No. 12-416

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

ACTAVIS, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICUS CURIAE*

The American Intellectual Property Law Association ("AIPLA") is a national bar association with approximately 15,000 members. AIPLA's members are engaged in all aspects of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property rights. They include lawyers who practice in law firms and corporate law departments, serve in government agencies and public interest organizations, and teach in law schools and universities. Representing both the owners and the users of intellectual property, AIPLA speaks for the full spectrum of interests relating to intellectual property law.[1]

Since its formation in 1897, AIPLA has worked to maintain high standards of professionalism and ethics among intellectual property lawyers, to improve the laws relating to intellectual property and their interpretation by the courts, and to provide legal education to its members and the public on intellectual property issues. AIPLA takes an active role in shaping American intellectual property policy through its work on legislation, federal regulations, and intellectual property cases in the courts.

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1. In accordance with Supreme Court Rule 37.6, *amicus curiae* states that this brief was not authored, in whole or in part, by counsel for a party, and no monetary contribution to the preparation or submission of this brief was made by any person or entity other than the *amicus curiae* or its counsel. After reasonable investigation, AlPLA believes that no member of its Board or *Amicus* Committee who voted to file this brief, or any attorney in the law firm or corporation of such a member, represents a party to this litigation. In accordance with Supreme Court Rule 37.3(a), all parties have consented to the filing of this brief in letters on file with the Clerk of the Court.

AIPLA submits this brief to assist the Court in understanding why the "scope of the patent" rule applied by the Eleventh Circuit is critical to preserving the important patent rights created by Congress, which are designed to advance consumer welfare by encouraging invention and risk-taking. The presumption of an antitrust violation urged by the Federal Trade Commission ("FTC") is inconsistent with patent law because it would significantly interfere with the economic rights intended by Congress for the resolution of patent litigation and will thus only harm consumers in the long run.

BACKGROUND

This case brings into focus the boundary between patent law and antitrust law for patent settlement agreements. Although the particular settlements at issue were entered into between branded and generic drug makers to resolve drug patent litigation arising in the context of the Drug Price Competition and Patent Restoration Act of 1984 (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585, the resolution of this case will likely have broad implications for all manner of patent settlements, and potentially for many common patent licensing arrangements between potential competitors.

1. Like many settlements of Hatch-Waxman litigation (and other patent settlements and licensing arrangements), the agreements negotiated among respondents expressly permitted the generic maker (the would-be competitor) to begin marketing the generic version of the branded drug on an agreed date before the expiration of the drug patent. The agreements also included the payment of money from the branded company (the patent holder)

to the generic maker (what the FTC calls a "reverse payment"). For many years, the FTC has pursued an enforcement policy condemning such patent settlements as unreasonable restraints of trade in violation of section 1 of the Sherman Act, 15 U.S.C. § 1, and as unfair methods of competition under section 5 of the FTC Act, 15 U.S.C. § 45. The FTC presumes that "reverse payment" patent settlements are unlawful under the antitrust laws (with no analysis required), unless the settling parties can prove that the payment does not exceed a reasonable estimate of litigation costs or is required to achieve some other offsetting competitive benefits; absent such a showing, the FTC says, "it is logical to conclude that the *quid pro quo* for [the] payment is an agreement by the [would-be competitor] to defer entry beyond the date that represents an otherwise reasonable litigation compromise." Pet. Br. at 34-35 (internal quotation marks omitted); *see id.* at 29, 33-36; *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012) (quoting and adopting the FTC analysis), *cert. pending*, Nos. 12-245 & 12-265 (U.S. filed Aug. 24 & 29, 2012). The FTC maintains that such a "pay for delay" *quid pro quo* in a patent settlement should be declared a *per se* violation of the Sherman Act.

2. Three courts of appeals, including the Eleventh Circuit here, have rejected the FTC's position and have, instead, applied the so-called "scope of the patent" rule to reverse-payment patent settlements. Courts have long relied on a similar "scope of the patent" principle in addressing antitrust challenges to restrictions on competition commonly included in patent licensing arrangements (such as pricing requirements, territorial restrictions, restrictions on production output or sales, time limitations, and other restraints). *See, e.g.*, *United*

States v. General Electric Co., 272 U.S. 476 (1926) (pricing restrictions); *United States v. Studiengeselschaft Kohle*, 670 F.2d 1122 (D.C. Cir. 1981) (restrictions on sales). Under this principle, courts hold that a patentee has the right under patent law to insist on such restraints—and the restraints are therefore permitted under the antitrust laws—as long they do not exceed the exclusionary scope of the patent. *See General Electric*, 272 U.S. at 488; *Studiengeselschaft*, 670 F.2d at 1128 (licensing restriction on sales held lawful because the patent holder "sought nothing beyond what the patent itself gave it").

