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 *AMICI CURIAE* BAYER AG AND BAYER CORP. IN SUPPORT OF RESPONDENTS

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CORPORATE DISCLOSURE STATEMENT

Bayer Corporation is a wholly-owned subsidiary of Bayer World Investments B.V., a limited liability company formed under the laws of The Netherlands. Bayer World Investments B.V. is a wholly-owned subsidiary of Bayer AG. There is no publicly-held company that owns more than 10% of Bayer AG.

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STATEMENT OF INTEREST OF *AMICI CURIAE* [1]

Bayer AG and Bayer Corporation ("Bayer") are members of the Bayer Group, which develops and manufactures patented pharmaceutical products. The question presented significantly affects Bayer because it is involved in litigation as to those products, and sometimes settles such litigation.

In 1997, Bayer entered into a so-called reverse-payment settlement of litigation concerning Bayer's Ciprofloxacin patent. Various plaintiffs challenged that settlement in several federal and state courts.

Bayer won summary judgment in the consolidated multi-district litigation, based on the "scope of the patent" rule. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005) (*Cipro II*). The Second and Federal Circuits both affirmed, adopting the same reasoning. *See* 604 F.3d 98, 106 (2d Cir. 2010) (*Cipro IV*), *cert. denied*, 131 S. Ct. 1606 (2011); 544 F.3d 1323, 1336-37 (Fed. Cir. 2008) (*Cipro III*), *cert. denied*, 557 U.S. 920 (2009).

This past year, however, the Third Circuit explicitly rejected the scope of the patent rule. *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012). The resulting uncertainty affects Bayer, currently defending a state case challenging the same Cipro settlement. *In re Cipro Cases I & II*, 269 P.3d 653 (Cal. 2012).

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

SUMMARY OF ARGUMENT

1. The scope of the patent rule derives from fundamental principles of antitrust and patent law. Antitrust plaintiffs bear the burden of pleading harm to *lawful* competition. Patent law rewards innovation with a statutory monopoly of limited duration. Thus, in their mutual effort to protect competition, both bodies of law respect an innovator's right to profit by excluding others from invading the boundaries of its patent.

The Court has applied these principles on multiple occasions, including in cases mounting antitrust challenges to patent settlements. In *Bement v. National Harrow Co.*, 186 U.S. 70 (1902), and *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931), the Court concluded that the Sherman Act was not intended to prohibit restraints of trade caused by settlement agreements within the scope of a patent holder's right to exclude. The Court did not question the right of the settling parties to provide in their agreements for the full measure of the patent's protection. *Bement*, 186 U.S. at 91 ("that the conditions in the contracts keep up the monopoly … does not render them illegal"). And, where there was no dispute that the patents were asserted in "good faith," it was unnecessary to resolve any "issues concerning the validity or scope of the cracking patents." *Standard Oil*, 283 U.S. at 181.

Walker Process Equipment, Inc. v. Food Machinery & Chemical Co., 382 U.S. 172 (1965), expanded on these cases, holding that the innovator's protection from antitrust liability might be lost if the patent was procured by fraud, but otherwise that "good faith"

when acting within the patent's scope would furnish a complete defense. *Id.* at 177.

Based on these and other decisions, lower courts have long followed the scope of the patent rule. This rule, which recognizes that there is no harm to competition so long as the challenged conduct is within the scope of a patent and the assertion of the patent is in good faith (that is, not "objectively baseless"), represents the only workable compromise between the innovation and competition fostered by patent and antitrust law. Thus, application of the scope of the patent rule benefits consumers in the long run by protecting both the patentee's and the generic's incentive to bring new drugs to the market.

2. Petitioner's argument entirely ignores the patent holder's right to exclude infringing competition. Under the FTC's proposed standard, the settlement is presumed illegal without regard to the patent merits. That presumption of illegality may be "rebutted," Petitioner claims, but not by any showing that the excluded competition was, in fact, infringing. This theory fails to recognize that, if the Court ignores the right to exclude, most agreements affecting patents, whether settlements or licenses, would be per se illegal market division agreements—including the very term-splitting settlement that the FTC prefers.

Petitioner seeks to cure this flaw in its reasoning by changing the meaning of "competition" in the context of Hatch-Waxman settlements. Petitioner thus assumes that consumers benefit only from accelerated entry of generic drugs, never from preservation of patent rights. That assumption has no support in logic or law. Consumers benefit both

from short-term price declines when *non-infringing* products enter, and from long-term innovation when *infringing* products are excluded.

Petitioner can distinguish the settlements it prefers from those it does not only by employing its one-sided concept of competition. But the merits of the patent claim, which are often uncertain and are the subject of the settlement, determine where consumer interests lie. Courts have therefore concluded that, if the patent claim is not objectively baseless, the tools of antitrust litigation cannot measure the "true" interest of consumers—other than by measuring the scope of the patent. *See* Part I.C, *infra*.

No theory of competitive harm advanced by Petitioner has merit. Though the FTC has changed its theory several times, it now advances its original theory rejected in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), that the settlement actually reached is anticompetitive because a different, term-splitting settlement would have resulted in a longer generic license. The argument is wrong on the facts and the law. It is wrong factually because the pioneer and generic do not value time in the same manner. The argument is fundamentally wrong on the law as agreements are not unreasonably anticompetitive simply because Petitioner can imagine one it finds more competitive. *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."). Petitioner's test renders the

patent holder's right to exclude meaningless and conflicts with established principles of law, including but not limited to the statutory presumption of validity.

