No. 12-416

Supreme Court of the United States

FEDERAL TRADE COMMISSION, PETITIONER

v.

ACTAVIS, INC., ET AL.

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

BRIEF FOR RESPONDENTS PAR/PADDOCK

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QUESTION PRESENTED

This case is about settlements of patent litigation brought under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act). Flaws in the Hatch-Waxman Act, including those relating to settlements concluded thereunder, prompted Congress to enact remedial amendments in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

The settlements in this case involve Abbreviated New Drug Applications (ANDAs) governed by the pre-amendment law, and thus are known in the industry as "pre-MMA" settlements. The United States twice advised this Court that the MMA's remedial changes warranted denying certiorari in cases involving pre-MMA settlements to address antitrust questions concerning reverse payments. Among other changes, the MMA added a specified antitrust penalty and an antitrust savings clause.

The question presented here is the same as stated by the United States when it opposed the FTC's petition for a writ of certiorari in *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (CA11 2005), cert. denied, 548 U.S. 919 (2006):

> Whether the antitrust laws prohibit a brand name drug patent holder and a prospective generic competitor from settling patent infringement litigation by agreeing that the generic manufacturer will not enter the market before a future date within the term of the patent and that the patent holder will make a substantial payment to the generic manufacturer.

U.S. Br. I, *supra* (No. 05-273) (filed May 17, 2006).

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PRELIMINARY STATEMENT AND SUMMARY OF ARGUMENT

The FTC asks this Court to hold that "reverse-payment" patent settlements are presumptively unlawful under "quick-look" antitrust analysis. The FTC contends that such a categorical rule of presumptive unlawfulness "serves the purposes of competition law, patent law, and the Hatch-Waxman Amendments." FTC-Br.19-40. None of those three considerations warrant such categorical departure from the traditional rule of reason.

1. The default analysis for alleged restraints of trade is the rule of reason. *Texaco* v. *Dagher*, 547 U.S. 1, 5 (2006). For patent-based restraints, the rule of reason accounts for statutory, time-limited patent monopolies by first inquiring whether the restraint is within the scope-of-the-patent. *E.g.*, *United States* v. *Line Material*, 333 U.S. 287, 353 (1948) ("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.").

This Court never has upheld an antitrust claim against patent enforcement or licensing within the scope of a non-sham patent. ("Sham" defined to include fraudulently procured patents.) And, as the FTC 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." *Standard Oil (Indiana)* v. *United States*, 283 U.S. 163, 171 (1931).

Without establishing the other elements under Sherman Act §§1-2, an antitrust claim is *not* established by: (i) enforcing a patent knowingly

procured by fraud, *Walker Process Equip.* v. *Food Mach. & Chem.*, 382 U.S. 172, 174 (1965); or (ii) bringing an objectively baseless patent suit with the improper subjective motivation of interfering with the purported infringer's market-participation, *Prof'l Real Estate Investors* v. *Columbia Pictures* (*PRE*), 508 U.S. 49, 60-61 (1993). The FTC nonetheless asks this Court to hold that a reverse-payment patent-settlement alone establishes a presumptive antitrust violation. FTC-Br.15.

That the FTC's rule disregards statutorily conferred patent monopolies is evident in the FTC's analogizing reverse-payment settlements to the "paradigmatic antitrust violation" of horizontal market-allocation that this Court has condemned as a *per se* violation. FTC-Br.19-20, 23 (citing *Palmer* v. *BRG of Georgia*, 498 U.S. 46 (1990)). Statute expressly authorizes patent-holders to engage in the type of market-allocation in *Palmer*, a case that did *not* involve patents. See 35 U.S.C. 261 ("The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States.").

By ignoring the lawful exclusionary power of patents—and the correspondingly lawful restraints in licenses thereunder—the FTC's *Palmer* analogy and proposed rule incorrectly assume that patent-settlement licenses entail horizontal, rather than vertical, restraints. Ascertaining whether such restraints are horizontal or vertical is impossible without predicting which side would have won the patent litigation:

> [A]ntitrust analysis of intellectual property licensing arrangements examines whether the relationship among the parties to the arrangement is primarily horizontal or vertical in nature, or whether it has substantial aspects of both.
>
> *** [T]he Agencies ordinarily will treat a relationship between a licensor and its licensees, or between licensees, as horizontal when they *would have been* actual or likely potential competitors in a relevant market *in the absence of the license*.

DOJ/FTC Antitrust Guidelines for the Licensing of Intellectual Property §3.3 (1995) (*DOJ/FTC Guidelines*) (emphasis added).

Here, 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. For convenience, the FTC's rule simply deems patent-settlements to be horizontal restraints.

Besides ignoring the patent, the FTC seeks an unprecedented departure from traditional antitrust principles, which assess the lawfulness of *restraints*, to a novel rule that instead assesses the consideration underlying the agreement. In other words, the same restraint may be upheld or condemned under the FTC's rule depending on whether the amount of consideration was minimal or substantial. In 120 years, no antitrust rule has turned on appraising parties' consideration.

Furthermore, the FTC concedes that removing financial consideration as a potential settlement term

will cause fewer cases to settle: "To be sure, in some paragraph IV litigation that might otherwise have been settled through reverse-payment agreements, a rule discountenancing reverse payments may cause the parties to litigate to judgment." FTC-Br.40.

To the FTC, requiring parties "to pursue the course that maximizes competition and consumer welfare accords with basic antitrust norms." FTC-Br.51. But "[a]s a general rule, businesses are free to choose the parties with whom they will deal, as well as the prices, terms, and conditions of that dealing." *Pac. Bell Tel.* v. *Linkline Commc'ns*, 555 U.S. 438, 448 (2009) (citing *United States* v. *Colgate*, 250 U.S. 300, 307 (1919)). And, "[c]ourts are ill suited 'to act as central planners, identifying the proper price, quantity, and other terms of dealing.'" *Id.* at 452 (quoting *Verizon Commc'ns* v. *Law Offices of Curtis V. Trinko*, 540 U.S. 398, 408 (2004)); see *Cont'l T.V.* v. *GTE Sylvania*, 433 U.S. 36, 58 n.29 (1977) ("The location restriction used by Sylvania was neither the least nor the most restrictive provision that it could have used. *** We are unable to perceive significant social gain from channeling transactions into one form or another."), overruling *United States* v. *Arnold, Schwinn & Co.*, 388 U.S. 365 (1967); see also Stephen Breyer, *Regulation and Its Reform* 157 (1982) ("[Antitrust laws] act negatively, through a few highly general provisions *prohibiting* certain forms of private conduct. They do not affirmatively order firms to behave in specified ways; for the most part, they tell private firms what not to do.").

Finally, the FTC's categorical presumption of unlawfulness is doctrinally unsound. This Court's last "quick-look" case rejected the FTC's quick-look at an advertising restriction imposed by a dentists' association, holding: "What is required, *rather*, is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint." *California Dental Ass'n* v. *FTC*, 526 U.S. 756, 781 (1999) (emphasis added). Even dissenters agreed with this "unobjectionable principle[]." *Ibid.* (Breyer, J., concurring in part and dissenting in part).

Before rejecting quick-look in *California Dental*, the Court had applied it in only three cases:

- *FTC* v. *Indiana Federation of Dentists*, 476 U.S. 447, 458-459 (1986) (evaluating group boycott by dentists' association under quick-look instead of *per se* rule: "[W]e decline to resolve this case by forcing the Federation's policy into the 'boycott' pigeonhole and invoking the *per se* rule.");
- *NCAA* v. *Board of Regents*, 468 U.S. 85, 100-101 (1984) (evaluating broadcasting output-limitation imposed by college football association under quick-look because the "industry [is one] in which horizontal restraints on competition are essential if the product is to be available at all"); and
- *Nat'l Soc'y of Prof'l Eng'rs* v. *United States*, 435 U.S. 679, 692-693 (1978) (evaluating engineers' association's concerted refusal to discuss prices with potential customers under quick-look by "analyzing the facts peculiar to the business, the history of the restraint, and the reasons why it was imposed").

Each time, the Court considered quick-look on an *ad hoc* basis for the circumstances of the alleged restraint (each involving unique justifications proffered by different associations). This Court never has applied a quick-look presumption of unlawfulness to *categories* of restraints prospectively. The *per se* rule applies categorically, and then, only after judicial experience demonstrates that a category of restraint is almost always anticompetitive. Because the FTC's presumption effectively can be rebutted only by proof that there was no "reverse-payment," the FTC is really seeking an unprecedented, watered-down category of *per se* violations.

2. The FTC's purported patent-law justifications for its presumption are unsound. The crux of the argument is that patents confer merely "probabilistic" rights and, because the FTC suspects many "weak" patents exist, patent-settlements require judicial appraisal beyond the scope-of-the-patent:

> [B]ecause the scope-of-the-patent approach assumes (at least once the non-sham threshold has been surmounted) that all patents are equally valid and infringed, it produces *the absurd result that an ironclad patent and a trivial patent have the same exclusionary force*.

FTC-Br.44 (emphasis added) (internal quotation marks omitted); see J.A.38 ¶40 (alleging that PTO examiners labor under "quotas [that] are reinforced by examiners' bonus compensation"); U.S.Br.11, *Schering-Plough*, *supra* ("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.'") (quoting FTC petition).

This Court recently rejected a similar challenge to the statutory presumption of patent validity, reaffirming challengers' burden of proving invalidity by clear-and-convincing evidence:

> Congress has amended the patent laws to account for concerns about "bad" patents, including by expanding the reexamination process to provide for *inter partes* proceedings. Through it all, the evidentiary standard adopted in [35 U.S.C.] § 282 has gone untouched. Indeed, Congress has left the Federal Circuit's interpretation of § 282 in place despite ongoing criticism, both from within the Federal Government and without.

Microsoft v. *i4i*, 131 S.Ct. 2238, 2252 & n.11 (2011) (citing FTC report advocating preponderance-of-the-evidence standard that the Court rejected); *id.* at 2243 (describing "the basic proposition that a government agency such as the PTO was presumed to do its job").