3. The courts of appeals that have applied a similar rule to reverse-payment patent settlements in the Hatch-Waxman context, like the Eleventh Circuit, have held that such settlements do not violate the antitrust laws provided they do not purport to expand the presumptive exclusionary scope of the drug patent beyond its term of years or beyond the claims covered by the patent, unless those challenging the settlement establish that the patent was procured by fraud or that the underlying patent infringement action was a sham (in other words, objectively baseless). *See* Pet. App. 15a-36a (reviewing the "scope of the patent" rule and adhering to it in the present case); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (vacating similar FTC enforcement order), *cert. denied*, 548 U.S. 919 (2006); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003) (adopting the "scope of the patent" rule in rejecting antitrust challenge to Hatch-Waxman reverse-payment settlement), *cert. denied*, 543 U.S. 939 (2004). The Second and Federal Circuits have followed the Eleventh Circuit in applying the same "scope of the patent" rule to uphold Hatch-Waxman drug patent settlements. *See In re Tamoxifen Citrate*

Antitrust Litig., 466 F.3d 187, 212-13 (2d Cir. 2005), *cert. denied*, 551 U.S. 1144 (2007); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008), *cert. denied*, 557 U.S. 920 (2009).

SUMMARY OF ARGUMENT

This Court should affirm the "scope of the patent" rule applied by the court of appeals below. This rule properly recognizes and protects the full array of economic rights conferred under patent law, which necessarily include the right to settle non-sham patent litigation on any terms that stay within the presumptive exclusionary scope of the patent grant. The "scope of the patent" analysis is well established in this Court as the guiding principle for maintaining the line between the legitimate exercise of patent rights and the pro-competition requirements of antitrust law. It is the principle long applied in resolving antitrust challenges to restrictive terms in patent licenses, as well as claims that a patent holder has violated the antitrust laws by improperly pursuing an infringement action to protect its right to limited exclusivity. It is also the governing principle for application of the patent "misuse" doctrine, under which a patent used in committing an antitrust violation will be rendered unenforceable until the effects of the violation are dissipated.

The same rule appropriately applies to the patent holder's right to settle patent litigation. Unless the patent was procured by fraud or the underlying infringement suit is objectively baseless, the parties to patent litigation are free to structure settlements however they wish, provided the terms of the settlement do not purport to extend the exclusionary scope of the patent beyond its lawful term

or to suppress competition for technologies not claimed in the patent. A reverse payment by itself cannot be a basis for the forfeiture of patent rights. All patent settlements involve some transfer of value from the patent holder to the alleged infringer, and such reverse payments are fully consistent with and actually encouraged by the procedural framework of the Hatch-Waxman Act. Moreover, the freedom to settle patent litigation on terms within the scope of the patent is a form of property granted to the patent holder and protected by the Fifth Amendment of the Constitution. As the Founders declared in granting Congress the power to create a patent system, the firm preservation of these legal rights is the surest way to stimulate innovation and thus to maximize the long-run welfare of consumers. U.S. Const. Art. I, § 8, cl. 8.

The presumption of an antitrust violation promoted by the FTC would seriously interfere with the exercise of legitimate patent rights by rendering such exercise presumptively unlawful. The FTC's approach should be rejected because it will bring antitrust enforcement policy and patent law into direct, repeated, and unavoidable conflict. By penalizing and thus suppressing the exercise of the lawful rights held by the patentee, the FTC's enforcement policy would operate to the detriment of both patent law and competition policy and would only harm consumers in the end, contrary to the intent of Congress and to the principles enshrined in the Constitution.

ARGUMENT

THE "SCOPE OF THE PATENT" RULE SHOULD BE AFFIRMED BECAUSE IT CORRECTLY PRESERVES THE SPHERE OF ECONOMIC FREEDOM PROVIDED BY CONGRESS FOR THE RESOLUTION OF PATENT DISPUTES.

The FTC and its supporting *amici* urge the Court to view this case primarily through the lens of antitrust doctrine. They invoke the general antitrust principle presumptively condemning any agreement between potential competitors that prevents or limits competitive entry into the market, and they argue that this same principle should apply to create a presumption of an antitrust violation for "reverse payment" patent settlements. *See* Pet. Br. 20-24; *id.* at (I) (Question Presented) (citing *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990) (per curiam)).[2] They maintain that giving priority to this antitrust policy would not unduly conflict with patent law because the patent holder will still retain the fallback ability to litigate the patent dispute to judgment (bearing the risk it might lose), an option specifically preserved by the Hatch-Waxman Act for branded drug makers. *See* Pet. Br. at 25-26.

