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 OF *AMICUS CURIAE* WASHINGTON LEGAL FOUNDATION IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Whether a complaint alleging that lawful competition has been injured because patent litigants entered into a settlement agreement states a claim under the antitrust laws when there is no dispute that:

(1) the agreement was within the scope of the patent, in that it excluded no more competition than the claims of the patent,

(2) the patent was not procured by fraud, and

(3) the patent claim being settled was not objectively baseless.

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INTEREST OF *AMICUS CURIAE* [1]

The Washington Legal Foundation ("WLF") is a nonprofit public interest law and policy center with supporters in all 50 States. WLF regularly participates as *amicus curiae* in federal and state court proceedings to promote economic liberty, free enterprise, and a limited and accountable government. To that end, WLF has appeared in numerous cases related to patent rights and antitrust law. In particular, WLF participated as an *amicus* before the Third Circuit in *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012), and before the Eleventh Circuit in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006), a decision addressing the very same patent settlements at issue here and reached a conclusion opposite from the Third Circuit's.

WLF successfully challenged the constitutionality of Food and Drug Administration (FDA) restrictions on speech relating to off-label uses of FDA-approved drugs. *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000). WLF has also filed briefs in numerous cases involving the sort of "reverse payments" alleged to be at issue here, including proceedings in state and federal court and before the Federal Trade Commission ("FTC").

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[1] Pursuant to Rule 37.6, *amicus curiae* affirms that no counsel for any party authored this brief in whole or in part, and that no person other than *amicus* or its counsel made a monetary contribution intended to fund the preparation or submission of this brief. All parties have consented in writing to the filing of this brief.

WLF believes that both "innovator" and generic manufacturers play an important role in delivering quality health care to the American public. The antitrust standard advocated by the Petitioner here and embraced by the Third Circuit in *K-Dur* would (1) deprive the holders of drug patents of critically important legal rights that are core attributes of any patent and (2) unduly burden the efforts of generic drug makers to bring their product to market through Hatch-Waxman challenges. By contrast, the Court of Appeals below correctly applied the majority rule protecting the right of patent litigants to enter into agreements no more exclusionary than the patent itself.

WLF therefore submits this brief in support of the Respondents and urges the Court to affirm the judgment below.

PRELIMINARY STATEMENT

The Court has been asked, explicitly by the parties and implicitly by the circuit courts, to choose a standard governing the antitrust analysis of agreements that settle patent litigation concerning generic drugs. The choice is stark.

On the one hand is the so-called "scope of the patent" test, which holds that agreements within the exclusionary effect of a patent do not injure lawful competition unless the patent was procured by fraud or the infringement claim was a sham (*i.e.*, "objectively baseless"). Under this standard, the patent holder's right to exclude infringing competition is fully respected unless the antitrust plaintiff can demonstrate that the patent had no exclusionary effect at all.

This is the test of the Second, Eleventh, and Federal Circuits, applied to settlements under the Hatch-Waxman Act in six separate appellate opinions. It is the test of Judge Richard Posner, who first articulated it when sitting by designation in *Asahi Glass Co v. Pentech Pharmaceuticals, Inc.*, 289 F. Supp. 2d 989, 994 (N.D. Ill. 2003). It is the test applied by the late Judge David Trager in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005) (*Cipro II*). Judge Trager was the former Dean of the Brooklyn Law School before being appointed to the bench by President Clinton, and (prior to the *K-Dur* opinion noted below) his opinions in the *Cipro* case had been cited with approval by every circuit court to address the issue of "reverse payments."[2] Indeed, the scope of the patent test is the test advocated by the most recent past General Counsel of the FTC, who concluded prior to joining the FTC that the most appropriate "proposed standard is the sham standard [of] Judge Posner [in *Asahi Glass*]." Kent S. Bernard

[2] *E.g.*, *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1313 (11th Cir. 2012); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 604 F.3d 98, 106 (2d Cir. 2010) (affirming Judge Trager), *cert. denied*, 131 S. Ct. 1606 (2011); *In re Ciprofloxacin Hydrochloride Antitrust Lit.*, 544 F.3d 1323, 1336-37 (Fed. Cir. 2008) (affirming Judge Trager), *cert. denied*, 557 U.S. 920 (2009); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007); *Schering-Plough*, 402 F.3d at 1068; *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F. 3d 1294, 1304 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004); *cf. In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 907-08 nn.12-13 (6th Cir. 2003) (approving Judge Trager's conclusion that the settlement in *Cardizem*, unlike *Cipro*, imposed restraints beyond the exclusionary effect of the patent).

& Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 Fed. Cir. B.J. 617, 632 (2006) ("Bernard & Tom").

On the other hand is the standard of presumptive illegality advocated here by the Solicitor General and the FTC ("the Government"). Under this test, any Hatch-Waxman settlement with "payments" to the generic challenger is presumptively anticompetitive. Under this test, the patent holder's right to exclude infringing competition plays no role whatsoever: the presumption applies whether or not the generic drug was infringing, and it may *not* be rebutted by any showing of actual infringement. (PB 37-39, 53-55.)

In contrast to the scope of the patent test, this "presumptive liability" test is that of a single circuit court, that is, the Third Circuit in *K-Dur*. It is a test that the FTC has advocated by supplying differing and inconsistent rationales since it lost on appeal in *Schering-Plough*, 402 F.3d 1056. This is the test that the Solicitor General has described, on at least three prior occasions when asked by the Court to address this issue, as bad law and bad policy: "[T]he public policy favoring settlements, and the statutory right of patentees to exclude competition within the scope of the patent, would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payments to automatic *or near-automatic* invalidation." U.S. Br. at 10-11, *Schering-Plough*, 548 U.S. 919 (2006) (No. 05-273) ("*Schering-Plough* Br."). That was when the Solicitor General described as erroneous "the FTC's view [that] the presence of a reverse payment … has necessarily rendered consumers worse off and lessened competition …." *Id.*

at 12. This, then, is a test of antitrust law that would render what the Solicitor General called the "right of patentees to exclude competition within the scope of the patent," *id.* at 10-11, a dead letter.

