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 RESPONDENT WATSON PHARMACEUTICALS, INC.

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QUESTION PRESENTED

Whether the federal antitrust laws permit the settlement of patent litigation between a patent-holding brand-name pharmaceutical manufacturer and a generic manufacturer when the terms of the settlement do not exceed the potential exclusionary scope of the patent.

RULE 29.6 STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Respondent Watson Pharmaceuticals, Inc., states the following:

Watson Pharmaceuticals, Inc., is a publicly held company that has no parent corporation, and no publicly held company owns 10% or more of its stock.

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BRIEF FOR RESPONDENT

Respondent Watson Pharmaceuticals, Inc. ("Watson") respectfully acquiesces in the petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eleventh Circuit in this case (the "Petition").

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Eleventh Circuit is reported at 677 F.3d 1298 and is reproduced at Pet. App. 1a–36a. The opinion of the District Court granting respondent's motion to dismiss is available at 687 F. Supp. 2d 1371 and is reproduced at Pet. App. 37a–61a.

JURISDICTION

The judgment of the Court of Appeals was entered on April 25, 2012. A petition for rehearing was denied on July 18, 2012. Pet. App. 62a-63a. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Certain pertinent statutory and regulatory provisions are noted in the Petition and set out in the Petition Appendix. Pet. 2; Pet. App. 64a-122a. In addition to those provisions, 35 U.S.C. § 282 is also relevant and provides in pertinent part: "A patent shall be presumed valid."

INTRODUCTION AND STATEMENT OF THE CASE

The Government's Petition correctly identifies a disagreement among the courts of appeals over the appropriate antitrust analysis of patent litigation

settlements in the pharmaceutical context, and is correct in stating that this is a recurring question of great economic importance. The Government is incorrect, however, in asserting that the decision below should be reversed.

The court below held, consistent with its own precedent and with precedent from two other courts of appeals, that a final settlement of litigation to enforce a patent is immune from antitrust attack so long as the patent was not obtained by fraud, the litigation to enforce the patent was not a sham, and the alleged exclusionary effects of the settlement fall within the scope of the exclusionary potential of the patent. The Government would have this Court eschew this clear rule in favor of an ambiguous, incorrect, and burdensome rule adopted by the Third Circuit that deems certain patent settlements presumptively unlawful and improperly shifts the burden to the settling parties to demonstrate that their settlement does, in fact, violate the antitrust laws.

Because patent infringement litigation is a recurring feature of the statutory scheme applicable to the approval of generic drugs, and given the size and significance of the pharmaceutical industry in this country, the question presented is one of critical importance as to which there is a clear conflict among the circuits, with overwhelming authority against the Government's position. Respondent and the pharmaceutical industry as a whole require clarity as to the terms on which they may lawfully settle the litigation that is contemplated by statute. Respondent therefore acquiesces in the petition for certiorari.

1. The Food and Drug Administration ("FDA") regulates the manufacture, sale, and labeling of prescription drugs in this country. *See* 21 U.S.C. § 355. In order to obtain approval for a new drug, a brand-name pharmaceutical manufacturer must submit a New Drug Application ("NDA") to the FDA that demonstrates the safety and efficacy of its product. *See* 21 U.S.C. § 355(b). The approval process for generic drugs was set out by legislation known as the "Hatch-Waxman Amendments" in 1984. *See* Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585. The basic goal of the Hatch-Waxman Amendments was to balance the need for pharmaceutical innovation with the need for generic drug competition. *See, e.g., Teva Pharm. Indus. Ltd.* v. *Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005) ("[A]s even the formal name of the Hatch-Waxman Amendments (the Drug Price Competition and Patent Term Restoration Act) reflects, the Congress sought to strike a balance between incentives, on the one hand, for innovation, and on the other, for quickly getting lower-cost generic drugs to market.") Pursuant to the Hatch-Waxman Amendments, a generic manufacturer need not conduct extensive clinical trials for its generic product, but may instead submit an Abbreviated New Drug Application ("ANDA") that relies upon the safety and efficacy data in the brand-name manufacturer's NDA. *See* 21 U.S.C. § 355(j). In order to obtain approval, the ANDA must demonstrate, among other things, that the proposed generic product is bioequivalent to the brand-name drug. *See id.* § 355(j)(2)(A)(iv).

A brand-name manufacturer who submits an NDA must provide the FDA with the patent number and the expiration date of "any patent which claims

the drug … or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)(G); *see also* 21 C.F.R. § 314.53. If the NDA is approved, the FDA will list the patent in its so-called "Orange Book." *See* 21 C.F.R. § 314.53. Where there is a patent listed in the Orange Book for a given brand-name drug, a generic manufacturer's ANDA must contain a certification by the generic manufacturer with respect to that patent. *See* 21 U.S.C. § 355(j)(2)(A)(vii).

Relevant here is the so-called "Paragraph IV" certification, which is a statement alleging that the listed patent is invalid or unenforceable, that the generic version would not infringe the patent, or both. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The filing of a Paragraph IV certification is deemed a constructive act of patent infringement under Hatch-Waxman and thus gives the brand-name drug company the ability immediately to bring a patent infringement lawsuit against the ANDA filer. 35 U.S.C. § 271(e)(2)(A); *See also Caraco Pharm. Labs. Ltd.* v. *Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012) ("Filing a paragraph IV certification means provoking litigation.").

