No. 12-416

In the Supreme Court of the United States

FEDERAL TRADE COMMISSION,
Petitioner,

v.

ACTAVIS, INC., ET AL.,
Respondents.

**On Writ of Certiorari
to the United States Court of Appeals
for the Eleventh Circuit**

BRIEF FOR RESPONDENT ACTAVIS, INC. (f/k/a WATSON PHARMACEUTICALS, INC.)

DAVID A. BUCHEN
ACTAVIS, INC.
Morris Corp. Center III
400 Interpace Parkway
Parsippany, NJ 07054

CLIFFORD M. SLOAN
Counsel of Record
STEVEN C. SUNSHINE
JULIA K. YORK
SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
1440 New York Ave., N.W.
Washington, DC 20005
(202) 371-7000
cliff.sloan@skadden.com

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

The Rule 29.6 statement contained in the brief filed at the certiorari stage is amended as follows.

On January 24, 2013, Respondent Watson Pharmaceuticals, Inc., officially changed its name to Actavis, Inc. Pursuant to Rule 29.6 of the Rules of this Court, Respondent Actavis, Inc. states the following:

Actavis, 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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INTRODUCTION

This case arises at the intersection of antitrust law, patent law, and the law of settlement. The Government's proposed approach does violence to all three. The Court of Appeals' approach, in contrast, respects the appropriate boundaries and principles of each body of law.

The central question is whether a settlement of *bona fide* patent litigation unlawfully restrains trade, where the patent was not procured by fraud and the settlement terms do not exceed the scope of the patent's exclusionary potential. Critical to this inquiry is the presence of the patent, which is presumed to be valid and grants its holder the *lawful* right to exclude competition within its scope. Despite the obvious importance of the patent to the antitrust analysis of the settlement agreements, the new test proposed by the Government lacks any reference to the patent's potential exclusionary effect. Indeed, the Government would have this Court write the patent out of the equation entirely.

Two fundamental errors in the Government's Question Presented highlight the Government's approach. Pet. Br. I. First, the Government characterizes a patentee as only "assertedly" holding a patent. However, a patentee to whom a patent has been granted by the U.S. Patent and Trademark Office (PTO) undisputedly holds that patent (not "assertedly"), with its attendant statutory right to exclude and presumption of validity. 35 U.S.C. §§ 154(a)(1), 282(a).

The Government's second error in its Question Presented is to disregard a critical element of the

Eleventh Circuit's approach—whether the scope of the patent's exclusionary potential has been exceeded by the settlement's terms. *See* Pet. Br. I ("[w]hether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud, or instead are presumptively anticompetitive and unlawful"). The Government's statement of the question is a serious misstatement of the Court of Appeals' holding: it omits the fundamental element that the settlement must not exceed the patent's exclusionary boundaries, and may be challenged under the antitrust laws if it does.

Nor is the Government's disregard of the patent limited to the Question Presented. The Government's brief barely mentions the complaint's numerous allegations that the patentee here was "unlikely to prevail" in its patent infringement suit. The brief also fails to mention that these very allegations formed the core of the Federal Trade Commission's (FTC) arguments to the court below, allegations that the Eleventh Circuit found to be key in concluding that the antitrust analysis does not require an assessment of which party was "more likely" to prevail. The Government's effort to distance itself from its own allegations at this stage is remarkable and telling. Because resting liability on a post-settlement evaluation of litigation probabilities would be extraordinary and fraught with problems, the Government now scorns that endeavor. But the logic of the Government's position, as well as its actual position *in this case*, requires precisely such an ill-advised inquiry.

The Government urges an ambiguous, burdensome, and improper rule. Its rule relies solely on the presence of a "payment" as the means of identifying supposedly anticompetitive patent litigation settlement agreements, and is premised upon the radical proposition that a patent is entitled to no weight at all unless and until it is proven valid and infringed in litigation. The rule, moreover, fails to qualify for "quick look" review as established by this Court, and improperly shifts the burden to defendants to disprove the elements of a plaintiff's *prima facie* case.

For the reasons set forth herein, this rule is logically incoherent, does not comport with this Court's precedent, and fails to provide an appropriate resolution of the principles of antitrust law, patent law, and the law of settlement.

In contrast to the Government's flawed presumption of illegality, the scope-of-the-patent approach applied by the Eleventh Circuit provides a clear and doctrinally sound mode of analysis for patent litigation settlements. Under this straightforward approach, "absent sham litigation or fraud in obtaining the patent," a so-called "reverse-payment" settlement does not violate the antitrust laws "so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." Pet. App. 28a.

The Court should reject the Government's misguided test and affirm the decision of the court below.

STATEMENT

1. To obtain approval for a new drug, a brand-name pharmaceutical manufacturer must submit a New Drug Application (NDA) to the Food and Drug

Administration (FDA) demonstrating the safety and efficacy of its product. 21 U.S.C. § 355(b).[1] Generic drug approval is governed by the "Hatch-Waxman Amendments" of 1984. *See* Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585. Hatch-Waxman's basic goal 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). Accordingly, a generic manufacturer may submit an Abbreviated New Drug Application (ANDA) relying upon the safety and efficacy data in the brand-name manufacturer's NDA and demonstrating, among other things, that the proposed generic product is bioequivalent to the brand-name drug. 21 U.S.C. § 355(j)(2)(A)(iv).

An NDA applicant must provide the FDA with the patent number and 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); *see also* 21 C.F.R. § 314.53 (2000). If the NDA is approved, the FDA will list the patent in its "Orange Book," *see* 21 C.F.R. § 314.53, and an ANDA must contain a certification regarding that patent. 21 U.S.C. § 355(j)(2)(A)(vii).

Relevant here is the "Paragraph IV" certification, a statement alleging that the listed patent is invalid or unenforceable, that the generic version would not

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[1] Unless otherwise noted, citations to Title 21 of the United States Code refer to the 2000 edition. *See* Pet. Br. 2 n.1.

infringe the patent, or both. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Filing a Paragraph IV certification is deemed a constructive act of infringement; the brand-name drug company may immediately sue the ANDA filer for patent infringement. 35 U.S.C. § 271(e)(2)(A).

When a lawsuit is filed within 45 days of receipt of notice of the Paragraph IV ANDA filing, the FDA generally 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). If the brand-name drug company prevails, the district court must issue an order preventing FDA approval of the generic alternative from becoming final before the patent expires. *Id.* § 355(j)(5)(B)(iii)(II); 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).[2]

2. The agreements at issue relate to AndroGel, a brand-name prescription testosterone replacement drug used to treat hypogonadism. Second Amended

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[2] 21 U.S.C. § 355 was amended in part by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, 2448 (MMA). The MMA generally does not apply to pre-MMA ANDAs, including those at issue here. *Id.* §§ 1101(c), 1102(b), 117 Stat. at 2456, 2460 (effective date provisions).

Complaint (Complaint) ¶¶ 1, 31-33, J.A. 28, 36-37; Pet. App. 38a. Unimed Pharmaceuticals, Inc. (Unimed) filed an NDA for AndroGel that was approved by the FDA in February 2000. Complaint ¶ 33, J.A. 37; Pet. App. 39a.[3]

Unimed and its development partner, Besins Healthcare S.A. (Besins), applied for a patent on the AndroGel formulation and methods of using that formulation in August 2000; the PTO granted the application and issued U.S. Patent No. 6,503,894 ('894 patent) in January 2003. Complaint ¶¶ 39, 42, J.A. 38, 39. The '894 patent expires in August 2020. Complaint ¶ 43, J.A. 39.

In May 2003, Respondent Actavis, Inc., formerly known as Watson Pharmaceuticals, Inc. (Watson), submitted a Paragraph IV ANDA, seeking FDA approval to market a bioequivalent, generic version of AndroGel. Complaint ¶ 44, J.A. 39. As the first ANDA filer, Watson was eligible for the 180-day marketing exclusivity. Complaint ¶45, J.A. 40. Respondent Paddock Laboratories, Inc. (Paddock), filed its own Paragraph IV ANDA shortly thereafter. Complaint ¶¶ 44, 45, J.A. 39-40.

Unimed and Besins filed patent infringement suits against Watson and Paddock in August 2003 in the United States District Court for the Northern District of Georgia. Complaint ¶ 47, J.A. 40; Pet. App. 41a-42a. Watson and Paddock denied infringement and alleged that the '894 Patent was invalid and/or unenforceable. Complaint ¶¶ 3, 88-89, J.A. 28,

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[3] Respondent Solvay Pharmaceuticals, Inc. (Solvay) later acquired Unimed. Solvay is now known as AbbVie Products LLC.

54-55.[4] From late 2003 to the middle of 2005, the parties engaged in discovery, scheduling, and other initial litigation matters. Pet. App. 42a. By late 2005, the parties had filed claim construction briefs, and Watson and Par/Paddock had filed motions for partial summary judgment, Complaint ¶ 90, J.A. 55; Pet. App. 42a-43a; these partial summary judgment motions would not have been case-dispositive even if Watson and Par/Paddock had prevailed. Br. for Appellees Unimed et al., at 10, *FTC* v. *Watson*, No. 10-12729-DD (11th Cir. filed Nov. 10, 2010).

In January 2006, the 30-month stay expired and Watson received final FDA approval for its ANDA; at that point, Watson legally could have launched its generic drug despite the pending infringement suit. Complaint ¶¶ 47, 52, J.A. 40, 41. Such a launch is 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. Complaint ¶ 65, J.A. 46.

In September 2006, the parties settled both patent infringement cases prior to any decision on claim construction or on the pending partial summary judgment motions. Complaint ¶¶ 65, 68, 76, 80, J.A. 46, 47, 49, 50; Pet. App. 12a, 43a. The terms of both settlements reflected an agreement to dismiss the patent cases, as well as the grant of licenses to Watson and Par/Paddock to launch their respective generic

[4] Respondent Paddock partnered with Par Pharmaceutical Companies, Inc. (Par), another generic drug company, to share litigation costs. Complaint ¶¶ 2, 46, J.A. 28, 40.