STATEMENT OF THE CASE

AndroGel is a testosterone replacement medication used to treat hypogonadism. (J.A. 28, at ¶¶ 31-33.). Respondent Solvay Pharmaceuticals, Inc. ("Solvay") controls the patent rights relating to AndroGel. The principal patent at issue here, the '894 patent, issued in January 2003 and expires in August 2020. (J.A. 39.)

In May 2003, Respondent Actavis, Inc., then known as Watson Pharmaceuticals, Inc., filed an Abbreviated New Drug Application ("ANDA") with the FDA pursuant to the Hatch-Waxman Act. *See* Drug Price Competition and Patent Term Restoration [Hatch-Waxman] Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of Titles 15, 21, and 35 U.S.C.). The ANDA requested approval to market a generic version of AndroGel. (J.A. 39.) Because Watson also sought to enter the market prior to the expiration of the '894 patent, it included a "Paragraph IV" certification stating that its product would not infringe the patent. (*Id.*)

A second generic applicant, Respondent Paddock Laboratories, Inc., filed another "ANDA IV" as to AndroGel shortly afterward. (J.A. 39.) Paddock would later partner with Respondent Par Pharmaceuticals Companies, Inc. in exchange for distribution rights as to its generic Androgel product. (J.A. 40.)

Solvay's predecessor filed suit in August 2003 for infringement of the '894 patent against both generic companies. (J.A. 40.) Because it did so within 45 days of being notified of the ANDAs, Solvay received an automatic 30-month stay during which the FDA could not finally approve either ANDA.

After three years of litigation, the parties settled the cases in September 2006. The agreements gave both generic challengers the right to launch their products in August 2015, five years before the '849 patent expires. (J.A. 46, 49.)

The settlements also included separate agreements for promotional and manufacturing services. Watson agreed that its sales force would promote AndroGel to urologists, and Solvay agreed to pay Watson a portion of such sales. (J.A. 45.) Par agreed to promote AndroGel to primary care physicians until 2012 in exchange for $10 million annually. (J.A. 49.) Paddock agreed to provide Solvay with backup manufacturing capacity until 2012 in exchange for $2 million annually. *Id.* The total payments by Solvay amounted to less than 10% of its AndroGel revenues at the time. (J.A. 28.)

After two years of investigation, the FTC filed suit against the settling parties. The complaint alleged that the separate agreements were not "independent" transactions, because Solvay overpaid for the services. (J.A. 50-53.) That "payment" allegedly caused the generic parties to accept a later entry date than they would have otherwise. (*Id.*) The FTC also alleged the patent holder was "not likely to prevail" in the patent suits. (J.A. 53.) The FTC did not allege that the settlement went beyond the scope of the patent,

that the patent was procured by fraud, or that the patent claim was objectively baseless.

The district court dismissed the FTC's complaint, rejecting the argument that settlements with reverse payments should be presumptively unlawful. (Pet. App. 51a.) The Eleventh Circuit affirmed, applying its "scope of the patent" test, which provides that, in the absence of procurement fraud or sham litigation, a settlement within the scope of a patent cannot injure competition. (Pet. App. 17a.) The circuit court also rejected the allegation that the patent was "likely" to fail, noting that "it is simply not true that an infringement claim that is 'likely' to fail actually will fail." (Pet. App. 30a.)

Shortly after the Eleventh Circuit ruled, a panel of the Third Circuit issued its *K-Dur* opinion. 686 F.3d 197. *K-Dur* accepted the FTC's proposed standard and held that Hatch-Waxman settlements with reverse payments are presumptively illegal. The court expressly rejected the scope of the patent test of the other circuits and stated that, in performing the antitrust analysis, "there is no need to consider the merits of the underlying patent suit …." *Id.* at 218.

This Court granted the FTC's petition for certiorari in this case and has not yet ruled on the petitions in *K-Dur*. Before this Court, the FTC no longer advances the theory that the generic defendant was "likely" to win, and in fact describes that test as "doctrinally anomalous and likely unworkable." (PB 53.) Instead, its proposed standard is similar to that of *K-Dur*. It would impose a presumption of illegality on all Hatch-Waxman "settlements that involve a reverse payment (or its functional equivalent) from the plaintiff to the defendant." (PB 46.) While less

than clear as to the definition of "payment" or "functional equivalent," the Government stresses that all a plaintiff need show is the presence of a reverse payment to trigger the presumption of illegality. (PB 46.) The patent merits are simply never to be considered in any attempt to rebut the presumption. (PB 37-39, 53-55.) The Government states that there are "two primary ways in which the parties to a reverse-payment settlement ... could rebut the presumption," (PB 37), but neither one relates to whether the generic product was infringing and hence unlawful. Under this proposed test, like the Third Circuit's test, "the merits of the underlying patent suit" are of no consequence. *K-Dur*, 686 F.3d at 218. The patentee's right to exclude is simply excluded.

SUMMARY OF ARGUMENT

I. The test of presumptive illegality advanced by the Government here lacks any support in this Court's decisions, in antitrust and patent policy, or in simple logic. Two fundamental fallacies in the Government's reasoning demonstrate why.

A. The first is the failure to recognize that the patent holder's right to exclude infringing competition is not merely the central question in the analysis — it is the *only* reason why virtually all patent settlements and patent licenses do not fit the definition of per se illegal market division agreements. *E.g.*, XII Herbert Hovenkamp, *Antitrust Law* ¶ 2040b (2d ed. 2005) ("[Licensing] agreements would generally be classified … as per se unlawful naked horizontal market divisions" in the "absence of a patent.") (footnote omitted)); *see also Valley Drug*, 344 F.3d at 1304 ("This is not … a case [of market

division], however, because one of the parties owned a patent.").