When such a lawsuit is filed within 45 days of receipt of notice of the Paragraph IV ANDA filing, the FDA may not grant final approval to the ANDA for 30 months after the lawsuit is filed or until the ANDA filer prevails in litigation, whichever occurs sooner. 21 U.S.C. § 355(j)(5)(B)(iii). On the other hand, if the brand-name drug company prevails, then the district court must issue an order preventing the

FDA approval from becoming final before the patent expires. *Id.* § 355(j)(5)(B)(iii)(II)(bb); 35 U.S.C. § 271(e)(4)(A).

Under Hatch-Waxman, the first ANDA filer for a generic version of the brand-name drug product is under certain circumstances entitled to 180 days of marketing exclusivity for its generic product, during which time the FDA will not grant final approval to subsequently-filed ANDAs. *See* 21 U.S.C. § 355(j)(5)(B)(iv). This 180-day marketing exclusivity, which can be quite valuable, serves as an incentive for generic manufacturers to challenge patents through a Paragraph IV ANDA.

2. The agreements at issue here relate to AndroGel, a brand-name prescription testosterone replacement drug used to treat a condition known as hypogonadism. FTC Complaint ¶¶ 1, 31-33;[1] Pet. App. 38a. AndroGel was developed and first marketed through the cooperative efforts of Besins Healthcare, S.A. ("Besins"), and Unimed Pharmaceuticals, Inc. ("Unimed"). *Id.* ¶ 32. Unimed was later acquired by Respondent Solvay Pharmaceuticals, Inc. ("Solvay").[2] *Id.* ¶ 16. The FDA approved Unimed's NDA for AndroGel in February 2000, and AndroGel came to market shortly thereafter. *Id.* ¶ 33; Pet. App. 39a.

Unimed and Besins applied for a patent on the AndroGel formulation and on methods of using that

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[1] The operative complaint, the Federal Trade Commission's ("FTC") Second Amended Complaint, is referred to herein for simplicity's sake as "FTC Complaint."

[2] Respondent Solvay was in turn acquired by Abbott Laboratories in 2010 and is now known as Abbott Products, Inc.

formulation in August 2000; the Patent and Trademark Office ("USPTO") granted the application and issued U.S. Patent No. 6,503,894 (the "'894 patent") in January 2003. FTC Complaint ¶¶ 39, 42. The '894 patent expires in August 2020. *Id.* ¶ 43. In May 2003, Respondent Watson submitted an ANDA containing a Paragraph IV certification, seeking FDA approval to market a bioequivalent, generic version of AndroGel.[3] *Id.* ¶ 44. Respondent Paddock Laboratories, Inc. ("Paddock"), filed its own Paragraph IV ANDA shortly thereafter. *Id.* ¶¶ 44, 45.

As provided for by the applicable statutory regime, Unimed and Besins filed patent infringement suits against Respondents Watson and Paddock in August 2003 in the United States District Court for the Northern District of Georgia. FTC Complaint ¶ 47; Pet. App. 41a-42a. Respondents Watson and Paddock both denied infringement and alleged that the '894 Patent was invalid and/or unenforceable.[4] FTC Complaint ¶¶ 3, 88-89. From late 2003 to the middle of 2005, the parties engaged in discovery, scheduling, and other initial litigation matters. Pet. App. 42a. By the end of 2005, the parties had filed claim construction briefs, and Watson and Par/Paddock had filed motions for partial summary

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[3] As the first ANDA filer, Watson was eligible for the 180-day marketing exclusivity for its proposed generic AndroGel product. FTC Complaint ¶ 45. Watson relinquished its claim to the 180-day marketing exclusivity as part of the patent litigation settlement challenged by the FTC in this case. *See* Pet. App. 49a.

[4] During the litigation, Respondent Paddock partnered with Par Pharmaceutical Companies, Inc. ("Par"), another generic drug company, in order to share litigation costs. FTC Complaint ¶¶ 2, 46. Par and Paddock are hereinafter referred to as "Par/Paddock."

judgment on specific issues. FTC Complaint ¶ 90; Pet. App. 42a-43a. Notably, the partial summary judgment motions that Watson and Par/Paddock did file would not have been case-dispositive even if Watson and Par/Paddock had prevailed on all of the pending issues. Br. for Appellees Unimed Pharm., Inc., Abbott Products, Inc., and Watson Pharm., Inc., at 10, *FTC* v. *Watson Pharm., Inc.*, Case No. 10-12729-DD (11th Cir. filed Nov. 10, 2010).

In January 2006, the 30-month stay of final approval of Watson's ANDA expired; at that point, and upon receiving final FDA approval, Watson legally could have launched its generic drug even though the infringement lawsuit against it was still in progress. FTC Complaint ¶¶ 47, 52. Such a launch is commonly referred to as an "at-risk launch." Had Watson launched but ultimately lost the infringement action, it would have been liable for significant damages. Watson did not launch its generic drug "at risk" in January 2006 or at any time thereafter. *Id.* ¶ 65.