1% testosterone gels in August 2015—five years *before* expiration of Unimed's '894 patent. Complaint ¶¶ 65, 76, J.A. 46, 49; Pet. App. 43a-44a. As part of its settlement, Watson relinquished its claim to the 180-day marketing exclusivity. *See* Pet. App. 49a.

In business deals concluded at the same time as the settlement agreements, Watson agreed that its sales force would promote AndroGel to urologists. Complaint ¶ 66, J.A. 46. In return, Solvay agreed to pay Watson based on the sale of AndroGel to urologists. Complaint ¶¶ 64, 66, J.A. 45. Solvay allegedly anticipated that Watson would receive approximately $20-30 million annually. Complaint ¶ 66, J.A. 45. 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 services. Complaint ¶ 77, J.A. 49. Paddock would provide backup manufacturing capacity for AndroGel from 2006 until 2012, and Solvay agreed to pay Paddock $2 million annually for this capacity. *Ibid.*

3. Shortly after the settlements, the FTC initiated an investigation into whether Solvay, Watson, and Par/Paddock had violated antitrust law by entering into the settlement agreements and business arrangements. *See* Pet. App. 45a. The FTC's investigation continued for over two years.

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. On respondents' motion, the cases were transferred to the Northern District of Georgia. *FTC* v. *Watson Pharm., Inc.*, 611 F. Supp. 2d 1081 (C.D. Cal. 2009). Once in Georgia, this case

and parallel private lawsuits were assigned to the same judge who had presided over the underlying patent lawsuits.

The Complaint emphasized the FTC's views about the likely outcome of the patent litigation as an important element of its antitrust case. The Complaint included an entire section alleging that "Solvay's Patent Was Unlikely to Prevent Generic Competition to AndroGel," J.A. 53, comprising seven paragraphs of allegations purporting to support the conclusion that "Solvay was not likely to prevail in each of its patent lawsuits to prevent competition to AndroGel." Complaint ¶ 86, J.A. 53. The Complaint alleged that the settlements violated section 5(a) of the FTC Act, 15 U.S.C. § 45(a)(1), and sought declaratory and injunctive relief. Complaint, Prayer for Relief, J.A. 62.

Respondents moved to dismiss. On February 22, 2010, the district court dismissed the Complaint, relying on Eleventh Circuit precedent. Pet. App. 47a-52a. The 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.* 48a (internal quotation marks omitted). The court found that the settlements did not exceed the scope of the patent's exclusionary potential given the lack of any allegation by the FTC that the agreements "exclude[d] any product other than generic AndroGel," and the undisputed fact that the settlements in fact "provide[d] for five years less exclusion than the '894 patent." *Id.* 48a-49a. Because the FTC had "not allege[d] that the

settlements exceed the scope of the '894 patent," the district court ruled that "it [did] not matter if the Defendants settled their patent disputes with reverse payments." *Id.* 52a.[5]

5. The Court of Appeals affirmed. Pet. App. 1a-36a. Rejecting the FTC's arguments that Eleventh Circuit precedent should be read to consider the strength of the patent, and in the alternative that reverse-payment settlements should be presumptively unlawful restraints of trade, the court hewed to its prior rule. Accordingly, "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *Id.* 28a.[6]

The Court of Appeals rejected the FTC's argument that it should find a "reverse-payment" settlement 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 ear-

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[5] The district court permitted private treble-damage suits challenging the same settlement agreements to proceed because those plaintiffs—unlike the FTC—alleged that the underlying patent litigation was sham litigation. Pet. App. 57a. Summary judgment was granted in defendants' favor on the sham litigation claims. *In re Androgel Antitrust Litig. (No. II)*, No. 1:09-MD-2084-TWT, 2012 WL 5352986 (N.D. Ga. Oct. 30, 2012). Appeals from that decision have been stayed pending the Court's resolution of this case. *See, e.g.*, *Meijer Inc.* v. *Unimed Pharm. Inc., et al.*, No. 12-15562-B (11th Cir. docketed Oct. 30, 2012).

[6] The court defined a so-called "reverse-payment" settlement as one where "a patent holder pays the allegedly infringing generic drug company to delay entering the market until a specified date[.]" Pet. App. 3a.

lier than the agreed-upon entry date." *Id.* 29a (internal quotation marks omitted). Emphasizing that its decisions "focus on the potential exclusionary effect of the patent, not the likely exclusionary effect," the court characterized the FTC's suggested approach as requiring 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.* 30a, 32a. Such a "retroactive[] predicti[on] from a past perspective [of] a future that never occurred" 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.* 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 court 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.* 33a, 36a. The Court of Appeals denied rehearing en banc. *Id.* 62a-63a.

SUMMARY OF ARGUMENT

This case arises at the intersection of patent law, antitrust law, and the law of settlement. It presents the question of how to adjudge, under the antitrust laws, the legality of final settlements of patent litigation, where the patent was not procured by fraud, the litigation was not a sham, and the settlement does not exceed the patent's exclusionary potential.

I. The Government's proposed solution is to apply a "quick look." The Government would declare pre-

sumptively illegal under the antitrust laws any settlement of patent litigation between a brand-name drug manufacturer and a generic drug applicant that provides for licensed generic entry at some future date, if a "payment" is made to the generic applicant—even when the entry date would be before the patent's expiration. Pet. Br. 2, 17. The Government bases its presumption upon what the Government calls a "natural inference" that the "payment has purchased an additional increment of market exclusivity." *Id*. 36.

Under the Government's test, if an antitrust plaintiff alleges and establishes that (i) a settlement agreement provides for non-immediate generic entry, and (ii) the generic patent infringement defendant received a "payment," the settlement is presumptively unlawful and the burden shifts to the settling parties to prove that the "payment" was for something other than a "delay" in generic entry. *Id.* 37-38. This Court's precedent, however, does not permit the "quick look" review—and presumptive illegality—the Government seeks. *See Cal. Dental Ass'n* v. *FTC*, 526 U.S. 756, 778 (1999).

A. The patent laws provide a patentee (here, the brand-name drug manufacturer) with a *lawful* right to exclude alleged infringers. 35 U.S.C. § 154(a)(1); *Dawson Chem. Co.* v. *Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). This Court's antitrust precedent recognizes that, so long as the patentee operates within the exclusionary bounds of its patent monopoly, the antitrust laws do not forbid the patentee's conduct. *United States* v. *Gen. Elec. Co.*, 272 U.S. 476, 485, 489 (1926); *United States* v. *Line Material Co.*, 333 U.S. 287, 300 (1948). The Government's

suggested approach simply disregards the patent's exclusionary potential. *See infra* pp. 16-20.

B. Moreover, this Court has held that "quick look" review is available only where the "great likelihood of anticompetitive effects can easily be ascertained." *Cal. Dental*, 526 U.S. at 770. The Government has failed to show "obvious" and "actual[] anticompetitive effects" flowing from the targeted settlements sufficient to justify a presumption that the challenged agreements are always, or almost always, illegal. *Id.* at 771, 775 n.12. Leading economists—and until recently, the Department of Justice (DOJ)—agree that the mere presence of a "payment" to the generic applicant is, without more, an insufficient indicator of the competitive effects of a patent litigation settlement. Nor do empirical data support the truncated analysis. The Government has failed to allege actual or theoretical anticompetitive effects that would justify quick look review. *See infra* pp. 20-31.

C. Apart from the lack of justification for "quick look" review, the Government's test reveals flaws fatal to its practical application. As proposed, the antitrust plaintiff's *prima facie* case would consist of showing (i) a "payment" to the generic applicant and (ii) a non-immediate generic entry date. Pet. Br. 2, 37. The first element, the Government's conception of "payment" in this context, is hopelessly ambiguous. Though the Government now asserts that this Court's consideration of the "payment" question need not stray beyond the facts presented (*i.e.*, alleged direct cash payments constituting overpayment for services rendered), the FTC previously argued in this case that "payment" encompasses provision of eco-

nomic value to the generic applicant *in any form*. The second element of the *prima facie* case, deferred entry, would be adequately pled by a simple allegation that the settlement contemplated a non-immediate date for licensed generic entry, regardless of whether that date represented a delay beyond what might have been agreed but for the payment. Because the antitrust plaintiff need not show that the "payment" actually occasioned any delay, the proposed *prima facie* test is unmoored from the relevant antitrust inquiry and sets an alarmingly low bar for pleading an antitrust violation. *See infra* pp. 31-36.

D. Not only is the *prima facie* case flawed, but the Government's envisioned rebuttal would preclude defendants from presenting procompetitive justifications based on patent merits, rendering the rule a *per se* prohibition. The purported anticompetitive effect of a "reverse-payment" settlement hinges upon allegedly delayed generic entry. Yet whether the agreed-upon generic entry date represented an *actual* delay compared to the likely date of generic entry, had the litigation been litigated to conclusion, can be ascertained only from a relitigation of the patent merits. After all, had the patent been upheld as valid and infringed, the provision for generic entry prior to patent expiration would be clearly procompetitive. Precluding defendants from responding to the presumption of illegality by addressing the patent merits—as the Government now proposes—would be unjust and inconsistent with this Court's precedent. At the same time, as the Court of Appeals emphasized (and as the Government apparently now recognizes), premising liability on a speculative determination about possible litigation outcomes would

be conceptually flawed and inherently unreliable. *See infra* pp. 36-39.

E. The Government's approach also would have consequences that the FTC surely cannot intend. The uncertainty generated by its ambiguous and burdensome rule would have a chilling effect on generic patent challenges and upon pharmaceutical innovation, and would impose unwarranted burdens upon the judicial system. *See infra* pp. 39-46.

II. The correct mode of antitrust analysis is the scope-of-the-patent test applied by the Court of Appeals, in which "absent sham litigation or fraud in obtaining the patent," a so-called reverse-payment settlement does not violate the antitrust laws "so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." Pet. App. 28a. This approach is mandated by antitrust law, patent law, and the law of settlement. This approach appropriately subjects settlements to antitrust scrutiny if the settlements (i) exceed the bounds of the patent monopoly, *United States* v. *Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963); (ii) settle sham litigation, *Professional Real Estate Investors, Inc.* v. *Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993) (*PRE*); or (iii) involve a patent obtained through fraud on the PTO. *Walker Process Equip., Inc.,* v. *Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965). Under this approach the Complaint failed to state a claim and was properly dismissed. *See infra* pp. 46-57.