This point dooms any attempt to articulate a standard — such as the one the Government advances — that neither includes nor accounts for the patent holder's potential ability to exclude the generic product as infringing. Because the antitrust laws do not protect unlawful competition, the controlling question is whether the competition being "excluded" is infringing and should be kept out, or is non-infringing and should be allowed in. In the antitrust analysis, the amount of consideration paid or the direction in which it flowed is wholly irrelevant. Unless the antitrust plaintiff demonstrates that the allegedly excluded competition was lawful, there is no effect on competition no matter how much was paid. On the other hand, if the patent claim was objectively baseless and the generic product non-infringing, the patentee could hardly defend the settlement by claiming that it did not pay much cash for it.

This point also exposes the error in the Government's repeated claims that a "quick look" analysis or some other heightened form of scrutiny is proper here because a reverse payment settlement "resembles" a market division agreement. (PB 15, 19-20, 34-35.) If we ignore the patent right, the resemblance is not simply strong, but virtually perfect. But add the patent right, and there is no meaningful resemblance at all. The crucial difference is the underlying legal right to engage in the conduct. If one adopts a standard that ignores that right, there will be nothing to take a "quick look" at.

B. The second fallacy in the Government's analysis is its false assumption that, when parties to

a Hatch-Waxman dispute negotiate a settlement, only the position of the generic challenger corresponds to the competitive interest of consumers. (PB 28.) But that simply assumes the answer to the very question being litigated and settled. If we knew in advance that the patent holder would lose the patent case, the Government's assumption might hold. But it is equally true that, if we knew the patentee would win, the competitive interest of consumers would be precisely the opposite. If the generic product would infringe a valid patent, consumers would *suffer* by early generic entry, as their competitive interest in innovation would be diminished. Bernard & Tom, *supra*, 15 Fed. Cir. B.J. at 622 ("[I]f the settlement prevents infringing entry, such prevention in itself is a *pro-competitive* effect." (emphasis added)).

It is simply not true that all consumers prefer the short-run benefits of lower generic prices to the long-run benefits of newly discovered, life-saving drugs. Only by adopting this one-sided and unsupported view of the consumer's competitive interest can the Government articulate any theory of competitive harm.

Even granting its false assumption, however, the Government's test remains logically and legally flawed. The Government concedes that not all cases can be settled with the "ideal" term-splitting settlement it imagines. Because parties to these settlements place very different values on the duration of any license, there is often no specific entry date that both can accept. Likewise, differing assessments of the strength of the patent claim and differing attitudes toward risk aversion — factors

that the Government simply ignores — show that other consideration, such as cash, is often necessary to bridge the settlement gap. The Government's response, that parties in such a situation should be forced to litigate to judgment rather than settle, describes a competitive interest unknown to antitrust.

Legally, of course, the potential existence of a settlement the Government deems "more "competitive" is not sufficient to show that the settlement actually reached was unreasonable. *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415-16 (2004) ("The Sherman Act ... does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition." (internal quotation marks and citation omitted)). Patent litigants "who wish only to settle the present litigation" are not required "to act as unwilling private attorneys general" for consumers — or at least those consumers that the Government seems to prefer. *Nestle Co. v. Chester's Market, Inc.*, 756 F.2d 280, 284 (2d Cir. 1985).

II. The test advanced by the Government would accomplish a radical revision to established antitrust and patent law principles. This Court's decisions have, for well over a century, acknowledged and protected the right of patent holders to enter into agreements no more exclusionary than the patent itself. The Government offers no limiting principle to its theory, which would distinguish patent licenses entered into outside of litigation from licenses entered into in settlement of litigation. The test advanced would thus endanger all such agreements,

including commonplace license terms widely used since the Constitution was adopted.

The right to enter into agreements concerning the use of a patented invention on any terms that do not extend the patent's scope is one of the oldest and most secure of all patent rights. *E.g.*, *United States v. Gen. Elec. Co.*, 272 U.S. 476, 489 (1926) ("[T]he patentee may grant a license … for any royalty or upon any condition the performance of which is reasonably within the … patent …."). This Court's decisions establish that a patentee may grant a single license, many licenses, or none at all. Yet the Government argues that the parties to a Hatch-Waxman suit not only *must* grant a license in settlement, but a license that is as long as the "ideal" term-splitting license it posits.

This Court's decisions further establish that a patentee may restrict its license by telling the licensee when it may sell, where it may sell, to whom it may sell, and how much it may sell. Yet the Government's theory would impose treble damages on the parties to a Hatch-Waxman suit if they include *any* term in the license other than the generic challenger's entry date. The Government provides no theory of competitive harm remotely justifying this proposal "to work a revolution in patent law." *Cipro II*, 363 F. Supp. 2d at 529.

Nor will the Government's test be limited to actual payments. The FTC recently attempted (without success) to persuade two district courts in the Third Circuit that Hatch-Waxman settlements that include exclusive licenses (or that convey to the generic party anything of "value") should be deemed for that reason to contain "reverse payments" within the meaning of

the *K-Dur* decision. This further demonstrates that the Government's standard has no limiting principle. Just as it cannot be limited to settlements, as opposed to licenses, it cannot be limited to payments, as opposed to other classical license terms.

III. As dangerous as the Government's standard is for routine patent agreements, it inflicts even more harm in the context of settlement. After all, settlement agreements produce a variety of independent pro-competitive effects that should make the Court even less receptive to the Government's attempt to redefine competition here. Settlements promote consumer welfare and conserve judicial resources to such a degree that one treatise has suggested that "some agreements that would be unlawful if undertaken in the absence of a reasonable dispute may be lawful when used to settle a bona fide [patent] dispute." XII Hovenkamp, *supra*, ¶ 2046, at 309.