In September 2006, the parties settled both cases prior to any decision on claim construction or on the pending partial summary judgment motions. FTC Complaint ¶¶ 65, 76; Pet. App. 12a, 43a. Unimed and Watson filed a voluntary stipulation of dismissal terminating the suit against Watson, and Unimed's suit against Par/Paddock was dismissed under a consent judgment filed by the parties. FTC Complaint ¶¶ 68, 80. The terms of both settlements reflected an agreement to dismiss the patent cases, as well as the grant of licenses to Respondents Watson and Par/Paddock to launch their respective generic 1% testosterone gels in August 2015 — in other words,

five years prior to expiration of the '894 patent. *Id.* ¶¶ 65, 76; Pet. App. 43a-44a.

In business deals concluded at the same time as the settlement agreements, Respondent Watson agreed that its sales force would promote AndroGel to urologists. FTC Complaint ¶ 66. In return, Respondent Solvay agreed to pay Watson a portion of the profits generated by the sale of AndroGel to urologists. *Id.* ¶¶ 64, 66. The FTC Complaint alleged that Solvay anticipated that Watson's portion of the profits under this contract would amount to approximately $20-30 million annually. *Id.* ¶ 66. As for Par/Paddock, Par agreed that its sales force would promote AndroGel to primary care physicians from 2006 until 2012, and Solvay agreed to pay Par $10 million annually for these promotion services. *Id.* ¶ 77. Paddock was to provide backup manufacturing capacity for AndroGel from 2006 until 2012, and Solvay agreed to pay Paddock $2 million annually for this backup capacity. *Id.* The FTC Complaint alleged that these business deals were not independent business transactions and that Solvay's payments exceeded the value of services provided. *Id.* ¶¶ 82, 84.

3. Shortly after the settlement of the patent litigations, in late 2006, the FTC initiated an investigation into whether Respondents Solvay, Watson, and Par/Paddock had committed antitrust violations by entering into the settlement agreements and business arrangements. *See* Pet. App. 45a. The FTC's investigation continued for over two years, during which extensive discovery was taken.

4. On January 27, 2009, the FTC filed suit in the United States District Court for the Central District of California, challenging the two patent settlements

under the antitrust laws. Respondents' motion to transfer venue pursuant to 28 U.S.C. § 1404(a) was granted by the California district court, and the cases were transferred to the Northern District of Georgia, where the underlying patent cases had been litigated. *See FTC* v. *Watson Pharm., Inc.*, 611 F. Supp. 2d 1081 (C.D. Cal. 2009). Once in Georgia, this case, as well as coordinated cases brought by private plaintiffs, were assigned to Judge Thomas W. Thrash, Jr. — the same judge who had presided over the underlying patent lawsuits between Respondents Solvay, Watson, and Par/Paddock.

The FTC Complaint alleged that the settlements were unfair methods of competition in violation of section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a)(1). It sought declaratory relief, as well as injunctive relief preventing the defendants from engaging in unspecified "similar" and "related" conduct. *See* FTC Complaint, Prayer for Relief.

Respondents moved to dismiss the FTC Complaint. On February 22, 2010, the district court dismissed the FTC's claims, relying on the Eleventh Circuit's decisions in *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (11th Cir. 2005), *Andrx Pharmaceuticals, Inc.* v. *Elan Corp. PLC*, 421 F.3d 1227 (11th Cir. 2005), and *Valley Drug Co.* v. *Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003). Pet. App. 47a-52a. The district court recognized that, in evaluating an antitrust challenge to a Hatch-Waxman patent settlement, Eleventh Circuit precedent required consideration of "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." *Id.* at 48a (quoting

Schering, 402 F.3d at 1066) (internal quotation mark omitted). The district court found that the settlements did not exceed the scope of the patent's exclusionary potential given the lack of any allegation that the settlement agreements "exclude[d] any product other than generic AndroGel," and the fact that the settlements in fact "provide[d] for five years less exclusion than the '894 patent." Pet. App. 48a-49a. Because the FTC had "not allege[d] that the settlements exceed the scope of the '894 patent," pursuant to *Valley Drug* and *Schering-Plough* the district court ruled that "it [did] not matter if the Defendants settled their patent disputes with reverse payments." *Id.* at 52a. The district court dismissed the FTC Complaint in its entirety and the FTC did not seek leave to amend.[5]

5. The Court of Appeals affirmed. Pet. App. 1a-36a. Rejecting the FTC's arguments that reverse-payment settlements should be presumptively unlawful restraints of trade, the court hewed to the rule established in *Valley Drug, Schering-Plough*, and *Andrx*. Accordingly, "absent sham litigation or fraud

[5] With regard to antitrust litigation by private plaintiffs regarding the same agreements at issue here, the district court permitted the cases to proceed because, unlike the FTC, those plaintiffs alleged that the underlying patent litigation was sham litigation. Pet. App. 57a. The district court recently granted summary judgment in defendants' favor on the sham litigation claims after finding that the positions Unimed took in the underlying patent litigation were not objectively baseless within the meaning of *Professional Real Estate Investors, Inc.* v. *Columbia Pictures Industries, Inc.*, 508 U.S. 49 (1993). *See In re AndroGel Antitrust Litig.*, 2012 WL 5352986 (N.D. Ga. Oct. 30, 2012). Appeals from that decision have been docketed. *See, e.g.*, *Meijer Inc.* v. *Unimed Pharm. Inc., et al.*, Case No. 12-15562-B (11th Cir. docketed Oct. 30, 2012).