Nevertheless, the FTC contends: "[T]he scope-of-the-patent approach allows the patentee to purchase the same period of exclusivity that a successful infringement suit would produce, *even if all would concede that the patentee had little likelihood* of *prevailing* in the infringement litigation." FTC-Br.44 (emphasis added). The FTC never explains how to establish this Greek chorus of agreement on the patent's slim chances if the case is *not* "objectively baseless." *PRE*, 508 U.S. at 60-61.

All here agree that attempting a more fine-tuned antitrust assessment of patent merits than *PRE*'s sham standard would be "doctrinally anomalous and likely unworkable in practice." FTC-Br.53. For antitrust purposes, there are no "weak" patents; there are sham patents and non-sham patents.

3. The FTC's final argument for departing from traditional antitrust analysis is that "reverse-payment agreements frustrate the purposes of the Hatch-Waxman Amendments." FTC-Br.30.

First, the FTC contends (without citation) that the "Hatch-Waxman Amendments reflect a strong congressional policy that favors testing the scope and validity of pharmaceutical patents." FTC-Br.30. But no Hatch-Waxman provision favors litigation-to-the-death over settlements, which are critical for generic entry:

> [G]eneric companies are successful, thus able to market the generic product before patent expiration, in just 48 percent of cases [that have gone to trial]. But when factoring in settlements, generics are successful in bringing the generic product to market before patent expiration in 76 percent of cases.

Generic Pharm. Ass'n, *Generic Drug Savings in the U.S.*, at 7 (4th ed. 2012).

Hatch-Waxman's balanced provisions are *not* designed to change the outcomes of pharmaceutical-patent litigation. *Caraco Pharm.* v. *Novo Nordisk*, 132 S.Ct. 1670, 1676 (2012) (explaining Hatch-Waxman's objective "[t]o facilitate the [FDA] approval of generic drugs as soon as patents allow").

Second, the FTC contends that "nothing in the Amendments contemplates that a patentee will pay an accused infringer in order to escape paragraph IV litigation." FTC-Br.31. That statement is literally true because the FTC defines "Amendments" to include only the Hatch-Waxman Act. The statement is misleading, however, because it ignores the MMA Amendments of 2003.

In response to reverse-payment settlements with restraints that *exceeded* patent scope, the MMA Amendments to Hatch-Waxman provided, among other remedial changes: (i) a requirement that patent-settlements be filed with DOJ/FTC; (ii) a specified-antitrust penalty; and (iii) an antitrust-savings clause expressly providing that such agreements are *not* presumed to violate the antitrust laws.

Indeed, due to the MMA's extensive remedial changes, the United States advised this Court *not* to grant certiorari in pre-MMA cases to address antitrust issues involving reverse-payment settlements. U.S.Br.19-20, *Joblove* v. *Barr Labs.*, 551 U.S. 1144 (2007) (No.06-830) (filed May 23, 2007) ("Congress amended the Hatch-Waxman Act to provide for forfeiture of the 180-day exclusivity period ***. [I]t may now be more difficult for a first-filing generic manufacturer to enter into a settlement and then use the 180-day exclusivity period effectively to lock other generic manufacturers out of the market ***."); U.S.Br.18, *Andrx Pharms.* v. *Kroger*, 543 U.S. 939 (2004) (No.03-779) (filed July 9, 2004) ("This Court's review also may be unwarranted in light of certain amendments to the Hatch-Waxman Act that were enacted by Congress in 2003 ***.").

Yet, having lobbied Congress to pass the MMA, the FTC's merits brief oddly ignores the MMA Amendments entirely. It is weird that in an antitrust case concerning Hatch-Waxman settlements, the government does not mention the MMA's remedial changes, which included, *inter alia*, a specified-antitrust penalty and an antitrust-savings clause.

Significantly, unlike the MMA, which did *not* change antitrust standards for reverse-payment settlements, pending legislation proposes the very standard the FTC seeks here. See Preserve Access to Affordable Generics Act, S.214, 113th Cong. (introduced Feb. 4, 2013), Par/Paddock-Br.App.1a-20a.

***

That the United States switched position on the reverse-payment issue since the last administration warrants special mention.

In *Schering-Plough*, the United States opposed the FTC's petition: "The decision below does not conflict with any decisions of this Court ***." U.S.Br.1, *supra*. Respondents settled under *Schering-Plough* in 2006, and the Eleventh Circuit applied *Schering-Plough* in upholding respondents' settlements in this case.

The United States continued: "[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). As the FTC concedes, that position is irreconcilable with the government's position here: "In those briefs [in 2004, 2006, and 2007], the United States did not endorse the FTC's view that reverse-payment settlements are presumptively anti-competitive." FTC-Br.41 n.9.

The United States' new position is entitled to little deference. See Transcript of Oral Argument at 44, *Kiobel* v. *Royal Dutch Petroleum*, No.10-1491 (Oct. 1, 2012) (Roberts, C.J.) ("[W]hatever deference you are entitled to is compromised by the fact that your predecessors took a different position.").

The Eleventh Circuit's decision here is no less correct than *Schering-Plough*, which the United States stated did "not conflict with any decisions of this Court." U.S.Br.1. (*Palmer* was decided sixteen years before that statement.) Respondents' reliance and repose interests in settlements concluded in 2006 in the Eleventh Circuit, undisputedly in conformity with circuit law, should not depend on the outcome of an election any more than this Court's antitrust jurisprudence should.

4. This case involves two separate settlements. Argument II addresses points applicable only to the settlement between respondents Solvay and Par/Paddock:

> (A) the district court's Consent Judgment and Order of Permanent Injunction currently restrains Par/Paddock's generic entry until 2015, conferring *Noerr-Pennington* immunity; and
>
> (B) the FTC fails to state a claim under any antitrust standard against the Par/Paddock settlement because as a second ANDA-filer under

pre-MMA rules, Par/Paddock could *not* have obtained an earlier settlement-entry date even absent any alleged reverse-payment.

STATEMENT

A. The Hatch-Waxman Act of 1984

The "Drug Price Competition and Patent Term Restoration Act of 1984" had two goals:

1. Drug Price Competition

Congress enacted Hatch-Waxman "[t]o facilitate the approval of generic drugs as soon as patents allow." *Caraco*, 132 S.Ct. at 1676. Hatch-Waxman created the ANDA process, 21 U.S.C. 355, to shorten the FDA's generic-drug approvals. *Eli Lilly* v. *Medtronic*, 496 U.S. 661, 676 (1990). Congress did *not* shorten patent-term or exclusive-sales periods for brand-name drugs. *Id.* at 676-678.

Hatch-Waxman encourages generic manufacturers to seek market-entry and makes pharmaceutical patent-litigation more efficient. Generics can instigate litigation through a "highly artificial act of infringement" without risking treble damages on infringing sales. *Id.* at 678. Brand-names, in turn, can obtain a thirty-month stay on generic marketing while litigating the case. 21 U.S.C. 355(j)(5)(B)(iii). To incentivize generics to file Paragraph-IV ANDAs, the first-to-file obtains 180-day generic exclusivity, 21 U.S.C. 355(j)(5)(B)(iv), which delays other generic entry and maintains higher drug prices.

This balanced scheme is not designed to expedite generic entry at all costs. Rather, Paragraph-IV procedures are "an important new mechanism designed to guard against infringement of patents

relating to pioneer drugs." *Eli Lilly*, 496 U.S. at 676-677. Hatch-Waxman facilitates litigation, but does *not* affect litigation outcomes.

2. Patent Term Restoration

"[T]he 1984 Act was designed to respond to two unintended distortions of the 17-year patent term produced by the requirement that certain products must receive premarket regulatory approval." *Id.* at 669. First, patent terms begin before related drugs clear the FDA's approval process: "[T]he 'clock' on his patent term will be running even though he is not yet able to derive any profit from the invention." *Id.* at 669-670. Hatch-Waxman responded by *extending* patent-holders' exclusive-marketing period up to five years. 35 U.S.C. 156(a); *Eli Lilly*, 496 U.S. at 671.

Second, Hatch-Waxman ended "an effective extension of the patent term" under the requirement that generics wait until patent expiration before beginning FDA's approval process. *Eli Lilly*, 496 U.S. at 670. Hatch-Waxman authorizes generics to use an invention during the patent term "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. 271(e)(1).

Hatch-Waxman thus enabled "generic substitutes on the market as quickly as possible *after the expiration of the patent*." H.R.Rep.No.857, 98th Cong., Pt.2, at 9 (1984) (emphasis added). Congress insisted that patent-holders' exclusive-sales periods remain uncompromised:

> [T]he only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute. The patent holder retains the right to exclude others from the major commercial marketplace during the life of the patent. Thus, the nature of the interference with the rights of the patent holder is not substantial.

Id. at 8.

B. The MMA Amendments of 2003

Two features of Hatch-Waxman's Paragraph-IV provisions created incentives for reverse-payment settlements.

First, as the United States explained in a 2007 CVSG, Hatch-Waxman's "highly artificial act of infringement" creates asymmetrical risks between brand-names and generics, incentivizing reverse-payment settlements even when the patent-holder is confident:

> Because the generic manufacturer will not have made infringing sales (that would give rise to claims for damages) or incurred production and marketing costs at the time of the infringement suit, its litigation risk will be minimal, whereas the patent holder faces potentially devastating consequences if it loses the litigation. The resulting disparity in the litigants' respective risks may tend to increase the cost of settlement for a patent holder and make reverse payments more likely, even when the patent holder's legal claims are relatively strong.

U.S.Br.10, *Joblove*, *supra*.

Illustrating this asymmetry, the FTC reports: "[F]or a drug with [annual] brand sales of $130 million, a generic that does not anticipate [authorized generic] competition will expect a patent challenge to be profitable if it has at least a 4 percent chance of winning [a Paragraph-IV challenge]." FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* iii n.7 (2011).