The Government's implication that Congress somehow limited the rights of parties to Hatch-Waxman suits to settle cannot be supported. There is no indication in the statute or its enactment history that Congress intended the rules affecting patent litigation to change — just the opposite. It defies credulity to argue that, in setting up a process that expressly included patent *litigation*, Congress also intended to work a fundamental and unprecedented restriction on the right to settle without saying so. *Cf. Am. Bar Ass'n v. Fed. Trade Comm'n,* 430 F.3d 457, 467 (D.C. Cir. 2005) ("Congress does not … hide elephants in mouse holes." (quoting *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001))).

ARGUMENT

The parties and other *amici* have demonstrated that the scope of the patent test is firmly grounded in this Court's decisions, such as *Bement v. National Harrow Co.*, 186 U.S. 70 (1902), *Standard Oil Co. v. United States*, 283 U.S. 163 (1931), and *Walker Process Equipment, Inc. v. Food Machinery & Chemical Co.*, 382 U.S. 172 (1965). (*See, e.g.*, Par/Paddock Br. at 39-44 (discussing *Standard Oil*); *id.* at 46-51 (discussing *Walker Process*).) None of these decisions was mentioned by the Third Circuit in *K-Dur*, and none are discussed by the Government here. The focus of this discussion is not on the test properly applied below, but on the Government's proposed standard. Here, we analyze the false premises from which it proceeds (Section I) and the dire consequences it portends for the conduct of business concerning patents (Sections II & III).

I. THE GOVERNMENT'S ATTEMPT TO JUSTIFY A STANDARD OF PRESUMPTIVE ILLEGALITY RESTS ON TWO ESSENTIAL FALLACIES

A. The Legality Of Agreements Concerning Patent Rights Depends Fundamentally On The Patentee's Right To Exclude.

As shown above, the Government's proposed standard completely ignores the right of the patent holder to exclude infringing competition. (*Supra*, pp. 7-8.) That essential right is not considered at all in imposing the presumption of illegality, nor deemed relevant to any attempt to rebut it. (*Id.*) The Government's proposal is not only unprecedented,

but unmoored to any concern grounded in *competition* policy.

The core fallacy in any antitrust standard that ignores patent rights is this: the patent holder's right to exclude infringing competition is not merely the central question in the analysis — it is the *only* reason why virtually all patent settlements and patent licenses do not fit the definition of per se illegal market division agreements. XII Hovenkamp, *supra*, at ¶ 2040b ("[Licensing] agreements would generally be classified … as per se unlawful naked horizontal market divisions" in the "absence of a patent." (footnote omitted)); *see United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981) ("[A] patent by definition restrains trade, and in effect makes most exclusive patent licenses per se violations of the antitrust laws.").

The existence of the patent, and the right it grants to exclude infringers, controls the antitrust analysis for a simple reason. The antitrust laws do not protect unlawful competition, [3] including products that infringe a patent: "[T]he public [i]s not entitled to profit by competition among infringers." *Rubber Tire*

[3] *In re Canadian Import Antitrust Litig.,* 470 F.3d 785, 790-92 (8th Cir. 2006) (finding no antitrust liability for precluding illegal importation of drugs); *see also, e.g.*, *RSA Media, Inc. v. AK Media Group, Inc.*, 260 F.3d 10, 15 (1st Cir. 2001) (holding that because RSA was legally ineligible to compete, "[a]ny injury suffered by RSA is therefore unrelated to AK's allegedly exclusionary conduct …."); *Access Telecom, Inc. v. MCI Telecomms. Corp.,* 197 F.3d 694, 712-13 (5th Cir. 1999) ("If there is no legal U.S. export market …, then there is no antitrust injury.").

Wheel Co. v. Milwaukee Rubber Works Co., 154 F. 358, 364 (7th Cir. 1907); *Hynix Semiconductor Inc. v. Rambus Inc.*, 527 F. Supp. 2d 1084, 1096 (N.D. Cal. 2007) ("[A]n infringer" has "no legal right to be competing in the product market."); *Monarch Marking Sys., Inc. v. Duncan Parking Motor Maint. Co.*, No. 82C2599, 1988 WL 5038, at *5 (N.D. Ill. Jan. 19, 1988) ("Neither [plaintiff] nor consumers have a right to the sale of labels which infringe Monarch's patents."), *partially vacated on other grounds*, 1988 WL 23830 (N.D. Ill. Mar. 8, 1988); Richard A. Posner, *Economic Analysis of Law* 91 (5th ed. 1998) ("We do not want an efficient market in stolen goods.").

The controlling question is whether the competition being "excluded" is infringing and should be kept out, or is non-infringing and should be allowed in. Even former Commissioner Leary, the author of the FTC's *Schering-Plough* opinion, conceded that actual competitive harm could not be divorced from the merit of the patent claim: "If a patent is valid, the pioneer manufacturer is entitled to its monopoly profit, and a settlement that merely transfers a portion of that profit to a potential generic manufacturer *causes no harm*." Thomas B. Leary, *Antitrust Issues in Settlement of Pharmaceutical Patent Disputes*, 14 ABA Antitrust Healthcare Chron. 1, 6 (Winter 2000/2001) (emphasis added).

The Eleventh Circuit thus explained in *Valley Drug* that, in evaluating a Hatch-Waxman settlement, the patent makes all the difference:

> If this case merely involved one firm making monthly payments to potential competitors in return for their exiting or refraining from entering the market, we

> would readily affirm the district court's order. *This is not such a case, however, because one of the parties owned a patent*.