ARGUMENT

I. The Government's Proposed Test is Erroneous.

Unhappy with the approach taken by the court below—which reflects the near-unanimous view of the courts of appeals to have considered the issue—the Government urges this Court to classify as presumptively unlawful all settlements of Hatch-Waxman patent litigation that include what it deems a "payment" from the patent holder to the generic manufacturer and non-immediate entry by the generic manufacturer. The Government's position is inconsistent with well-settled principles of antitrust law, patent law, and the law of settlement.

The Government's suggested approach appears to be as follows: "Reverse-payment agreements should . . . be treated as presumptively anticompetitive under a 'quick look' rule of reason analysis." Pet. Br. 17. First, a plaintiff must establish the existence of a reverse-payment agreement. *Id.* 37. The Government defines such an agreement as one whereby "a patentee (the brand-name manufacturer) agrees to pay an accused infringer (its would-be generic competitor), and the competitor agrees that it will not enter the market for a specified period of time." *Id.* 2. Second, once the plaintiff has made out this *prima facie* case, the settlement agreement is presumed illegal and the burden shifts to the antitrust defendants to rebut the presumption. *Id.* 37. The defendants can rebut the presumption by showing that (1) "'any money that changed hands was for something other than delay, . . . such as the generic manufacturer's provision of property or services unrelated to the brand-name manufacturer's

monopoly,'" *ibid.* (quoting *In re K-Dur Antitrust Litigation*, 686 F.3d 197, 218 (3d Cir. 2012)); (2) the payment was commensurate with litigation costs that the brand-name manufacturer avoided by settling, *id.* 38; or (3) in "likely rare" circumstances, the existence of "certain unusual business or litigation justifications" justified the payment. *Ibid.*[7]

The Court should decline the Government's invitation. The proposed test is not only internally incoherent, but it also is inconsistent with patent rights, lacks a sound basis in this Court's antitrust precedent, and reflects an improper effort to shift the burden of persuasion to defendants to justify a settlement of litigation. Contrary to the Government's assertions, adoption of this test would lead to consumer harm in the form of fewer generic patent challenges and reduced innovation. It would burden the judicial system by forcing parties to litigate their patent disputes to conclusion when they would prefer to settle. Those that did settle with a future entry date and an alleged value transfer to the generic manufacturer would face the potent threat of collateral attack by treble-damage-seeking antitrust plaintiffs benefiting from an easy-to-establish *prima facie* case and a presumption that the settlement was illegal. Although the Government now claims patent merits are irrelevant to the defense, once embroiled in the antitrust case, the settling parties would have

[7] The Third Circuit stated the test as follows: "the finder of fact must 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 the payment (1) was for a purpose other than delayed entry or (2) offers some procompetitive benefit." *K-Dur*, 686 F.3d at 218.

to be afforded the opportunity to disprove the presumption of delayed generic entry. The only way to disprove delay, however, is through the "turducken" task of relitigating the patent case inside the antitrust case, Pet. App. 36a, defeating the repose obtained through settlement.

A. The Government's Test Disregards the Patent.

The Constitution endows Congress with the power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. Congress, in turn, has granted a patentee the right to exclude others from profiting from his patented invention. 35 U.S.C. § 154(a)(1) (providing "a grant to the patentee . . . of the right to exclude others from making, using, offering for sale, or selling the invention . . . ."); *Dawson*, 448 U.S. at 215. The Patent Act also provides that a patent is "presumed valid." 35 U.S.C. § 282(a).

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 Line Material*, 333 U.S. at 300 ("[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"); *Gen. Elec. Co.*, 272 U.S. at 485, 489 ("[I]t is only when . . . [the patentee] steps out of the scope of his patent rights" that he comes within the operation of the Sherman Act); *Simpson* v. *Union Oil Co. of Cal.*, 377 U.S. 13, 24 (1964) (the patent laws "are *in pari materia* with the antitrust laws

and modify them *pro tanto*"). This Court has long recognized that settlement of patent litigation does not, without more, violate the antitrust laws. *Standard Oil Co. (Ind.)* v. *United States*, 283 U.S. 163, 171 (1931) ("Where there are legitimately conflicting claims or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act.").

The Government nevertheless urges the Court to adopt an antitrust analysis for patent litigation settlements that disregards the patent. The effect is to treat the patent as though it were presumptively *in*valid—indeed, the Government explicitly takes the position that the patent has *no* scope until courts have established its validity and coverage in litigation. Pet. Br. 25-26 ("simply holding a patent does not result in the automatic exclusion of potential rivals;" "[t]o enforce a contested patent, a patentee must prove that the accused product or process falls within the scope of the patent's claims as properly construed."); *id*. 40 (parties unable to settle without a payment need to litigate to final judgments that "reflect determinations by judges and juries, based on adversary presentations by the brand-name and generic manufacturers, as to the *actual* exclusionary force of the relevant patents.") (emphasis in original).

That the Government now endorses a test devoid of reference to the patent's exclusionary potential is all the more remarkable given the Complaint's allegations. In contrast to the Government's position here, where it asserts that consideration of the patent merits is unnecessary, the Complaint contains a section titled "Solvay's Patent was Unlikely to Prevent Generic Competition to AndroGel," comprised of

seven paragraphs of allegations purporting to establish that the patentee "was not likely to prevail" in the patent litigation. Complaint ¶¶ 86-92, J.A. 53-55. Indeed, those allegations formed the core of the FTC's opening arguments to the Eleventh Circuit, *see* Br. for Appellant FTC 20-37, *FTC* v. *Watson Pharmaceuticals, Inc.*, No. 10-12729-DD (11th Cir. filed July 26, 2010), and were the "lynchpin" allegations that the Eleventh Circuit rejected. Pet. App. 14a, 30a.[8]

Recognition of the patent's lawful exclusionary potential is crucial to the correct antitrust analysis. *Verizon Commc'ns, Inc.* v. *Law Offices of Curtis V. Trinko*, 540 U.S. 398, 411 (2004); *E. Bement & Sons* v. *Nat'l Harrow Co.*, 186 U.S. 70, 88 (1902) (the "most material fact" to antitrust analysis of patent-related agreements "is that the agreements concern articles protected by letters patent"). The Government's conspicuous disregard of the patent—save for where patent validity and scope are established in bitter-end litigation—is itself a reason to reject the Government's test.

B. "Quick Look" Review is Not Warranted.

Categorical condemnation of certain types of agreements is typically reserved only for those restraints classified as *per se* unlawful. *Leegin Creative Leather Prods., Inc.* v. *PSKS, Inc.,* 551 U.S. 877, 886 (2007) (the *per se* rule "treat[s] categories of re-

[8] The "not likely to prevail" allegations were contained in the original Complaint (Dkt. No. 4, J.A. 8) and First Amended Complaint (FAC) (Dkt. No. 8, J.A. 8), both filed in California prior to transfer. *E.g.*, FAC at 21, ¶ 92. Thus, the Government cannot argue that the allegations were merely an effort to comply with what it believed to be Eleventh Circuit precedent.

straints as necessarily illegal" and "eliminates the need to study the reasonableness of an individual restraint in light of the real market forces at work"). *Per se* treatment "is appropriate only after courts have had considerable experience with the restraint at issue" and "only if courts can predict with confidence that it would be invalidated in all or almost all instances under the rule of reason." *Id*. at 886-87. Where "the economic impact of certain practices is not immediately obvious," *per se* rules are inappropriate. *Id*. at 887 (internal quotation marks omitted).

Here the Government advocates for application of a truncated, "quick look" approach. Pet. Br. 17, 33-40. "Quick look" review applies "where the restraint is sufficiently threatening to place it presumptively in the *per se* class, but lack of judicial experience with a significant element requires at least some consideration of proffered defenses or justifications." 11 Philip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶1911a (3d ed. 2011). Only when "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets" may this shortcut apply. *Cal. Dental*, 526 U.S. at 770. Such truncated review is reserved for "business activities that are so plainly anticompetitive that courts need undertake only a cursory examination before imposing antitrust liability," *Texaco, Inc.* v. *Dagher*, 547 U.S. 1, 7 n.3 (2006); "quick-look analysis carries the day when the great likelihood of anticompetitive effects can easily be ascertained." *Cal. Dental*, 526 U.S. at 770.

The burden of showing that the challenged agreement has a substantial anticompetitive effect

ordinarily rests with the antitrust plaintiff. *United States* 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); *Times-Picayune Publ'g Co.* v. *United States*, 345 U.S. 594, 622 (1953) ("Under the broad general policy directed by §1 against unreasonable trade restraints, guilt cannot rest on speculation;" holding that the government had failed to meet its burden of showing "actual unlawful effects [or] facts which radiate a potential for future harm.").

In determining whether an alleged restraint qualifies for "quick-look" review, the court must first "properly identif[y] the theoretical basis for the anticompetitive effects [of the restraint] and consider[] whether the effects actually are anticompetitive" before the burden may be shifted to an antitrust defendant to show "empirical evidence of procompetitive effects." *Cal. Dental*, 526 U.S. at 775 n.12. However, where "the circumstances of the restriction are somewhat complex, *assumption alone will not do*." *Ibid.* (emphasis added). Rather, the inquiry into allegedly anticompetitive effects must be sufficiently rigorous to justify shifting the burden. *Id.* at 776 (criticizing the "leniency of [the Court of Appeals'] enquiry into evidence of the restrictions' anticompetitive effects" and the court's "adversion to empirical evidence at the moment of this implicit burden shifting" to the defendants); *see also Major League Baseball Props., Inc.* v. *Salvino, Inc.*, 542 F.3d 290, 340 n.10 (2d Cir. 2008) (Sotomayor, J., concurring)

("When empirical analysis is required to determine a challenged restraint's net competitive effect, neither a *per se* nor a quick-look approach is appropriate . . . . ").