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." *Id.* at 4a, 28a.[6]

The Court of Appeals further rejected the FTC's argument that Eleventh Circuit precedent should be interpreted to find a "reverse-payment" settlement to be unlawful "'if, viewing the situation objectively as of the time of settlement, it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date.'" *Id.* at 29a. Emphasizing that its decisions "focus on the potential exclusionary effect of the patent, not the likely exclusionary effect," the court noted that the FTC's suggested approach would require an "after-the-fact calculation of how 'likely' a patent holder was to succeed in a settled lawsuit if it had not been settled." *Id.* at 30a, 32a. Such a "retroactive[] predicti[on] from a past perspective [of] a future that never occurred," the court said, was "too perilous an enterprise to serve as a basis for antitrust liability and treble damages," and would "impose heavy burdens on the parties and the courts." *Id.* at 32a, 33a. Concerned that our legal system "can ill afford" an approach that would require mining through "mountains of evidence" to assay the infringement claim, thereby "undo[ing] much of the benefit of settling patent litigation" and "discourag[ing] settlements," the

[6] As defined by the Court of Appeals, a so-called "reverse-payment" settlement is a settlement where "a patent holder pays the allegedly infringing generic drug company to delay entering the market until a specified date, thereby protecting the patent monopoly against a judgment that the patent is invalid or would not be infringed by the generic competitor." Pet. App. 3a.

Court of Appeals declined the FTC's invitation to "attempt to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to judgment." *Id.* at 33a, 36a.

The Court of Appeals denied rehearing en banc, *Id.* at 62a-63a, and this Petition followed.

REASONS FOR GRANTING THE WRIT

This Court should grant a writ of certiorari to resolve this recurring question of national importance. As the Petition points out, the U.S. pharmaceutical industry, which brings many life-saving brand-name drugs and generic equivalents to market each year, is a multi-billion-dollar industry. Pet. 16. The Petition also acknowledges that the likelihood of patent infringement litigation inheres in the statutory and regulatory framework for generic drug approval (*id.* at 4) — indeed, as this Court has recognized, the relevant framework "provok[es] litigation." *Caraco*, 132 S. Ct. at 1677. Once embroiled in expensive and lengthy patent litigation, the litigating parties must know on what terms they may settle, or otherwise face treble-damages exposure from antitrust claims brought years later by unrelated third parties who allege that the patent litigation might have ended quite differently if litigated to conclusion.

Prior to July 2012, the courts of appeals were in agreement that the "scope of the patent" test, reaffirmed by the court below, was the appropriate mode of antitrust analysis for Hatch-Waxman patent litigation settlements. Under the "scope of the patent" test, a final settlement of *bona fide* litigation to enforce a non-fraudulently obtained patent is immune

from antitrust attack so long as its alleged exclusionary effects fall within the exclusionary potential of the patent, regardless of whether the settlement is accompanied by consideration to the generic manufacturer. The recent decision by the Court of Appeals for the Third Circuit expressly rejected this previous consensus in adopting the notion that reverse-payment settlements are presumptively unlawful. The Government now urges the Court to reject the clear and tested "scope of the patent" rule, reverse the court below, and instead adopt the ambiguous, incorrect, and burdensome rule announced by the Third Circuit.

For the reasons set out below, the Court should grant the Petition in order to resolve this intractable split and restore certainty to the antitrust analysis of pharmaceutical patent litigation settlements.

I. There is a Direct and Acknowledged Split in the Circuits.

At the time the Court of Appeals issued its decision reaffirming the "scope of the patent" rule, three courts of appeals had expressly agreed that this rule correctly balanced the intellectual property rights of patent holders with the pro-competitive tenets of the antitrust laws. *See* Pet. App. 1a-36a; *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005), *amended*, 466 F.3d 187 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) ("*Cipro*"), *cert. denied*, 129 S. Ct. 2828 (2009).[7]

[7] As the Government notes, the Sixth Circuit and the District of Columbia Circuit have not expressly adopted a specific standard for analyzing Hatch-Waxman patent settlements. Pet.

This clear line of case law was disrupted by the recent decision of the Court of Appeals for the Third Circuit in *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012), *petitions for cert. pending*, No. 12-245 (filed Aug. 24, 2012) ("Merck Petition") and No. 12-265 (filed Aug. 29, 2012) ("Upsher-Smith Petition"). Faced with a patent litigation settlement, the Third Circuit expressly rejected the approach taken by the Eleventh, Second, and Federal Circuits. *Id*. at 218 ("we reject the scope of the patent test"). Instead, the Third Circuit announced its own rule in which patent litigation settlements involving a payment are presumptively unlawful under the antitrust laws. The Third Circuit directed the finder of fact to "treat any 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," which could be rebutted "by showing that

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13 (citing *In re Cardizem CD Antitrust Litig*., 332 F.3d 896 (6th Cir. 2003) and *Andrx Pharm., Inc.* v. *Biovail Corp. Int'l*., 256 F.3d 799 (D.C. Cir. 2001)). Notably, the United States, in an amicus brief to this Court in which it was joined by the FTC, has interpreted *Cardizem* as concerning an agreement that was clearly beyond the exclusionary potential of the patent at issue. *See* Br. for the United States as *Amicus Curiae,* 2004 WL 1562075, at *13, *Andrx Pharm., Inc.* v. *Kroger Co.*, 543 U.S. 939 (July 9, 2004) (No. 03-779), (arguing that *Cardizem* is "better read . . . as limited to the particular agreement before the court," which "extend[ed] beyond the legitimate scope of the patent claims"). *Andrx* v. *Biovail* concerned the same agreement, and focused on the alleged harm flowing from the first-filing generic manufacturer's agreement to "continue to prosecute its ANDA" and to exclude others by "do[ing] nothing to jeopardize its 180-day exclusivity." *Andrx* v. *Biovail*, 256 F.3d at 814; *see also id.* at 808-11.

the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit." *Id.*

This case, therefore, undeniably implicates a square split among the courts of appeals.

