

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 *AMICUS CURIAE* OF
NATIONAL ASSOCIATION OF MANUFACTURERS
IN SUPPORT OF RESPONDENTS**

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QUESTION PRESENTED

Whether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud, or instead are presumptively anticompetitive and unlawful.*

* This is the Question as formulated by Petitioner. Respondents have each proposed slightly different versions of the Question.

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Other Authorities

- Carol Corrado, Charles Hulten, Daniel Sichel, Measuring Capital and Technology: An Expanded Framework, Federal Reserve Board, Finance and Economics Discussion Series No. 2004-65 (August 2004), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=877453. 9
- Frank H. Easterbrook, *Ignorance and Antitrust*, in Thomas M. Jorde & David J. Teece (EDS), *Antitrust, Innovation, and Competitiveness* (1992). . . . 26
- Economic and Statistics Administration and U. S. Patent and Trademark Office, Intellectual Property and the U.S. Economy: Industries in Focus 45 (2012), available at http://www.uspto.gov/news/publications/IP_Report_March_2012.pdf. 7-8
- C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629 (2009). 20
- Herbert Hovenkamp *et al.*, 12 ANTITRUST LAW ¶ 2040b (1999). 22

- Nam D. Pham, The Impact of Innovation and the Role of Intellectual Property Rights on U.S. Productivity, Competitiveness, Jobs, Wages, and Exports (2010), available at http://www.theglobalipcenter.com/sites/default/files/reports/documents/NDP_IP_Jobs_Study_Hi_Res.pdf. 9-10
- Jonathan Rothwell, José Lobo, Deborah Strumsky, and Mark Muro, Patenting Prosperity: Invention and Economic Performance in the United States and its Metropolitan Areas (Brookings Institution, February 2013), available at <http://www.brookings.edu/research/reports/2013/02/patenting-prosperity-rothwell>. 6
- Robert J. Shapiro, The Role of Innovation and Intellectual Property in Economic Competition (American Enterprise Institute 2011), available at [http://www.aei.org/files/2011/09/29/Innovation, and Intellectual Property/Shapiro.pdf](http://www.aei.org/files/2011/09/29/Innovation_and_Intellectual_Property/Shapiro.pdf). 9

Briefs

Brief for United States as Amicus Curiae,
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INTEREST OF *AMICUS CURIAE*¹

The National Association of Manufacturers (“NAM”) is the nation’s largest industrial trade association, representing small and large manufacturers in every industrial sector and in all 50 states. The NAM’s mission is to enhance the competitiveness of manufacturers by shaping a legislative and regulatory environment conducive to economic growth in the United States and to increase understanding among policymakers, the media and the general public about the vital role of manufacturing to America’s economic future and living standards.

Many of its members hold patents, trademarks or copyrights, and consider intellectual property to be important assets, and many of them will be affected by the decision in this case.

¹ Pursuant to Rule 37.2(a), all parties have consented to the filing of this brief. Copies of those consents have been lodged with the Clerk.

Pursuant to Rule 37.6, *amicus* affirms that no counsel for any party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae* nor its counsel made a monetary contribution to the preparation or submission of this brief.

**PRELIMINARY STATEMENT AND
SUMMARY OF ARGUMENT²**

This case arises from settlements of patent litigation brought under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act). The settlements in this case involve Abbreviated New Drug Applications (ANDAs) governed by the Hatch-Waxman Act before it was amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), and thus are known in the industry as “pre-MMA” settlements.

As is not uncommon, the patent owner, Solvay Pharmaceuticals’ predecessor, sued the generic manufacturers [both of whom had filed “Abbreviated New Drug Applications” for a generic equivalent)]. That litigation went through discovery and some motion practice in the Northern District of Georgia, and was then settled after partially dispositive motions were filed, but before they were decided. The FTC does not claim that the underlying patent litigation was a sham, nor does the agreement at issue give Solvay a monopoly for a period beyond that granted by its patents.