Second, as the United States also explained, Hatch-Waxman's 180-day exclusivity period, designed to incentivize generics by rewarding first-filers, unwittingly enabled first-filer settlements to "bottleneck" subsequent generic entry:

> [T]he 180-day exclusivity period created an incentive for the parties to settle the litigation with a non-entry payment to the generic, under which the generic would delay commercialization of the generic product, thus postponing the commencement of the 180-day exclusivity period and locking other generics out of the market indefinitely.

U.S.Br.11, *Joblove*, *supra*.

The resulting reverse-payment settlements drew FTC attention. *E.g.*, *In re Abbott Labs.*, No.C-3945 ¶37 (F.T.C. May 22, 2000) (administrative complaint); *In re Hoechst Marion Roussel*, No.9293 ¶31 (F.T.C. Mar. 16, 2000) (same).

This enforcement activity led Congress to ask the FTC to study Hatch-Waxman and recommend legislative changes:

> As a result of the cases we brought, Congress granted the FTC the authority to conduct an

> industry-wide study to assess the effectiveness of generic entry under Hatch-Waxman. Based on this study, we made a number of legislative recommendations geared toward facilitating generic entry and thus better achieving the goals of the Hatch-Waxman Act.

Orson Swindle, Commissioner, FTC, *A Regulator's Perspective on Protecting Consumers and Competitive Marketplaces*, Remarks before ABA Section of Administrative Law and Regulatory Practice (Nov. 7, 2003).

Significantly, pre-MMA judicial decisions on reverse-payment settlements concerned agreements with restraints that *exceeded* patent scope and, in particular, provisions prohibiting first-filers from relinquishing 180-day exclusivity. *Valley Drug* v. *Geneva Pharms.*, 344 F.3d 1294, 1311-1313 (CA11 Sept. 15, 2003) (agreement not to relinquish 180-day exclusivity and not to sell certain non-infringing products); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 907-908 (CA6 June 13, 2003) (agreement not to relinquish 180-day exclusivity); *Andrx Pharms.* v. *Biovail*, 256 F.3d 799, 809-810 (CADC 2001) (same).

Neither settlement here includes any restraint outside the scope-of-the-patent.

1. Remedial Changes to Hatch-Waxman

The MMA Amendments of 2003 recalibrated the competitive landscape for Hatch-Waxman litigation and settlements. In particular, "there are two separate exclusivity frameworks—one for first-filed ANDA applications submitted before December 8, 2003 (pre-MMA) and one for first-filed ANDA

applications submitted on or after December 8, 2003 (post-MMA)." *ANDA Litigation: Strategies and Tactics for Pharmaceutical Patent Litigators* 68 (Kenneth L. Dorsney et al. eds., 2012).

First, the MMA added forfeiture provisions that can deprive a first-filer of exclusivity. In a 2007 CVSG, the United States predicted (correctly) that the MMA's elimination of 180-day "bottle-necking" would reduce incentives for reverse-payments:

> Congress amended the Hatch-Waxman Act to provide for forfeiture of the 180-day exclusivity period for various reasons ***. As a practical matter, therefore, it may now be more difficult for a first-filing generic manufacturer to enter into a settlement and then use the 180-day exclusivity period effectively to lock other generic manufacturers out of the market ***.

U.S.Br.19-20, *Joblove*, *supra*.

Second, the MMA added shared-exclusivity provisions, facilitating *multiple* first-filer exclusivity. 21 U.S.C. 355(j)(5)(B)(iv)(II)(bb). In a 2004 CVSG, the United States predicted (again correctly) that this shared-exclusivity amendment would reduce incentives for reverse-payments:

> [A]llowing multiple ANDA applicants to obtain the 180-day exclusivity period[] may increase the transaction costs for pioneer drug companies that seek to enter into agreements with those applicants. On balance, therefore, the 2003 amendments may reduce the number of agreements containing reverse payments.

U.S.Br.18, *Andrx*, *supra*.

In this case, the Eleventh Circuit echoed the competitive significance of multiple challengers:

> If the patent actually is vulnerable, then presumably other generic companies, which are not bound by the first challenger's reverse payment settlement, will attempt to enter the market and make their own challenges to the patent. Blood in the water can lead to a feeding frenzy. Although a patent holder may be able to escape the jaws of competition by sharing monopoly profits with the first one or two generic challengers, those profits will be eaten away as more and more generic companies enter the waters by filing their own paragraph IV certifications attacking the patent.

Pet.App.35a-36a.

Beyond the MMA's new 180-day forfeiture and shared-exclusivity provisions, the FTC recommended five additional remedial changes prompted by its investigation of pre-MMA settlements. Congress enacted all five. See Par/Paddock-B.I.O.7 n.2 (detailing those amendments).

2. The MMA's Specified Antitrust Penalty

Post-MMA, Paragraph-IV settlements and related agreements are filed with DOJ/FTC for antitrust review. 21 U.S.C. 355 note.

Furthermore, Congress specified a penalty for agreements challenged by DOJ/FTC and held to violate the antitrust laws. Tellingly, the penalty is forfeiture of 180-day exclusivity, which applies when:

> The first applicant enters into an agreement with another [ANDA] applicant ***[,] the holder of the application for the listed drug, or an owner of the patent that is the subject of the [Paragraph IV certification], the [FTC] or the [DOJ] files a complaint, and there is a final decision of the [FTC] or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws ***.

21 U.S.C. 355(j)(5)(D)(i)(V); see 355(j)(5)(D)(ii) (providing resulting forfeiture of 180-day exclusivity).

Thus, contrary to the FTC's suggestion that Congress never "contemplate[d] that a patentee will pay an accused infringer in order to escape paragraph IV litigation," FTC-Br.31, Congress contemplated precisely that and specified an antitrust penalty tailored to Congress's primary concern: settlements that restrain the first-filer's use of 180-day exclusivity (thereby exceeding patent scope) to "bottleneck" subsequent generic entry.

3. The MMA's Antitrust Savings Clause

Along with the MMA's provision for DOJ/FTC antitrust review, came an antitrust-specific savings clause:

> **Sec. 1117. SAVINGS CLAUSE.**
>
> Any action taken by the [DOJ] or the [FTC], or any failure of the [DOJ] or the [FTC] to take action, under this subtitle shall not at any time bar any proceeding or any action with respect to any agreement between a brand name drug

> company and a generic drug applicant, or any agreement between generic drug applicants, under any other provision of law, *nor shall any filing under this subtitle constitute or create a presumption of any violation of any competition laws*.

21 U.S.C. 355 note (emphasis added).

Congress thus expressly declined to alter the default, common-law antitrust standard for Hatch-Waxman settlements. See *Astoria Federal Savings* v. *Solimino*, 501 U.S. 104, 108 (1991) ("Congress is understood to legislate against a background of common-law adjudicatory principles."); 2B Singer & Singer, *Statutes and Statutory Construction* §50.1 (7th ed. 2012) ("All legislation is interpreted in the light of the common law and the scheme of jurisprudence existing at the time of its enactment.").

C. Post-MMA, Reverse-Payment Rates Declined; FTC Has Not Challenged Settlements Since.

Post-MMA, the FTC issues annual reports on Hatch-Waxman settlements, including "potential pay-for-delay" settlement statistics. According to the FTC, "settlements potentially involve pay for delay [when] they contain both compensation to the generic manufacturer and a restriction on the generic manufacturer's ability to market its product." *Agreements Filed with FTC under MMA Act of 2003: Overview of Agreements Filed in FY 2012*.

Thus, a settlement that (i) provides for anything other than immediate generic entry (regardless of how long before patent expiration entry is permitted), and (ii) confers any value to the generic beyond early entry constitutes "potential pay-for-delay."

The FTC's FY2004-2011 reports indicate that "potential pay-for-delay" rates peaked at 50% in FY2006, declining to a low of 18% in FY2011.[1]

Because of the time-lag (often several years) between a Paragraph-IV filing and any subsequent litigation settlement, a settlement occurring after the MMA Amendments (in 2006 for example) may still involve a pre-MMA ANDA and, therefore, be governed by pre-MMA rules. That is true of the 2006 settlements here (J.A.34 ¶23; Pet.App.27a n.9), but is decreasingly likely for settlements occurring in 2007 and later. This lag explains the decline in reverse-payment rates after 2006. The MMA's remedial changes just took time to affect ensuing settlements.

Declining 2006-2011 rates are particularly significant because that period coincides with the

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[1] Overview of Final Settlements

(2004-2011)

Fiscal Year	2004	2005	2006	2007	2008	2009	2010	2011
Final Settlements	14	11	28	33	66	68	113	156
Potential Pay-for-Delay	0	3	14	14	16	19	31	28
	0%	27%	50%	42%	24%	28%	27%	18%

From presentation by Bradley S. Albert, Deputy Assistant Director, FTC, *"Are Reverse Payments Dead?"* program sponsored by ABA Section of Antitrust Law, Healthcare and Pharmaceuticals Committee (Nov. 10, 2011).

scope-of-the-patent test being the unanimous rule among the circuits that had adjudicated antitrust challenges to final Hatch-Waxman settlements (CA11, CA2, CAFC). During this natural experiment, reverse-payment rates continued falling despite favorable case law.[2]

Beyond the decline in reverse-payment rates post-MMA, the government has not challenged *any* alleged reverse-payment settlement governed by post-MMA law. See *Overview of FTC Antitrust Actions in Pharmaceutical Services and Products* 13-19 (Sept. 2012).

The government has litigated only three reverse-payment cases, including this one, each involving settlements occurring in a discrete era (1997-2006), and all governed by pre-MMA law. See Par/Paddock-B.I.O.20-21 (detailing cases, including FTC's *Provigil* case that *survived* dismissal under the scope-of-the-patent approach).