II. The Petition Presents an Important Issue, and the Split Should Be Resolved By this Court.

Given the size and importance of the pharmaceutical industry, and the fact that patent litigation regularly arises in the approval process for generic drugs, clear guidance from this Court is warranted now on the appropriate antitrust analysis of settlements of Hatch-Waxman patent litigation. In light of the likely impact of the Third Circuit's erroneous decision on the pharmaceutical industry, further percolation of this issue through the courts will not be meaningful.

A. A National Rule Establishing the Correct Antitrust Analysis of Patent Settlements is of Paramount Importance.

1. The uncertainty created by the circuit split will have profound effects within the pharmaceutical industry. As noted above, patent infringement litigation is very likely in the process to obtain approval for a Paragraph IV ANDA (the only type of ANDA for which generic entry prior to expiration of an Orange Book-listed patent is a possibility). Any generic pharmaceutical company contemplating the filing of a Paragraph IV ANDA must know *prior to filing*, *i.e.*, well in advance of any lawsuit against it, the rule of law applicable to any potential litigation. Moreover, fairness dictates that litigating parties who are considering settlement of Hatch-Waxman

patent litigation ought to be able to gauge at the time of settlement whether their agreement comports with the antitrust laws.

The "scope of the patent" rule, reaffirmed by the court below, provides precisely this type of clarity. So long as the terms of the settlement do not exceed the patent's exclusionary potential, the parties may settle their dispute and, in many cases, allow for generic entry earlier than patent expiration. This rule had been followed by the courts of appeals consistently since *Valley Drug* in 2003. *See Valley Drug*, *supra*; *Schering-Plough*, *supra*; *Tamoxifen*, *supra*; *Cipro*, *supra*; *Ark. Carpenters Health & Welfare Fund* v. *Bayer AG*, 604 F.3d 98 (2d Cir. 2010), *cert. denied*, 131 S.Ct. 1606 (2011); Pet. App. 1a-36a.

The rule endorsed by the Third Circuit and in the Government's Petition[8] leaves litigants the "choice" of settling with some consideration to the generic company and facing the very real risk of treble-damage antitrust liability, or litigating to the bitter end. Neither law nor logic supports creation of this Hobson's choice, nor is it sound policy.

The Third Circuit's statement that its rule of presumptive illegality does not extend to settlements based only on a negotiated entry date for the marketing of the generic drug (known as "entry-date-only" settlements) fails to ameliorate this problem. *K-Dur*,

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[8] As the Government acknowledges, in the proceedings before the Court of Appeals, the FTC actually suggested two possible approaches to analyzing the legality of Hatch-Waxman patent settlements: (i) the "more likely than not" test that the FTC argued was consistent with Eleventh Circuit precedent (Pet. 8); and (ii) the presumptively unlawful/*K-Dur* test it endorses now. *Id.* at 10.

686 F.3d at 217-18. As numerous commentators, including the FTC's current General Counsel, have explained, an entry-date-only settlement frequently is not possible where the parties have varying risk tolerances or where information asymmetries exist. *See, e.g.,* Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements*, 15 Fed. Cir. B. J. 617, 619, 628-31(2005) ("there are a number of reasons why such a [simple split of the patent term] may not be available," including "asymmetric time horizons and asymmetric risk profiles or expectations"; if the parties have asymmetric expectations about litigation success, "[a] cash payment can bridge that gap."); *see also* Bret Dickey, Jonathan Orszag, & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Ann. Health Law 367, 391 (2010) ("Under certain conditions, without the bargaining tool of a payment from the brand-name manufacturer to the generic manufacturer, the parties will be unable to reach agreement on a settlement, even if that settlement would benefit consumers.").

2. Where the choice faced by the settling parties is either risking subsequent antitrust liability or maintaining prolonged litigation to final judgment, the long-term result is likely to be fewer Paragraph IV ANDA challenges overall. For generic pharmaceutical companies, Paragraph IV litigation requires a substantial commitment of resources, and this commitment of resources must be considered in the earliest stages of development of any given generic drug; in other words, well in advance of any ANDA filing. If, unlike in other litigation, there is no meaningful settlement option and the only possibility is a

drawn-out, expensive, uncertain litigation to final judgment, generic pharmaceutical companies may well decide, in the face of potentially catastrophic treble damages exposure and exorbitant litigation costs, not to file Paragraph IV ANDAs. *See Asahi Glass Co., Ltd.* v. *Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) ("A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive."); *see also* Br. of *Amicus Curiae* Generic Pharm. Ass'n at 9-14, *Upsher-Smith Labs., Inc.* v. *La. Wholesale Drug Co.,* Case No. 12-265 (filed Oct. 1, 2012). The aggregate effect of fewer challenges and fewer settlements may well mean that consumers in the long run have less — and delayed — access to generic drugs, a result contrary to the goals that the FTC generally aims to promote.