The settlement of the patent litigation “split the baby.” The generic manufacturers agreed not to

² *Amicus* adopts the Statement of Respondent Actavis, Inc.

market their product for a period equal to approximately one-half of the remaining period of patent protection, and Solvay agreed to pay Watson and Paddock fees for “marketing assistance” for the brand-name AndroGel product during the remaining patent-protected period and to provide “back up production capacity.”

The FTC asserts that the settlement is an anticompetitive agreement because it involves a payment to the generic manufacturers to stay out of the market for a time, giving the patent holder a monopoly for a period of time, notwithstanding the fact that the agreed period of generic abstention was shorter than the monopoly period inherent in the patent.

The district court dismissed the FTC’s lawsuit and the Eleventh Circuit, agreeing with precedent in the Second and Federal Circuits (*In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005), *amended*, 466 F.3d 187 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (“*Cipro*”)), affirmed the district court’s dismissal of the FTC’s complaint because the underlying patent litigation was not a sham, and because the non-compete term was no greater than the period during which Solvay would have had exclusivity had its patent been upheld.

The central question is whether a settlement of *bona fide*, non-sham, patent litigation unlawfully restrains trade, where the patent was not procured

by fraud and the settlement terms do not exceed the scope of the patent's exclusionary period. Critical to this inquiry is the existence of the patent, which is presumed to be valid and grants its holder the right to exclude competition within the patent's scope.

The FTC asks this Court to hold that "reverse-payment" patent settlements are presumptively unlawful. The FTC contends that a rule of presumptive unlawfulness "serves the purposes of competition law, patent law, and the Hatch-Waxman Amendments." FTC-Br.19-40.

The test proposed by the FTC omits any consideration of the inherent right to exclude emanating from the patent, which, by its nature, is a grant by the government to the patentee of a legal monopoly for a period of time.

The FTC's "Questions Presented" and the arguments it makes, moreover, are not limited to the Hatch-Waxman Amendments or to the pharmaceutical industry and have immense implications. This Court's answer to the question as posed by the FTC will affect all patentees, and will affect broad and vital sectors of the United States' economy.

If the FTC's rule were adopted, it would put patent holders at risk whenever they settle an infringement action – which is frequently an expensive "crap shoot" – by licensing the patent in exchange for a significant license fee or by entering

into a “reverse payment” arrangement. A decision in favor of the FTC could well discourage companies from undertaking lengthy and expensive research and development programs, the cost of which can be recouped only through a significant period of patent monopoly protection.

The FTC’s proposed rule would throw the long-established intellectual property (patent, trademark, copyright) (“IP”) regimes into turmoil; it would upset the reasonable economic expectations of broad swaths of industry in the United States grounded in decades of patent and antitrust law. It would likely do immeasurable damage to the domestic economy and the United States’ competitiveness in the world economy.

The decision and judgment of the Court of Appeals for the Eleventh Circuit should be affirmed because that court’s decision and reasoning are consistent with this Court’s precedents, the purposes of the Patent Act, and the Sherman Act, 15 U.S.C. § 1.

ARGUMENT

I.

THE FTC’S PROPOSED RULE WILL HAVE AN IMMENSE IMPACT ON THE ECONOMY

The impact of the FTC’s proposed rule on the economy is difficult to exaggerate. This Court’s resolution of this case will have a broad impact on innovators and patent holders in the manufacturing sector. Although the focus of this case is the pharmaceutical industry, the rule proposed by the FTC is not limited to that industry, and would apply to all intellectual property, and all industrial sectors that are intellectual property-intensive.

Inventions, embodied in patents, are a major driver of long-term regional economic performance. *See*, Jonathan Rothwell, José Lobo, Deborah Strumsky, and Mark Muro, *Patenting Prosperity: Invention and Economic Performance in the United States and its Metropolitan Areas* (Brookings Institution, February 2013), available at <http://www.brookings.edu/research/reports/2013/02/patenting-prosperity-rothwell> (last accessed Feb. 26, 2013).