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In the end, this Court's precedent and basic principles of antitrust law require that the significance of the patentee's right to exclude be accounted for in the antitrust analysis. That alone mandates rejection of the Petitioner's test, which would "undermine the presumption of validity of patents in all cases ..., and would work a revolution in patent law." *Cipro II*, 363 F. Supp. 2d at 529. The decision below should be affirmed.

ARGUMENT

I. THIS COURT'S PRECEDENTS FULLY SUPPORT THE SCOPE OF THE PATENT RULE

A. Fundamental Antitrust And Patent Principles Establish That Agreements, Including Settlements, Within The Scope Of A Patent Cannot Harm Lawful Competition

The antitrust laws and the patent laws each promote competition, but through different means. Antitrust laws protect competition by prohibiting market distortions. *See Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 339 n.8 (1990). Patent laws promote competition by rewarding innovative products with a statutory monopoly of limited duration. U.S. Const., art. I, § 8. Because of their shared pro-competitive vision, both bodies of law respect an inventor's right to profit by actions within the scope of a valid patent.

1. **Antitrust.**

a. Harm to competition is an essential element of any antitrust claim. "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); *see also* 15 U.S.C. § 45(n) ("The Commission shall have no authority … to declare unlawful an act or practice … unless [it] causes or is likely to cause substantial injury to consumers ….").

An antitrust plaintiff bears the burden of pleading and proving competitive harm. "The burden of proof in antitrust cases remains with the plaintiff." *United States v. Arnold, Schwinn & Co.*, 388 U.S. 365, 374 n.5 (1967) (rejecting "a standard of presumptive illegality" urged by the United States), *overruled on other grounds by Cont'l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36 (1977); *see also Times-Picayune Publ'g Co. v. United States*, 345 U.S. 594, 622 (1953) ("[G]uilt cannot rest on speculation; the Government here has proved neither actual unlawful effects nor facts which radiate a potential for future harm."). The placement of this burden is especially important because the Sherman Act is both a civil *and criminal* statute. *Ill. Tool Works, Inc. v. Independent Ink, Inc.*, 547 U.S. 28, 45 (2006) ("[I]t would be unusual for the Judiciary to replace the normal rule of lenity that is applied in criminal cases with a rule of severity for a special category of antitrust cases."). Any contrary rule would violate the due process principle "that regulated parties should know what is required of them so they may act accordingly." *FCC v. Fox TV Stations, Inc.*, 132 S. Ct. 2307, 2317 (2012).

The plaintiff's burden necessarily includes proof that the allegedly excluded competition is *lawful*. Otherwise, antitrust law is not necessary "to protect the public from the failure of the market," because there is no lawful market. *Spectrum Sports*, 506 U.S. at 458; *see, e.g.*, *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 790-92 (8th Cir. 2006) (no antitrust liability for precluding illegal importation of drugs); Richard A. Posner, *Economic Analysis of Law* 91 (5th ed. 1998) ("We do not want an efficient market in stolen goods.").[2]

b. These principles apply fully to competition that infringes a valid patent. *Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.*, 154 F. 358, 364 (7th Cir. 1907) ("[T]he public [i]s not entitled to profit by competition among infringers."); *see Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964) ("The patent laws ... are *in pari materia* with the antitrust laws and modify them *pro tanto*.").[3]

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[2] *See also, e.g.*, *RSA Media, Inc. v. AK Media Group, Inc.*, 260 F.3d 10, 15 (1st Cir. 2001) (RSA "was excluded because of the Massachusetts regulatory scheme that prevents new billboards from being built.... Any 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."); *see generally Town of Concord, Mass. v. Boston Ed. Co.*, 915 F.2d 17, 22 (1st Cir. 1990) (Breyer, C.J.) ("An antitrust rule that seeks to promote competition but nonetheless interferes with regulatory controls could undercut the very objectives the antitrust laws are designed to serve.").

[3] *See also, e.g.*, *Hynix Semiconductor v. Rambus*, 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

These principles refute Petitioner's claim that antitrust protects "uncertain" competition as is relevant here. (PB 20-21.) As in the authority Petitioner cites, antitrust only protects competition where there is uncertainty as to the competitor's *likelihood of success* resulting from market factors. But antitrust law simply does not protect competition of uncertain *legality*. *See, e.g.*, *Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 864-65 (D.C. Cir. 2008) (affirming dismissal of antitrust complaint because plaintiffs could not show generic competition would have been approved by the FDA); *Maltz v. Sax*, 134 F.2d 2, 5 (7th Cir. 1943) (Antitrust plaintiff who claimed injury in the conduct of unlawful business "had no legal rights to protect.").

2. **Patent.**

"[P]atent law seeks to foster and reward invention." *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979). Thus, "the essence of a patent grant is the right to exclude others from profiting by the patented invention." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980).

The patent's limited monopoly "is the reward stipulated for the advantages derived by the public for the exertions of the individual, and is intended as a stimulus to those exertions." *Grant v. Raymond*, 31 U.S. (6 Pet.) 218, 242 (1832) (Marshall, C.J.). The right to exclude "serves a very positive function in our system of competition, *i.e.*, the encouragement of investment based risk." *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 876 (Fed. Cir. 1985) (quotation

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[plaintiff'] nor consumers have a right to the sale of labels which infringe Monarch's patents.").

marks and citation omitted). Thus, Petitioner's former general counsel warned against ignoring "the first principle that enforcing valid patents makes a major contribution to consumer welfare by providing the incentive for innovation." 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 (2006).

"[T]he boundary of a patent monopoly is to be limited by the literal scope of the patent claims." *Dawson Chem. Co.*, 448 U.S. at 221. Within the scope of the patent, however, this Court has held that a patentee is free to maximize its reward, whether by licensing others for profit or refusing to license others to maintain a monopoly. *See, e.g.*, *id.* at 221-23 (holding that refusal to license is not patent misuse and refusing to consider whether "questions of public policy" or "principles of free competition" supported contrary result); *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 reward which the patentee by the grant of the patent is entitled to secure." (emphases added)).