The "ultimate focus" of the inquiry is to form a judgment about the restraint's "impact on competition." *NCAA* v. *Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 103-04 (1984).

1. Here, the Government has fallen short of showing that reverse-payment settlements have "obvious" and "actual[] anticompetitive effects" sufficient to justify a quick look approach and a presumption of illegality. *Cal. Dental*, 526 U.S. at 771 & 775 n.12. Disregarding the patent's potential exclusionary scope, the Government relies on unwarranted assumptions and equivocal data to support its sweeping conclusion that "the presence of a reverse payment raises concern about the integrity of the competition restricting features of the settlement." Pet. Br. 29. In fact, the literature explains that "reverse-payment" agreements often have pro-competitive virtues, which DOJ itself until recently had acknowledged.

a. As a threshold matter, the Government cannot demonstrate *actual* anticompetitive effects, and instead substitutes a proxy that merely *assumes* them. The assumption is that, if Paragraph IV patent litigants were prohibited from settling with a payment, they would reach a settlement with a "deferred entry date" that "roughly corresponds to the parties' assessments of their likelihood of success in the litigation." *Id.* 28. If the parties are permitted to bargain with a payment, however, the Government assumes that the payment serves to delay entry "re-

gardless of the parties' assessments of the suit's likely outcome." *Id.* 29.

The Government's assumption that a "reverse payment" implies that the patent litigants could have reached a "better" settlement without a payment and with an earlier entry date is unwarranted and unproven. As noted economists have explained,

> there are many different sets of circumstances where the two firms will be unable to reach a mutually agreeable settlement without the payment of net consideration by the incumbent to the entrant. In the absence of such a payment, the firms will continue to litigate and the outcome of the litigation may be worse for consumers than the settlement that could have been achieved with a payment of net consideration because such settlements may result in entry sooner than the expected entry date under litigation. Th[e] invalid simple argument [that a settlement with an earlier entry date is available] *merely assumes* that an earlier entry date can substitute for the payment of net consideration. But . . . this assumption is inapplicable under at least the circumstances of asymmetric information, asymmetric expectations, and predictable entry by a nonlitigant before the end of the patent's life.

Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 Antitrust Bull. 655, 676 (2004) (emphasis added); *id.* at 659.

Other economists and commentators agree that the mere presence of a payment is a poor indicator of the competitive effects of a particular settlement, and that settlements whose terms include a payment to the generic manufacturer can benefit consumers. *See, e.g.*, Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. 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."); Mark G. Schildkraut, *Patent-Splitting Settlements & the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1034 (2004) ("[A] reverse payment is necessary [in many circumstances] to resolve a patent litigation and that resolution is better for consumers than continued litigation"); Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 Fed. Cir. B.J. 617, 618-619, 628-31 (2005) ("[T]here are a number of reasons why a settlement based on . . . a [simple] split [of the remaining patent term] may not be available," including "asymmetric time horizons and asymmetric risk profiles or expectations").[9]

This notion that reverse-payments have the procompetitive potential of achieving settlement, and

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[9] These commentators are all critical of an overly-restrictive rule limiting settlement options. While they are not all in agreement on the appropriate rule, as set forth in Section II, *infra*, the scope-of-the-patent approach is consistent with this Court's precedents.

even permitting early generic entry where it might otherwise not have occurred, has been recognized by courts of appeals that have adopted the scope-of-the-patent approach. *See, e.g.*, *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056, 1073 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 215 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1333 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (2009).

Indeed, DOJ until recently was of the view that reverse-payment settlements have pro-competitive potential, and it explicitly disagreed with a presumption of illegality. In response to this Court's invitation, DOJ submitted a brief opposing certiorari in *Schering-Plough*. DOJ argued that "the public policy favoring settlements, and the statutory rights of patentees to exclude competition within the scope of their patents, would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation," and that "the Hatch-Waxman context creates a litigation dynamic that makes some settlements reasonable." Brief for United States as Amicus Curiae, *FTC* v. *Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273), 2006 WL 1358441, *10-11 (*Schering* U.S. Br.). Noting the "high degree of suspicion" of reverse-payments reflected in the FTC's approach, *id.* at *12, DOJ's view was that "the mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful." *Id.* at *11. Although the Government now acknowledges its sudden volte-face, Pet. Br. 41 n.9, no explanation for it is provided. In light of this unexplained reversal, DOJ's newfound

enthusiasm for a presumption of illegality should be viewed with skepticism.

Economic analysis and judicial experience make clear that the purported "natural inference" that a reverse payment "has purchased an additional increment of market exclusivity," Pet. Br. 36, is an unsupported assumption. Accordingly, "the plausibility of competing claims about the effects of the [alleged restraints] rules out the indulgently abbreviated review" that the Government seeks; "[t]he obvious anticompetitive effect that triggers abbreviated analysis has not been shown." *Cal. Dental*, 526 U.S. at 778.

b. Not only does the Government's position rely on unwarranted assumptions, but empirical analyses cited in support of its position, *see* Pet. Br. 6-7, 44-45, either are flawed or fail to support the Government's far-reaching rule.

One statistic cited by the Government derives from a 2002 FTC report stating that "generic competitors prevailed over brand-name manufacturers with respect to 73% of the drug products that were the subject of a court decision in paragraph IV litigation initiated between 1992 and 2000." Pet. Br. 6, 44 (citing FTC, *Generic Drug Entry Prior to Patent Expiration* 10, 19-20 (July 2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (2002 FTC Report)). This decade-old statistic is flawed. First, it fails to include many victories by patentees. *See* Protecting Consumer Access to Generic Drugs Act of 2007: Hearing Before the Subcomm. on Commerce, Trade, & Consumer Protection of the H. Comm. on Energy and Commerce, 110th Cong. 102-104 (2007) (prepared statement of Phillip A. Proger) (FTC baseline

for litigated cases excluded cases in which the same drug patent was litigated more than once). Second, to the extent it is offered as evidence of the general vulnerability of patents, the study's findings regarding trials adjudicating patent *validity* show that patentees prevailed 72% of the time. 2002 FTC Report at 20 (28% invalidity rate for patents where parties chose to litigate to conclusion). Third, the percentage of generic wins in the 2002 FTC Report is based on a universe of only 40 court decisions. *Id.* at 19-20. A more recent study on paragraph IV patent challenges considered 171 cases and found a far lower generic success rate. Adam Greene & D. Dewey Steadman, *Pharmaceuticals: Analyzing Litigation Success Rates*, RBC Capital Markets Corp., 4 (Jan. 15, 2010), http://amlawdaily.typepad.com/pharmareport.pdf (generics won 82 court rulings and lost 89).

Beyond the Paragraph IV context, another study is cited by the Government for the proposition that nearly half of *all* litigated patents are declared invalid. Pet. Br. 4 (citing statistic that 46% of all litigated patents were declared invalid). However, the same study notes that *pharmaceutical* patents were upheld 72.7% of the time. *See* John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 217 (1998).

Yet another study cited as illustrating the purported anticompetitive effects of reverse-payment settlements is a 2010 FTC report concluding that "settlements with reverse payments were associated with generic entry an average of nearly 17 months later than settlements without," and that "[s]uch agreements are demonstrably associated with delayed entry of generic competition, costing consumers

billions of dollars each year." Pet. Br. 31, 45 (citing FTC, *Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions*, 2 (2010), http://www.ftc.gov/os/2010/01/100112payfordelayrtp.pdf (2010 FTC Report)). Economists have criticized the FTC's analysis as "unreliable" and "oversimplified" in a way "that has material bearing on its utility and reliability for predicting generic entry or estimating costs under alternative rules." Bret Dickey, Jonathan Orszag & Robert Willig, *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on "Reverse Payment" Settlements*, 3 (August 10, 2010), http://www.compasslexecon.com/highlights/Documents/Dickey%20Orszag%20Willig%20CBO.pdf. These authors observe that, "[a]s a matter of economics, 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." *Id.* They conclude that the Congressional Budget Office estimate of billions of dollars in savings from increased restrictions on reverse-payment settlements is likely overstated because it is premised upon the FTC's flawed studies. *Id.* at 6-7.

Given the broad variation in the statistics and criticism of the methodology used in these studies, the cited studies fail to provide an empirical basis for judicial adoption of quick look review. *See Cal. Dental*, 526 U.S. at 775 n.12 (requiring "proper[] identif[ication] of the theoretical basis of the anticompetitive effects and consider[ation] [of] whether the effects actually are anticompetitive" before burden may be shifted to defendants).

c. Still another infirmity in the Government's proposed quick-look analysis is the false dichotomy between "reverse-payment" settlements and "entry-date-only" settlements. The Government argues that "reverse-payment" settlements ought to be subject to "quick-look" review because they supposedly "closely resemble" horizontal market allocation agreements that have been found to be *per se* illegal. Pet. Br. 15, 19, 33-35.[10] Yet while the Government acknowledges that entry-date-only settlements also are agreements among potential horizontal competitors that restrict competition, *id.* 25 (entry-date-only settlements equally "entail[] a restriction of competition"), these, in the Government's view, do not raise antitrust concerns at all because they lack a "payment." *Ibid.* ("antitrust liability [should not] ordinarily attach to a settlement by which the parties to paragraph IV litigation simply agree on a compromise date of generic entry."). The better analysis is to recognize that it is the *patent*, and not the payment, that is the source of the exclusion. That is why *Palmer* v. *BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990) (per curiam), and *United States* v. *Griffith*, 334 U.S. 100, 107 (1948), are inapposite and why no presumption of illegality should apply.