The Government's Petition, and the Third Circuit rule, disregard entirely these long-term systemic effects that would have a tremendously detrimental impact on the availability of generic alternatives in the marketplace.

B. Further Percolation in the Courts Will Only Exacerbate the Problem.

Further percolation of the issue will not be meaningful, and, as the Government acknowledges, will only lead to forum shopping. Pet. 15. The fact that only one Court of Appeals has adopted a divergent test is not cause to deny the Petition; rather, in this case, it underscores the urgency for a clear rule.

The FTC's Chairman has already announced publicly that so long as the Third Circuit's *K-Dur* decision stands, the FTC will bring all of its "reverse-payment" cases in the Third Circuit. *See* Jon Leibowitz, FTC Chairman, Remarks at Sixth Ann. Georgetown L. Global Antitrust Enforcement Symposium 4 (Sept. 19, 2012), http://www.ftc.gov/speeches/leibowitz/120919jdlgeorgetownspeech.pdf (last visited Nov. 7, 2012). The Petition, moreover, acknowledges that the FTC will no longer use administrative proceedings to challenge "reverse-payment" settlements because they might be subject to review outside of the Third Circuit. Pet. 15 (the adoption of the "scope of the patent" rule by numerous courts of appeal has "effectively disabled the FTC from proceeding administratively against any reverse-payment agreement" because a Commission decision finding a reverse-payment agreement unlawful could be appealed to courts besides the Third Circuit).

In addition, many of the nation's pharmaceutical companies, including Respondent Watson, are headquartered in the Third Circuit. If the circuit split is permitted to stand, there exists a high probability that many, if not most, cases challenging reverse-payment settlements as unlawful will simply be brought there. For these reasons, this single, erroneous appellate decision will have an outsized effect on the pharmaceutical industry.

III. The Rule Adopted By the Eleventh, Second, and Federal Circuits is Correct, and the Third Circuit's Rule is Erroneous.

The "scope of the patent" rule is consistent with this Court's precedents and with the judicial policy that settlement of disputes is to be encouraged. In

contrast, the Government's proposed "presumptively unlawful" rule — which effectively classifies settlements of Hatch-Waxman patent litigation that include a payment as naked restraints of trade — is inconsistent with this Court's precedents, fails properly to account for intellectual property rights, disregards the fact that such settlements are often pro-competitive, and is premised upon economic analysis and data that are far from sufficient to support the Government's sweeping approach.

A. Contrary to the Government's position, the Eleventh Circuit Rule is Plainly Correct.

The rule reaffirmed by the court below, and followed by the Second and Federal Circuits, reflects the appropriate evaluation of the exclusionary rights of patent holders and the antitrust laws. The analysis of the court below correctly took the existence of the patent — granted by the USPTO and entitled to a presumption of validity, 35 U.S.C. § 282 — as its point of departure. Under this Court's longstanding precedents, the scope of the patent forms the zone within which the patent holder may operate without facing the specter of antitrust liability. *See, e.g.*, *U.S.* v. *Line Materials Co.*, 333 U.S. 287, 300 (1948) ("[T]he precise terms of the grant define the limits of a patentee's monopoly and the area in which the patentee is freed from competition of price, service, quality or otherwise."); *U.S.* v. *Gen. Elec. Co.*, 272 U.S. 476, 485, 489 (1926) ("it is only when . . . [the patentee] steps out of the scope of his patent rights" that he comes within the operation of the Sherman Act).

Moreover, the scope of the patent rule is consistent with the general judicial policy and rule of law favoring settlement. The court below recognized the immense burden that a relitigation of the patent merits — inherent in the Government's suggested approach (*see infra* III.C.) — would impose upon litigants and the courts, something our legal system "can ill afford." Pet. App. 33a (collecting cases emphasizing the importance of settlement to our judicial system).

B. The Government's Characterization of Patent Litigation Settlements is Erroneous.

By advocating a "presumptively unlawful" standard, the Government endorses an approach whereby an antitrust plaintiff can make out a *prima facie* case for an antitrust violation without any affirmative proof of anticompetitive effect, and where there is in fact no consensus that there is such an effect. Although the Petition nominally characterizes the "presumptively unlawful" test as a "rule of reason" approach (as did the Third Circuit in *K-Dur*), the Petition places reverse-payment settlements on par with naked restraints on trade. Pet. 11, 22 ("the federal antitrust laws flatly prohibit potential competitors from forming naked agreements not to compete"); *id.* at 26 (reverse-payment settlements are "collusive agreements").

Ordinarily, restraints are not considered to be naked restraints subject to *per se* condemnation until courts have had sufficient experience with the restraints to know that the anticompetitive effects are obvious. *See Bus. Elecs. Corp.* v. *Sharp Elecs. Corp.*, 485 U.S. 717, 723 (1988) ("*per se* rules are appropri-

ate only for 'conduct that is manifestly anticompetitive,'" that is, conduct "that would always or almost always tend to restrict competition and decrease output") (internal citation omitted); *State Oil Co.* v. *Khan*, 522 U.S. 3, 10 (1997) ("[W]e have expressed reluctance to adopt per se rules with regard to restraints imposed in the context of business relationships where the economic impact of certain practices is not immediately obvious.") (internal quotation marks omitted). Contrary to this established authority, the rule endorsed by the Government and the Third Circuit finds agreements presumptively unlawful without sufficient judicial experience or economic justification demonstrating that the agreements are, in fact, pernicious. *Cf. Cal. Dental Ass'n* v. *FTC*, 526 U.S. 756, 770 (1999) ("quick-look analysis carries the day when the great likelihood of anticompetitive effects can easily be ascertained").