The patent monopoly is secured through suits for infringement damages and/or an injunction prohibiting further unlawful competition. 35 U.S.C. §§ 271, 283. And, as with all litigation, this Court has recognized a judicial policy favoring settlement of patent suits. *E.g.*, *Standard Oil*, 283 U.S. at 171.

Petitioner offers no reason why a patentee's right to settle disputes should be any more constricted than its right to license. In fact, the ability to settle

patent litigation is such a fundamental part of the right to exclude that the Federal Circuit utilizes control of settlement as an indicia of patent ownership. *See Sicom Sys. Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 979 (Fed. Cir. 2005) ("Sicom … has failed to show that it has all substantial rights under the patent. For instance, Sicom does not have the right to settle litigation ….").

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In their effort to protect innovation and competition, both antitrust and patent law respect a patentee's right to exclude. That is why the Federal Circuit observed that "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 the patent." *Cipro III*, 544 F.3d at 1336.

B. This Court's Precedents Protect Agreements Within The Scope of a Patent Asserted In "Good Faith"

Since 1902, this Court has recognized that the antitrust inquiry must account for the patent right to exclude. Three cases in particular are instructive.

1.a. This Court decided *Bement*, 186 U.S. 70, at a time when the per se rule governed all antitrust cases. That case also concerned a challenge to the settlement of patent litigation on terms that maintained the patent monopoly. Consistent with the scope of the patent rule, the *Bement* Court declared that "[t]he first important and most material fact in considering this [antitrust] question

is that the agreements concern articles protected by letters patent." *Id.* at 88.

The patents were important because the "very object of these [patent] laws is monopoly, and the rule is ... that any conditions which are not in their very nature illegal ..., imposed by the patentee and agreed to by the licensee ..., will be upheld by the courts." *Id.* at 91. "The fact that the conditions in the contracts keep up the monopoly ... does not render them illegal." *Id.*

Indeed, *Bement* found the settlement agreements pro-competitive and beneficial. "This execution of these contracts did in fact settle a large amount of litigation regarding the validity of many patents …. *This was a legitimate and desirable result in itself*." *Id.* at 93 (emphasis added).

Bement thus held that where settlement agreements exclude no more competition than the patent itself, they do not harm lawful competition. "But [the Sherman Act] clearly does not refer to that kind of a restraint of interstate commerce which may arise from reasonable and legal conditions imposed upon the assignee or licensee of a patent …." *Id.* at 92.

b. In *Standard Oil*, 283 U.S. 163, this Court again considered an antitrust attack on patent settlements. *Standard Oil* explicitly concluded that a settlement of patent disputes "by agreement, rather than litigation, is not precluded by the [Sherman] Act." *Id.* at 171. In so holding, the Court rejected the government's argument that a "division of royalties[] constitutes an unlawful combination," reasoning that "division of royalties are not in themselves conclusive evidence of illegality." *Id.*

The *Standard Oil* Court refused to "consider any of the issues concerning the validity or scope of the cracking patents" because the government failed to cross-appeal the findings that the patentees had acted in good faith. *Id.* at 180-81. Crucial to this point was the master's finding that "the scope of the several groups of patents," however disputed, was sufficient "to justify the threats and fear of litigation." *Id.* Thus, absent a dispute over a patentee's good faith, *Standard Oil* establishes that no antitrust claim lies against a settlement agreement within the scope of the patent.

c. This Court further expanded on the intersection of antitrust and patent law in *Walker Process*, 382 U.S. 172. *Walker Process* represents "[t]he only time the Supreme Court has addressed the circumstances under which the patent immunity from antitrust liability can be pierced" when a patentee's conduct is within the scope of its patent. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1307 (11th Cir. 2003).

Walker Process sought to achieve "a suitable accommodation ... between the differing policies of the patent and antitrust laws." 382 U.S. at 179 (Harlan, J., concurring). The Court held that proof of actual fraud in securing a patent "would be sufficient to strip [the patentee] of its exemption from the antitrust laws," and thus allow an antitrust claim for wrongful enforcement. *Id.* at 177.

Walker Process stressed, however, that beyond such intentional misconduct in obtaining the patent, the patentee's "good faith would furnish a complete defense" to antitrust claims. *Id.*; *see also, e.g.*, *Globetrotter Software, Inc. v. Elan Computer Group,*

Inc., 362 F.3d 1367, 1375 (Fed. Cir. 2004). And Justice Harlan emphasized that antitrust liability requires actual fraud, not merely invalidity "under one or more of the numerous technicalities attending the issuance of a patent." 382 U.S. at 180 (Harlan, J., concurring).

Together, *Bement*, *Standard Oil*, and *Walker Process* provide the doctrinal basis for the scope of the patent rule: Conduct within the disputed scope of the patent does not violate antitrust laws absent objective baselessness, whether due to fraud on the PTO or sham litigation.

2. Petitioner nonetheless never cites *Bement* and mentions *Standard Oil* and *Walker Process* only once, in passing. (PB 26.) Instead, it seeks solace in other, inapposite precedents.

Petitioner first relies on two cases condemning horizontal agreements between competitors. (PB 20.) Those cases, however, did not involve intellectual property rights that could have precluded competitors from entering the market. *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46 (1990) (agreement to stop selling competing bar review materials); *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150 (1940) (agreement to withdraw surplus spot oil supply from market).