Indeed, there is no limiting principle to the Government's rule. Virtually any patent settlement

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[10] The Government ignores entirely that many so-called reverse-payment settlements, such as those at issue here, actually allow for generic entry years prior to patent expiration. Although the Government notes that the scope-of-the-patent test permits deferral of generic entry until the end of the patent term, Pet. Br. 43 n.10, this does not justify disregarding the fact that these settlements can—and do—allow for assured generic entry prior to patent expiration.

could be characterized as involving a "payment" to the alleged infringer under the Government's approach, opening the floodgates to antitrust litigation. Consider the example of a settlement negotiation over a royalty-bearing license. If a settlement occurs in 2013, and the patent expires in 2023, the patent holder could offer an entry date in 2016 with a 7% royalty, or instead a later entry date in 2018 with a 5% royalty. Would the later entry date with the lower royalty rate constitute a "payment" to move the generic to accept the later date? Indeed, even a royalty-free license could be considered a windfall to the generic/licensee if a "fair" royalty would have been higher. *See also* Section I.C., *infra* (discussing ambiguity in Government's proposed *prima facie* case).[11]

For all of these reasons, the Government has fallen short of establishing that an exceptional "quick look" analysis is warranted for the settlements of patent litigation that include (i) a non-immediate generic entry date and (ii) something that the Government deems a "payment" from the patentee.

C. The Elements of the Government's "*Prima Facie*" Case are Fundamentally Flawed.

The FTC has for many years branded "reverse-payment" settlements as "pay-for-delay." *E.g.*, 2010

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[11] The Government says that its rule applies at least to direct payments, and that the Court need not now decide the rule's applicability to "alternative arrangements" having "parallel" "economic realities." Pet. Br. 36 n.7. However, the FTC already has urged an expansive interpretation of the term "payment." See Section I.C., *infra*. Moreover, here the FTC is not alleging simply a "payment" but rather a purported *over*-payment for services.

FTC Report. Its proposed *prima facie* case, however, requires the antitrust plaintiff to prove neither "payment" nor "delay" before a settlement is declared presumptively illegal. Rather, disproving these elements is left to defendants, who bear the burden of proving their own innocence.

The proposed *prima facie* test requires a plaintiff to show the existence of a "reverse-payment" agreement. Pet. Br. 37. The Government defines such an agreement as one whereby "a patentee (the brand-name manufacturer) agrees to pay an accused infringer (its would-be generic competitor), and the competitor agrees that it will not enter the market for a specified period of time." *Id.* 2. The elements are highly ambiguous and would lead to confusion.

1. The Government asserts that its test applies only to Hatch-Waxman patent litigation settlements that are accompanied by a "payment." *Id.* 16. Yet the Government is remarkably vague on what counts as a "payment," even though it is the "payment" that renders the litigation settlement presumptively anti-competitive under the antitrust laws, causing the burden to shift to the defendants.

At one point the Government's brief mentions a "monetary payment," *id.* 16; at another point it references "money *or similar consideration*," *id.* 27 (emphasis added); and in a footnote it asserts that the rule could also apply to "an alternative form of consideration" having similar effects to "direct payments." *Id.* 36 n.7 (citing C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 663-66 (2009), which describes a broad array of transactions that might supposedly

"disguise the fact of payment"). The Government fails to mention that (i) the FTC *in this case* urged adoption of its presumptive illegality rule "whenever the patent holder provides economic value to the challenger *in any form* in connection with delayed entry," FTC Pet. for Reh'g En Banc 13, *Watson Pharms.*, No. 10-12729-DD (11th Cir. filed June 11, 2012) (emphasis added); and (ii) the FTC recently characterized as a "reverse-payment" an agreement unaccompanied by *any* direct cash payment. *See* Brief of FTC as Amicus Curiae 1-2, *In re Lamictal Direct Purchaser Antitrust Litig.*, Doc. No. 89-3, No. 2:12-cv-00995-WHW-MCA (D.N.J. filed Oct. 5, 2012) (brand-name pharmaceutical company's agreement not to launch "authorized generic" during first-filing generic manufacturer's 180-day exclusivity period constitutes a "payment"); *see also* Order at 10, *In re Lamictal*, Doc. No. 105 (D.N.J. filed Dec. 6, 2012) (reading *K-Dur* as limited to cash payments). The broad definition of "payment" urged to the Court of Appeals could ensnare a myriad of types of value transfers, many of a nature that could be extremely difficult to isolate. *See also* pp. 30-31, *supra* (discussing royalty negotiations).

The present case demonstrates the difficulties with the Government's amorphous standard. Here the Government asserts that it adequately alleged a "payment" by alleging that "Solvay agreed to make payments to Watson (starting at approximately $19 million during the first year of their agreement in 2006 and rising to more than $30 million annually by 2015)." Pet. Br. 56. Under the Government's view, this allegation would suffice to render the settlement agreement presumptively unlawful under the antitrust laws, and shift the burden to *respondents* to

disprove the (presumed) anticompetitive effects. Pet. Br. 17.

Here, however, the Complaint does not allege that money changed hands at the time of Watson's settlement or that any "valuation" was ever agreed by the parties. Rather, Watson entered into a second agreement at the same time as the settlement agreement, providing that Watson would perform promotional services for Solvay in connection with AndroGel, *i.e.*, a specified number of sales calls ("details") to urologists. Complaint ¶¶ 64, 66, J.A. 46. These are services of a nature that this Court recently recognized as having value. *See Sorrell* v. *IMS Health, Inc.*, 131 S. Ct. 2653, 2658 (2011) ("many listeners find detailing instructive"). The Government's actual allegation is that Watson received *disguised* compensation in the form of an alleged *over*payment for co-promotion services. Complaint ¶ 82, J.A. 51. However, in the Government's view, it—or any antitrust plaintiff—need not attempt to isolate any net payment, as opposed to compensation for *bona fide* services at fair market value, in order to make out a *prima facie* case. The mere fact of *any* transfer of value is enough to presume the agreement unlawful, shift the burden to the defendants, and move the case into discovery. *See* Pet. Br. 17 (the "principal means of rebuttal would be through proof that the payment was instead consideration for unrelated property or services.").

To ascertain whether the value provided to the generic manufacturer was really payment for delay, an antitrust court would necessarily have to determine what the "fair" or "appropriate" value of the associated business deal should have been. *Cf. Pac.*

Bell Tel. Co. v. *linkLine Commc'ns*, 555 U.S. 438, 452 (2009) (courts are "ill-suited to act as central planners, identifying the proper price, quantity, and other terms of dealing") (internal quotation marks omitted). Should the antitrust court (or jury) determine that the defendants failed to meet their burden, finding the business deal to have been "richer" than it should have been, under the Government's proposed rule the defendants would, without more, be subject to treble-damage antitrust liability and Government enforcement.

2. The second element of the Government's confused *prima facie* test relates to the agreed generic entry date: the plaintiff must show that "the [generic] competitor agrees that it will not enter the market for a specified period of time." Pet. Br. 2. In contrast, the Third Circuit's *K-Dur prima facie* case requires a showing that "a generic patent challenger [has] agree[d] *to delay* entry[.]" *K-Dur*, 686 F.3d at 218 (emphasis added). The distinction is subtle, but critical to an adequate allegation of anticompetitive effects.

According to the Government, its Complaint stated this second element with the allegation that respondents Watson and Par/Paddock agreed to an entry date nine years in the future. Pet. Br. 56. Evidently, the Government believes its *prima facie* test is satisfied upon a simple showing of a future agreed generic entry date, without reference to when the generic manufacturer might *actually* have entered the market in the absence of a settlement, or even when entry would have occurred in a hypothetical "entry-date-only" settlement. The supposedly anticompetitive effect—*i.e., delayed* generic entry—is thus

uncoupled entirely from the *prima facie* showing of a presumptively unlawful antitrust violation under the Government's test.[12]

In short, permitting a plaintiff to state a *prima facie* case of "payment" without demonstrating an actual net value transfer, and of "delay" with the simple allegation that the parties agreed that generic entry would occur at some date in the future, not only unmoors the *prima facie* case from the competitive effects inquiry, but also sets an alarmingly low—and speculative—bar for pleading an antitrust violation.

D. The Government's Limitation on Defendants' Ability to Rebut the Presumption of Delay Would Result in a Rule with *Per Se* Effect.

As set out in the foregoing discussion, because the presumption is improper, the burden should not be on defendants to prove their innocence by disproving a (presumed) payment. However, even were the burden appropriately shifted to the defendants, the limitations the Government seeks to place on the defense imbues the rule with *per se* effect.

Under the Government's proposed rule, once an antitrust plaintiff has made out the simple *prima facie* case of a "payment" to the generic manufacturer

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[12] While the Third Circuit's requirement that "a generic patent challenger [has] agree[d] to delay entry" may avoid this problem with the Government's formulation, it raises a host of nettlesome questions: How is "delay" determined? What is the starting point? Must a court (or jury) determine when the generic manufacturer otherwise would have entered the market? How does one assess such an entry date in light of the vagaries of litigation?

and a non-immediate entry date, the agreement is presumed to be illegal and the burden shifts to the defendants. The defendants then have the "opportunity" to show that (1) "'any money that changed hands was for something other than a delay,'" Pet. Br. 37 (quoting *K-Dur*, 686 F.3d at 218), such as for "the generic manufacturer's provision of property or services unrelated to the brand-name manufacturer's monopoly," (2) the payment was commensurate with "litigation costs that the brand-name manufacturer avoided by settling," *id.* 37-38; or (3) other "unusual business or litigation justifications" which are "likely rare." *Id.* 38. The Government concludes that "in general defendants should be fully heard on each of their 'proffered justifications.'" *Id.* 39 (citing *NCAA*, 468 U.S. at 113).

