patent holder did in fact have a lawful right to exclude the generic manufacturers. The court of appeals' approach is sometimes described as the "scope of the patent" test, but that label is inaccurate, because the true scope of the patent plays no role in the test. Rather, the test is based solely on the ostensible right to exclude competition asserted on *the face* of the patent, with no acknowledgement that a patent holder's actual right to exclude competition may well be narrower than is asserted on the patent's face or, in the case of an invalid patent, nonexistent. In referring to the patent holder's "lawful right" to exclude others, the Eleventh Circuit 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.

The serious problems that would follow from this Court's adoption of the "scope of the patent" approach are best seen by examining the systematic effects such an approach would have. The "scope of the patent" approach 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 competition to stay out of the market. It would not matter whether a brand-name manufacturer's patent was strong or weak. In case after case, the level of drug manufacturers' monopoly profits, rather than the strength of their patents, would determine the degree to which they avoided generic competition. Instead of rewarding innovation, the "scope of the patent" approach would simply reward brand-name drug manufacturers for buying off their competition, and reward generic competitors for agreeing to share in the brand-name manufacturer's monopoly rents.[17]

[17]The court below mistakenly believed that it would not be profitable for brand-name manufacturers to buy off a generic competitor, because other generic competitors would simply fill the void by bringing their own challenges to the patent. (Pet. App. 35a-36a.) While there may be multiple generic challengers for some drugs, this can hardly be counted on. Once the first challenge has been filed, other generic competitors may not find it profitable to challenge the patent because the valuable 180-day period of exclusivity is available only to the first challenger, and because

This would cause direct harm to the purchasing public through increased prices and restricted choice across the pharmaceutical industry.

A. The systematic consequence of the Eleventh Circuit's rule is to deprive the public of the benefits of antitrust protection wherever it is in the economic interest of patent holders to pay off their potential competitors—and the pharmaceutical industry is rife with such situations. The result will be to enable brand-name drug manufacturers to suppress competition for the full duration of disputed patents, despite the fact that many patents are vulnerable to meritorious challenge, and therefore do not represent a right to exclude competition that would withstand legal scrutiny. An FTC study shows that weak patents are widespread in the pharmaceutical sector: generic competitors who challenge drug patents

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subsequent challengers are prevented from entering the market until the first filer has enjoyed the statutory period of exclusivity. Future generic challengers may also be deterred by provisions in pay-for-delay settlements in which the bought-off generic is allowed to market its own drug in the event of a future successful challenge by another generic. (*See* J.A. 46, 49.) Even if there are multiple generic challengers, a brand-name manufacturer may find it profitable to buy them all off. Indeed, a recent report documents a number of cases in which brand companies paid multiple generic challengers to delay competing with a single brand drug. *See* 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 2012* at 1 (Jan. 17, 2013), http://www.ftc.gov/os/2013/01/130117mmareport.pdf. Since only the first challenger is eligible for the 180-day exclusivity period, later challengers can be bought off more cheaply—as illustrated here by the fact that Watson, the first filer (J.A. 40 ¶ 45), received significantly more under the settlements than Paddock and Par (Pet. App. 12a-13a).

prevail nearly three-fourths of the time.[18] There is also evidence that patent practices in the drug industry are growing more aggressive and weak patents are becoming more common. *See, e.g.,* C. Scott Hemphill and Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. Empirical Legal Studies 613, 640-43 (2011) (discussing empirical evidence of a rise in weaker patents).

The allegations in this case suggest that Solvay's AndroGel patent may well be an example of a weak patent that does not serve the purposes of patent law or promote 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 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. (J.A. 54 ¶ 88.) 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. (*Id.*) 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.* at 53-55 ¶¶ 86-92.)