Next, Petitioner provides a string cite of five cases—all without quotation or explanation—in support of the proposition that antitrust law forbids a patentee from inducing others not to infringe. (PB

29.) All of those cases, however, condemned conduct beyond *the scope of the patent* at issue.[4]

Finally, Petitioner uses three precedents to suggest that public policy supports judicial testing of patents. (PB 48.) Each case, however, expressly acknowledged an equal interest in protecting patent holders from infringing competition: "As recognized by the Constitution, [a patent] is a special privilege designed to serve the public purpose of promoting the 'Progress of Science and useful Arts.'" *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945); *see also, e.g.*, *Pope Mfg. Co. v. Gormully*. 144 U.S. 224, 234 (1892) (recognizing the public importance of protecting the monopoly held by "the patentee of a really valuable invention"); *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 102 (1993) (rejecting Federal Circuit's rule of vacating validity rulings in part because "the patentee may have lost the practical value of a patent

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[4] *United States v. Singer Mfg.Co.*, 374 U.S. 174 (1963) (patent pooling among competitors to create entry barrier); *United States v. New Wrinkle, Inc.*, 342 U.S. 371 (1952) (same); *United States v. Line Material, Co.*, 333 U.S. 287 (1948) (same); *United States v. U.S. Gypsum Co.*, 333 U.S. 364 (1948) (restricting sale of non-patented goods); *United States v. Masonite Corp.*, 316 U.S. 265 (1942) (limiting resale after patent exhaustion).

To the extent these cases are relevant, they provide support for Respondents. For example, *Gypsum* held that the "appeal must be considered on a record that *assumes the validity of all the patents involved*." 333 U.S. at 388 (emphasis added). Likewise, Justice White's concurrence in *Singer* makes plain that the condemned actions included a conspiracy to defraud the PTO—conduct also forbidden by the scope of the patent rule. *See* 374 U.S. at 200 (White, J., concurring).

that should be enforceable against different infringing devices").[5]

C. Until *K-Dur*, The Lower Courts Properly And Consistently Applied The Scope Of The Patent Rule

Lower courts have consistently and correctly held that, when patents are involved, "the protection of the patent laws and the coverage of the antitrust laws are not separate issues." *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981) (discussing *Bement*, 186 U.S. at 91).

Years before the first antitrust challenges to Hatch-Waxman settlements, the rule was settled that antitrust analysis of patent agreements must always begin with the patent's exclusionary effect. *Id.* ("[T]he conduct at issue is illegal if it threatens competition in areas other than those protected by the patent, and is otherwise legal."); *accord, e.g.*, *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 703, 708 (Fed. Cir. 1992) (citing *Bement* and holding "[s]hould the restriction be found to be reasonably

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[5] Petitioner's suggestion that the Hatch-Waxman Act reflects a "strong congressional policy … favoring testing the scope and validity of pharmaceutical patents," (PB 48), is inaccurately one-sided. As other courts have recognized, the statute attempted "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" generic competition. *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 230 (4th Cir. 2002) (quotation marks and citation omitted; emphasis added). Senator Hatch himself has therefore criticized Petitioner's proposed standard, noting that it could "effectively discourage pro-consumer settlements." S. Rep. No. 111-123, at 23 (2010).

within ... the scope of the patent claims, that ends the [antitrust] inquiry"); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1204, 1206 (2d Cir. 1981) (citing *Bement* and concluding "where a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger [antitrust] liability"); *see USM Corp. v. SPS Techs., Inc.*, 694 F.2d 505, 513 (7th Cir. 1982) (Posner, J.) (Antitrust liability may lie "only upon proof of an anticompetitive effect beyond that implicit in the grant of the patent.").

Bayer's *Cipro* case was among the first to apply these principles to reverse-payment settlements. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 249 (E.D.N.Y. 2003) (*Cipro I*). ("[T]he proper analysis in this case is whether the ... challenged agreements restrict competition beyond the exclusionary effects of the [Cipro] patent."). Citing *Bement* three times, and *Walker Process* thirty-three, the district court concluded: "Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." *Cipro II*, 363 F. Supp. 2d at 535.

Cipro I recognized that application of the scope of the patent rule was especially appropriate in light of the incentive structure created by Hatch-Waxman. 261 F. Supp. 2d at 252.[6] The Solicitor General

[6] By creating a "highly artificial" act of infringement without damages, Hatch-Waxman created an incentive to initiate even marginal lawsuits. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); *See* Kelly Smith & Jonathan Gleklen, *Generic Drugmakers Will Challenge Patents Even When They Have a*

previously agreed. *See* Brief for United States as *Amicus Curiae* at 9-10, *Joblove v. Barr Labs., Inc.*, 551 U.S. 1144 (2007) (No. 06-830) ("*Tamoxifen* Br.") ("A patent holder may enter into such a settlement even if it believes that the likelihood that its patent will be held invalid is relatively small, out of concern that it would suffer enormous consequences in the event of invalidation.").

Seven federal appellate opinions have explicitly approved *Cipro*'s reasoning, with six rejecting antitrust claims because the settlements were within the patent's exclusionary effects. *E.g.*, *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1313 (11th Cir. 2012); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006); *Schering-Plough*, 402 F.3d at 1068; *Valley Drug*, 344 F.3d at 1306; *cf. In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 907-08 nn.12-13 (6th Cir. 2003) (expressly distinguishing *Cipro* and finding liability because the settlement in *Cardizem* imposed restraints beyond the exclusionary effect of the patent).

97% Chance of Losing, 9 CPI Antitrust Chron. 1, 1-2 (2012). Thus, "Hatch-Waxman creates a context in which payments from the patent owner to the infringer become explicit *rather than implicit*, but it does not ... make them more anti-competitive than such payments in the traditional context." Bernard & Tom, *supra*, 15 Fed. Cir. B.J. at 621 (emphasis added).