In urging the Court to accept a rule that equates "reverse-payment" settlements with naked restraints of trade, the Government inappropriately assumes away a patent holder's intellectual property rights. *See, e.g.*, Pet. I (taking as its point of departure the premise that a patent holder only "assertedly" holds a patent). Such a disregard for the rights of the patentee overlooks established precedent holding that so long as the patent holder operates within the scope of its patent's protections, there is no restraint of trade beyond that which is statutorily granted. *See U.S.* v. *Gen. Elec. Co.*, *supra*; *Dawson Chem. Co.* v. *Rohm & Haas Co.,* 448 U.S. 176, 215 (1980) (a patent grants the patent holder the lawful "right to exclude others from profiting by the patented invention"); *In re Indep. Serv. Orgs. Antitrust Litig.,* 203 F.3d 1322, 1327 (Fed. Cir. 2000), *cert. denied*, 531 U.S. 1143

(2001) ("[I]n the absence of any indication of illegal tying, fraud in the Patent and Trademark Office, or sham litigation, the patent holder may enforce the statutory right to exclude others from making, using, or selling the claimed invention free from liability under the antitrust laws."); *cf. U.S.* v. *Masonite Corp.*, 316 U.S. 265 (1942). Moreover, "[i]t is inappropriate to use an analytical model in which the benefits of price competition on one side of the equation are taken into account, but the benefits of innovation on the other side of the equation are not." Bernard & Tom at 621.

Perhaps most importantly, however, such a characterization is inappropriate in light of the broad recognition, *including by the Government and the FTC in a brief filed with this Court*, that patent litigation settlements with payments are often procompetitive. *See, e.g.*, Br. for the United States as Amicus Curiae at *12, *Andrx* v. *Kroger* ("Certain settlements of patent litigation may benefit consumers and the public, regardless of the presence of a payment to the alleged infringer, and thus application of a per se rule would be inappropriate."); Bernard & Tom at 622 ("if the settlement prevents infringing entry, such prevention is itself a *pro-competitive* effect"); Dickey, Orszag, and Tyson at 368 (article demonstrates "that patent settlements between branded and generic pharmaceutical manufacturers, including those that involve reverse payments, . . . can benefit consumers."); *see also* Bret Dickey, Jonathan Orszag, & Robert Willig, *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on "Reverse-Payment" Settlements*, at 3-4 (Aug. 10, 2010), http://www.compasslexecon.com/highlights/Document

s/Dickey%20Orszag%20Willig%20CBO.pdf (last visited Nov. 7, 2012) (discussing how "reverse-payment" settlements can lead to lower drug costs).

Finally, there is evidence that the statistics underpinning the Government's allegations as to the "delay" supposedly achieved through "reverse-payment" settlements are far from adequate to justify the Government's sweeping position. For example, the Government relies on decade-old statistics in asserting that "generic competitors have prevailed three quarters of the time in paragraph IV patent litigation against brand-name manufacturers." Pet. 18. Yet a more recent study found a far lower success rate for the generic drug industry. *See* Adam Greene & D. Dewey Steadman, *Analyzing Litigation Success Rates*, RBC Capital Markets, at 4 (January 15, 2010), http://www.amlawdaily.typepad.com/pharmareport.pdf (last visited Nov. 8, 2012) ("the overall success rate for the generic [drug] industry is 48%"). Economists have also questioned the FTC's statistic that the average "delay" of generic entry following settlement with a "reverse-payment" was 17 months. *Compare* Pet. 20 *and* Dickey, Orszag, & Willig at 3 ("there is no sound rationale for assuming that the inclusion of a payment from the branded to the generic manufacturer as part of the settlement agreement *caused* the observed differences in entry dates by the generic manufacturers."). Moreover, the FTC's study does not account for the true "but-for" world, including how many generic challenges would otherwise have been filed, or whether the litigation outcomes would have been different if those more uncertain cases had been forced to trial.

The foregoing factors demonstrate fundamental flaws in the Government's suggestion that "reverse-payment" patent settlements properly belong in the category of presumptively unlawful restraints.

C. In Endorsing the Third Circuit Rule, the Government's Analysis of the Antitrust Issue is Erroneous.

Antitrust law does not prohibit settlements of litigation by competitors as such; it is only those agreements that unreasonably restrain trade that concern the antitrust laws. *See Khan*, 522 U.S. at 10. In an antitrust case, it is ordinarily the plaintiff's burden to show that the challenged agreement has a substantial anticompetitive effect. *See U.S.* v. *Arnold Schwinn & Co.*, 388 U.S. 365, 374 n.5 (1967) ("The burden of proof in antitrust cases remains with the plaintiff, deriving such help as may be available in the circumstances from particularized rules articulated by law – such as the per se doctrine."), *overruled on other grounds by Cont'l T.V., Inc.* v. *GTE Sylvania, Inc.*, 433 U.S. 36, 58-59 (1977).