Though the Government *says* that defendants should be fully heard on each of their proffered justifications, *ibid.*, rebutting the presumption of delay is apparently not one of these. *Id.* 37-38. Indeed, the Government would now bar inquiry into how the patent litigation might have ended, had it been litigated to conclusion, asserting variously that a patent merits inquiry is "inappropriate," "cumbersome," "doctrinally anomalous," and "likely unworkable in practice." *Id.* 53, 54-55.[13] In other words, under the

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[13] The Government's position on patent merits is remarkable for several reasons. *First*, the FTC's own Complaint includes the "key allegation," Pet. App. 3a, that the patent holder was "not likely to prevail" in the patent suit. Complaint ¶ 86, J.A. 53. *Second*, the California district judge initially hearing this case understood the FTC to have "admitted . . . 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." *Watson*, 611 F. Supp. 2d at 1088. *Third*, despite reject-

Government's approach, defendants cannot justify their settlement on the basis of the patent. *Cf. NCAA*, 468 U.S. at 103 (a "fair evaluation of [the restraints'] competitive character requires consideration of [defendants'] justifications for them"); *FTC* v. *Ind. Fed'n of Dentists*, 476 U.S. 447, 459-60 (1986) (reviewing proffered justifications); *Nat'l Soc'y of Prof'l Eng'rs* v. *United States*, 435 U.S. 679, 693-96 (1978) (same). Restricting the defendants' defense in this way renders the FTC's test a rule with *per se* effect.

An example helps to illustrate the problem with the Government's approach. Suppose an antitrust plaintiff has alleged and demonstrated that some form of consideration was provided to the generic manufacturer as compensation for a business agreement. Suppose the defendants are unable to show conclusively that the business agreement is at fair market value. At that point, in the face of treble-damage liability, the defendants must also have the ability to disprove the presumption of anticompeti-

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ing a patent-merits inquiry at the liability phase, the Government nevertheless concedes that "[q]uantification of damages in a private antitrust action might require an assessment of what sequence of events would likely have ensued in the absence of a reverse payment." Pet. Br. 55 n.11. But this raises the question of why an inquiry that would be "cumbersome" and "inappropriate" in a case involving injunctive relief would be any less so in a private antitrust treble-damages action. *Fourth*, in contrast to its position here, DOJ recently (and repeatedly) took the position that the "relative likelihood of success of the parties' claims" should be considered. *Schering* U.S. Br. 11; Brief for United States as Amicus Curiae, *Joblove* v. *Barr Labs.*, 551 U.S. 1144 (2007) (No. 06-830), 2007 WL 1511527, at *12 (rule of reason requires considering "the strength of the patent as it appeared at the time at which the parties settled").

tive effects through an objective determination of the likely outcome of the patent litigation. After all, the "reality of patent litigation and risks it presents to the patent holder" are "precisely why a party is likely to choose to settle a patent dispute even if it might well prevail." Pet. App. 31a. But the Government now would deny defendants such an opportunity, apparently in recognition of the "turducken" judicial complexity that would necessarily result.[14]

The lack of authority for the Government's rule, the uncertainty created by its presumption of illegality, and the very real potential for relitigation of the patent case to avoid treble-damages exposure would have tremendous social costs.

E. Adoption of the Government's Test Would Result in Unintended Consequences.

Were this Court to adopt the Government's test for "reverse-payment" settlements, a number of unintended consequences would result.

1. The Government's brief focuses entirely on the purported short-term consumer interest, turning a blind eye to long-term consumer harm that would result from its overly restrictive rule. A rule that too severely restricts settlement options will chill settlements and result in continued litigation. *See Williams* v. *First Nat'l Bank*, 216 U.S. 582, 595 (1910) ("Compromises of disputed claims are favored by the courts[.]"); *Tamoxifen*, 466 F.3d at 212 n.26 (a rule

[14] An objective inquiry into patent merits, rather than an "*ex ante*" inquiry into the parties' subjective views of the likely outcome of the patent litigation, would be required to ascertain the patent's *actual* exclusionary effect.

making patent litigation settlements "subject to the inevitable, lengthy and expensive hindsight of a jury as to whether the settlement constituted a 'reasonable' restraint" "would place a huge damper on such settlements contrary to the law . . . that settlements are not only permitted, they are encouraged."); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 529 (E.D.N.Y. 2005) ("[M]aking the legality of a patent settlement agreement, on pain of treble damages, contingent on a later court's assessment of the patent's validity might chill patent settlements altogether."), *aff'd*, 544 F.3d 1323 (Fed. Cir. 2008). The uncertainty flowing from such a rule could well lead to fewer Paragraph IV ANDA challenges and reduced incentives to innovate—surely not the FTC's intended outcome.

a. Paragraph IV litigation requires a substantial commitment of resources, which must be considered in the earliest stages of developing any 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 drawn-out, expensive, uncertain litigation to final judgment, generic companies may well decide, in the face of potentially catastrophic treble-damages exposure and exorbitant litigation costs, not to file Paragraph IV ANDAs.[15]

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[15] *See* Bret Dickey & Daniel Rubinfeld, *Would the* Per Se *Illegal Treatment of Reverse Payment Settlements Inhibit Generic Drug Investment?*, 8 J. Comp. L. & Econ. 615, 619-20 (2012) ("[I]f antitrust policy towards patent settlements reduces the ability of generic manufacturers to settle litigation and therefore increases the cost and risk associated with bringing a generic version to market, generic manufacturers' investments

A Paragraph IV certification is not a conclusive determination of invalidity or non-infringement by the PTO or any court. *Cf.* Pet. Br. 5, 18, 43-44. Rather, it represents a generic manufacturer's good-faith assertion that "in the opinion of the applicant and to the best of its knowledge," the patent is invalid and/or not infringed, 21 U.S.C. § 355(j)(2)(A)(vii), and it is an invitation to litigation over precisely this point. *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012) ("Filing a paragraph IV certification means provoking litigation.").

Nevertheless, the Government hails the possibility that "in some paragraph IV litigation that might otherwise have been settled through reverse-payment agreements, a rule discountenancing reverse payments may cause the parties to litigate to judgment." Pet. Br. 40. It applauds this result because "in the aggregate, those judgments on the merits will reflect results more in keeping with the policies of the antitrust laws, the Patent Act, and the Hatch-Waxman Amendments than if all the cases had been settled with reverse payments." *Id.* This

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in these challenges are likely to be diminished"); Dickey, Orszag, & Tyson at 398 ("[r]estricting the range of settlement options will reduce the ability of generic manufacturers to settle these cases and increase the cost and risk of bringing a generic drug to market," which "[o]n the margin, . . . will lower the incentives for generic pharmaceutical manufacturers to challenge patents in the first place" and can have a "[substantial] collective impact on future generic competition"); *Asahi Glass Co.* v. *Pentech Pharms., 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.").

view requires acceptance of two interrelated policy positions: (1) forcing parties to litigate to conclusion when they would rather settle is in the public interest; and (2) forcing such litigation is preferable to a settlement accompanied by a "reverse-payment," even though that settlement might well have permitted *more* competition (guaranteed early entry) than the litigation outcome (a win by the patentee).

Nothing in Hatch-Waxman or the Patent Act evidences a congressional intent to *require* Paragraph IV patent litigants to litigate their cases to conclusion, that is, to conscript generic manufacturers as "unwilling private attorneys general." *Cipro*, 363 F. Supp. 2d at 532; *accord Tamoxifen*, 466 F.3d at 202-03. Nothing in the antitrust laws requires pharmaceutical manufacturers to channel funds into litigation that might otherwise be invested in developing other products.

Nor does adoption of a policy discouraging settlement square with the fact that antitrust law is generally leery of rules that might chill procompetitive conduct. *United States* v. *U.S. Gypsum Co.*, 438 U.S. 422, 441 (1978) ("[S]alutary and procompetitive conduct . . . might be shunned by businessmen who chose to be excessively cautious in the face of uncertainty. . . ."); *Am. Needle, Inc.* v. *Nat'l Football League*, 130 S. Ct. 2201, 2209 n.2 (2010) (expressing concern over deterring "perfectly competitive conduct by firms that are fearful of litigation costs and judicial error").

To the extent the Government purports to base its presumption of illegality on the public policy concern over weeding out "voidable" or weak patents, *e.g.*, Pet. Br. 7, 48, this is a red herring. An antitrust rule of

presumptive illegality, with its potential for treble-damage liability, is not the appropriate mechanism for addressing this concern. First, as this Court recently observed, Congress has acted by "amend[ing] the patent laws to account for concerns about 'bad' patents, including by expanding the reexamination process to provide for *inter partes* proceedings." *Microsoft Corp.* v. *i4i P'ship*, 131 S. Ct. 2238, 2252 (2011). Second, an antitrust court reviewing a reverse-payment settlement would ordinarily not be in a position to declare a patent invalid or not infringed; it would typically only decide the question of whether the settlement of the patent litigation violates the antitrust laws. Third, under the Government's framework, even an entry-date-only settlement could involve what the Government views as a supposedly "weak" patent, preserving exclusivity longer than what a decision on the merits might have "warranted."

As to the Government's repeated invocation of the alignment of interests between generic manufacturers and consumers as a basis for its rule (*e.g.*, Pet. Br. 16, 23, 28, 29, 35-36), patent litigants have no duty to agree to terms that, in the view of the FTC, will provide consumers with the *most* competition:

> This concept of a public property right . . . does not translate well into the realities of litigation, and there is no support in the law for such a right. There is simply no legal basis for restricting the rights of patentees to choose their enforcement vehicle (*i.e.*, settlement versus litigation). Equally important, there is no duty to use patent-derived market power in a

> way that imposes the lowest monopoly rents on the consumer.

Cipro, 363 F. Supp. 2d at 531-32 (citing, *inter alia*, *Bement*, 186 U.S. at 91).

b. In addition to disincentivizing generic manufacturers from filing Paragraph IV ANDA challenges, the Government's rule would dampen innovation. Even the Government's brief recognizes the importance of "preserv[ing] the incentives to innovate that benefit consumers in the long run," Pet. Br. 45; yet it proposes a rule that would have the opposite effect. *See Tamoxifen*, 466 F.3d at 203 ("Rules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation."); *Schering*, 402 F.3d at 1075 ("the caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product"); Bernard & Tom at 618 ("'[a]n antitrust policy that reduced prices by 5 percent today at the expense of reducing by 1 percent the annual rate at which innovation lowers the cost of production would be a calamity. In the long run a continuous rate of change, compounded, swamps static losses.'") (quoting Frank H. Easterbrook, *Ignorance and Antitrust*, in *Antitrust, Innovation, and Competitiveness*, 119, 122-23 (Thomas M. Jorde & David J. Teece eds., 1992)).