344 F.3d at 1304 (emphasis added). What matters to the antitrust inquiry is the character of the allegedly excluded competition, not the consideration paid or the direction in which it flowed. *Id.* at 1309 ("The failure to produce the competing … drug, rather than the payment of money, is the exclusionary effect."). If the antitrust plaintiff cannot demonstrate that the allegedly excluded competition was lawful, there is no effect on competition no matter how much was paid. On the other hand, if the generic product were known to be non-infringing, the patentee could hardly defend the deal by pointing out that the consideration was something other than cash. In all but the rarest cases, the only justification can be that the licensee had no independent right to be in the market — because of the patent.[4]

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[4] As the Respondents have demonstrated in their merits briefs, this point makes the scope of the patent test the only one that properly accounts for the patentee's right to exclude. (*E.g.*, Solvay Br. at 38-41.) The tools of antitrust litigation will allow a court to measure with appropriate confidence whether a claim was objectively baseless or not. Beyond that, an attempt to "relitigate" the patent case in a later antitrust case is not only speculative, *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 his case."), but pointless. When, as here, the claim was brought in good faith (*i.e.*, with probable cause), we already know that either side could have won. Having a later antitrust jury pick a winner on a given date adds nothing to the antitrust analysis. By definition, another jury could reasonably disagree. "It is not 'bad faith' … to assert patent rights that one is not certain will be upheld in a suit for infringement pressed to judgment and to

The D.C. Circuit recognized the flaw in the Government's approach decades ago in *Studiengesellschaft*, 670 F.2d 1122. There, because the district court conducted a rule of reason analysis that gave no weight to "the scope of patent protection, ... its method of analysis had the effect of applying a per se rule." *Id.* at 1128. But that simply dictated an erroneous outcome: "[O]nce the protection of the patent was removed, the license conditions, like the patent itself, inevitably had the effect of restricting competition." *Id.*

This point reveals the error in the Government's repeated claims that a "quick look" analysis or some other heightened form of scrutiny is proper here because a reverse payment settlement "resembles" a market division agreement. (PB 15, 19-20, 34-35.) If the right to exclude is deemed irrelevant, that resemblance is quite striking. But add the patent right, and there is no meaningful resemblance at all. The Government's repeated citation to *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990) (PB I, 20, 24), actually illustrates its error. There, the parties were *current* competitors who agreed to divide their market. There was no suggestion that anyone's intellectual property rights precluded competition in any way. The subsequent agreement allowed one of the parties to use the other's trademark, but they had competed for years without any such provision. *Id.* at 48-49. Thus, saying that a patent settlement with payments resembles the agreement in *Palmer* is like

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settle the suit to avoid risking the loss of the rights. No one can be *certain* that he will prevail in a patent suit." *Asahi Glass*, 289 F. Supp. 2d at 993 (original emphasis).

saying that a soldier's firing his weapon in battle resembles the act of an assassin and so should be presumed unlawful. The crucial difference is the underlying legal right to engage in the conduct.

"Quick look" antitrust scrutiny applies only where "the great likelihood of anticompetitive effects can be easily ascertained," or "a confident conclusion about the principal tendency of a restriction may be drawn." (PB 34 (quoting *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 770-71 (1999)). That condition obviously cannot be met when, without accounting for the question of infringement, we do not know that the settlement threatened competition at all.

B. The Government's One-Sided Concept Of The Consumer Interest In Patent Settlements Is Unsupported And Wrong

1. There can be no antitrust claim without an injury to competition. "The law directs itself not against conduct which is competitive, … but against conduct which unfairly tends to destroy competition itself." *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993). In attempting to articulate a theory of harm to competition that ignores the patent right, the Government imagines an ideal settlement in which the patent litigants negotiate over one term only, *i.e.*, "a compromise date of generic entry." (PB 27.)

But the Government must also concede that, if the patent is to be ignored, this ideal term-splitting license would also be a market division agreement. (PB 27-28 ("[S]uch a compromise settlement of paragraph IV litigation will entail the parties' agreement not to compete ….").) To solve that

problem, the Government offers a rationale that redefines the meaning of competition. It argues that a settlement negotiation limited to a generic entry date "has the practical effect of aligning [the generic's] interests in paragraph IV litigation with that of consumers, who benefit from the lower prices that generic competition provides." (PB 28.)

This assumption — that when parties to a Hatch-Waxman dispute negotiate a settlement, only the position of the generic challenger corresponds to the competitive interest of consumers — is false. Indeed, it simply assumes the answer to the very question being litigated and settled. If we knew in advance that the patent holder would lose the patent case, the Government's assumption might hold. But it is equally true that, if we knew the patentee would win, the competitive interest of consumers would be precisely the opposite. If the generic product would infringe a valid patent, consumers would *suffer* by early generic entry, as their competitive interest in innovation would be diminished.

> Even in ordinary industries, the undercutting of the reward for innovation is a much more serious matter than is the loss of an opportunity for price reductions.... Judge Easterbrook reminded us that an antitrust policy that reduces prices today, even by a substantial amount, at the expense of a small annual reduction in the rate at which innovation occurs "would be a calamity." Pharmaceuticals, however, are no ordinary industry.

Bernard & Tom, *supra*, 15 Fed. Cir. B.J. at 623 (quoting Frank H. Easterbrook, *Ignorance and Antitrust*, in *Antitrust, Innovation, and Competitiveness* 119, 123 (Thomas M. Jorde & David J. Teece eds., 1992)).

The Government's one-sided definition of competition is insupportable, because the benefits of protecting valid patents are not simply pro-consumer, but *pro-competitive*. *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 876 (Fed. Cir. 1985) (recognizing the right to exclude infringers "serves a very positive function in our system of competition"); Charles F. Rule, *Patent-Antitrust Policy: Looking Back and Ahead*, 59 Antitrust L.J. 729, 730 (1991) (stating that the existence and protection of patent rights "driv[e] economic growth and increas[e] consumer welfare.") As a result, the exclusion that accompanies a settlement may just as easily be characterized as procompetitive (for excluding potentially infringing entry) as anticompetitive (for excluding potentially non-infringing entry). Bernard & Tom, *supra*, 15 Fed. Cir. B.J. at 622 ("[I]f the settlement prevents infringing entry, such prevention in itself is a pro-competitive effect."). As the Solicitor General once told this Court, "legitimate patent settlements ... further the important goals of encouraging innovation and minimizing unnecessary litigation." U.S. Br. at 8-9, *Tamoxifen*, 551 U.S. 1144 (2007) (No. 06-830) ("*Tamoxifen* Br.").