With all respect, this argument has the analysis exactly backwards. The FTC's position ignores the full scope of the rights granted to the patent holder, including

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2. *See also* Br. for States as *Amici Curiae* in Support of Pet'r 10-18; Br. for 118 Law, Econ., & Bus. Profs., *et al.*, as *Amici Curiae* in Support of Pet'r 11-25; Br. for La. Wholesale Drug Co., *et al.*, as *Amici Curiae* in Support of Pet'r 13-17.

the sphere of economic freedom Congress intended for the resolution of patent litigation. The statutory rights granted with a patent establish a firm and clear zone of permissible activity where antitrust law has no application because antitrust liability would be incompatible with the full exercise of those rights. *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*."). The theory behind the American system of patent law, as declared in the Constitution and supported by nearly 225 years of experience, is that the grant to inventors of exclusive and unrestricted rights to exploit their inventions for a limited period will benefit consumers and ultimately promote competition by encouraging and rewarding innovation. Nothing in the Hatch-Waxman Act reverses that fundamental premise in the context of drug patents.

Accordingly, the proper analysis should start from the perspective of patent law and should take care to preserve the full scope of rights granted with the patent. Unless the underlying patent litigation is shown to be a sham, or the patent was procured by fraud, any settlement terms that fall within the presumptive exclusionary scope of the patent should be free from antitrust scrutiny. The presumption of antitrust liability urged by the FTC cannot be squared with the intent of Congress and the principles embodied in the Constitution because it will seriously diminish the substantive property rights conferred by patent law. The firm maintenance of these legal rights is the surest means to promote invention and thereby to maximize competition and consumer welfare in the long run.

A. The Patent Act Confers on Patent Holders the Right to Settle Bona Fide Patent Disputes on Any Terms that Fall Within the Presumptive Exclusionary Scope of the Patent, Regardless of Whether Those Terms Include the Transfer of Value from the Patent Holder.

1. The Constitution declares that Congress is empowered "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the *exclusive Right* to their respective . . . Discoveries." U.S. Const. Art. I, § 8, cl. 8 (emphasis added). Congress has implemented that constitutional purpose through the Patent Act, codified at 35 U.S.C. §§ 1, *et seq.*, which confers on inventors the *exclusive right* to own, control, and profit from their innovations for a definite period of years. Thus, the defining attribute of a patent is "*the right to exclude others* from making, using, offering for sale, or selling the invention" claimed by the patent or, in the case of a process patent, the "products made by that process," for a period of years. 35 U.S.C. § 154(a)(1), (2) (emphasis added).

While patent law and antitrust law are both intended to benefit consumers by promoting innovation, they do so in very different and equally important ways. Antitrust doctrine protects consumers by *preserving competition*; patent law fosters invention and risk-taking by permitting the temporary *exclusion of competition* within specified limits. *See Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 221 (1980) ("The policy of free competition runs deep in our law. . . . But the policy of stimulating invention that underlies the entire patent system runs no less deep."). "The grant of a patent," in essence, "is the grant

of a statutory monopoly," *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229 (1964), and "the essence of a patent grant is the right to exclude others from profiting by the patented invention," *Dawson Chem. Co.*, 448 U.S. at 215. The lawful monopoly and exclusionary rights granted to the patent holder imply a corresponding exemption from the demands of antitrust law, and this exemption necessarily mirrors and accommodates the full scope of those exclusionary rights.

2. The Patent Act reinforces the exclusionary nature of the patent by giving the patentee all legal rights necessary to enforce the grant of exclusivity against any person who would infringe the patent. The patent holder has the right to bring a civil action in court to enjoin the offending competition and may seek an award of damages to compensate for lost profits or other economic loss caused by the infringement. 35 U.S.C. §§ 281, 283, 284. This Court has held that an exercise of these legal rights by the patentee to enforce the exclusivity granted in the patent against would-be competitors can only be challenged under the antitrust laws where the enforcement action is a sham (objectively baseless) or where the patent was procured by fraud on the Patent and Trademark Office (and thus was never validly issued). *See Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 176-77 (1965); *Prof. Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56-57 (1993); *Concrete Unlimited Inc. v. Cementcraft, Inc.*, 776 F.2d 1537, 1539 (Fed. Cir. 1985) (patent holder does not engage in unfair competition by "threatening alleged infringers with suit"), *cert. denied*, 479 U.S. 819 (1986).