Intellectual property (“IP”) intensive industries accounted for about \$5.06 trillion in value added³:

³ “Value added” is the difference between an
(continued...)

34.8 percent of total U.S. gross domestic product (GDP), in 2010.

IP-intensive industries accounted for 18.8 percent of all jobs in the economy in 2010. *See* Economic and Statistics Administration and U. S. Patent and Trademark Office, Intellectual Property and the U.S. Economy: Industries in Focus 45 (2012), available at http://www.uspto.gov/news/publications/IP_Report_March_2012.pdf (last accessed Feb. 25, 2013) (“IP and U.S. Economy”).

The 75 industries classified as IP-intensive (out of a total of 313 industries categorized) accounted for 27.1 million American jobs, or 18.8 percent of all employment in the economy, in 2010; IP-intensive industries, while direct and indirect activities account for 27.7 percent of all jobs in the economy. Patent-intensive industries, while employing fewer persons than trademark- or copyright-intensive industries, supported a larger multiple of outside supply chain employment. Jobs in IP-intensive industries also pay significantly

³(...continued)

industry’s total output (sales plus change in inventories arising from production) and the value of its intermediate purchases from other industries (that is, from its supply chain).

better than other jobs.⁴ IP and U.S. Economy at 43-44.

United States IP-intensive industries have a significant beneficial impact on the U.S. international trade. Merchandise exports of U.S. IP-intensive industries totaled \$775 billion in 2010, accounting for 60.7 percent of total U.S. merchandise exports. Manufacturing industries were responsible for almost 99 percent of IP-intensive merchandise exports in 2010, with pharmaceuticals and medicine accounting for \$49.4 billion and medical equipment and supplies accounting for \$26.2 billion. From 2000 to 2010, exports of IP-intensive industries increased 52.6%. IP and U.S. Economy at 53.

In the first decade of the twenty-first century, U.S. businesses invested as much in “idea-related intangibles” (approximately \$1 trillion) as they did in plant, equipment and other tangible forms of investment. The development of new information technology (“IT”) accounted for 28 percent of

⁴ Average weekly wages for IP-intensive industries were \$1,156 in 2010, 42 percent higher than the \$815 average weekly wages in non-IP-intensive private industries. The difference is even greater for workers in patent-intensive industries, who earned \$1,407 per week on average. The comparatively high wages in IP-intensive industries correspond to, on average, the completion of more years of schooling by these workers. IP and the U.S. Economy at 50-51.

productivity gains. Capital investment in IT accounted for 34 percent of productivity gains; and research and development (“R&D”) accounted for 10 percent of productivity gains. *See* Carol Corrado, Charles Hulten, Daniel Sichel, “Measuring Capital and Technology: An Expanded Framework,” Federal Reserve Board, Finance and Economics Discussion Series, No. 2004-65, August 2004, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=877453 (last accessed Feb. 26, 2013); *see also* Robert J. Shapiro, *The Role of Innovation and Intellectual Property in Economic Competition* (American Enterprise Institute 2011), available at http://www.aei.org/files/2011/09/29/Innovation_and_Intellectual_Property_Shapiro.pdf (last accessed Feb. 25, 2013).

From 2000 to 2007, IP-intensive industries spent almost 13 times more on R&D per employee than non-IP-intensive industries (\$27,839 versus \$2,164 per employee per year) and workers in IP-intensive industries generated approximately double the output and sales per employee than workers in non-IP-based industries: annual output (as measured by value-added) was \$218,373 per employee in IP-intensive industries and only \$115,239 in non-IP-intensive industries); annual sales averaged \$485,678 per employee in IP-intensive industries versus \$235,438 per employee in non-IP-intensive industries. *See* Nam D. Pham, *The Impact of Innovation and the Role of Intellectual Property Rights on U.S. Productivity*,

Competitiveness, Jobs, Wages, and Exports (2010), available at http://www.theglobalipcenter.com/sites/default/files/reports/documents/NDP_IP_Jobs_Study_Hi_Res.pdf (last accessed Feb. 25, 2013).