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[2] Two business days before filing its brief, the FTC issued its FY2012 report, which indicates that of 140 "final settlements," 40 were "potential pay-for-delay." *FY2012 Overview*, *supra*. That would constitute a 28.6% rate, but the FTC reports: "In nearly half of these potential pay-for-delay agreements (19 out of 40 such agreements), compensation took the form of a brand manufacturer's promise not to market an authorized generic ('AG') in competition with the generic manufacturer's product for some period of time ***." *Ibid.* A recent decision applying the Third Circuit's *K-Dur* rule held that such settlements involving a brand-name's agreement not to launch an authorized-generic are *not* "pay-for-delay." *In re Lamictal Direct Purchaser Antitrust Litig.*, No.2:12-cv-00995-WHW-CLW, 2012 WL 6725580, at *6 (D.N.J. Dec. 6, 2012). If that ruling is correct, the "potential pay-for-delay" rate in FY2012 was only 15%.

As the United States twice predicted, the MMA Amendments have reduced incentives for reverse-payment settlements.

D. Pending Legislation to Change the Antitrust Standard for Reverse-Payment Settlements.

Pending legislation would change the antitrust standard for Hatch-Waxman settlements in FTC suits under the FTC Act (*i.e.*, not private cases):

> (2) **Presumption**.—
>
> (A) In General.— *** [A]n agreement shall be presumed to have anticompetitive effects and be unlawful if—
>
> (i) an ANDA filer receives anything of value; and
>
> (ii) the ANDA filer agrees to limit or forego [sic] research, development, manufacturing, marketing, or sales of the ANDA product for any period of time.

S.214, 113th Cong. §3(2) (introduced Feb. 4, 2013), Par/Paddock-Br.App.5a.

Similar bills proposing to change the antitrust standard for FTC actions challenging Hatch-Waxman settlements have stalled in each Congress since 2006. See Solvay-Cert.Br.19 n.7 (listing unenacted bills).

E. The Solvay and Par/Paddock Settlement

Solvay sued Watson and Paddock, separately, for patent-infringement in 2003. The cases proceeded in the Northern District of Georgia until 2006, when Solvay settled separately with Watson and Par/Paddock. The court encouraged respondents to

settle. J.A.97-98 ("[Solvay and Par/Paddock] consented to judgment through a final settlement, which was encouraged by the Court pursuant to its Local Rules ***."); J.A.95 ("This has all the appearances of a long, complicated, expensive, difficult case. Is there anything that I can do to prevent any of that from happening?").

Claim-construction briefs and *partial* summary judgment motions remained pending at settlement, and the court never made any substantive rulings. J.A.55 ¶90.

Respondents settled under Eleventh Circuit precedent holding that final settlements of non-sham Hatch-Waxman litigation that do not restrict generic competition beyond the patent's exclusionary grant do *not* violate the antitrust laws, regardless of reverse-payments. *Andrx Pharms.* v. *Elan*, 421 F.3d 1227, 1235 (CA11 2005); *Schering-Plough*, 402 F.3d at 1065-1066; *Valley Drug*, 344 F.3d at 1308.

The FTC investigated the settlements for two years (taking twenty-one depositions). The district court dismissed the FTC's ensuing complaint, relying on the same Eleventh Circuit precedents under which respondents settled. *In re AndroGel Antitrust Litig.*, 687 F.Supp.2d 1371 (N.D.Ga. 2010), Pet.App.37a-61a. The Eleventh Circuit affirmed under the same precedents. Pet.App.1a-36a.

Follow-on private cases survived dismissal because the private plaintiffs alleged sham-litigation. The district court ultimately granted summary judgment against the private plaintiffs, holding that neither the patent litigations nor the settlements were shams. *In re AndroGel Antitrust Litig.*, No.

1:09-MD-2084-TWT, 2012 WL 5352986, at *7-18 (N.D.Ga. Oct. 30, 2012).

***

The following is undisputed:

1. *This is a pre-MMA case and, therefore, is not governed by current Hatch-Waxman law.*

This case involves ANDAs filed before the MMA became effective. J.A.34 ¶23. Consequently, except for the requirement that the settlements and related agreements were filed with the DOJ/FTC, the MMA's remedial changes do not apply.

2. *Paddock copied AndroGel® unaware of any patent because under the old Patent Act, Solvay's patent application was not public.*

The FDA approved Solvay's New Drug Application (NDA) for AndroGel® in February 2000, and Solvay began sales *without* patent protection. J.A.37-38 ¶¶33-34, 39. Solvay's sales nonetheless were exclusive for three years under FDA regulation—an important fact because it explains (to us now and to the generic industry then) why AndroGel® had exclusive, growing sales without patent protection. J.A.37 ¶34; Pet.App.39a.

Solvay applied for a patent in August 2000. J.A.38 ¶39. But that application was confidential under then-existing law; Congress amended the Patent Act three months later to make future applications public. 35 U.S.C. 122(b)(1)(A) (effective Nov. 29, 2000) ("[E]ach application for a patent shall be published ***.").

AndroGel®'s growing sales and apparent lack of patent protection, along with the publicly discernible sunset on its three-year exclusivity, attracted generic attention. In December 2000, more than two years before Solvay's regulatory exclusivity would expire in February 2003, Paddock undertook to copy AndroGel® "as close as humanly possible," intending to file a *Paragraph-I* ANDA (which applies when there is *no patent*), as opposed to a Paragraph-IV. *AndroGel*, 2012 WL 5352986, at *3.

Paddock's world changed in January 2003 when, one-month before the three-year exclusivity would expire, Solvay's patent issued. J.A.39 ¶42; *AndroGel*, 2012 WL 5352986, at *3 n.4 ("The Generics did not realize that AndroGel® was patent protected because Solvay's patent application was not public."). Paddock stopped its bioequivalence work, later resuming with the fallback hope of becoming the first Paragraph-IV filer. See *AndroGel*, 2012 WL 5352986, at *3.

Paddock filed its Paragraph-IV in May 2003, unaware that Watson had filed days earlier. *Ibid.*; Pet.App.41a; J.A.39-40 ¶¶44-45. Paddock never had been involved in a Paragraph-IV case and had *not* anticipated one, so it partnered with Par to manage the inevitable litigation in exchange for a share of potential generic profits. Pet.App.41a; J.A.40, 47 ¶¶46, 69.

When Solvay subsequently sued Watson and Paddock in August 2003, the ANDA-filing numbers in the complaints were the first public indication that there were two Paragraph-IV filers and that Watson was first-filer. J.A.40 ¶47; *ANDA Litigation*, *supra*,

at 138 ("A key driver for nonlitigation alternatives is whether the generic party is a Paragraph IV first-filer, and this may not be known until around the time of the initial pleadings.").

3. *Par/Paddock could not have obtained an earlier settlement-entry date even absent any alleged reverse-payment.*

Throughout the litigations, Par/Paddock were blocked by Watson's first-filer exclusivity. J.A.40 ¶45. When the Hatch-Waxman thirty-month stay expired in January 2006, Watson, as first-filer, received final FDA approval and was free to launch its product, but FDA regulation barred Par/Paddock from marketing until 180-days after Watson. J.A.28, 33-34, 41-42 ¶¶2, 22-23, 52-54. Because Watson never launched, Par/Paddock never could. *Ibid*.

After three-years of litigation, Solvay reached settlement terms with Watson, permitting Watson to enter no later than August 2015 (five years *before* patent expiration). J.A.44-47 ¶¶60-67. After concluding its settlement terms with Watson, Solvay separately offered Par/Paddock the same entry terms subject to Watson's exclusivity. J.A.47 ¶71. Because that was the earliest settlement-entry date possible for a second-filer, Par/Paddock "quickly accepted." *Ibid.* Solvay's internal negotiation documents indicate a counter-offer by Watson, J.A.115-vol.2, but none by Par/Paddock, who were an entry-date taker, not maker.

When Par/Paddock settled with Solvay, Watson's 180-day exclusivity still applied. J.A.40 ¶45. Thus, Par/Paddock could obtain the same entry date as Watson "only if Watson did not assert its 180-day

generic exclusivity period." Pet.App.44a. After the parties executed separate, confidential settlement agreements, Watson later relinquished its first-filer exclusivity with the FDA, furnishing Par/Paddock an unanticipated windfall: the same entry date as the first-filer. J.A.100.

4. *The FTC does not allege that Par/Paddock were aware that Solvay planned to introduce a new AndroGel® version in 2015.*

The FTC alleges that the 2015 settlement-entry date had little value:

> *Watson* agreed not to market generic AndroGel until 2015 even though it knew of Solvay's plans to introduce a "line extension" product that would eliminate or substantially reduce potential sales of generic AndroGel by 2015. *** *Solvay told Watson* of its plans for a line extension product during settlement negotiations.

J.A.45 ¶¶62-63 (emphasis added); see FTC-Br.11.

Conspicuously absent from these allegations is any mention of Par/Paddock, who were in the pre-MMA backseat throughout.

5. *Respondents settled under Eleventh Circuit precedent.*

The scope-of-the-patent test governed respondents' settlements, which undisputedly qualify for its safe-harbor. After two-years of investigation and compulsory process, the FTC does *not* allege that either settlement entails restrictions beyond the patent's exclusionary grant, Solvay's patent was obtained by fraud, or the patent-litigations were shams. J.A.46, 49, 53 ¶¶65, 76, 86.

Contemporaneous with the settlements, Solvay and Watson, and Solvay and Par, entered into separate co-marketing agreements for AndroGel®. J.A.46, 49-50 ¶¶66, 77. No legal objection to the co-marketing agreements exists beyond the FTC's objection to the simultaneity with settlement. See *Sorrell* v. *IMS Health*, 131 S.Ct. 2653, 2659 (2011) ("Speech in aid of pharmaceutical marketing *** is a form of expression protected by the Free Speech Clause of the First Amendment.").

Solvay and Paddock entered a manufacturing agreement, without which Solvay's sole source for AndroGel® was a company in Europe. J.A.36-37, 52-53 ¶¶32, 84.