This Court's recognition that the zealous exercise of patent rights is presumptively free from antitrust challenge, except in the narrow cases of sham litigation or patent fraud, is also supported by the presumption of patent validity mandated by Congress. The Patent Act declares that "[a] patent shall be presumed valid," and in any legal dispute, "[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." 35 U.S.C. § 282(a). This presumption of validity is not a mere "procedural device"; it imposes a "heightened standard of proof" against anyone challenging the exclusionary force of the patent that can only be overcome by clear and convincing evidence of invalidity. *Microsoft Corp. v. i4i Limited Partnership*, 564 U.S. ___, 131 S. Ct. 2238, 2246-47 (2011).

3. A patent also confers on the holder broad rights to license the patented technology to others on terms and conditions agreeable to the patent holder, or to refuse to license. *See* 35 U.S.C. § 271(d)(4)-(5); *cf. id.* § 261 (providing that a patentee may freely assign the patent "or any interest therein" to others). Provided the terms and conditions imposed by the patent holder do not purport to restrain competition beyond the exclusionary reach of the patent, the license will be free from antitrust challenge, even if it incorporates an agreement between actual or potential competitors that would constitute a naked restraint of trade in the absence of the patent.

Thus, patent licensing agreements may (and commonly do) include terms and conditions like price restrictions, territorial divisions, and other restraints on competition between the patent holder and the licensee that, if not for the patent, would be unlawful *per se* under the

Sherman Act (that is, in the absence of an efficiency-producing business integration). *See United States v. General Electric*, 272 U.S. at 488 (holding that antitrust law does not preclude a patentee from licensing patented technology to a competitor subject to a restriction on the price the competitor may charge for products made with the technology); *see also Simpson v. Union Oil Co.*, 377 U.S. at 23-24 (relying on *General Electric* to reaffirm a patent holder's right to license a patent on any terms and conditions that do not exceed the exclusionary scope of the patent); *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 704-05 (Fed. Cir. 1992) (same); *United States v. Westinghouse Elec. Corp.*, 648 F.2d 642, 647 (9th Cir. 1981) (holding that the government may not challenge territorial restrictions in patent licenses on the ground that they unreasonably stifle potential competition because applying antitrust law to licensing terms that fall within the exclusionary scope of the patents "would severely limit the protection extended by Congress in the [patent] laws").

4. The courts' established reliance on the "scope of the patent" principle to preserve the proper boundary between patent rights and antitrust liability is further demonstrated and underscored by cases applying the doctrine of patent "misuse." To wield a patent as leverage in the commission of an antitrust violation is patent misuse, which renders the patent unenforceable until the effects of the misuse are purged. *See Mallinckrodt*, 976 F.2d at 706, 708; *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1001-02 (Fed. Cir.), *cert. denied*, 477 U.S. 905 (1986); *see also Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 491-93 (1942). But under this doctrine, there can be no patent misuse unless the patent holder

has acted "to expan[d] the patent beyond the legitimate scope of its monopoly." *Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 38, 41 (2006) (internal quotation marks and citations omitted); *see Princo Corp. v. ITC*, 616 F.3d 1318, 1328 (Fed. Cir. 2010) (en banc) ("[T]he key inquiry under the patent misuse doctrine is whether, by imposing the condition in question, the patentee has impermissibly broadened the physical or temporal scope of the patent grant and has done so in a manner that has anticompetitive effects. Where the patentee has not leveraged its patent beyond the scope of rights granted by the Patent Act, misuse has not been found.") (citations omitted), *cert. denied*, 131 S. Ct. 2480 (2011); *Mallinckrodt*, 976 F.2d at 708 ("Should the restriction [at issue] be found to be reasonably within the patent grant, *i.e.*, that it relates to subject matter within the scope of the patent claims, that ends the [misuse] inquiry.").

5. The foregoing discussion leads to a further conclusion about the patentee's statutory rights: The combination of the patent holder's express rights (i) to enforce the exclusivity granted in the patent through a civil action in court (35 U.S.C. §§ 281, 283, 284) and (ii) to agree to license the patent to would-be competitors on any terms and conditions that fall within the patent's exclusionary scope (*General Electric*, *supra*) necessarily implies that the Patent Act also protects the holder's right (iii) to settle bona fide patent litigation on any terms and conditions that do not restrain competition beyond the exclusionary sweep of the patent. The right to bring an infringement action in court implies the right to settle the litigation, including by granting a limited license of the patent rights; and the right to license the patent on any terms within the scope of the patent implies that a

license agreed to in a settlement may be conditioned on any terms of exchange, including "reverse payments," provided the agreement does not purport to extend the exclusion of competition to markets, technologies, parties, or time periods beyond what the full enforcement of the patent would allow.