IP-intensive industries made up nearly half of output and sales of all U.S. industries engaged in international trade and employed more than 30 percent of American workers in those industries. IP-intensive industries accounted for approximately 60 percent of total U.S. exports and in the period 2000-2007, and the annual value of exports per employee in IP-intensive industries was 3.4 times (235 percent) higher than in non-IP-intensive industries (\$91,607 versus \$27,369). In the period 2000-2007, the annual salaries of workers in IP-intensive industries were, on average, 60 percent higher than the salaries of workers in non-IP-intensive industries (\$59,041 versus \$37,202/employee/year, respectively). Pham, *id.*

II.

PATENT HOLDERS' RIGHTS

A. Patents Create Legal Monopolies.

The Constitution gives Congress the authority “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” U.S. Const. art. I, § 8, cl. 8. This language, made explicit in the Patent

Act, 35 U.S.C. § 154(a)(1) grants patent holders the right to exclude others from using or selling the patented invention. *Dawson Chem. v. Rohm & Haas*, 448 U.S. 176, 215 (1980) (“[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention.”); *Microsoft Corp. v. i4i P’ship*, 131 S. Ct. 2238, 2242 (2011) (“[A] patent grants certain exclusive rights to its holder, including the exclusive right to use the invention during the patent’s duration.”).

A patent is, simply put, a legal monopoly:

The very object of [the patent] laws is monopoly, and the rule is, with few exceptions, that any conditions which are not in their very nature illegal with regard to this kind of property, imposed by the patentee and agreed to by the licensee for the right to manufacture or use or sell the article, will be upheld by the courts.

Bement & Sons v. Nat’l Harrow Co., 186 U.S. 70, 91 (1902).⁵

Patentees can engage in restraints of trade and exclusionary conduct that would violate the antitrust laws absent patent protection: “The

⁵ Ignoring the constitutional and statutory condonation of patent monopolies, the FTC falsely analogizes licensing or cross-licensing to agreements by competitors to divide markets where no patents are involved, which is *per se* illegal

patent laws which give a 17-year monopoly on 'making, using, or selling the invention' are *in pari materia* with the antitrust laws and modify them *pro tanto*." *Simpson v. Union Oil*, 377 U.S. 13, 24 (1964). "[P]atent grants [are] an exception" to antitrust restrictions. *United States v. Line Material Co.*, 333 U.S. 287, 309 (1948) unless the patent was improperly acquired (for fraud on the PTO) or improperly asserted (sham litigation). See *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 178 (1965); *Profl Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 51 (1993).⁶ "The [patent] monopoly is a property right." *Festo v. Shoketsu Co.*, 535 U.S. 722, 730 (2002); see *DOJ/FTC Guidelines* §1.0 (patent laws "establish[] enforceable property rights for the creators of new and useful products").

⁶ A patentee may, of course, lose antitrust immunity by demanding royalties beyond the patent term, see *Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964), by using its patent to control the sale of unpatented products, see *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 491 (1942), or by restricting the resale of patented products, see *United States v. Masonite Corp.*, 316 U.S. 265, 310-11 (1942), "Patent pools," by which multiple patent holders jointly restrain trade beyond what a single patentee could achieve may also not have antitrust immunity. See *Line Material*, 333 U.S. at 288-89; *United States v. New Wrinkle, Inc.*, 342 U.S. 371, 376-79 (1952).

The FTC's proposed rule wipes out over a century of patent-antitrust law.

B. The FTC's Proposed Rule Ignores the Essential Characteristics of Patents.

The “most material fact” in an appropriate antitrust analysis of patent-related agreements “is [that] the agreements concern articles protected by letters patent.” *Bement, supra* at 88). It is essential in an antitrust analysis of patent-based transaction to acknowledge the patent holder's lawful exclusionary rights. *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 411 (2004). The FTC's rule fails completely to do this.