The Government's brief pays lip service to this procompetitive effect, (PB 45 ("[P]reserv[ing] the incentives to innovate … benefit[s] consumers in the long run.")), but it finds no place in the Government's one-sided definition of consumer harm. The FTC's

former General Counsel has pointed out the flaw in this approach: "It is inappropriate to use an analytical model in which the benefits of price competition on one side of the equation are taken into account, but the benefits of innovation on the other side of the equation are not." Bernard & Tom, *supra*, 15 Fed. Cir. B.J. at 621. If that mistake is made, "it is easy to get to a conclusion of presumptive illegality." *Id.* at 622.

It is simply not true that all consumers prefer the short-run benefits of lower generic prices to the long-run benefits of newly discovered, life-saving drugs. Only by adopting this crabbed view of the consumer's competitive interest can the Government articulate *any* theory of competitive harm.

2. Even with its false assumption, however, the Government's test is logically and legally flawed.

a. The Government concedes that not all cases can be settled with the "ideal" term-splitting settlement it imagines. (PB 40 ("To be sure, ... a rule discountenancing reverse payments may cause the parties to litigate to judgment.").) There are several reasons why.

Because the generic entrant will charge a lower price than the innovator charges, the parties to these settlements place highly different values on the duration of any license. Thus, there will often be no specific entry date that both can accept. *See* Mark G. Schildkraut, *Patent Splitting Settlements and The Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1067 (2004). For example, suppose the parties are only $10 million apart in negotiations. If the generic needs six more months to generate that much extra

profit, but those six months will cost the innovator $30 million in profit, no settlement will happen. In such a case, a $10 million payment bridging that gap does not shorten the license; it makes the license possible.

In addition, differing assessments of the strength of the patent claim and differing attitudes toward risk aversion show that other consideration, such as cash, is often necessary to achieve any settlement. Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391, 408 (2003) ("This is not to say that such payments are necessarily anticompetitive if other factors are brought into the analysis, such as risk aversion and asymmetric information about market conditions, as 'reverse cash payments' may be important in more complex settings for successful settlement.").

To solve this problem, the Government proposes a codicil to its already creative redefinition of competition: that the antitrust laws *prefer* that such parties should be forced to litigate to judgment rather than settle. (PB 40 ("But 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.").) No authority is cited to support this curious claim, because none is available. Such a proposition is directly contrary to this Court's decision in *Standard Oil*, 283 U.S. at 171 (holding that a settlement of patent disputes "by agreement, rather than litigation, is not precluded by the [Sherman] Act."). The Government's novel

proposition thus describes a competitive "interest" unknown to antitrust.

b. The Government's preference for a pure term-splitting settlement also founders legally. Simply because the FTC deems such a settlement "more competitive" is not sufficient to show that the settlement actually reached was unreasonable. *Trinko*, 540 U.S. at 415-16 (2004) ("The Sherman Act ... does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition." (internal quotation marks and citation omitted)).[5] Accordingly, so long as the settlement excludes no more competition than does the patent itself, "consumers have no right to second-guess whether some different agreement would have been more palatable." *Cipro II*, 363 F. Supp. 2d at 536 (citing *Trinko*, 540 U.S. at 415-16); *see also, e.g.*, *Nestle Co.*, 756 F.2d at 284 (litigants, "who wish only to settle the present litigation," are not required "to act as unwilling private attorneys general" for consumers.).

[5] *Buffalo Broad. Co. v. ASCAP*, 744 F.2d 917, 933 (2d Cir. 1984) (holding that an intellectual property license is "not even amenable to scrutiny under Section 1 unless it is a restraint of trade. The fact that it may be in some sense unnecessary does not make it a restraint."); *Am. Motor Inns, Inc. v. Holiday Inns, Inc.*, 521 F.2d 1230, 1249 (3d Cir. 1975) (rejecting least restrictive alternative test).

II. THE STANDARD OF PRESUMPTIVE ILLEGALITY HAS NO LIMITING PRINCIPLE AND THREATENS ESTABLISHED RIGHTS OF PATENT HOLDERS TO LICENSE THEIR INVENTIONS

The Government ignores the implications of its standard for patent licenses, but this Court cannot. Nowhere does the Government's brief offer any justification in logic or law for limiting its rule to settlement agreements. Nor could it. In nearly every settlement, the agreement in question contains a patent license. Whether that license came before or after a lawsuit has no impact on its propensity to injure competition.[6] As one of the commentators on which the Government relies has acknowledged, "[v]irtually every patent license can be viewed as a settlement of a patent dispute." Shapiro, *supra*, 34 Rand J. Econ. at 392. What prevents the FTC or any other plaintiff from arguing that the entry date for a license might have been earlier but for some other element of consideration, whether payments, favorable royalty rates, or field of use restrictions? Again, the Government has no answer.

Yet placing the established rights of patentees to license side-by-side with the circumscribed right to enter settlement agreements advocated here demonstrates just how radical the Government's proposed test really is. After all, the right to enter into agreements concerning the use of a patented

[6] As we show below (see Section III), a settlement agreement may have a slightly greater tendency to *increase* competition, a point the Government also ignores.

invention on any terms that do not extend the patent's scope is one of the oldest and most secure of all patent rights. *E.g.*, *Bement*, 186 U.S. at 92 ("[A] restraint of interstate commerce [cannot] arise from reasonable and legal conditions imposed upon the … licensee of a patent …."); *see Studiengesellschaft,* 670 F.2d at 1129 (finding no liability where the same exclusion "would have resulted from a conventional grant of an exclusive license").