II. PETITIONER'S THEORIES OF COMPETITIVE HARM IGNORE THE PRO-COMPETITIVE EFFECTS OF PATENT RIGHTS, CONFLICT WITH ESTABLISHED PRINCIPLES OF LAW, AND WOULD REPEAL THE STATUTORY PRESUMPTION OF VALIDITY

Petitioner's proposed standard elides the central focus of appropriate antitrust analysis in this context—the patent. In stark contrast to the scope of the patent test, the right to exclude plays no role in Petitioner's proposed presumption of illegality and no role in Petitioner's proposed methods of rebutting that new presumption.

Thus, Petitioner's proposed standard raises two fundamental questions: Can antitrust law ignore patent rights when assessing harm to lawful competition? And if not, can any test other than the scope of the patent rule properly account for the effect of the patent?

The relevant statutory language, this Court's precedents, and simple logic all dictate that the answer to both questions is no.

A. Any Antitrust Analysis of Patent Settlements Must Account For The Patent Holder's Right To Exclude

1. Petitioner seeks to impose a presumption of illegality on all "settlements that involve a reverse payment (*or its functional equivalent*) from the plaintiff to the defendant." (PB 46 (emphasis added).) That is, to trigger the presumption of illegality, a plaintiff need only show the presence of a reverse payment. (*Id.*) The patent merits are then to be ignored. (PB 53-55.) Like the court in *K-Dur*,

Petitioner contends that "there is no need to consider the merits of the underlying patent suit." *K-Dur*, 686 F.3d at 218. Thus, the patentee would be precluded from even asserting validity or infringement as defenses to antitrust claims. (*See* PB 37-39 (recognizing "two primary ways in which the parties to a reverse-payment settlement ... could rebut the presumption," neither of which have to do with the patent merits).

The fundamental fallacy in any antitrust standard that ignores the patentee's right to exclude is that the existence of that right is usually the *only* reason that patent agreements are legal in the first place. Indeed, in the absence of the right to exclude, most patent agreements—including virtually all licenses—would be illegal. *Studiengesellschaft*, 670 F.2d at 1128 ("[A] patent by definition restrains trade, and in effect makes most exclusive patent licenses *per se* violations of the antitrust laws."); *see generally* XII Herbert Hovenkamp, *Antitrust Law* ¶ 2040b (2d ed. 2005) ("[Licensing] agreements would generally be classified either as per se unlawful naked price fixing, or as per se unlawful naked horizontal market divisions" in the "absence of a patent." (footnote omitted)).

As the Eleventh Circuit explained in *Valley Drug*, the patent is not merely the central focus of the inquiry; it is usually the only thing that matters:

> 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).[7]

The decision in *Studiengesellschaft* made the point expressly. In that case, because the district court had conducted a rule of reason analysis that ignored "the scope of patent protection, ... its method of analysis had the effect of applying a *per se* rule." 670 F.2d at 1128. That was reversible error, "because once the protection of the patent was removed, the license conditions, like the patent itself, inevitably had the effect of restricting competition." *Id.* So, too, Petitioner's standard here "in effect makes most exclusive patent licenses *per se* violations of the antitrust laws." *Id.*

Petitioner ignores the implications of its standard for patent licenses, but offers no reason in logic or law for limiting its rule to agreements that happen to arise from patent litigation within the pharmaceutical industry. Indeed, Petitioner could just as easily attack the terms of a patent license on the grounds that, without those terms, the licensed-entry date may have been earlier. Yet such restrictions on the right to exploit the patent right would be directly contrary to law. *See Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964) ("A patent empowers the owner to exact royalties as high as he can

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[7] Even former FTC Commissioner Leary recognized that "*[i]f 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) (emphases added).

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" (emphases added)).

Judge Trager recognized that Petitioner's proposed standard would threaten all patent agreements, regardless of the method of compensation or industry:

> If the settlement with a payment to a generic is to be subject to antitrust liability, … 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. This lack of any limiting principle explains why no court, not even *K-Dur*, has accepted Petitioner's proposed standard wholesale.[8]

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[8] Even *K-Dur*, which adopted Petitioner's rule of presumptive illegality, carefully limited 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. Thus, district courts in the Third Circuit have appropriately rejected—over the FTC's objection—arguments seeking to apply a presumption of illegality to settlements involving other forms of compensation, including the venerable exclusive license. *See, e.g.*, *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 2:12-cv-0995, 2012 WL 6725580, at *6 (D.N.J. Dec. 6, 2012) ("[T]he term 'reverse payment' is not

2. Recognizing the fundamental point that agreements within a patent's scope are either lawful under the antitrust laws based on the right to exclude or unlawful, has several consequences for Petitioner's proposed standard.

Initially, it demonstrates that the existence or non-existence of money or other consideration in a settlement is beside the point: "The failure to produce the competing … drug, rather than the payment of money, is the exclusionary effect." *Valley Drug*, 344 F.3d at 1309. Even without payments, "the parties ... could settle on an early entry date *with a license calibrated to achieve a similar financial result to the parties as an exclusion payment.*" *Cipro II*, 363 F. Supp. 2d at 537 (emphasis added). The antitrust question remains whether the excluded entry can be proven lawful. If the generic was infringing, no amount of money can make its exclusion harmful; if it was not infringing, no absence of money can make its exclusion helpful to consumers.