The crux of the FTC's purported patent-law justification for its proposed rule is that patents confer merely “probabilistic” rights and, because the FTC suspects many “weak” patents exist and therefore patent settlements require judicial appraisal beyond the scope-of-the-patent. FTC Br. 44. These arguments are also unsound, because they ignore the presumption of validity attaching to patents, *see* 35 U.S.C. § 282(a) and *United States v. Masonite Corp.*, 316 U.S. 265, 280 (1942), and would usurp the functions of the agency charged with administering the patent system.

The FTC's disregard of the patentee's exclusive rights, unless and until the validity of the patent is established through a judgment after litigation, creates an unworkable and pernicious rule at odds

with precedent.⁷ The FTC concedes that basing antitrust analysis on a *prediction* of which side would have prevailed would be “doctrinally anomalous and likely unworkable in practice.” FTC Br. 53.

C. The Scope of the patent Rule.

Under the Court’s precedents, which the FTC’s rule would in effect overrule, the “scope of the patent” rule, a rule which creates predictable guidelines within which the patent holder may operate without facing the threat of antitrust liability. See *United States v. Gen. Elec. Co.*, 272 U.S. 476, 485, 489 (1926) (“[I]t is only when . . . [the patentee] steps out of the scope of his patent rights” that he comes within the operation of the Sherman Act); *United States v. Line Material*, 333 U.S. 287, 300 (1948) (“[T]he precise terms of the grant define the limits of a patentee’s monopoly and the area in which the patentee is freed from competition of price, service, quality or otherwise” but “[i]f the limitations in a license reach beyond the scope of the statutory patent rights, then they must be tested by the terms of the Sherman Act”).

⁷ In one of many paradoxes in the FTC’s litigation position in this case, it concedes, FTC-Br.26-27, “Where there are legitimately conflicting claims, or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act,” citing *Standard Oil (Indiana) v. United States*, 283 U.S. 163, 171 (1931).

To determine whether a patentee engaged in conduct beyond the protection of its temporary monopoly and is, therefore, potentially in violation of the antitrust laws, one begins by examining whether the restraint exceeds the scope-of-the-patent. *See, e.g., Gen. Talking Pictures v. Western Electric*, 305 U.S. 124, 127 (1938) (“[T]he patentee may grant a license 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.”); *Line Material*, 333 U.S. at 353 (“If the limitations in a license reach beyond the scope of the statutory patent rights, then they must be tested by the terms of the Sherman Act.”); *Cipro*, 544 F.3d at 1336 (“[T]he 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.”).⁸

D. Patent Litigation Settlements.

This Court has long recognized that settlement of patent litigation, without more, does not violate the antitrust laws. *Standard Oil Co. (Ind.) v. United States*, 283 U.S. 163, 171 (1931) (“Where there are legitimately conflicting claims or

⁸ The “scope of the patent” test harmonizes patent and antitrust law, while the FTC’s rule creates an unavoidable and irreconcilable tension between the two legal regimes.

threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act.”).

The FTC nevertheless urges the Court to adopt an antitrust analysis for patent litigation settlements that disregards the patent, in effect treating the patent as though it were nugatory.⁹

The FTC’s proposed rule in this case is at odds with “[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.” U.S. Br. 10-11 (emphasis added) in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1073 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006) (filed May 17, 2006), 2006 WL 1358441 at *12. As the FTC now concedes, the government’s position in *Schering-Plough* is irreconcilable with its position here (“In those [earlier] briefs], the United States did not endorse the FTC’s view that

⁹ The FTC takes the position that the patent has *no* scope until courts have established its validity and coverage in litigation. See FTC Br. 25-26 (“simply holding a patent does not result in the automatic exclusion of potential rivals;” and *id.* at 40 (“[t]o enforce a contested patent, a patentee must prove that the accused product or process falls within the scope of the patent’s claims as properly construed.”))

reverse-payment settlements are presumptively anticompetitive.” FTC Br.41 n.9.