This Court's decisions establish that a patentee may grant one wholly exclusive license, many licenses, or none at all. *E.g.*, *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980); IIIB Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 772c, at 212 (3d ed. 2008) ("[R]efusal to license a patent seem[s] absolutely privileged, as does the refusal to give rivals the benefit of one's R & D."). Yet the Government argues that the parties to a Hatch-Waxman suit not only *must* grant a license in settlement, but a license that is as long as the ideal term-splitting license it posits.[7] (PB 27.)

This Court's decisions also establish that a patentee may restrict any license term that does not extend the patent: It may tell the licensee when it may sell, where it may sell, to whom it may sell, and how much it may sell. *E.g.*, *Brulotte v. Thys Co.*, 379

[7] The Department of Justice made this point explicitly in briefs filed in the *K-Dur* litigation, stating that every settlement must allow a license of some duration. U.S. Br. as Amicus Curiae at 30, *K-Dur*, 686 F.3d 197 (3d Cir. 2012) (No. 10-2077) ("The defendants will be unable to carry their burden [of rebutting the presumption of illegality] if the settlement allowed no generic entry until patent expiration.").

U.S. 29, 33 (1964) ("A patent empowers the owner to exact royalties as high as he can negotiate with the leverage of that monopoly."); *Gen. Elec. Co.*, 272 U.S. at 489 ("[T]he patentee may grant a license … for any royalty or upon any condition the performance of which is reasonably within the … patent"); *see generally* 6 Donald S. Chisum, *Chisum on Patents* § 19.04[3][h] (2005) (territorial restrictions); *id.* at § 19.04[3][i] (use restrictions). Yet the Government proposes a test under which the parties to a Hatch-Waxman suit should face treble damages if they include *any* term in the license that one can argue delayed the generic challenger's entry date.

If the Court wonders why so many patent rights heretofore inviolate in the context of licenses are now to be presumptively illegal in the context of settlements, it will find no answer in the Government's brief. Judge Trager saw clearly how unlimited this presumption of illegality would be:

> If the settlement with a payment to a generic is to be subject to antitrust liability, even though it does not exceed the scope of the patent, the next antitrust challenge to a patent settlement might well take place in the context of a license with royalty .... To open royalty-bearing patent license agreements to antitrust scrutiny simply because patents are often held invalid … would undermine the settled expectations of patentees and potential infringers/licensees across countless industries.

Cipro II, 363 F. Supp. 2d at 533. As shown above, the Government provides no theory of competitive harm

remotely justifying this proposal "to work a revolution in patent law." *Id.* at 529.

As further evidence that the Government's position has no limiting principle, the FTC has demonstrated that, if the rule of *K-Dur* is adopted, it will seek to brand classic exclusive licenses as presumptively illegal "reverse payments." When *K-Dur* was decided in July of 2012, the Third Circuit tried to limit its holding to (1) cash payments, and (2) the pharmaceutical context: "We caution that our decision today is limited to reverse payments between patent holders and would be generic competitors in the pharmaceutical industry." 686 F.3d at 216. Shortly afterward, the FTC took the unusual step of filing amicus briefs in two district courts in the Third Circuit, which were bound by *K-Dur*. There the FTC argued that the term "reverse payments" would include any consideration in an agreement that provided "value" to the generic party, including a promise to keep the license wholly exclusive by allowing no other authorized generic product. *E.g.*, FTC Br. as Amicus Curiae at 10 & n.29, *In re Lamictal Direct Purchaser Antitrust Litig.*, 2012 WL 6725580 (D.N.J. Dec. 6, 2012) (No. 2:12-cv-0995) (payment may be "money *or some other valuable thing*" (original emphasis)).[8]

[8] This argument signaled another about-face for the FTC, which had for years insisted that monetary payments were different from other forms of consideration. "A settlement agreement is not illegal simply because it delays generic entry until some date before expiration of the pioneer's patent.… [T]he payment of money by Schering … is what makes this case different." *In re Schering-Plough Corp.*, 136 F.T.C. 956, 987 (F.T.C. 2003), *rev'd sub nom. Schering-Plough Corp. v. FTC*, 402

Because all settlements convey value to both parties, all settlements may now run afoul of the Government's proposed rule. "*[A]ny* settlement agreement can be characterized as involving 'compensation' to the [generic] defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements." *Asahi Glass*, 289 F. Supp. 2d at 994 (original emphasis).

The *Lamictal* Court rejected the argument and refused to find that the exclusive nature of the license was a reverse payment. 2012 WL 6725580, at *6 ("[T]he term 'reverse payment' is not sufficiently broad to encompass any benefit … to [the generic] in a negotiated settlement."). The other court declined to accept the *amicus* brief, finding the FTC too "partial" to participate. *Prof'l Drug Co. v. Wyeth Inc.*, No. 3:11-cv-05479, 2012 WL 4794587, at *2 (D.N.J. Oct. 3, 2012) ("[T]he extent to which the FTC is partial to a particular outcome weighs against granting the agency's motion.").

In sum, it is clear that the Government has articulated no limiting principle for its requested

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F.3d 1056; *see* Paying Off Generics to Prevent Competition with Brand Name Drugs: Hearing Before the S. Comm. on the Judiciary, 110th Cong. 120, 132 (2007) (prepared statement of the FTC) ("All settlements include some form of consideration flowing between the parties; *it is the type of consideration that matters* in the antitrust analysis. Some types of consideration, such as an early entry date, a royalty to the patent-holder, or compromising on a damage claim, do not generally involve sharing the benefits that come from eliminating potential competition." (emphasis added)).

standard, and that the FTC does not think any such principle necessary. The Government's rationale — that generic entry, infringing or not, is the holy grail of competition policy — does not admit one. That rationale applies as fully to other licensing terms as to payments, and as fully to licenses as to settlements.