This case is not unusual. Empirical research has demonstrated that challenges to patents are more likely

[18]FTC, Generic Drug Entry Prior to Patent Expiration 16 (2002), http://www.ftc.gov/os/2002/07/genericdrug study.pdf.

to occur when a patent is legally weak and the case against its validity or infringement is therefore strong. Hemphill and Sampat, *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 than unchallenged patents 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. The "scope of the patent" approach fits badly with these realities of drug patent practice, because many of the patents that are the subject of pay-for-delay agreements could not succeed in excluding competition to the full extent that the patents claim on their faces.

Across the range of cases, if these patents are effectively tested in litigation, or if parties settle patent disputes through negotiations over entry date based on the strength of the patents, the public will benefit from substantial generic competition that the patents, on their faces, purport to exclude. By contrast, if brand-name manufacturers were permitted to obtain the maximum exclusion claimed on the faces of their patents by offering unlimited reverse payments to generic challengers, the public should expect to receive little or no real benefit from generic challenges to drug patents. The approach taken below would enable brand-name drug manufacturers in the aggregate to exclude far more generic competition by agreement than their patents themselves could legally exclude.

B. The systematic harms to the public from pay-for-delay drug settlements are already serious and widespread and would become only more so if this Court were to bless the practice. To date, pay-for-delay settlements have existed under a cloud of questionable legality, as shown by the examples of settlements that mask their pay-for-delay nature through use of in-kind exchanges or camouflaged payment arrangements, such as the "services agreements" that were part of the AndroGel settlement here. Despite questions about their lawfulness, pay-for-delay drug settlements have commonly occurred and have caused significant harm to drug purchasers. A 2010 analysis by the FTC found that pay-for-delay settlements cost drug purchasers $3.5 billion annually.[19] 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).

As would be expected, decisions by the courts of appeals immunizing pay-for-delay settlements from antitrust scrutiny have made pay-for-delay drug settlements more popular. *See Arkansas Carpenters*, 604 F.3d at 109 (noting that pay-for-delay settlements have become more common after the *Tamoxifen* decision). A new FTC report finds that out of the 140 final patent settlements filed in fiscal year 2012, forty contained a payment to the generic and a restriction on the generic's ability to market its product, and these forty drugs had

[19] FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 2 (2010), http://www.ftc.gov/os/2010/01/10011payfordelayrpt.pdf.

combined annual U.S. sales of more than $8.3 billion.[20] The FTC has found that the number of pay-for-delay drug settlements has risen every year since 2004.[21]

A ruling by this Court that adopted the "scope of the patent" test would cause brand-name drug manufacturers to become yet more brazen in their use of reverse payments to exclude competition. That rule would result in the systematic use of untested patents to maintain improper monopolies at serious cost to health-care consumers, even when the patents are invalid or are not infringed by the generic alternative that the settlement keeps off the market. The rule would also encourage drug manufacturers to apply for marginal patents more frequently than they already do, since they could be assured of their ability to insulate those patents from legal scrutiny by paying off potential generic challengers. Antitrust law would be disabled from policing whether brand-name drug manufacturers were preserving monopolies by splitting monopoly rents with their potential generic competitors, rather than by virtue of the strength of their patents.

C. Defenders of pay-for-delay drug settlements sometimes claim that analogous settlements are pervasive outside the Hatch-Waxman context. *See, e.g.*, Br. in Opp. for Solvay Pharms., at 17 (Nov. 13, 2012). However, they

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[20] *See* FTC, *supra* note 17.

[21] *Id.*; *see also* FTC, "FTC Study: In FY 2012, Branded Drug Firms Significantly Increased the Use of Potential Pay-for-Delay Settlements to Keep Generic Competitors off the Market (Press Release, Jan. 17, 2013), http://www.ftc.gov/opa/2013/01/mmarpt.shtm.

have failed to adduce any evidence of such settlements. Instead, they have offered inapt comparisons to another, different kind of patent settlement that they say occurs elsewhere, namely settlements under which a patent holder agrees to forgo some portion of accrued damages claimed for patent infringement, and the alleged infringer accepts an injunction. But the comparison is flawed, because settlements outside the pharmaceutical industry where damages claims are compromised do not present the systematic anticompetitive consequences that pay-for-delay drug settlements do.