6. *The District Court's Consent Judgment and Order of Permanent Injunction binds Solvay and Par/Paddock and restrains Par/Paddock's generic entry until 2015.*

Solvay and Par/Paddock ended their litigation by petitioning the court to enter a consent judgment. J.A.47, 50 ¶¶68, 80. The resulting Consent Judgment and Order of Permanent Injunction (J.A.97-102) is a final judgment with *res judicata* effect that restrains Par/Paddock's generic entry, binding Solvay and Par/Paddock to their compromise entry terms.

7. *After the Eleventh Circuit affirmed dismissal, the Third Circuit decided* K-Dur.

"The key allegation in the FTC's complaint is that [Solvay] was 'not likely to prevail' in the infringement actions that it brought against the generic manufacturers and then settled." Pet.App.3a; see J.A.53 ¶86. The Eleventh Circuit held that this

allegation did not state an antitrust claim against settlements within the scope-of-the-patent. Pet.App.28a-30a. That decision followed Eleventh Circuit precedent and accorded with the circuits that had adjudicated antitrust challenges to final Hatch-Waxman settlements. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (CAFC 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (CA2 2005).

Three months later, the Third Circuit became the only circuit to reject the scope-of-the-patent approach in favor of a presumption that "treat[s] any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade." *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (CA3 2012).

In rejecting three circuits' decisions, the Third Circuit purported that its "practical analysis is supported by a long line of Supreme Court cases recognizing that valid patents are a limited exception to a general rule of the free exploitation of ideas." *Id.* at 215. But the only Supreme Court case the Third Circuit discusses is *Edward Katzinger Co.* v. *Chicago Metallic*, 329 U.S. 394 (1947), abrogated by *Lear* v. *Adkins*, 395 U.S. 653 (1969), overruling in part *Automatic Radio* v. *Hazeltine Research*, 339 U.S. 827 (1950).

The Third Circuit overlooked that *Lear* abrogated *Katzinger*, which relied on the now-overruled patent-licensee-estoppel rule. See Par/Paddock-B.I.O.33-40. Neither any other court adjudicating antitrust

challenges to Hatch-Waxman settlements nor the FTC cites *Katzinger*.

ARGUMENT

I. For Patent-Based Restraints Of Trade, The Rule Of Reason Begins With The Scope Of The Patent.

A. First Principles

Statutory patent monopolies authorize restraints of trade and exclusionary conduct that would violate our antitrust laws absent patent protection. The Constitution provides: "Congress shall have Power *** To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries ***." U.S.Const.art.I, §8, cl.8. As this Court observed:

> This subject was among the first which followed the organization of our government. It was taken up by the first congress at its second session, and an act was passed authorising a patent to be issued to the inventor of any useful art, etc. on his petition, 'granting to such petitioner, his heirs, administrators or assigns, for any term not exceeding fourteen years, the sole and exclusive right and liberty of making, using, and vending to others to be used, the said invention or discovery.'

Grant v. *Raymond*, 31 U.S. 218, 241 (1832) (Marshall, C.J.) (quoting Act of Apr. 10, 1790, ch.7, §1).

Our founders thus viewed patent rights as essential for the innovation that would power our nation's free-market economy. *Id.* at 241 ("To promote the progress of useful arts, is in the interest

and policy of every enlightened government[,] [and] entered into the views of the framers of our constitution ***.").

"The law has thus impressed upon [a patent] all the qualities and characteristics of property, for the specified period; and has enabled [a patentee] to hold and deal with it the same as in case of any other description of property belonging to him ***." *Wilson* v. *Rousseau*, 45 U.S. 646, 674 (1846); see *Festo* v. *Shoketsu Co.*, 535 U.S. 722, 730 (2002) ("The [patent] monopoly is a property right ***."); *DOJ/FTC Guidelines* §1.0 (recognizing that patent laws "establish[] enforceable property rights for the creators of new and useful products").

The most basic right of any patentee is the right to exclude others from using her property. 35 U.S.C. 154(a)(1) ("Every patent shall contain *** a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention ***."); *Microsoft* v. *i4i*, 131 S.Ct. at 2242 ("[A] patent grants certain exclusive rights to its holder, including the exclusive right to use the invention during the patent's duration."); *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.").

Our law recognizes that to enjoy fully her property right and maximize her return during the patent term, a patentee may enter all manner of licenses:

> 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 v. *Nat'l Harrow*, 186 U.S. 70, 91 (1902).

Our nation early-on made the *policy choice* to accept exclusion in the short-run for sake of promoting innovation and competition in the long-run, and, thereby, achieve hoped-for *net* gains for consumer welfare. *E.g.*, *Scott Paper* v. *Marcalus Mfg.*, 326 U.S. 249, 255 (1945) ("The aim of the patent laws is not only that members of the public shall be free to manufacture the product or employ the process disclosed by the expired patent, but also that the consuming public at large shall receive the benefits of the unrestricted exploitation, by others, of its disclosures."); *DOJ/FTC Guidelines* §1.0 (observing patent law's "purpose of promoting innovation and enhancing consumer welfare"); Frank H. Easterbrook, *Ignorance and Antitrust*, in *Antitrust, Innovation, and Competitiveness* 119, 122-123 (Thomas Jorde & David Teece eds., 1992) ("An 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 costs of production would be a calamity. In the long run a continuous rate of change, compounded, swamps static losses.").

Exclusion is short-lived, while the public-benefit is enduring: "A suppression can endure but for the life of the patent, and the disclosure he has made will enable all to enjoy the fruit of his genius." *Heaton-*

Peninsular v. *Eureka Specialty*, 77 F. 288, 294-295 (CA6 1896), quoted in *Bement*, 186 U.S. at 90.

For these reasons, patentees can enter into restraints of trade and engage in exclusionary conduct that would violate the antitrust laws absent patent protection: "The 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).

Examples of restraints of trade or exclusionary conduct that do *not* violate the antitrust laws because they are within the scope-of-the-patent include: (i) territorial market-allocation; (ii) field-of-use restrictions and customer-allocation; (iii) output-limitation; and (iv) refusals-to-deal.

(i) Territorial market-allocation. Statute authorizes patentees to allocate markets with or among licensees: "The applicant, patentee, or his assigns or legal representatives may in like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States." 35 U.S.C. 261; *e.g.*, *Dunlop* v. *Kelsey-Hayes*, 484 F.2d 407, 417 (CA6 1973) (holding licenses with exclusive territories "cannot be characterized as true horizontal agreements dividing markets" but are "merely territorial licenses granted by a patentee such as are permitted by 35 U.S.C. § 261"), cited in U.S.Br.6, *Andrx*, *supra* ("[A] patent license with territorial restrictions [was] held not to offend the antitrust laws in *Dunlop*."); *Brownell* v. *Ketcham Wire*, 211 F.2d 121, 128-129 (CA9 1954) ("It is a fundamental

rule of patent law that the owner of a patent may license another and prescribe territorial limitations. *** Exclusive territorial licenses granted under patents are old in the law."); 6 Donald S. Chisum, *On Patents: A Treatise on the Law of Patentability, Validity, and Infringement* §19.04[3][h] (2005) ("[A] patent owner may assign or license the right to practice the invention on a territorially restricted basis.").

Thus, in the "paradigmatic" example of *per se* unlawful market-allocation discussed in FTC-Br.19-24, *Palmer* v. *BRG of Georgia*, the market-allocation agreement would have been upheld if it had been a patent license.

Palmer involved an agreement between Harcourt Brace Javanovich (HBJ), the nation's largest bar-review course provider, and BRG, a course provider in Georgia. 498 U.S. at 46-47. The two competed in Georgia until HBJ granted BRG an exclusive-license to use the "Bar/Bri" trade-name there. *Ibid.* They agreed that BRG would operate inside Georgia, and HBJ elsewhere. *Ibid.* *Palmer* held the agreement unlawful *per se* because "[e]ach agreed not to compete in the other's territories[,] [and] [s]uch agreements are anticompetitive regardless of whether the parties split a market within which both do business or whether they merely reserve one market for one and another for the other." *Id.* at 49-50.

If *Palmer* had involved a legitimate dispute between HBJ's *patented* product and BRG's alleged-infringing product, to resolve the dispute and *induce* BRG to cease infringing, HBJ could have granted BRG an exclusive-license in Georgia (*i.e.*, exclusive

even as to HBJ) while HBJ practiced the patent elsewhere. See 35 U.S.C. 261; *Brownell*, 211 F.2d at 128-129 (upholding against antitrust claims an exclusive-license for U.S. sales, reserving to the patentee ex-U.S. sales); *Becton, Dickinson* v. *Eisele*, 86 F.2d 267, 271 (CA6 1936) (holding that territorial market-allocation is "within the scope of patent monopoly *** and so does not offend against the anti-trust laws"); 2 Herbert Hovenkamp et al., *IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law* §33.3 (2012) (explaining that §261 "authorizes the patentee to give one licensee an exclusive right to practice the patent in one territory, a second licensee to practice in a second territory, and so on").

Patent-infringement suits commonly settle through such rent-sharing licenses. See 1 Hovenkamp, *supra*, §7.1a. Statutory patent monopolies authorize patentees and *patentless* infringers to enter licenses that would constitute illegal "treaties with competitors" absent the patent. FTC-Br.23 (alteration omitted).

(The trade-name license in *Palmer* could not achieve this result because trade-names do not entail the monopolies granted to patents. *DOJ/FTC Guidelines* §1.0 n.1 (explaining that "innovation-related issues that typically arise with respect to patents" are different than the "product-differentiation issues that typically arise with respect to trademarks").)

(ii) ***Field-of-use restrictions and customer-allocation.*** Patentees can enter field-of-use restrictions with licensees, including allocating

classes of customers. *E.g.*, *Gen. Talking Pictures* v. *Western Electric*, 305 U.S. 124, 125-127 (1938) (upholding license restricting sales to residential users, not commercial users, as "reasonably within the reward which the patentee by grant of the patent is entitled to secure"); 6 Chisum, *supra*, §19.04[3][i] ("[T]he Supreme Court held that use-restricted licenses were not illegal and violation of such restrictions could be enforced through suit for infringement.").