Unless the underlying infringement claim is frivolous or the patent was obtained through fraud, settlement terms that fall within the outer bounds of the lawful monopoly held by the patentee are properly shielded, in accordance with the established "scope of the patent" principle, from "the hot coals of antitrust litigation," *Asahi Glass Co., Ltd. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 992 (N.D. Ill. 2003) (Posner, J., sitting by designation). Thus, this Court long ago held that "[w]here there are legitimately conflicting claims or threatened interferences [involving patents], a settlement by agreement, rather than litigation, *is not precluded by the [Sherman] Act*." *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931) (emphasis added).

The lawfulness (for antitrust purposes or otherwise) of patent settlement terms cannot turn on a prediction that the court in the underlying infringement litigation might not have upheld the full exclusionary scope of the patent. Any such analysis by a reviewing court is precluded by the statutory presumption of patent validity. A patentee that enjoys the statutory presumption "is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them, whatever its private doubts" about the strength of its litigating position. *Asahi Glass Co.*, 289 F. Supp. 2d at 992-93. Unless the patent is fraudulent or the infringement claim a sham, it cannot be an antitrust

violation "to assert patent rights that one is not certain will be upheld in a suit . . . pressed to judgment and to settle the suit to avoid risking the loss of the rights. No one can be *certain* that he will prevail in a patent suit." *Id.* at 993 (emphasis in original).

6. Similarly, there is no legitimate basis, consistent with patent rights, to assume that a "reverse payment" in a patent settlement reflects an agreement to forestall competition "beyond the date that represents an otherwise reasonable litigation compromise." Pet. Br. at 34-35 (internal quotation marks omitted). Provided the agreed date of entry for the would-be competitor (the date when it is granted a license to use the patented technology) is no later than the end of the lawful patent term, the parties to the settlement are free to choose any date they wish, and the selection of the date is not subject to second judgment by an antitrust court (based on an assessment of the strength of the patent suit or otherwise).

The transfer of value from the patent holder to the would-be competitor, instead of the other way around, does not result in any forfeiture of statutory patent rights. The amount paid and the direction of the payment are terms of settlement that lie within the discretion of the settling parties; by themselves, such payment terms do not purport to extend the patent monopoly beyond its lawful bounds.

Moreover, every patent settlement in every context involves some transfer of value from the patent holder to the alleged infringer. *See Asahi Glass Co.*, 289 F. Supp. 2d at 994 ("*any* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not

settle unless he had something to show for the settlement") (emphasis in original). Settlement agreements are contracts, and all contracts require the exchange of consideration. *See* Restatement (Second) of Contracts § 17 (1981). Such "reverse" consideration may take various forms: A license with a favorable royalty rate, for example; a cross-licensing arrangement; the settlement of other disputes; the reimbursement of attorney's fees; the surrender of a claim for money damages; or compensation paid to the licensee for a later licensing date than was originally sought.

Given that the parties to a patent settlement have broad discretion to structure the mutual exchange of consideration as they see fit, the fact that some payment flows from the patent holder to the licensee cannot be sufficient to support a presumption of an antitrust violation. "[T]he exclusionary effect of the patent" is the only proper touchstone for determining whether the negotiated settlement is unlawful under the Sherman Act. *Valley Drug Co.*, 344 F.3d at 1306. *See Studiengeselschaft*, 670 F.2d at 1128 (conduct may be illegal under antitrust law "if it threatens competition in areas other than those protected by the patent"; if not, the conduct "*is otherwise legal*") (emphasis added); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981) ("where a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws"), *cert. denied*, 455 U.S. 1016 (1982).

B. The Freedom to Settle Bona Fide Patent Disputes on Terms Falling Within the Exclusionary Scope of the Challenged Patent Also Finds Protection in the Constitution.

The Patent Act provides that patents "have the attributes of personal property." 35 U.S.C. § 261. The core right of the patent holder to exclude others from using the patented technology is "the very definition of 'property,'" *Schenck v. Nortron Corp.*, 713 F.2d 782, 786 n.3 (Fed. Cir. 1983), and this Court has long considered patents "a species of property," *Fl. Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627, 642 (1999).

As with other property interests, patent rights are protected by the Fifth Amendment, and a patentee may not be deprived of those rights without due process of law. *Cedars-Sinai Med. Ctr. v. Watkins*, 11 F.3d 1573, 1582 (Fed. Cir. 1993), *cert. denied*, 512 U.S. 1235 (1994). These protected rights "necessarily includ[e] the right to license and exploit patents" as permitted by the Patent Act. *Id.* (internal quotation marks omitted). And this Court held nearly 90 years ago that they include the right to sue in court to recover for infringement. *See Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 345 (1928) (to take away a patent holder's right to recover for infringement would be tantamount to "tak[ing] away from a private citizen his lawful claim for damage to his property" and would raise serious Fifth Amendment concerns).