2. The Government's rule also would impose a significant and unwarranted burden on the judicial

system. As noted in Section I.C., *supra*, the Government's proposed *prima facie* test sets an extraordinarily low bar for pleading an antitrust violation. Coupled with the presumption of illegality and shifting of the burden to defendants, the Government's approach provides a sizeable incentive for private plaintiffs to file questionable antitrust suits in hopes of proceeding into discovery and extracting a settlement.

This Court has recognized that "proceeding to antitrust discovery can be expensive," and the importance of "avoid[ing] the potentially enormous expense of discovery in cases with no reasonably founded hope that the discovery process will reveal relevant evidence to support a [Section] 1 claim." *Bell Atl. Corp.* v. *Twombly*, 550 U.S. 544, 558-59 (2007) (internal quotation omitted); *Asahi*, 289 F. Supp. 2d at 995 ("[S]ome threshold of plausibility must be crossed at the outset before a patent antitrust case should be permitted to go into its inevitably costly and protracted discovery phase"). For those antitrust cases that continue past discovery, either courts will be faced with relitigation of the merits of the patent suit that the parties had hoped to resolve through settlement, or defendants will be deprived of a necessary tool for a just and appropriate result. Pet. App. 33a (recognizing the "heavy burdens" that relitigation of the patent merits would impose on courts, a burden that "[o]ur legal system can ill afford").

Nor should the Court overlook the Eleventh Circuit's additional concern regarding review of patent cases by the regional circuits: "Congress has given [the Federal Circuit] exclusive jurisdiction over pa-

tent cases"; because "[the Eleventh Circuit] and the other non-specialized circuit courts have no expertise or experience in this area," they are "ill-equipped to make a judgment about the merits of a patent infringement claim, which is what we would have to do in order to decide how likely the claim was to prevail if it had been pursued in the end." Pet. App. 34a-35a.

Finally, the Government's rule would thwart the established judicial policy favoring settlement. *See McDermott, Inc.* v. *AmClyde,* 511 U.S. 202, 215 (1994); *see also* Section II.A.1., *infra*.

For all of these reasons, the Court should decline to adopt the presumption of illegality urged by the Government.

II. The Scope-of-the-Patent Approach Reflects the Correct Interpretation of Patent Law, Antitrust Law, and the Law of Settlement.

The correct antitrust analysis of patent litigation settlements that are accompanied by a payment from the brand-name manufacturer to the generic manufacturer is the so-called "scope-of-the-patent" approach adopted by the Eleventh, Second, and Federal Circuits. *See* Pet. App. 1a-36a; *Tamoxifen*, 466 F.3d at 212-13; *Cipro*, 544 F.3d at 1333. Under that clear and straightforward approach, "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement" does not violate the antitrust laws "so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." Pet. App. 28a.

A. The Scope-of-the-Patent Approach Appropriately Evaluates the Exclusionary Rights of Patent Holders and the Antitrust Laws.

This Court has long recognized that "[t]he essence of a patent grant is the right to exclude others from profiting by the patented invention." *Dawson*, 448 U.S. at 215; *see also* 35 U.S.C. § 154(a)(1); Section I.A., *supra*. Given this exclusionary right, this Court has repeatedly recognized that a patentee does not face antitrust liability so long as it operates within the zone of its patent. *See, e.g.*, *Walker Process*, 382 U.S. at 177 ("A patent . . . is an exception to the general rule against monopolies.") (internal quotation marks omitted); *Line Material*, 333 U.S. at 300; *Gen. Elec. Co.*, 272 U.S. at 485, 489. Antitrust liability may, however, potentially attach when the patent holder (i) exceeds the bounds of his patent monopoly, *Singer*, 374 U.S. at 196-97; (ii) engages in sham litigation to enforce the patent, *PRE*, 508 U.S. at 60-61; or (iii) has obtained the patent through fraud on the PTO. *Walker Process*, 382 U.S. at 177.

1. Consistent with these considerations, the Court of Appeals recognized that, in an antitrust analysis of a patent litigation settlement, "[t]he patent ma[kes] all the difference" given the patent holder's "lawful right to exclude others." Pet. App. 17a (internal citation omitted); *accord Cipro*, 544 F.3d at 1333 (finding "no error" in the district court's analysis where it had "simply recognized that any adverse anticompetitive effects within the scope of the [] patent could not be redressed by antitrust law").

Given that the '894 patent gave respondent Solvay the right to exclude competition at the time of

the settlement, and the legality of the settlement must be adjudged as of the time the parties entered into the agreement, the Eleventh Circuit correctly treated the patent holder as having the exclusionary right at that time. Pet. App. 20a. In light of the risks of litigation, it is of course reasonable for the parties to settle to eliminate that risk. Indeed, in this case, the FTC's position—that the settlement was unlawful because Solvay was "less likely" to prevail—would have meant that the settlement would have been inappropriate even if Solvay's chances had been "49% to 51%." *Id.* 31a. As the Court of Appeals concluded, in view of the vagaries of litigation, settlement of drug patent litigation "is not a violation of the antitrust laws" when the applicable three conditions are met. *Ibid.*

It is incorrect to treat a presumptively valid patent as having "*no* exclusionary potential if its holder was not likely to win the underlying infringement suit." Pet. App. 29a (emphasis in original). Such an argument "equates a likely result (failure of an infringement claim) with an actual result," when it is "simply not true that an infringement claim that is 'likely' to fail actually will fail." *Id.* 30a. Where the antitrust laws permit resolution of patent litigation through settlement, *Standard Oil*, 283 U.S. at 171, and the patentee does not seek to obtain rights beyond those contemplated in his exclusionary grant, *Line Material*, 333 U.S. at 300, *Gen. Elec. Co.*, 272 U.S. at 485, 489, there is no basis in antitrust law to prohibit the settlement. This was the conclusion reached by the Eleventh, Federal, and Second Cir-

cuits. Pet. App. 28a; *Cipro*, 544 F.3d at 1333; *Tamoxifen*, 466 F.3d at 205.[16]

This Court's antitrust precedent and settled patent law principles clearly look to the bounds of the patent monopoly as the line of demarcation between conduct that is lawful and conduct that may be suspect. Whether the scope-of-the-patent approach is viewed as a structured application of the rule of reason in this context, or instead as a recognition that antitrust law simply does not reach a final settlement of *bona fide* litigation over a *bona fide* patent where the settlement terms remain within the patent's exclusionary potential, the outcome is the same:

> in cases such as this, wherein all the anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent. The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of

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[16] The Sixth Circuit has not expressly adopted a standard for analyzing Hatch-Waxman patent settlements; while it rejected one settlement as illegal, that settlement's terms exceeded the scope of the patent. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 n.13 (6th Cir. 2003); *see also* Brief for United States as Amicus Curiae, *Andrx Pharms, Inc.* v. *Kroger Co.*, 543 U.S. 949 (2004) (No. 03-779), 2004 WL 1562075, at *13-14 (restraints in *Cardizem* "extended beyond the legitimate scope of the patent claims"); *Andrx Pharms, Inc.* v. *Biovail Corp., Int'l*, 256 F.3d 799, 815 (D.C. Cir. 2001) (addressing same agreement as *Cardizem*).

> the patent. This analysis has been adopted by the Second and the Eleventh Circuits . . . and we find it to be completely consistent with Supreme Court precedent.

Cipro, 544 F.3d at 1336 (citing *Walker Process*, 382 U.S. at 175-77). Thus, the scope-of-the-patent approach can be viewed as a structured rule-of-reason inquiry whereby the court, upon finding that the settlement's terms do not exceed the patent's exclusionary scope, may deem the agreement reasonable and lawful.[17]

The scope-of-the-patent approach's easily discernible demarcation between lawful and potentially unlawful conduct adheres to this Court's concern that antitrust rules be clear and explainable. *See linkLine*, 555 U.S. at 452 ("[w]e have repeatedly emphasized the importance of clear rules in antitrust law."); *accord Town of Concord* v. *Bos. Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990) (antitrust rules "must be clear enough for lawyers to explain them to clients" and "must be designed with the knowledge that firms ultimately act, not in precise conformity with the literal

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[17] In many contexts, it is well-established that a structured rule-of-reason approach is appropriate—*i.e.*, if certain conditions are satisfied, then the rule of reason is also satisfied. *See, e.g.*, *PSKS, Inc.* v. *Leegin Creative Leather Prods., Inc.*, 615 F.3d 412, 418 (5th Cir. 2010) ("a market power screen is [] compatible with *Leegin* and our precedent and that of our sister circuits") (citing *Leegin*, 551 U.S. 877); *Valley Liquors, Inc.* v. *Renfield Imps., Inc.*, 822 F.2d 656, 667-69 (7th Cir. 1987) (applying market share screen); *Assam Drug Co.* v. *Miller Brewing Co.*, 798 F.2d 311, 315-16 (8th Cir. 1986) ("courts have narrowed the [necessary] unlimited inquiry" of the rule of reason by "requiring at the threshold . . . [proof of] defendant's substantial market power in a relevant market").

language of complex rules, but in reaction to what they see as the likely outcome of court proceedings"). The scope-of-the-patent approach provides Hatch-Waxman litigants with a bright-line metric for determining the legality of their conduct at the time of settlement.

The need for clear rules is magnified where the agreements subject to antitrust scrutiny are entered to resolve inherently uncertain patent litigation. *Whitmore* v. *Arkansas*, 495 U.S. 149, 159-60 (1990) ("It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in this case."); Pet. App. 31a ("[p]atent litigation can also be a high stakes, spin-the-chambers, all or nothing undertaking"); *Asahi*, 289 F. Supp. 2d at 993 ("No one can be *certain* that he will prevail in a patent suit.").