The same principle renders inapt the petitioner's repeated assertions that a settlement with reverse payments "resembles" or is "similar" to classical market-division agreements. (PB 15, 19-20, 34-35.) The critical difference, as these courts noted, is that "one of the parties owned a patent" *Valley Drug,* 344 F.3d at 1304. The central precedent on which Petitioner relies, *Palmer*, 498 U.S. 46 (PB 20), underscores the difference. In that case, the parties

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sufficiently broad to encompass any benefit … to [the generic] in a negotiated settlement."); *see Prof'l Drug Co. v. Wyeth Inc.*, No. 3:11-cv-05479, 2012 WL 4794587, at *2 (D.N.J. Oct. 3, 2012) (denying FTC motion to file *amicus* brief).

had competed head-to-head in the same market area for years. There was no suggestion that anyone's intellectual property rights precluded such competition in any way. The parties' later decision to share one of their trademarks was thus irrelevant to the existence of the prior competition they unlawfully agreed to end. *Id.* at 48-49.

Similarly, Petitioner's suggestion that the Court apply heightened antitrust scrutiny in a "quick look" analysis misses the point. This Court undertakes "quick look" antitrust scrutiny 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 resolving the patent claim merits, we do not know that the settlement threatened competition *at all*.

The quick look approach, moreover, is "reserved for circumstances in which the restraint is sufficiently threatening to place it presumptively in the per se class, but *lack of judicial experience* requires at least some consideration of proffered defenses or justifications." X Areeda et al., *supra*, ¶ 1911a. It would be particularly anomalous to apply quick look scrutiny where, but for the *K-Dur* decision, the overwhelming weight of judicial experience has rejected Petitioner's proposed rule, and instead embraced the scope of the patent test. *See supra*, § I.C.

The absence of any consensus that settlements with payments are highly likely to be anticompetitive may be best reflected in the inconsistent positions

that the Solicitor General has taken before this Court. The Solicitor General previously explained that there was no doctrinal foundation for use of 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." Brief for the United States as *Amicus Curiae* at 10-11, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273) (emphasis added) ("*Schering-Plough* Br."). He now acknowledges the inconsistency (PB 41 n.9), but this change of heart is reason alone to conclude that the settlements he now opposes are not "obviously" anticompetitive.[9]

Finally, reviewing the history of litigated reverse settlements provides no support for the proposition that such settlements invariably delay generic competition. In the *Cipro* cases, Bayer's compound patent was validated on reexamination by the PTO and in three subsequent generic challenges litigated to judgment. *See Cipro II*, 363 F. Supp. 2d at 530 n.14. The same occurred in *Tamoxifen*: following the settlement, Zeneca defeated three subsequent generic patent challengers. 466 F.3d at 195. In both cases, the settlements allowed early entry that litigation of the patent right would have foreclosed.

Even in a case where a settlement went beyond the scope of the patent—and thus was held to constitute

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[9] To be sure, the former Solicitor General suggested that some showing less than objective baselessness would suffice. Such an argument has been abandoned by Petitioner here and, in any event, fails for the reasons explained *infra*, § II.B.3.

a *per se* antitrust violation—the FTC itself *still* failed to find any harm to competition. "[I]t does not appear that there was any delay in the entry into the market ... , or that the conduct or agreement at issue delayed consumer access to a generic version of Cardizem CD." *In re Hoechst Marion Roussel, Inc.*, 131 F.T.C. 925, 955 (2001); *see also, e.g.*, *Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1041 (9th Cir. 2009) (jury verdict of $0 damages from Hytrin settlement).

In sum, Petitioner's attempt to extract the only important competitive factor from the analysis of patent settlements—the right to exclude—must fail.[10] Along with it goes Petitioner's strained attempt to analogize (i) time-honored licensing agreements that allocate patent rights to (ii) per-se illegal horizontal agreements that allocate markets.

B. Petitioner's Theories Of Competitive Harm, Which Seek To Redefine Competition, Are Unsupported In Logic And Contrary To Law

In attempting to articulate a theory of harm to competition, Petitioner posits a competitive "ideal" in which the settling parties agree only upon an entry date for the generic product:

> When the parties to a Hatch-Waxman settlement simply agree upon a

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[10] To make this error more palatable, Petitioner suggests in a footnote that it may in fact be necessary to address the patent merits for "[q]uantification of damages in a private antitrust action." (PB 55 n.11.) But Petitioner neglects to see that the alleged injury here, both to competition and to any individual purchaser, has the same source: the exclusion of the generic product. If that exclusion was justified by the merits of the patent claim, there is no harm to lawful competition at all.

> compromise date of generic entry, with no money or similar consideration flowing from the brand-name to the generic manufacturer, the settlement is unlikely to raise antitrust concerns.

(PB 27.)

The first difficulty with this ideal, as Petitioner concedes, is that, if the patent is to be ignored, such term-splitting 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.").) That is, Petitioner's ideal settlement also "delays" generic entry by definition and "resembles" classical market division agreements to the same extent as those with reverse payments. Thus, to save its preferred settlement method from its own presumptive illegality standard, the FTC must redefine protected competition solely for purposes of Hatch-Waxman settlements. This attempt fails.

1. Petitioner's argument depends on the critical, and unsupported, assumption that, in the course of private patent litigation, the competitive interest of consumers *always* favors generic entry and lower drug prices. Petitioner thus asserts that a settlement negotiation strictly limited to a generic entry date "has the practical effect of aligning [the generic's] interests in paragraph IV litigation with those of consumers, who benefit from the lower prices that generic competition provides." (PB 28.) This view, however, "ignores the first principle that enforcing valid patents makes a major contribution to consumer welfare." Bernard &. Tom, *supra*, 15 Fed. Cir. B.J. at 618.