The same conclusion applies generally to the full range of legal rights granted with the patent. Because, as discussed above, the freedom to settle patent litigation

on any terms and conditions that fall within the scope of the patent springs from the right to enforce the patent in court and from the broad grant of discretion to "license and exploit" the patent however the patent holder wishes, *Cedars-Sinai*, 11 F.3d at 1582, this freedom, too, qualifies as a property right fully protected by the Fifth Amendment.

The protection guaranteed by the Due Process Clause provides a separate constitutional basis for this Court to conclude that the patent rights at issue here may not be stripped away merely on the basis of some administrative policy preference promoted by the FTC. At a minimum, where a government agency is claiming that some other statutory prohibition, such as the Sherman Act, creates a *per se* rule or presumption of unlawfulness that overrides one or more of the property rights conferred on the patent holder under the Patent Act, due process requires that the supervening statutory prohibition be clear and unavoidable. This Court has only accepted *per se* rules and presumed violations in antitrust enforcement based on long experience in the courts establishing that the particular challenged commercial arrangements have no valid purpose and no redeeming pro-competitive consequences. *See Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 886-87 (2007); *Business Elec. Corp. v. Sharp Elec. Corp.*, 485 U.S. 717, 723 (1988). The policy arguments offered by the FTC in support of the presumption advanced in this case do not come close to satisfying that standard and cannot overcome the protection for patent rights found in the Fifth Amendment.

C. Subjecting "Reverse Payment" Patent Settlements to the Presumption of Unlawfulness Advocated by the FTC Would Contradict the Intent of Congress by Substantially Interfering with the Exercise of Economic Freedom by Patent Litigants.

It follows from the preceding discussion that the presumption of an antitrust violation advanced by the FTC would substantially diminish the rights conferred with a patent. Patent litigants would inevitably suffer a significant loss of economic freedom in crafting settlement arrangements—a result that conflicts intolerably with the patent laws.

If the FTC's preferred enforcement policy were approved by this Court, no patent holder would enter into a patent settlement that involves a direct payment of money to the alleged infringer not specifically earmarked for litigation costs or as consideration for a separate, identified side-deal. Furthermore, the presumption of a violation would also substantially constrain the patent holder's willingness to enter into other forms of settlement that include non-monetary "reverse" transfers of value, and potentially any kind of licensing agreement, even outside the context of settlement, that arguably involves such a transfer.

In all of these cases, the patent holder would be highly reluctant to risk the possibility of running afoul of the FTC's presumption because of the dire consequences that would follow under the patent misuse doctrine, which holds that the illegal use of a patent as part of an antitrust violation will render the patent unenforceable, at least until

the competitive effects of the violation are fully dissipated or cured. *See Mallinckrodt*, 976 F.2d at 708. To render a patent unenforceable by operation of a presumption of an antitrust violation, particularly one founded on the FTC's assumption that the patent holder is unlikely to prevail in the underlying infringement litigation, would conflict head-on with the Patent Act's statutory presumption of patent validity, which requires that the full *potential* exclusionary scope of the patent be respected unless and until the party challenging the patent establishes its invalidity. *See* Pet. App. 19a-20a, 29a-30a. Thus, the FTC's position is tantamount to presuming the patent invalid or not infringed.

The chilling effect on patent settlements created by the FTC's presumption would be anathema to public policy. Patent settlements provide certainty and save valuable resources that firms can put to better use. The result advocated by the FTC would substantially alter the landscape in patent litigation, certainly in the Hatch-Waxman context but also potentially more broadly, by disrupting and dislocating patent rights and settlement options for patent litigants. The interference with established patent rights and practice that would follow should lead this Court to reject the FTC's approach. *See Int'l Wood Processors v. Power Dry, Inc.*, 792 F.2d 416, 427 (4th Cir. 1986) (holding that the application of antitrust law "to a specific patent-related practice" must be rejected where the introduction of antitrust sanctions "will frustrate the purposes of the patent laws").

D. Nothing in the Hatch-Waxman Act Negates the Settlement Rights of Patent Litigants or Otherwise Undermines the "Scope of the Patent" Rule Applied by the Eleventh Circuit.