III. NOTHING IN THE ANTITRUST LAWS OR THE HATCH-WAXMAN ACT JUSTIFIES THE GOVERNMENT'S ATTEMPT TO LIMIT THE RIGHTS OF PATENT LITIGANTS TO SETTLE

The danger to common licensing practices is not the full extent of the harm that the Government's standard portends. For there *is* a difference between settlement agreements and licensing agreements, but it cuts the other way: patent settlements have all the procompetitive benefits of patent licenses and much more. That is, settlements also produce the independent benefits flowing from the efficiencies that attend to ending litigation.

Thus, the proposition that antitrust limitations on agreements within the scope of a patent should be *more* restrictive in the context of a settlement than a license is counter-intuitive. Indeed, settlements promote consumer welfare and conserve judicial resources to such a degree that one treatise has suggested that "some agreements that would be unlawful if undertaken in the absence of a reasonable dispute may be lawful when used to settle a bona fide [patent] dispute." XII Hovenkamp, *supra*, ¶ 2046, at 309. It follows that the Government's hostility toward settlements reflected in its proposed test and arguments is not just harmful to consumers, but anticompetitive.

A. As noted, the Solicitor General has previously recognized that the fact of patent settlements alone "furthers the important goals of encouraging innovation and minimizing unnecessary litigation." *Tamoxifen* U.S. Br. at 8-9. Three such benefits bear special mention here.

First, settlements foster innovation in part because they avoid the risk of *erroneous* patent invalidation. Bernard & Tom, *supra*, 15 Fed. Cir. B.J. at 622 ("[I]f the settlement prevents infringing entry, such prevention in itself is a *pro-competitive* effect." (emphasis added)). Even Petitioner concedes that erroneous patent invalidation causes consumer harm. (*See* PB 45 ("When the brand-name manufacturer holds a strong patent, it is *likely* to prevail in litigation ... *as it should*, in order to preserve the incentives to innovate that benefit consumers in the long run." (emphasis added)).)

Second, settlements save litigants (and the public) the time and expense of trial, even if the result would have properly upheld the patent. *Bradley v. Chiron Corp.*, 136 F.3d 1317, 1322 (Fed. Cir. 1998) ("[S]ettlement reduces costs for all parties, conserves judicial and private resources, and promotes good will."); *see Marek v. Chesny*, 473 U.S. 1, 10 (1985) ("And, even for those who would prevail at trial, settlement will provide them with compensation at an earlier date without the burdens, stress, and time of litigation.").

These two reasons alone have been sufficient for the Government in the past to reject quick look scrutiny: "[T]he public policy favoring settlements, and the statutory right 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." *Schering-Plough* Br., *supra*, at 10-11 (emphasis added).

Third, the availability of Hatch-Waxman settlements fosters more patent challenges in the long run, by reducing the generic manufacturer's costs and risks. A generic manufacturer's interest in filing a Paragraph IV challenge depends in part on having the flexibility to decide when, and on what terms, to resolve the litigation rather than engage in a multi-million dollar fight to the death in every case. *See Asahi Glass*, 289 F. Supp. 2d at 994 ("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."); *accord In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 256 (E.D.N.Y. 2003) ("[A] generic company should be permitted to choose not only when to commence patent litigation, but also when to terminate it. Otherwise, the incentives to mount an ANDA IV challenge could be reduced.").

B. The Government's implication that Congress somehow limited the rights of parties to Hatch-Waxman suits to settle cannot be supported. There is no indication in the statute or its enactment history that Congress intended the rules affecting patent litigation to change. Indeed, the few indications there are in the legislative history lead to the opposite conclusion.

First, it is well known that the statute had the dual purpose of promoting generic drugs while simultaneously promoting the incentives of pioneer drug companies to innovate:

> Hatch-Waxman amended both the FDCA and the patent laws in an effort to strike a balance between two conflicting policy objectives: *to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products*, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market.

aaiPharma Inc. v. Thompson, 296 F.3d 227, 230 (4th Cir. 2002) (quotation marks and citation omitted; emphasis added).

Thus, the generic entry in question was expressly intended to be *non-infringing* entry. As Congressman Waxman explained, "as a matter of public policy we, under the patent law, give that protection to the person who has put money into research and development for an innovative and new product." 130 Cong. Rec. 24,427 (Sept. 6, 1984); *see also* H.R. Rep. No. 98-857, pt. 1, at 28 (1984) ("The provisions of this bill ... are not intended to modify existing patent law with respect to the burden of proof and the nature of proof to be considered by the courts in determining whether a patent is valid or infringed.").[9]

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[9] If a later Congress had wanted to prohibit reverse-payment settlements, it could have done so. It did not do so in 2003, when it made significant changes to the statute.

It defies credulity to argue that, in setting up a process that expressly included patent *litigation*, Congress also intended to work a fundamental and unprecedented restriction on the right to settle without saying so. *Cf. Am. Bar Ass'n v. FTC*, 430 F.3d 457, 467 (D.C. Cir. 2005) ("Congress does not … hide elephants in mouse holes." (quoting *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001))).

In sum, there is no "policy" of Hatch-Waxman that limits the rights of litigants to settle or the rights of patent holders to enter into agreements that maximize the value of a patent without extending its scope. Even if there were such a policy, it would not thereby enact a silent amendment to the *antitrust* laws. For antitrust embraces the procompetitve benefits of patents and of settlements as well as the benefits of low prices. By choosing to promote one benefit at the expense of the others, the Government's proposed standard would harm the *competitive* interest of the very consumers it pretends to champion.

Bills to ban reverse payments have been introduced in each of the last several Congresses, moreover, thus far to no avail. *E.g.*, S. 27, 112th Cong. (2011). Senator Hatch opposed a prior Senate bill to outlaw reverse payments in committee, S. Rep. No. 111-123, at 7 (2010); *id.* at 23 (bill could "effectively discourage pro-consumer settlements.")

CONCLUSION

The Court should affirm the judgment below.

Respectfully submitted,

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