Indeed, the patentee's right to exclude is not simply beneficial, but *procompetitive*. It is widely recognized that the existence and protection of valid patent rights "driv[e] economic growth and increas[e] consumer welfare." Charles F. Rule, *Patent-Antitrust Policy: Looking Back and Ahead*, 59 Antitrust L. J. 729, 730 (1991) (comments of former Assistant Attorney General for the Antitrust Division); *Loctite Corp.*, 781 F.2d at 876. (right to exclude infringers "serves a very positive function in our system of competition").[11]

Accordingly, settlements that protect that right benefit consumers. *See* 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." (first emphasis added)). The Solicitor General has made the same point to this Court. *Tamoxifen* Br. at 8-9 ("[L]egitimate patent settlements ... further the important goals of encouraging innovation and minimizing unnecessary litigation."). And even Petitioner concedes that

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[11] This Court has observed that "[d]evelopment of new uses for existing chemicals .... is extraordinarily expensive. It may take years of unsuccessful testing before a chemical having a desired property is identified, and it may take several years of further testing before a proper and safe method for using that chemical is developed." *Dawson Chem.*, 448 U.S. at 221-22 (1980). More so for chemicals for human use: "To be deemed 'safe and effective' and thereby obtain FDA approval, a new drug must undergo an extensive application and approval process.... The test is rigorous, requiring expensive and time-consuming clinical trials estimated by some to cost more than $800 million per drug." *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 388-89 (5th Cir. 2008) (quotations and footnotes omitted).

"preserv[ing] the incentives to innovate … benefit[s] consumers in the long run." (PB 45.)

As a result, Petitioner's theory of harm fails in its underpinnings: "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.

2. Petitioner thus argues that reverse payments are unlawful, because a term-splitting settlement would produce a longer license and hence be better for consumers. (PB 40 ("[T]he parties may settle with an earlier entry date and no reverse payment, which would benefit consumers ....").)

a. As a legal matter, this conclusion is irrelevant. Antitrust liability does not attach simply because a court can hypothesize a "better" settlement than the one actually reached. *Verizon*, 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)); *Am. Motor Inns, Inc. v. Holiday Inns, Inc.*, 521 F.2d 1230, 1249 (3d Cir. 1975) ("Application of the rigid 'no less restrictive alternative' test in cases such as this one would place an undue burden on the ordinary conduct of business."); *see also Buffalo Broad. Co. v. ASCAP*,

744 F.2d 917, 933 (2d Cir. 1984) (similar). [12] Accordingly, as 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).

Petitioner has no persuasive response to Judge Posner's point that the assumption of competitive harm from reverse payments "may be doubted, since if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent." *Asahi Glass Co v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 989, 994 (N.D. Ill. 2003) (Posner, J., by designation).

b. As a matter of fact, moreover, the "better settlement" presumption is simply false. Even Petitioner admits that settlement is not always possible when negotiations are limited to the date of generic entry. (PB 40 ("To be sure, ... a rule discountenancing reverse payments may cause the parties to litigate to judgment.").)

Generic and branded companies value the time period of a license differently. Due to the difference in prices charged, the time-value of a license to the generic is much less than the amount the brand-name manufacturer would have to sacrifice. In such a case, money can bridge the gap, making a settlement possible where negotiating only on the

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[12] *Trinko*'s rule applies with especial force where Petitioner's proposed solution—requiring an earlier license—is itself contrary to the patent statute. *See* 35 U.S.C. § 271(d)(4) (providing that "refus[al] to license" is not patent misuse).

length of the license would not. *See, e.g.*, Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1062 (2004).

It thus is incorrect to say that the money caused the entry date to be delayed: without the payment, there would be no settlement (and no early licensed entry) at all. *Cf.* Brief for United States and FTC as *Amicus Curiae* at 9, *Andrx Pharms., Inc. v. Kroger Co.*, 543 U.S 939 (2004) (No. 03-779) ("Cardizem Br.") ("Reverse payments may have the salutary effect of facilitating efficient settlements that advance consumer welfare.").

3.a. In advancing its "better settlement" theory, Petitioner reverts to its original rationale for attacking reverse payments that the Eleventh Circuit rejected in *Schering-Plough*, 402 F.3d 1056. When the FTC sought certiorari in that case, however, it adopted a new rationale, described by the Solicitor General as follows: "The FTC's petition emphasizes what it calls the "'probabilistic' nature of the property interest created by the patent laws" and the view that "a patent is not a right to exclude, but rather a right to *try* to exclude." *Schering-Plough* Br. at 11.

This so-called "probabilistic" patent theory sought to create a consumer right to the *potential* invalidation of the patent. *See* Petition for Certiorari at 10-11, 18, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273) (if the patent had a 50% chance of defeat, the settlement would cause consumers to "lose the 50 percent chance they had of enjoying the benefits of competition."). The FTC has wisely abandoned this theory here, for "there is no support in the law for such a" "concept of a public

property right in the outcome of private lawsuits." *Cipro II*, 363 F. Supp. 2d at 531; *see also, e.g.*, *Nestle Co. v. Chester's Market, Inc.*, 756 F.2d 280, 284 (2d Cir. 1985) ("We see no justification to force these defendants, who wish only to settle the present litigation, to act as unwilling private attorneys general and to bear the various costs and risks of litigation," which include "the non-trivial risk of" exclusion by unfavorable judgment).

b. Nor does Petitioner substantively advance the argument of the Justice Department in the *Cipro* case, which bases the injury to competition on the subjective expectation of the parties as to how the litigation might turn out, *i.e.*, "the amount of competition anticipated by the parties to the patent litigation." (PB 16); *see* U.S. Br. at 24, *Cipro IV*, 604 F.3d 98 (No. 05-2851) (filed July 6, 2009). Such a subjective standard would turn an antitrust violation into a thought crime whereby a bashful patentee, who fears that he is likely to lose, must choose a settlement that transfers far more value to consumers than that of a recklessly confident patent holder.