In its recent decision accepting the FTC's proposed presumption of unlawfulness, the Third Circuit relied on the Hatch-Waxman Act as evidence that Congress intended to subject reverse-payment drug patent settlements to heightened antitrust scrutiny. *See In re K-Dur Antitrust Litig.*, 686 F.3d at 217-18. That conclusion is not warranted. The Hatch-Waxman Act was designed to address issues created by the drug approval process, to expedite approval for generic versions of established drugs, and to create a procedure for encouraging the timely resolution of patent disputes so that generic makers would have certainty as to when they could begin marketing generic drugs, but Hatch-Waxman did not reduce the substantive rights of holders of pioneer drug patents to settle litigation with generic makers over patent validity or infringement. In truth, the Hatch-Waxman Act is fully consistent with and supports the "scope of the patent" rule applied by the Eleventh Circuit.

1. Under Hatch-Waxman, a generic drug maker may file an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") for expedited approval of the bioequivalent form of a branded drug already approved for safety and efficacy. *See* 21 U.S.C. § 355(j). If the branded drug is protected by a patent and the generic maker desires to market its version of the drug before the patent expires, the generic maker must file a so-called "Paragraph IV certification," affirming that the patent is invalid or that it would not be infringed by the

manufacture, use, or sale of the generic equivalent. *Id.* § 355(j)(2)(A)(vii)(IV). The Hatch-Waxman Act provides that the holder of the branded drug patent must bring a patent infringement suit against the ANDA filer within 45 days of receiving the Paragraph IV certification in order to obtain a 30-month stay of FDA approval of the generic maker's ANDA. *Id.* § 355(j)(5)(B)(iii). In this manner, Hatch-Waxman strongly encourages the drug makers to resolve their patent dispute expeditiously, without reducing the term or substantive scope of the patent held by the branded drug maker.

2. Hatch-Waxman litigation, like other patent litigation, frequently ends with a settlement, but in the Hatch-Waxman context, "reverse payments are particularly to be expected . . . because the Hatch-Waxman Act created an environment that encourages them." *In re Tamoxifen*, 466 F.3d at 206 (citation omitted); *see Schering-Plough*, 402 F.3d at 1074 (observing that Hatch-Waxman shifted the relative risks of the parties in a way that "explains the flows of settlement funds and their magnitude"). As the Second Circuit has explained, in a "typical patent infringement case" (outside the Hatch-Waxman context), "the alleged infringer enters the market . . . after the investment of substantial sums of money for manufacturing, marketing, legal fees, and the like," and thus the risk of litigation weighs on the alleged infringer, since it may lose the value of its entire initial investment, in addition to paying money damages, if the patent holder prevails. *Tamoxifen*, 466 F.3d at 206. For that reason, the settlement of patent litigation often involves the payment of money by the alleged infringer to the patent holder. *See id.* Conversely, the Hatch-Waxman Act shifts the risk of litigation to the holder of the branded drug patent

by providing for the initiation of infringement litigation before the generic maker has incurred any significant costs in manufacturing, marketing, or selling the generic drug. The generic maker "has relatively little to lose in the litigation," whereas the holder of the branded drug patent has much to lose and little to gain from pressing the litigation to judgment, and this dynamic creates a strong incentive for reverse-payment patent settlements under Hatch-Waxman. *Id.* at 207.

3. The "scope of the patent" rule appropriately accommodates the reversal of incentives created by the Hatch-Waxman Act while taking care to protect substantive patent rights. In doing so, this rule actually promotes competition from generic drug makers by preserving the freedom of the parties to settle their patent dispute in a manner that permits entry by the generic maker on a date certain before expiration of the branded maker's patent. On the other hand, by significantly constraining the settlement options available to the drug makers, the FTC's presumption of unlawfulness for reverse-payment settlements would create a disincentive for generic makers to challenge the pioneer patent in the first place by suppressing the generic's prospects for obtaining an advantageous settlement, and it would therefore end up reducing the availability of low-cost generic drugs for consumers. *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."); *see also Schering-Plough*, 402 F.3d at 1075 (concluding that reverse-payment settlements "benefit the public by introducing a new rival

into the market, facilitating competitive production, and encouraging further innovation"). Such an anticompetitive result runs directly against both the goals of antitrust policy and the purposes of the Hatch-Waxman scheme.

4. Contrary to the suggestions of the FTC's *amici*,[3] the legislative history of the Hatch-Waxman Act provides no support for the FTC's position. It only confirms that Congress did not intend to cut short the term of the branded drug patent or diminish the substantive patent settlement rights of the holder in enacting the Hatch-Waxman framework.