The FTC concedes that *Standard Oil* establishes the general rule that patent settlements do not violate the antitrust laws, FTC Br.26-27. *Standard Oil* teaches that (1) parties may settle patent litigation without antitrust liability as long as there were “legitimately conflicting claims,” 283 U.S. at 171; (2) such conflict turns on the nominal scope-of-the-patent, which is not to be second-guessed by inquiring whether infringement would have been proven, *id.* at 181¹⁰; and (3) the financial terms and consideration of a settlement are irrelevant, *id.* at 171-172.

The Court in *Standard Oil* noted the frequent necessity of exchanging financial consideration in reaching settlements: “An interchange of patent rights and a division of royalties according to the value attributed by the parties to their respective patent claims is frequently necessary if technical advancement is not to be blocked by threatened litigation.” *Id.*¹¹

¹⁰ Because the patents are presumptively valid, and there was no allegation of bad-faith in its acquisition, the Court did “not consider any of the issues concerning the validity or scope of the . . . patents.”

¹¹ The Court rejected the government’s contention that the royalties imposed by the settlement and cross-licenses were so large as to exclude potential
(continued...)

The scope-of-the-patent test subjects settlements to antitrust scrutiny if the settlements (1) exceed the bounds of the patent monopoly, *United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963); (2) settle sham litigation, *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993); or (3) involve a patent obtained through fraud on the PTO. *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965).

The scope-of-the-patent approach creates a reasonably bright line between lawful and unlawful conduct, consistent with the need to have antitrust rules that are clear and explainable. See *Bell Tel. Co. v. linkLine Commc'ns*, 555 U.S. 438, 452 (2009) (“[w]e have repeatedly emphasized the importance of clear rules in antitrust law.” The need for clear rules is magnified where the agreements subject to antitrust scrutiny are entered into to resolve inherently uncertain patent litigation. See *Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990) (“It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in this case.”); *Asahi Glass Co. v. Pentech Pharms. Inc.*, 289 F. Supp. 2d

¹¹(...continued)

competitors from using the patented processes and unreasonably restrained gasoline supply because “[t]his argument ignores the privileges incident to ownership of patents.” *Id.* at 172.

986, 993 (N.D. Ill. 2003) (Posner, J.) (“No one can be *certain* that he will prevail in a patent suit.”).

III.

THE FTC’S PROPOSED RULE IS PERNICIOUS

A. The FTC’s Proposed Rule Creates Ambiguity.

The Question Presented as framed by the FTC (“Whether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud, or instead are presumptively anticompetitive and unlawful” (See FTC Br. I.)) completely disregards the traditional analysis of the legality of a patent settlement – whether the scope of the patent has been exceeded by the terms of the settlement.

The FTC urges an ambiguous and burdensome rule, which relies solely on the presence of a “payment” (a term the FTC does not define¹²) as

¹² Virtually any patent settlement could be seen as involving a “payment” to the alleged infringer under the FTC’s approach. While at one point the FTC mentions “monetary payment,” *id.* 16; at another point it refers to “money or similar consideration,” *id.* at 27 (emphasis added); later the FTC writes that the rule could also apply to “an alternative form of consideration” having similar effects to “direct payments.” *Id.* at 36 n.7.

Even a license with no payment, either by the
(continued...)

the means of identifying supposedly anticompetitive patent litigation settlements¹³, and is grounded on the unprecedented and mischievous premise that a patent is entitled to no weight at all unless and until it is proven through litigation to judgment to be valid and infringed. The FTC's rule would condemn many typical settlements both inside and outside the pharmaceutical context.

The rule would give the FTC unfettered discretion to challenge almost any settlement it

¹²(...continued)

patentee or the licensee, might be considered by the FTC, or alleged by a private plaintiff, to be a "payment" to the licensee if a "fair" royalty would have been, in their view, greater, or some other term of the license could have been different. The FTC's brief cites with approval C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 663-66 (2009), which describes numerous types of transactions that allegedly "disguise the fact of payment."