Among many other flaws, neither the "expected value" nor the "probabilistic property" theories has anything to do with payments, reverse or otherwise. Every settlement deprives consumers of the chance that the patent will be defeated—whether that chance is measured objectively (the "probabilistic property" theory) or subjectively (the "expected value" theory).

c. The FTC also advanced a new theory below, arguing that it should be permitted to show only that the defeat of the patent was "likely." Although not

advocated here, any such 'likely' winner legal standard merely raises the question: What degree of likely success is sufficient for a patentee to avoid antitrust liability? 30%? 50%? More? And how can a lay jury with no patent training determine those odds?

Indeed, "[i]t is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case." *Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990); *see also, e.g.*, *Christianburg Garment Co. v. EEOC*, 434 U.S. 412, 422 (1978) ("[S]eldom can a prospective plaintiff be sure of ultimate success .... [T]he course of litigation is rarely predictable.").

Courts adjudicating challenges to Hatch-Waxman settlements have accordingly rejected a 'likely' winner standard. *See, e.g.*, *Valley Drug*, 344 F.3d at 1308 ("Patent litigation is too complex and the result too uncertain for parties to accurately forecast ….").

C. Acceptance Of The FTC's Standard Would Repeal The Presumption Of Validity

Petitioner's standard would also effectively repeal Congress's decision to afford patents a statutory presumption of validity. "A patent shall be presumed valid .... The burden of establishing invalidity ... shall rest on the party asserting such invalidity." 35 U.S.C. § 282.

Just two terms ago, this Court confirmed that this statute is more than a simple procedural device. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2247 (2011) ("[W]e cannot accept Microsoft's argument that Congress used the words presumed valid to adopt only a procedural device for shifting the burden of production or ... the burden of persuasion." (quotation marks omitted)). In its

recent *K-Dur* decision, the Third Circuit simply got this wrong. *K-Dur*, 686 F.3d at 214 ("[T]his presumption is intended merely as a procedural device ....").

Instead, the presumption of validity has a long common-law heritage. As early as 1934, this Court held that a "patent regularly issued, and even more obviously a patent issued after a hearing of all the rival claimants, is presumed to be valid *until the presumption has been overcome by convincing evidence of error.*" *Radio Corp. of Am. v. Radio Eng'g Labs., Inc.*, 293 U.S. 1, 7 (1934) (emphasis added). Nor is there any doubt that the presumption applies in antitrust cases. *See Standard Oil*, 283 U.S. at 181 (where good faith of patent claim was uncontested, presumption of validity applied in full).

Petitioner's only response to the presumption of validity is to note that the presumption can be rebutted. (PB 26.) But Petitioner's proposed standard does not require antitrust plaintiffs to rebut the presumption at all. Petitioner's standard does not allow the validity of the patent to become relevant at any stage. Under Petitioner's standard, therefore, the rebuttable statutory presumption of validity is converted to an irrebutable presumption of patent invalidity. Because the FTC intends its standard to govern all cases, the FTC's presumption of illegality will have the effect in numerous cases of contradicting the presumption of validity that Congress duly enacted.

For example, where an innovator holds a patent on a drug's active pharmaceutical compound, the ANDA applicant must necessarily admit infringement in order to claim bioequivalence as required by statute.

See 21 U.S.C. § 355(j)(2)(A); *Cipro II*, 363 F. Supp. 2d at 518 ("[B]ecause Barr was required in its ANDA to certify that its generic version of Cipro was bioequivalent to Bayer's Cipro, there is no dispute that Barr's product would have infringed Bayer's patent."). In such cases, validity is the only disputed patent issue. The settling parties should be entitled to rely on Congress's decision to treat patents as presumptively valid without fear of presumptive antitrust liability.

Permitting liability on any lesser showing, in contrast, would create an antitrust claim based on the exclusion of *unlawful* competition. For example, Petitioner's standard could treat the Cipro settlement as presumptively unlawful, even though the Federal Circuit (twice), three district courts, and the PTO all reaffirmed the patent. *See Cipro II*, 363 F. Supp. 2d at 530 & n.14 ("[T]here is something anomalous about the notion that plaintiffs could collect treble damages for settlement of a litigation involving a patent that has been subsequently upheld by the Federal Circuit.").[13]

The presumption of validity is not the source of the scope of the patent rule, which is grounded in basic principles of antitrust and patent law. *See, e.g.*, *Tamoxifen*, 466 F.3d at 209 n.22 ("[I]rrespective of

[13] The Direct Purchasers' *amicus* brief suggests that Bayer won these later cases because the challengers lacked time to raise inequitable conduct as a defense. (DP Br. at 7-8.) "But this argument is not very convincing in light of the fact that one of the challenges—Carlsbad's, on the ground of obviousness—also required extensive discovery and resulted in a nine-day bench trial." *Cipro II*, 363 F. Supp. 2d at 530; *aff'd*, *Cipro III*, 544 F.3d at 1341 ("[W]e agree[] that no fraud occurred.").

whether there was a presumption or where any such presumption lay at the time of settlement, we think that Zeneca was then entitled to protect its tamoxifen patent monopoly through settlement."). But the presumption of validity is most assuredly another legal principle that acceptance of Petitioner's proposed standard would violate – and another reason why a standard wholly ignoring a patentee's right to exclude cannot stand.

CONCLUSION

The Court should affirm the judgment below.

Respectfully submitted,

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