In patent disputes outside the Hatch-Waxman context, a patent holder may seek damages for past patent infringement and an injunction to bar ongoing practice of the patented technology. By contrast, Hatch-Waxman patent disputes rarely involve a claim by the patent holder seeking damages for past infringement because the Hatch-Waxman Act affords the brand-name drug manufacturer the ability to block the FDA's approval of the generic's application simply by filing suit within a designated period after the application was filed. 21 U.S.C. § 355(j)(5)(B)(iii). Therefore, in these patent disputes, the generic competitor has not entered the market at the time of suit.

Where damages for infringement are sought outside the Hatch-Waxman context, the fact that a patent holder settles a claim for damages for less than the amount of damages sought in the complaint does not suggest that the patent holder has given any financial inducement for the alleged infringer to agree to greater exclusion from the market than the infringer otherwise would. Plaintiffs typically release claims for damages in exchange for payments lower than the amount of damages sought in

a complaint, due to uncertainty as to whether they will prevail and to what extent, as well as the expenses of litigation. The mere fact that the patent holder settles for less than the amount of damages sought in the complaint thus has no significance; the settlement amount may merely reflect the fair value of the damages claim. A patent holder's agreement to compromise a damages claim in a settlement that also involves a period of exclusion is not suspect from an antitrust perspective, unless the patent holder agrees to settle the damages claim more cheaply than it would if it were the only relief sought in the litigation.

By contrast, when a Hatch-Waxman settlement features a reverse payment from brand-name manufacturer to generic manufacturer, that compensation ordinarily represents an inducement to the generic competitor to delay its entry beyond the date to which the generic would have agreed if negotiations had proceeded solely on the strength of the patent. Economic modeling confirms that as long as the amount of the reverse payment exceeds the patent holder's anticipated future litigation costs, drug patent settlements will generally delay entry beyond what the patent-holders believe they could achieve through negotiation on the basis of the patent's strength. *See* Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 Tex. L. Rev. 283 (2012). Reverse-payment drug patent settlements therefore carry a strong anticompetitive tendency that is not present in settlements where patent holders compromise damages claims for less than the amount claimed in the complaint.

Moreover, though it is theoretically possible that a patent holder could settle its damages claim at a discount to the claim's fair value for the purpose of

inducing a competitor to agree to greater delay in entry, this possibility does not raise the broad potential for systematic exclusion of competition that is created by the pay-for-delay drug settlements at issue here. The amount of the inducement a patent holder can offer by settling its damages claim cheaply is limited by the fair value of the damages claim in the first place. That value is likely to be small in the case of a weak or narrow patent, and therefore the holder of such a patent will have little ability to use a heavily discounted settlement of a damages claim to pay the generic competitor for delay.

By contrast, if pay-for-delay drug settlements featuring reverse payments were immunized from antitrust scrutiny under a "scope of the patent" rule, the brand-name drug manufacturer would have the freedom to pay the generic competitor as much as it would like to pay to obtain additional exclusion, all the way through the expiration date of the patent. A brand-name manufacturer would therefore purchase additional exclusion as long as the manufacturer could earn more in surplus profits by maintaining its monopoly than it would have to pay to induce generic competitors to stay out of the market for the additional period. It would not matter whether the brand-name manufacturer's patent was strong and broad or whether it was weak and narrow. The potential to earn surplus monopoly profits, not the strength of the patent, would determine how much exclusion a brand-name drug manufacturer would obtain in a drug-patent settlement.

This potential for far-reaching and systematic exclusion of competition makes pay-for-delay drug settlements deeply damaging to basic principles of antitrust and patent law. If the "scope of the patent" test were adopted, brand-name manufacturers and generic

competitors would split monopoly rents in case after case, thereby reviving in the pharmaceutical industry a classic form of antitrust problem thought put to rest long ago.[22]

## CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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