Hatch-Waxman was designed to address anomalies created by the interaction between patent law and the FDA's new drug approval process, and in so doing, the legislation reflected a compromise that provided benefits to both branded and generic manufacturers. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-71 (1990). First, the legislation permitted term extensions of up to five years for owners of pioneer patents to compensate for the delay in the initial marketing of the patented product caused by the FDA approval process. *See* 35 U.S.C. § 156. In this way, the act benefited the branded maker by correcting a costly regulatory distortion that was occurring at the front end of the patent term. *See Eli Lilly*, 496 U.S. at 669-70. Second, the legislation also corrected a regulatory distortion at the back end of the patent term that was effectively giving the patent holder a *de facto* extension of the patent term at the expense of

3. *See* Br. for Rep. Henry A. Waxman as *Amicus Curiae* in Support of Pet'r 11-14; Br. for Nat'l Ass'n of Chain Drug Stores as *Amicus Curiae* in Support of Pet'r 15-22.

the generic maker: It did this by establishing an expedited approval process (the ANDA process) for bioequivalent generic drugs that could begin before the expiration of the branded drug patent, and by providing a safe harbor from patent infringement liability that permitted the generic maker to engage in the research, development, and manufacture of the bioequivalent drug required for early ANDA approval. *See* 21 U.S.C. § 355(j); 35 U.S.C. § 271(e)(1); *Eli Lilly*, 496 U.S. at 670-71. Finally, the legislation established the Paragraph IV certification procedure and the patent litigation-stay framework for prompting an early resolution of the inevitable patent disputes between the branded and generic makers, so that the generic maker would have certainty that it could begin marketing the generic drug no later than the date when the branded drug patent expired. *See* 21 U.S.C. §§ 355(j)(2)A)(vii), 355(j)(5)(B)(iii); H.R. Rep. No. 857 pt. 1, at 27, 98th Cong., 2d Sess. (1984) ("House Rep. pt. 1") ("some ANDA's will be submitted and ready for approval before the patent on the listed drug has expired," and the Paragraph IV procedural framework thus "permits the commencement of a legal action for patent infringement before the generic drug maker has begun marketing").

The legislative history is quite clear that in crafting this litigation framework, Congress did not intend to diminish in any way the substantive patent rights of the branded drug maker. The principal committee report accompanying the legislation stated that this framework "fairly balances the rights of a patent owner to prevent others from making, using, or selling its patented product and the rights of third parties to contest the validity of a patent or to market a product which they believe is not

claimed by the patent." House Rep. pt. 1, at 27. *See id.* at 28 (emphasis added):

> The provisions of this bill relating to the litigation of disputes involving patent validity and infringement are *not intended to modify existing patent law* with respect to the burden of proof and the nature of the proof to be considered by the courts in determining whether a patent is valid or infringed. . . . [A] patent would have the same statutory presumption of validity as is afforded under current law.

Thus, the chief sponsor of the legislation, Rep. Waxman, specifically explained that it was the purpose and effect of the Hatch-Waxman Act compromise to give the branded maker extra patent protection to cover the time needed for upfront research and development while giving the generic maker the opportunity to market the generic drug *after the expiration* of any blocking patent held by the branded maker, *not* to reduce in any way the term of the patent or the rights of the branded patent holder to enforce its patent and prevent the early marketing of the generic drug. *See* Cong. Rec. H9118 (Sept. 6, 1984) (statement of Rep. Waxman) (emphasis added):

> [T]he whole conceptuality of this bill is to give more time for the firm developing the patented drug, to give them further incentive for research and development. There is public good in that. The other side of it is to give the

> opportunity for competition in generic drugs to be on the market *after that patent has expired*.[4]

In sum, the Hatch-Waxman scheme was never intended to override the drug patent holder's basic patent-law right to settle infringement litigation with the generic on any terms falling within the exclusionary scope of the patent, whether or not those terms include a "reverse payment" to the generic maker.

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4. Nor did Congress mandate an antitrust prohibition on reverse-payment drug patent settlements in the later Hatch-Waxman amendments made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, 117 Stat. 2066. In relevant part, the MMA amendments to Hatch-Waxman required that patent settlements between branded and generic drug makers be submitted to the FTC and the Justice Department for antitrust review and provided that the generic maker would forfeit its priority rights under Hatch-Waxman if the settlement were found to violate the antitrust laws or the FTC Act. MMA §§ 1102, 1111-1118, 117 Stat. 2458-59, 2461-64, *codified at* 21 U.S.C. §§ 355(j)(5)(D), 355 note. Contrary to the suggestion of *amici*, *see* Br. for Rep. Henry A. Waxman as *Amicus Curiae* 14-19, the review process added by the MMA does not evidence any conclusion by Congress one way or the other concerning the appropriate outcome of the agency's antitrust review.

CONCLUSION

For the foregoing reasons, *amicus curiae* the American Intellectual Property Law Association urges the Court to affirm the judgment of the court of appeals.

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