(iii) Output-limitation. Patentees and licensees generally may enter output-limitation restraints. *E.g.*, *North Drive-In Theatre* v. *Park-In Theatres*, 248 F.2d 232, 236 (CA10 1957) (holding patentee acted within patent scope by limiting licensee to constructing only one of the patented product); *Aspinwall Mfg.* v. *Gill*, 32 F. 697, 698 (C.C.N.J. 1887) ("[D]efendants cannot pretend that their license to build 100 machines gave them any right to build any more than that; and it is clear, therefore, that in making the remaining 25 machines they were acting without authority."); 2 Hovenkamp, *supra*, §32.1 ("[C]ourts have generally been tolerant of horizontal output limitations in intellectual property licenses, at least when the restriction was imposed by the licensor in each license individually and there was no proof of an output limitation agreement among the licensees themselves.").

(iv) Refusals-to-deal. Patentees have broader refusal-to-deal rights than antitrust monopolists. *E.g.*, *In re Independent Service Organizations Antitrust Litigation*, 203 F.3d 1322, 1324-1327 (CAFC 2000) (upholding Xerox's refusal to sell patented parts to independent service organizations

that competed with Xerox in servicing its copiers, concluding that Xerox's "intent in refusing to deal and any other alleged exclusionary acts *** are irrelevant to antitrust law," because "the right of the patentee to refuse to sell or license in markets within the scope of the statutory patent grant" is settled), cited in U.S.Br.8, *Andrx*, *supra* ("[P]atent holders can lawfully refuse to license competitors to produce the patented article ***."); 6 Chisum, *supra*, §19.04[3][f] ("Generally, the patent owner has discretion whether and to whom he will issue a license.").

But a non-patentee monopolist may under certain circumstances violate the antitrust laws by refusing to deal. *Aspen Skiing* v. *Aspen Highlands*, 472 U.S. 585, 610-611 (1985) (holding that ski company's refusal to participate in joint-lift ticket program with smaller competitors violated the antitrust laws).

***

It is settled law that to reap the full reward of their time-limited monopolies, patentees may enter into agreements that restrain the practice of the patent (or engage in exclusionary unilateral conduct) for the patent-holder's financial benefit, including by entering into mutually beneficial agreements with alleged infringers.

The equally settled test to determine whether a patentee has entered into a restraint (or engaged in conduct) outside the protection of the temporary monopoly and, therefore, potentially in violation of the antitrust laws, begins by inquiring whether the restraint or conduct exceeds the scope-of-the-patent. *E.g.*, *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."); *Gen. Talking Pictures*, 305 U.S. at 127 ("[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."); *Cipro*, 544 F.3d at 1336 (CAFC 2008) ("[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.").

B. This Court never has upheld an antitrust claim against patent enforcement or licensing within the scope of a non-sham patent.

1. *Standard Oil*

Standard Oil resolves the key questions here, teaching that: (i) parties may settle patent-litigation without antitrust liability as long as there were "legitimately conflicting claims," 283 U.S. at 171; (ii) such conflict turns on the nominal scope-of-the-patent, which is *not* second-guessed by inquiring whether infringement would have been proven, *id.* at 181; and (iii) the financial terms and consideration of a settlement are irrelevant, *id.* at 171-172.

All the circuits that have ruled on final Hatch-Waxman settlements, except the Third Circuit, have relied on *Standard Oil*. See *Schering-Plough*, 402 F.3d at 1072 ("That the parties to a patent dispute may exchange consideration to settle their litigation has been endorsed by the Supreme Court."); *Cipro*, 544 F.3d at 1333; *Tamoxifen*, 466 F.3d at 202. The FTC's concession that *Standard Oil* establishes the

general rule that patent-settlements do not violate the antitrust laws, FTC-Br.26-27, makes the Third Circuit's failure to cite it particularly telling.

In *Standard Oil*, the government sought to enjoin, under Sherman Act §§1-2, agreements among four "primary defendants" concerning competing patents on "cracking" processes for extracting gasoline from crude-oil residue. Standard first patented the process, earning royalties for seven years by licensing it to fifteen companies. 283 U.S. at 167.

Because "cracking was not controlled by any fundamental patent," three companies subsequently patented competing processes. *Ibid.* Patent litigation ensued. To settle and avoid further litigation, the companies cross-licensed the patents, enabling each to use the previously competing processes and to license them to third-parties for royalties shared among the defendants. *Id.* at 168.

The government alleged that the settlement and licenses constituted unlawful restraints on cracking-supplied gasoline: "Control is alleged to be exerted by means of seventy-nine contracts concerning patents relating to the cracking art." *Id.* at 165-166.

The Court unanimously held, in an opinion by Justice Brandeis, that neither the settlement nor the patent-licensing and royalty arrangements violated the Sherman Act. Because the patents were presumptively valid, with no allegation of bad-faith acquisition, the Court did "not consider any of the issues concerning the validity or scope of the cracking patents." *Id.* at 181. The Court's methodical analysis (numbered as below) is instructive.

First, the Court rejected defendants' contention that patent-settlements and -licenses are exempt from antitrust scrutiny: "Such contracts must be scrutinized to ascertain *whether the restraints imposed* are regulations reasonable under the circumstances, or whether their effect is to suppress or unduly restrict competition." *Id.* at 169 (emphasis added). The Court emphasized special concerns with combinations among *multiple* patent-holders:

> And pooling arrangements may obviously result in restricting competition. *** Hence the necessary effect of patent interchange agreements, and the operations under them, must be carefully examined in order to determine whether violations of the Act result.

Id. at 169-170.

Second, the Court rejected the government's contention that dividing royalties (*i.e.*, monopoly rents) through settlement and cross-licenses among formerly competing patent-holders necessarily violated the Sherman Act: "Where there are legitimately conflicting claims or threatened interferences, a settlement by agreement, rather than litigation, is not precluded by the Act." *Id.* at 171 (citing *Virtue* v. *Creamery Package*, 227 U.S. 8, 33 (1913)).[3]

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[3] *Virtue* v. *Creamery* rejected a private antitrust claim alleging that competing patent-holders had settled patent-litigation with a license-and-royalty agreement that eliminated competition between them and restrained third-parties' manufacturing of certain dairy equipment. The Court held: "[P]atents are not so used [in violation of law] when the rights conferred upon them

Standard Oil observed, moreover, 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." *Ibid.* Thus, the Court wholly rejected the government's attempt to interject the parties' financial consideration into the antitrust analysis.

Third, the Court rejected the government's contention that royalties imposed through the settlement and cross-licenses were so onerous as to exclude potential competitors from using the cracking processes and, thereby, unreasonably restrained gasoline supply: "This argument ignores the privileges incident to ownership of patents." *Id.* at 172.

Fourth, because patent-pooling to sustain industry royalty rates would exceed patent scope, the Court agreed that the government's "main contention" required an evidentiary assessment:

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by law are only exercised." 227 U.S. at 33 (McKenna, J.). The Court observed that the agreement "was but a settlement of claims growing out of reciprocal charges of infringement." *Ibid.* The Court also rejected the claim that because the patent-holders ultimately were unsuccessful in asserting one of the patents, the settlement violated the antitrust laws: "[T]his is not an action for malicious prosecution. It is an action under the Sherman Anti-trust Act for the violation of the provisions of that act, seeking treble damages." *Id.* at 38. In other words, the adjudicated scope-of-the-patent was irrelevant.

> [A] pooling of competing process patents, or an exchange of licenses for the purpose of curtailing the manufacture and supply of an *unpatented* product, is beyond the privileges conferred by the patents and constitutes a violation of the Sherman Act. The lawful individual monopolies granted by the patent statutes cannot be unitedly exercised to restrain competition.

Id. at 174 (citing *Standard Sanitary* v. *United States*, 226 U.S. 20 (1912)) (emphasis added).[4]

Fifth, the Court assessed the evidence and held that none indicated that defendants acted beyond their patent grants: "To warrant an injunction which would invalidate the contracts here in question, *and require either new arrangements or settlement of the conflicting claims by litigation*, there must be a definite factual showing of illegality." *Id.* at 179 (citing *Chicago Board of Trade* v. *United States*, 246 U.S. 231, 238 (1918)) (emphasis added).[5]

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[4] Justice McKenna's opinion for the Court in *Standard Sanitary*, invalidating unlawful patent-pooling only one year before his opinion for the Court upholding legitimate patent-licenses in *Virtue* v. *Creamery*, see p.41 n.3, *supra*, underscores the difference between the two types of restraints. *Standard Sanitary* upheld the government's antitrust claim against multiple companies that consolidated their competing patents on the manufacture of enameled-ironware (*e.g.*, bathtubs) in one party. That party then set prices for 85% of manufacturers and re-sale prices for distributors. 226 U.S. at 47-49.

[5] *Chicago Board of Trade* rejected the government's claim that the commodity exchange's "call" rule, which prohibited trading grains afterhours at prices other than those bid at the close of trading, necessarily violated the Sherman Act. The Court

Sixth, disposing of the case, the Court rejected the government's attempt to base its antitrust claim on the judicially tested strength *vel non* of the patents. The government contended that the "patents were either invalid or narrow in scope; [and] that there was no substantial foundation for the alleged conflicts and threatened infringement suits[.]" *Id.* at 180. The Court rejected these contentions *despite* the district court having questioned what the adjudicated scope-of-the-patents would have been:

> The District Court stated that the particular claims should be interpreted narrowly, and that the respective inventions might be practised without infringement of adversely owned patents. *But it confirmed the finding of presumptive validity and did not question the finding of good faith.*

Id. at 181 (emphasis added).