Here, the Government proposes a rule whereby its *prima facie* case is stated upon (i) the allegation of the existence of a patent settlement agreement between a brand-name manufacturer and a generic manufacturer; and (ii) the allegation that a "payment" was made to the generic manufacturer. Pet. 13, 22. As a preliminary matter, the ambiguity in the word "payment" is problematic, given that in the Government's view, the "payment" serves as the trigger for potential antitrust liability. *See Id.* at 13 ("any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market [is] *prima facie* evidence of an unreasonable

restraint of trade"). The Government clearly interprets this rule broadly to include not only naked cash payments, but also alleged overpayment for business deals (even where the brand-name manufacturer is concededly receiving actual services in exchange for that "payment", *see* FTC Complaint ¶¶ 66, 82). Indeed, the FTC urged the Court of Appeals to adopt its burden-shifting approach "whenever the patent holder provides economic value to the challenger *in any form* in connection with delayed entry," Pet. of Fed. Trade Comm'n for Rehr'g En Banc at 13, *FTC v. Watson Pharm., Inc.*, Case No. 10-12729 (11th Cir. filed June 11, 2012) (emphasis added), and has urged in other courts that "payment" under the *K-Dur* test should include non-cash consideration in the form of an agreement by the brand-name manufacturer not to launch an authorized generic product during the first-filing generic manufacturer's 180-day exclusivity. *See* Br. of the Fed. Trade Comm'n as *Amicus Curiae* at 1-2, *In re Lamictal Direct Purchaser Antitrust Litig.*, Doc. No. 89-3, Case No. 2:12-cv-00995-WHW-MCA (D.N.J. filed Oct. 5, 2012).[9]

Perhaps more troublesome, however, is that the "presumptively unlawful" test frees the plaintiff entirely from having to prove the anticompetitive nature of the alleged restraint. By presuming delay, this test shifts the burden to the defendants to prove the negative, *i.e.*, that their settlement agreement is *not* anticompetitive. Pet. 13 (once a *prima facie* case

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[9] An "authorized generic" is a drug that is chemically identical to the brand-name drug, but is sold as a generic product under the same FDA approval as the brand-name drug. *See* Br. of Fed. Trade Comm'n as *Amicus Curiae* at 5, *In re Lamictal Direct Purchaser Antitrust Litig.*

is made out, the settling parties must prove either "'that there is in fact no reverse payment because any money that changed hands was for something other than a delay,'" or "'that the reverse payment offers a competitive benefit that could not have been achieved in the absence of a reverse payment.'"). Inherent in the presumption of "delay," however, is the presumption that the underlying litigation would have ended some other way; to exonerate itself, an antitrust defendant would necessarily have to relitigate the patent merits in order to show what the "true" entry date would have been had the case been litigated to conclusion.[10] This Court should be wary of a test that requires courts to "attempt to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to judgment." Pet. App. 36a. This would be the "turducken task" that the court below correctly recognized as inherently unreliable (*Id.* at 33a, 36a), an inappropriate drain on party and judicial resources (*id.* at 33a), and contrary to the judicial policy favoring settlement. *Id.*

For all these reasons, the "scope of the patent" rule as articulated by the Eleventh Circuit is the correct rule for analyzing the legality of Hatch-Waxman patent settlements under the antitrust laws.

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[10] As observed by the California district court in which the FTC originally filed this case, while the FTC "still [took] the position under the per se theory that 'these [reverse payment] agreements are flat out illegal,'" the FTC "admitted in the hearing before this Court that it could not litigate this case without also including a theory of competitive harm that would necessitate looking to the merits of the patent cases." *FTC* v. *Watson*, 611 F. Supp. 2d at 1088 (citing Tr. of Mot. to Transfer Hr'g at 35-39).

IV. This Case Presents A Compelling Vehicle For The Court's Consideration of This Issue.

This case comes to the Court on a clean record, as an appeal of a final judgment dismissing the FTC Complaint, with the issue crisply presented. The dispute is contained within the four corners of the FTC Complaint. As the district court and the Court of Appeals recognized, the FTC Complaint does not allege that the challenged settlements exceeded the scope of the exclusionary potential of the patent. *See* Pet. App. 48a (emphasizing that the FTC did "not allege that the settlements . . . exceed the scope of the '894 Patent"); Pet. App. 29a, n.10 ("[the FTC's Complaint] does not contend that any of the three companies knew the patent was invalid or not infringed or that there was no objective basis to believe the patent was valid and infringed.").

As the Government points out, unlike the *K-Dur* case, for which two petitions for certiorari are pending (*see* Merck and Upsher-Smith Petitions), the present case is devoid of factual issues that could bog down a clear resolution of this important question and comes to this Court on a motion to dismiss. Pet. 30. In contrast, *K-Dur* comes to this Court on an extensive summary judgment record. Moreover, the *K-Dur* case represents an interlocutory appeal; this case, in contrast, presents a final judgment, and no additional issues remain.

For the reasons stated above, the Court should grant the Government's Petition. In the alternative, the Court may wish to grant the Petition in tandem with the pending petitions in *K-Dur*, and provide additional time for oral argument.

CONCLUSION

For the foregoing reasons, the Court should grant the petition for a writ of certiorari.

Respectfully submitted,

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