¹³ The FTC's position is inconsistent with Department of Justice's position only a few years ago. Noting the "high degree of suspicion" of reverse-payments reflected in the FTC's approach, Brief for United States as Amicus Curiae, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273) (filed May 17, 2006), 2006 WL 1358441 at *12, the Department of Justice's view was that "the mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful." *Id.* at *11.

believed could conceivably have been structured to provide more “consumer benefits.”¹⁴ The FTC’s rule would also give *private* plaintiffs and their lawyers, with the incentive of possible treble damages and attorneys’ fees, the same opportunity.¹⁵ Such “second-guessing” and the threat of litigation is inimical to calculating the value to the patentee of its property rights in the patent and in R&D investment.

The FTC’s proposed rule encourages litigation and its attendant expense and distraction for businesses on both sides of an IP dispute.

¹⁴ The FTC does not satisfactorily explain this *ipse dixit* conclusion.

¹⁵ The burden of showing that the challenged agreement has a substantial anticompetitive effect ordinarily rests with the antitrust plaintiff. *United States v. Arnold, Schwinn & Co.*, 388 U.S. 365, 374 n.5 (1967), *overruled on other grounds by Cont’l T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36, 58-59 (1977). Under the FTC’s test, if an antitrust plaintiff alleges that (i) a settlement agreement provides for delayed entry into the market by the non-patentee, and (ii) the non-patentee defendant received a “payment,” the settlement is presumptively unlawful and the burden shifts to the settling parties to prove that the “payment” was for something other than a “delay” in market entry. FTC Br. 37-38.

B. The FTC's Rule Discourages Settlement.

The FTC's rule would thwart the judicial policy favoring settlement and impose a significant and unwarranted burden on the judicial system. The FTC's rule restricts settlement options¹⁶, chills settlements¹⁷ and leads to protracted litigation, all contrary to greater societal interests. *See*

¹⁶ *See Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (“A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger’s settlement options should he be sued for infringement, and so might well be thought anticompetitive.”).

¹⁷ Settlements in complex commercial cases frequently include cooperative business dealings, such as exchanges of assets, including licensing or cross-licensing of intellectual property. In antitrust analysis, licenses divide markets among competitors. 12 Herbert Hovenkamp *et al.*, ANTITRUST LAW ¶ 2040b (1999) (“[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.”

Granting an exclusive license has long been thought to be one of the most legally important and secure rights of a patentee – it is an incident of the patentee’s property interest. The Supreme Court held over a century ago that antitrust law does not prohibit “a restraint of commerce that may arise from reasonable and legal conditions imposed upon the ... licensee of a patent.” *Bement v. Nat’l Harrow Co.*, 186 U.S. 70, 92 (1902).

Tamoxifen, 466 F.3d at 212 n.26 (a rule making patent litigation settlements “subject to the inevitable, lengthy and expensive hindsight of a jury as to whether the settlement constituted a ‘reasonable’ restraintwould place a huge damper on such settlements contrary to the law . . . that settlements are not only permitted, they are encouraged.”); *Cipro*, 363 F. Supp. 2d 514, 529 (E.D.N.Y. 2005) (“[M]aking the legality of a patent settlement agreement, on pain of treble damages, contingent on a later court’s assessment of the patent’s validity might chill patent settlements altogether.”), *aff’d*, 544 F.3d 1323 (Fed. Cir. 2008).¹⁸

Compromise and settlement of disputed claims is favored by the courts. *See Williams v. First Nat’l Bank*, 216 U.S. 582, 595 (1910); *McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994); *Schering-*

¹⁸ The FTC recognizes that its rule would require relitigating the underlying patent dispute in private antitrust lawsuits, FTC Br. 40, but it favors this result because “in the aggregate, those judgments on the merits “will reflect results more in keeping with the policies of the antitrust laws, the Patent Act, and the Hatch-Waxman Amendments than if all the cases had been settled with reverse payments.” *Id.* The FTC concedes, however, that any standard that requires relitigating the underlying patent dispute would be unmanageable and would create a “powerful disincentive to settlement.” FTC Br. 54. The FTC does not explain this paradox.