By asking this Court to adopt a rule requiring judicial appraisal of financial consideration underlying settlements of undisputedly good-faith patent litigation, the FTC asks this Court to reject *Standard Oil*.

2. *The Cartel Cases*

The FTC cites five precedents for the proposition that "this Court has never suggested that the bundle of rights a patent provides to its holder includes the right to share the patentee's monopoly profits to induce potential competitors to abandon their efforts

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upheld the practice under the rule of reason. 246 U.S. at 237-239 (Brandeis, J.).

to compete or stay out of the market altogether." FTC-Br.29. But none of the cases involve a single patentee granting a license to a *patentless* infringer to settle litigation.

Instead, each case—following *Standard Oil*'s admonition that patents "cannot be unitedly exercised to restrain competition," 283 U.S. at 174—held that patent-holders exceeded their patent scopes by entering into numerous combinations concerning numerous patents in attempts to cartelize an industry:

- *United States* v. *Singer*, 374 U.S. 174, 197 (1963) ("By aggregating patents in one control, the holder of the patents cannot escape the prohibitions of the Sherman Act. That Act imposes strict limitations on the concerted activities in which patent owners may lawfully engage, and those limitations have been exceeded in this case.");
- *United States* v. *New Wrinkle*, 342 U.S. 371, 380 (1952) ("An arrangement was made between patent holders to pool their patents and fix prices on the products for themselves and their licensees. The purpose and result plainly violate the Sherman Act.");
- *United States* v. *U.S. Gypsum*, 333 U.S. 364, 400-401 (1948) (holding that owner of multiple patents entering into industry-wide licenses requiring royalties on both patented *and unpatented* products exceeded the scope-of-the-patents: "[A patentee] acting in concert with all members of an industry, to issue substantially identical licenses to all members of the industry under the terms of which the industry is completely regimented, the

production of competitive unpatented products suppressed, a class of distributors squeezed out, and prices on unpatented products stabilized [violates the antitrust laws].");

- *United States* v. *Line Material*, 333 U.S. 287, 314 (1948) ("[W]hen *patentees* join in an agreement as here to maintain prices on their several products, that agreement *** is unlawful *per se* under the Sherman Act.") (emphasis added);
- *United States* v. *Masonite*, 316 U.S. 265, 280 (1942) (holding patent-pooling and price-fixing conspiracy exceeded patent scope: "[T]he price regulation was based on mutual agreement among distributors of competing products, some of whom had competing patents, as we have noted. None of these patents *** had been held to conflict with or infringe the Masonite patents.").

The out-of-bounds restraints in each case rather than the financial consideration underlying the agreements controlled the outcome. *Singer*, *New Wrinkle, Gypsum*, *Line Material*, and *Masonite* confirm this Court's long-adherence to the scope-of-the-patent approach in evaluating patent-based restraints of trade. The FTC's reliance on these cases underscores the lack of authority for a different approach.

3. *Walker Process*

Walker Process teaches that, fraud aside, patent-enforcement within the patent's nominal scope is protected from antitrust scrutiny—regardless of any ensuing merits determination. 382 U.S. at 177. For antitrust purposes, within-the-scope patent-enforcement is risk-free. (Non-antitrust, patent-law

consequences for trivial suits exist. *E.g.*, 35 U.S.C. 285.)

Walker Process refutes the FTC's unprecedented, *citeless* contention that patents confer antitrust protection only if patentees accept litigation risk-of-loss. FTC-Br.26. Absent fraud/sham, patentees' antitrust exposure is unrelated to the vicissitudes of patent-litigation, much less any requirement to embrace those risks by forfeiting the right to self-insure through settlement. See *Watson*, Pet.App.32a ("Even the confident patent owner knows that the chances of prevailing in patent litigation rarely exceed seventy percent.").

Walker Process established a fraudulent-procurement exception to the general antitrust exemption for patent-enforcement: "[E]nforcement of a patent procured by fraud on the Patent Office may be violative of §2 of the Sherman Act provided the other elements necessary to a §2 case are present." 382 U.S. at 174. The Court did *not* distinguish a patentee's unilateral enforcement from that of an assignee acting by agreement: "This conclusion applies with equal force to an assignee who maintains and enforces the patent with knowledge of the patent's infirmity." *Id.* at 177 n.5.

The Court rejected the contention that knowingly enforcing a fraudulent patent alone establishes an antitrust claim: "[T]he area of *per se* illegality is carefully limited. We are reluctant to extend it on the bare pleadings and absent examination of market effect and economic consequences." *Id.* at 178.

Walker Process explained that fraudulent procurement may expose a patent-holder to antitrust

liability for exceeding the legitimate scope-of-the-patent:

> The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies *spring from backgrounds free from fraud or other inequitable conduct and that such monopolies* are kept within their legitimate scope.

Precision Instrument v. *Automotive Maintenance Machinery*, 324 U.S. 806, 816 (1945), quoted in *Walker Process*, 382 U.S. at 177 (emphasis supplied to highlight the language elided from the FTC's quotation of *Precision Instrument* at FTC-Br.48).[6]

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[6] The FTC cites *Precision Instrument* for the proposition that antitrust law should look beyond nominal patent scope because of "the public benefit from judicial testing of patent scope and elimination of invalid patents." FTC-Br.48. But *Precision Instrument* has nothing to do with judicial testing of patent scope or validity. Like *Walker Process*, *Precision Instrument* is about fraudulent-procurement. Patent-interference litigation settled only after Precision conceded that its interfering application was fraudulent. 324 U.S. at 810-814. Notwithstanding Automotive's knowledge of the fraud, Automotive agreed through settlement to be assigned Precision's application. *Id.* at 813-814. When Automotive enforced the ensuing patent against Precision, the Court balked: "The guiding doctrine in this case is the equitable maxim that 'he who comes into equity must come with clean hands.'" *Id.* at 814.

The FTC's omission of the words "*spring from backgrounds free from fraud or other inequitable conduct*" from its quotation of *Precision Instrument* is a telling admission of the lack of precedent for the FTC's contention that antitrust analysis requires "judicial testing of patent scope and elimination of invalid patents." FTC-Br.48.

Walker Process's use of "legitimate scope" was thus nominal patent scope—"free from fraud or other inequitable conduct," 382 U.S. at 177—not adjudicated scope as would be determined on the merits in a patent-infringement proceeding.

Justice Harlan elaborated on this important distinction between nominal and adjudicated scope in his oft-cited concurrence:

> [A] private cause of action would *not* be made out if the plaintiff: (1) showed no more than invalidity of the patent arising, for example, from a judicial finding of "obviousness," or from other factors sometimes compendiously referred to as "technical fraud"; ***.
>
> It is well also to recognize the rationale underlying this decision, aimed of course at achieving a suitable accommodation in this area between the differing policies of the patent and antitrust laws. To hold, as we do, that private suits may be instituted under §4 of the Clayton Act to recover damages for Sherman Act monopolization knowingly practiced under the guise of a patent procured by deliberate fraud, cannot well be thought to impinge upon the policy of the patent laws to encourage inventions and their disclosure. Hence, as to this class of improper patent monopolies, antitrust remedies should be allowed room for full play. On the other hand, to hold, as we do *not*, that private antitrust suits might also reach monopolies practiced under *patents that for one reason or another may turn out to be voidable* under one or more of the numerous technicalities attending the issuance of

> a patent, might well chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits.

Id. at 179-180 (emphasis added).

Walker Process's antitrust safe-harbor for non-fraudulent enforcement protects against the chilling effect on innovation that would ensue if patentees were subject to antitrust liability simply because they lost a (non-sham) case. Nothing in *Walker Process* suggests that a patentee forfeits that protection by settling the very same non-sham litigation. And, imputing such an exception to the non-sham, scope-of-the-patent safe-harbor would be unsound for two reasons.

First, given that the FTC rejects antitrust assessment of patent merits beyond fraud/sham standards as "doctrinally anomalous and likely unworkable in practice," FTC-Br.53, in a non-sham case there is no principled distinction between the exclusion resulting from litigation versus the exclusion resulting from settlement as long as each is within the scope-of-the-patent. See *PRE*, 944 F.2d 1525, 1528 (CA9 1991) ("A decision to accept or reject an offer of settlement is conduct incidental to the prosecution of the suit and not a separate and distinct activity which might form the basis for antitrust liability."), aff'd, 508 U.S. 49 (1993); *Valley Drug*, 344 F.3d at 1309 ("[L]itigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement.").

Without such a principled distinction, the FTC's rule would merely enact a policy preference for

litigation-to-the-end over settlement. Compare *Microsoft* v. *i4i*, 131 S.Ct. at 2252 ("We find ourselves in no position to judge the comparative force of these policy arguments.").

Second, it would be anomalous if the antitrust rule for patent-settlements were stricter than the rule for pre-suit licenses. Patentees routinely reach mutually beneficial compromises of their patent rights with would-be infringers in pre-suit licenses that entail all manner of bargained-for consideration. See pp.32-33, 34-37, *supra*. The FTC neither (i) explains why a different rule should apply post-suit nor (ii) proffers any limiting-principle to cabin the presumption from spilling into heightened antitrust scrutiny of pre-suit licensing (including treble-damages claims).

4. *Professional Real Estate Investors (PRE)*

PRE teaches that: (i) to pierce *Noerr-Pennington*'s general antitrust immunity for litigation conduct, the suit must be objectively baseless, and the litigant must have an improper subjective motivation; (ii) "objective baselessness" is a threshold inquiry that must be satisfied *before* subjective motivation becomes relevant; (iii) objective baselessness is determined by the nominal (not adjudicated) claim; and (iv) basing antitrust liability solely on parties'

subjective-litigation views would vitiate *Noerr-Pennington*.[7]

PRE thus precludes using parties' subjective-litigation views as the sole basis for a presumptive antitrust violation. The FTC's theory here is that reverse-payments demonstrate shared subjective recognition that a settlement-without-payment would have resulted in an earlier generic-entry date:

> If a settlement without a reverse payment is ultimately consummated, that dynamic provides good reason to *presume* *** that the period of brand-name monopoly the settlement allows is

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[7] *E. R.R. Presidents Conference* v. *Noerr Motor Freight*, 365 U.S. 127 (1961), unanimously reversed a judgment that railroads violated Sherman Act §§1-2 through deceptive publicity against trucking:

> [T]he railroads' sole purpose in seeking to influence the passage and enforcement of laws was to destroy the truckers as competitors for the long-distance freight business. *** The right of the people to inform their representatives in government of their desires with respect to the passage or enforcement of laws *cannot properly be made to depend upon their intent in doing so*. It is neither unusual nor illegal for people to seek action on laws in the hope that they may bring about an advantage to themselves and a disadvantage to their competitors.