Finally, the scope-of-the-patent approach is consistent with this Court's long-standing view that "public policy wisely encourages settlements." *McDermott*, 511 U.S. at 215; *see also id.* at 215 n.22 ("less than 5% of cases filed in federal court end in trial," and "the bulk of [] nontrial terminations reflect settlements"); *Williams*, 216 U.S. at 595. This policy is fully applicable to patent litigation. *Schering*, 402 F.3d at 1072, 1075 (the general policy favoring settlements "extends to the settlement of patent infringement suits," and "[t]here is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation."); *Flex-Foot* v. *CRP, Inc.*, 238 F.3d 1362, 1369 (Fed. Cir. 2001) ("[W]hile the federal patent laws favor full and free competition in the use of ideas in the public domain over the technical re-

quirements of contract doctrine, settlement of litigation is more strongly favored by the law."); *Asahi*, 289 F. Supp. 2d at 991 ("The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.").

2. The Government's arguments against the scope-of-the-patent approach are unavailing.

a. The Supreme Court precedent cited by the Government in opposition to the scope-of-the-patent approach is either entirely consistent with that approach or inapposite.

Because *Palmer*, 498 U.S. 46, and *Griffith*, 334 U.S. 100, do not address the exclusionary rights inherent in a patent grant, they are inapposite.

Several of the Government's cases relate to attempts to extend the patent monopoly beyond the patent grant; these are consistent with the scope-of-the-patent approach. *See United States* v. *Masonite Corp.*, 316 U.S. 265, 277, 278-79 (1942) (patentee cannot impose restrictions on patented item once it has passed beyond the bounds of the patent monopoly; "the owner of a patent cannot extend his statutory grant by contract or agreement. A patent affords no immunity for a monopoly not plainly or fairly within its grant."); *Line Material*, 333 U.S. at 311 ("no case of this Court has construed the patent and [antitrust] statutes to permit separate owners of separate patents by cross-licenses or other arrangements to fix the prices to be charged by them and their licensees for their respective products."); *United States* v. *U.S. Gypsum Co.*, 333 U.S. 364, 400-01 (1948) (despite the "assumed legality of each separate patent license,"

patents "grant no privilege to their owners of organizing the use of those patents to monopolize an industry through price control, through royalties for the patents drawn from patent-free industry products and through regulation of distribution"); *United States* v. *New Wrinkle, Inc.*, 342 U.S. 371, 379-80 (1952) (because "[p]rice control through cross-licensing [is] barred as beyond the patent monopoly," "[a]n arrangement . . . made between patent holders to pool their patents and fix prices on the products for themselves and their licensees . . . plainly violate[s] the Sherman Act."); *Singer*, 374 U.S. at 189, 193-94 (patentee had "engaged in a series of transactions with [two of its competitors] for an illegal purpose, i.e. to rid [themselves] of infringements by their common competitors"; patentee's agreement to enforce patent to benefit all three parties and exclude foreign competitors constituted an arrangement that "the Sherman Act will not permit").

Two other precedents, moreover, relate to a licensee-plaintiff's ability to challenge the validity of the patent under which it is licensed even though it has agreed not to do so. *Lear, Inc.* v. *Adkins*, 395 U.S. 653 (1969); *Pope Mfg. Co.* v. *Gormully*, 144 U.S. 224 (1892). Nothing in those cases stands for the proposition that an alleged patent infringer *must* litigate its patent challenge to a final judgment, when it would prefer to settle.[18]

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[18] Other cases cited by the Government are similarly unavailing. *See Precision Instrument Mfg. Co.* v. *Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945) (involving perjury in obtaining patent; emphasizing public policy against assertion of patent claims infected by fraud); *Blonder-Tongue Labs., Inc.* v. *Univ. of Ill. Found.*, 402 U.S. 313, 343 (1971) (Court has "condemned

b. The Government also seeks to characterize reverse-payment settlements as anomalous, contending that "[p]ayments from patentees to accused infringers (or from defendants to plaintiffs more generally)[19] are not a traditional settlement term." Pet. Br. 29.[20] The Government disparages as "faulty reasoning" the *Asahi Glass* conclusion that reverse-payment agreements are no different in principle from the "typical settlement." *Id.* 30; *see Asahi*, 289 F. Supp. 2d at 994 (observing that "*any* settlement agreement can be

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attempts to broaden the physical or temporal scope of the patent monopoly"; emphasizing judicial economy concerns in relitigation of patent validity); *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 99-103 (1993) (reiterating judicial economy concerns).

[19] We assume the Government means "from plaintiffs to defendants."

[20] The Government's assertion that reverse-payment settlements do not occur outside the Hatch-Waxman context overlooks that the terms of private settlement agreements are not generally publicly available, nor are most private settlement agreements subject to federal government review—hence the lack of statistics on settlements involving a value transfer to the defendant is not surprising. Such cases do exist. *See, e.g.*, *Metro-Goldwyn Mayer, Inc.* v. *007 Safety Prods., Inc.*, 183 F.3d 10, 13 (1st Cir. 1999); *In Time Prods. Ltd.* v. *Toy Biz, Inc.*, 38 F.3d 660, 662 (2d Cir. 1994); Joris Evers, *Microsoft, Lindows Make a Deal*, PC World (July 19, 2004), www.pcworld.com/article/id,116947-page,1-c,lindowslinspire/article.html ($20 million payment by plaintiff Microsoft to defendant Lindows in settlement of trademark infringement action); Donald Zuhn, *Invitrogen and Agilent Technologies Settle Patent Suits* (Feb. 6, 2008) http://www.patentdocs.org/2008/02/invitrogen-and.html (patent settlement in which defendant agreed to discontinue its product and make a payment in exchange for royalty fees from plaintiff on another patent).

characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement"). But the Government does not argue that the mere *existence* of consideration to the defendant is unusual—indeed it concedes that "any settlement that a defendant accepts presumably affords some benefit that the defendant would not receive if it litigated the suit *and lost*." Pet. Br. 30. Rather, the Government takes issue with the *amount* and nature of the consideration. *Ibid*. Yet as the courts of appeals have held, given the risks at stake, the amount and nature of the payment (let alone its mere existence) do not serve as a reliable indicator of the competitive effects of a patent-litigation settlement agreement. Pet. App. 31a-32a ("[w]hen hundreds of millions of dollars of lost profits are at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.") (internal quotation marks omitted); *Tamoxifen*, 466 F.3d at 208-09 (any suspicion about a reverse-payment "abates upon reflection" for "so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of a patented product").

c. Nor is the scope-of-the-patent approach a rule of *per se* legality; it is incorrect that this approach "gives no meaningful antitrust scrutiny to reverse-payment agreements." Pet. Br. 17. First, a focus on the patent's "potential exclusionary power" does *not* mean that all reverse-payment settlements of patent litigation are immune from antitrust attack: "[a] patent holder and any of its challengers cannot enter

into an agreement that excludes more competition than the patent has the potential to exclude." Pet. App. 20a. To be within the scope-of-the-patent test, the settling parties cannot agree, for example, to defer generic entry beyond the patent term, impose restrictions on products unrelated to the intellectual property rights at issue, or manipulate the generic first-filer's 180-day marketing exclusivity. Similarly, a patentee who sues on a patent it knows is invalid or not infringed, or was obtained by fraud, would be subject to antitrust scrutiny for seeking to obtain more exclusion than the patent grant provides. Pet. App. 28a n.10. The sham and fraud requirements are "not artificial obstacles to recovery," but rather are "essential components of real market injury" in this context. *Brooke Grp. Ltd.* v. *Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 226 (1993). By weeding out agreements that seek to extend the patent's exclusionary potential, the inquiries of (i) sham litigation, (ii) fraud on the PTO, and (iii) conduct beyond the patent's exclusionary potential, reflect the appropriate calibration of the antitrust analysis.

d. Finally, the Government claims that the scope-of-the-patent approach upends the balance that Congress sought to achieve through Hatch-Waxman between encouraging generic entry and incentives for innovation. Pet. Br. 32. Yet when Congress last acted in the Hatch-Waxman sphere, enacting the MMA in 2003, Congress did not implement any provisions outlawing reverse-payment settlements or declaring them presumptively illegal. *See* MMA, Pub. L. No. 108-173, 117 Stat. 2066. In the years since, Congress has repeatedly declined to enact legislation addressing reverse-payment settlements despite the introduction of numerous bills including such a legis-

lative change. *See* H.R. 3995, 112th Cong. (2012); S. 27, 112th Cong. (2011); S. 3677, 111th Cong. § 746 (2010); H.R. 4899, 111th Cong. § 4201 (2010); H.R. 3962, 111th Cong. § 2573 (2009); H.R. 1706, 111th Cong. (2009); S. 369, 111th Cong. (2009); S. 316, 110th Cong. (2007); H.R. 1902, 110th Cong. (2007); H.R. 1432, 110th Cong. (2007); S. 3582, 109th Cong. (2006). A new bill was recently introduced in the Senate, again containing provisions that would render presumptively unlawful a patent litigation settlement where (i) an ANDA filer receives "anything of value"; and (ii) the ANDA filer "agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time." S. 214, 113th Cong. (2013). To the extent that a new rule should be applied to reverse-payment settlements, it is Congress that should act, with appropriate legislative attention to the complexities and nuances of new statutory rules.

B. Under the Scope-of-the-Patent Approach, the Complaint Failed to State a Claim.

The FTC's Complaint failed to allege that the settlements' terms exceeded the '894 patent's exclusionary potential. It likewise failed to allege that the '894 patent was procured by fraud. And it failed to allege that Solvay's suits against Watson and Par/Paddock to enforce the patent were shams. Accordingly, the district court properly dismissed the Complaint for failure to state a claim.

CONCLUSION

For the foregoing reasons, the judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

DAVID A. BUCHEN
ACTAVIS, INC.
Morris Corp. Center III
400 Interpace Parkway
Parsippany, NJ 07054

CLIFFORD M. SLOAN
Counsel of Record
STEVEN C. SUNSHINE
JULIA K. YORK
SKADDEN, ARPS,
SLATE, MEAGHER &
FLOM LLP
1440 New York Ave., NW
Washington, DC 20005
(202) 371-7000
cliff.sloan@skadden.com

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