Plough, 402 F.3d at 1072, 1075 (the general policy favoring settlements “extends to the settlement of patent infringement suits,” and “[t]here is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation.”)

As the FTC concedes, forcing relitigation of the merits of a patent case in a subsequent antitrust suit would create a “powerful disincentive to settlement” because litigants would know that by settling the patent dispute, they were inviting one or more antitrust cases. FTC Br. 54. Forcing relitigation would mitigate or negate entirely the benefits of settlement by having treble-damage antitrust liability depend on a subsequent court’s analysis of what the outcome of highly technical and uncertain patent litigation might have been.

The presumption of illegality and shifting of the burden to defendants inherent in the FTC’s proposed rule provides an incentive for private plaintiffs to file weak antitrust suits in hopes of proceeding to discovery and extracting a settlement of their claim, but it discourages settlement of the underlying patent dispute. This Court has recognized that “proceeding to antitrust discovery can be expensive,” and the importance of “avoid[ing] the potentially enormous expense of discovery in cases with no reasonably founded hope that the discovery process will reveal relevant evidence to support a [Section] 1 claim.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558-59 (2007)

(internal quotation omitted). In those cases that survive dispositive motions, courts and the parties will have to re-try the merits of the patent suit that the parties (and probably the judge) had hoped were settled.

Despite acknowledging that it would be undesirable and unworkable to relitigate the patent merits in a subsequent antitrust case, the FTC recognizes that its proposed rule would have precisely that effect in private antitrust actions for “[q]uantification of damages.” FTC Br. 55 n.11. Private antitrust actions far outnumber those brought by the FTC and will be subject to whatever test the Court adopts in this case.¹⁹

C. The FTC Rule Discourages Innovation.

Although the FTC recognizes the importance of “preserv[ing] the incentives to innovate that benefit consumers in the long run,” FTC Br. 45, it proposes a rule that would discourage innovation. *See Tamoxifen*, 466 F.3d at 203 (“Rules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay

¹⁹ In fact, relitigating the patent case would occur in all cases because no conclusion about a patent settlement’s effect on competition could logically be reached without determining if the patent was valid and infringed.

innovation.”); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1073 (“the caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer’s ability to research, develop, and market the patented product or allegedly infringing product”); see *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294, 1308 (11th Cir. 2003) (“restricting settlement options, which would effectively increase the cost of patent enforcement . . . would impair the incentives . . . and innovation”). The FTC’s approach would have harmful long-term effects on innovation, and is not only legally wrong, but is bad policy. See Frank H. Easterbrook, *Ignorance and Antitrust*, in Thomas M. Jorde & David J. Teece, eds., *Antitrust, Innovation, and Competitiveness*, 119, 122-23 (1992) (“[a]n antitrust policy that reduced prices by 5 percent today at the expense of reducing by 1 percent the annual rate at which innovation lowers the cost of production would be a calamity. In the long run a continuous rate of change, compounded, swamps static losses.”)

The uncertainty created by the FTC’s ambiguous and burdensome rule would have a chilling effect on innovation and, consequently, the United States’ economy and its competitiveness in the global economy, and would impose unwarranted burdens upon the judicial system.

The scope-of-the-patent approach is a clear and doctrinally sound method for analyzing patent litigation settlements. Equally important, it creates readily discernable criteria, and does not vest virtually unlimited discretion in the FTC to commence proceedings challenging settlements. To the world of industry and commerce, minimizing legal and regulatory uncertainty is an important virtue, allowing business to gauge accurately the risks and rewards of investment in innovation.

CONCLUSION

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

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Respectfully submitted,

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