Id. at 138-139 (emphasis added); see *United Mine Workers* v. *Pennington*, 381 U.S. 657, 670 (1965) ("*Noerr* shields from the Sherman Act a concerted effort to influence public officials regardless of intent or purpose.").

California Motor Transport v. *Trucking Unlimited*, 404 U.S. 508 (1972), extended *Noerr-Pennington* immunity to parties jointly seeking anticompetitive outcomes from courts. See p.64, *infra*.

> roughly commensurate with the *perceived strength* and scope of the relevant patent.
>
> By contrast, when a Hatch-Waxman settlement provides for a substantial reverse payment, the *most natural inference* is that the payment has purchased an additional increment of market exclusivity.

FTC-Br.35-36 (emphasis added).

This theory has two problems: it incorrectly presumes that a payment reflects the parties' shared subjective-litigation views; and, in any event, *PRE* bars antitrust liability based solely on parties' subjective-litigation views.

First, because Paragraph-IV litigation is a "highly artificial act of infringement," *Eli Lilly*, 496 U.S. at 678, the resulting asymmetry of risks between brand-names and generics renders an exchange of financial consideration an unreliable proxy for the parties' subjective views of the patent case. As the United States explained in a 2006 CVSG, "the resulting gross disparities in the litigants' respective risks may tend to increase the cost of settlement for patentees in the Hatch-Waxman context and make reverse payments more likely, even when the patentee's legal claims are strong." U.S.Br.10, *Schering-Plough*, *supra*.

Second, contravening *PRE*, the FTC's presumption improperly establishes antitrust liability on a "natural inference," FTC-Br.36, to be drawn from parties' supposed subjective-litigation views. See U.S.Br.12, *Schering-Plough*, *supra* ("The FTC's approach, however, appears to place undue weight on the parties' subjective views of the strength of the

claims as reflected in the settlement agreement ***."). Critically, this proposed inference would *replace* plaintiffs' burden of proving that defendants "had a conscious commitment to a common scheme designed to achieve an unlawful objective." *Monsanto* v. *Spray-Rite*, 465 U.S. 752, 758, 764 (1984) (rejecting test that "proof of [distributor] termination following competitor complaints is sufficient to support an inference of concerted action," holding: "There must be evidence that tends to *exclude the possibility* that the manufacturer and nonterminated distributors were acting independently.") (emphasis added).

PRE precludes such a presumptive antitrust violation predicated solely on parties' subjective-litigation views. Columbia sued PRE for copyright-infringement. PRE counter-claimed under Sherman Act §§1-2, alleging "that Columbia's copyright action was a mere sham that cloaked underlying acts of monopolization and conspiracy to restrain trade." 508 U.S. at 52.

Although Columbia lost its IP claim on summary judgment, Columbia won summary judgment against PRE's sham-litigation counterclaim because PRE failed to show that Columbia's IP claim was objectively baseless and, therefore, any factual questions as to Columbia's subjective motivation were irrelevant. *Id.* at 53-54. This Court granted certiorari to resolve divergent standards for establishing a sham-litigation antitrust claim under *Noerr-Pennington*. See *Nobelpharma* v. *Implant Innovations*, 141 F.3d 1059, 1071 (CAFC 1998) ("*PRE* and *Walker Process* provide alternative legal grounds

on which a patentee may be stripped of its immunity from the antitrust laws[.]").

PRE concluded that sham-litigation claims cannot be based solely on a litigant's subjective motivation: "[F]idelity to precedent compels us to reject a purely subjective definition of 'sham.' The sham exception so construed would undermine, if not vitiate, *Noerr*. And despite whatever 'superficial certainty' it might provide, a subjective standard would utterly fail to supply 'real intelligible guidance.'" *PRE*, 508 U.S. at 60 (quoting *Allied Tube* v. *Indian Head*, 486 U.S. 492, 508 n.10 (1988)).

Sham-litigation thus requires: (i) an objectively baseless claim; and (ii) an improper subjective motivation by the claimant:

> We now outline a two-part definition of "sham" litigation. First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr*, and an antitrust claim premised on the sham exception must fail.

Ibid.

"Objective baselessness" is a threshold inquiry: "Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. *** This two-tiered process requires the plaintiff to disprove the challenged lawsuit's *legal* viability before the court will entertain evidence of the suit's *economic* viability." *Id.* at 60-61.

Like *Walker Process*, *PRE* explained that even if both elements of the sham exception are met, the antitrust plaintiff still must prove the elements under Sherman Act §§1-2:

> [E]ven a plaintiff who defeats the defendant's claim to *Noerr* immunity by demonstrating both the objective and the subjective components of a sham *must still prove a substantive antitrust violation*. Proof of a sham merely deprives the defendant of immunity; it does not relieve the plaintiff of the obligation to establish all other elements of his claim.

Id. at 61 (emphasis added).

Critically, *PRE* emphasized that the nominal claim, *not* the adjudicated outcome of that claim, controls the antitrust analysis (unless the claimant won, which ends the inquiry altogether):

> [W]hen the antitrust defendant has lost the underlying litigation, a court must "resist the understandable temptation to engage in *post hoc* reasoning by concluding" that an ultimately unsuccessful "action must have been unreasonable or without foundation." The court must remember that "[e]ven when the law or the facts appear questionable or unfavorable at the outset, a party may have an entirely reasonable ground for bringing suit."

Id. at 60 n.5 (quoting *Christiansburg Garment* v. *EEOC*, 434 U.S. 412, 421-422 (1978)).

Echoing Justice Harlan's warning in *Walker Process* about the chilling effect on innovation that would ensue if antitrust liability turned on the

uncertain, adjudicated outcome of litigation, *PRE* held that antitrust liability based solely on subjective intent would thwart incentives for creativity: "[T]o condition a copyright upon a demonstrated lack of anticompetitive intent would upset the notion of copyright as a 'limited grant' of 'monopoly privileges' intended simultaneously 'to motivate the creative activity of authors' and 'to give the public appropriate access to their work product.'" *Id.* at 64 (quoting *Sony* v. *Universal City Studios*, 464 U.S. 417, 429 (1984)).

PRE explained that if a suit has an objective basis, it is beyond the purview of antitrust plaintiffs—or courts—to second-guess the litigant's economic motivations by questioning, for example, whether the suit was worth the candle:

> PRE could not pierce Columbia's *Noerr* immunity without proof that Columbia's infringement action was objectively baseless or frivolous. Thus, the District Court *had no occasion to inquire* whether Columbia was indifferent to the outcome on the merits of the copyright suit, whether any damages for infringement would be too low to justify Columbia's investment in the suit, or whether Columbia had decided to sue primarily for the benefit of collateral injuries inflicted through the use of legal process. Such matters concern Columbia's *economic motivations* in bringing suit, which were rendered *irrelevant* by the objective legal reasonableness of the litigation.

Id. at 65-66 (using "*Contra*" signal to disapprove *Grip-Pak* v. *Illinois Tool Works*, 694 F.2d 466, 472 (CA7 1982) (Posner, J.)) (emphasis added).

PRE thus rejected *Grip-Pak*'s holding that a suit with some objective basis nonetheless could constitute a sham for antitrust purposes if the litigant's improper subjective motivation were evidenced by, for example, spending more in the litigation than it hoped to gain. *Grip-Pak*, 694 F.2d at 472.

For patent-litigation with an objective basis and ensuing settlements within the nominal scope-of-the-patent, a rule presuming such settlements unlawful solely based on alleged "reverse-payments" would vitiate *PRE*'s holding that parties cannot be subjected to antitrust liability solely predicated on subjective-litigation views. The settling parties' *economic* motivations only become relevant if the *legal* infirmity of the settlement is demonstrated by restraints outside the scope-of-the-patent.

C. Traditional antitrust principles do not regulate parties' consideration or compel firms "to pursue the course that maximizes competition and consumer welfare," FTC-Br.51.

Traditional antitrust principles do not generally regulate financial consideration underlying agreements. See, *e.g.*, *Linkline*, 555 U.S. at 448; *Trinko*, 540 U.S. at 408; *Standard Oil*, 283 U.S. at 171-172. The FTC's presumption would depart from these principles by requiring courts to *appraise* any business transactions entered into contemporaneously with Hatch-Waxman settlements. According to the FTC:

> [A] court would need to consider the totality of the circumstances surrounding the agreement,

> relevant considerations would include [1] whether the payment reflected bona fide fair consideration for the property or services; [2] whether other terms of the side transaction comported with industry standards; [3] the existence of previous dealings between the parties on the subject matter of the side transaction; [4] a history of demonstrated interest in or need for the property or services on the part of the brand-name manufacturer; and [5] the course and content of the manufacturers' negotiations over the agreements.

FTC-Br.37-38.

The FTC inaccurately states that the agreements in this case involve "direct payments of money." FTC-Br.36 n.7 (citing nothing). Rather, the alleged "reverse-payments" here are separate co-promotion and manufacturing agreements entered into contemporaneously with the settlements. When stuck with its allegations, the FTC can only contend: "Those agreements made economic sense only as a mechanism for Solvay to pay its nascent generic competitors to delay competing with it, because the marketing agreements and the back-up manufacturing deal had little value to Solvay." FTC-Br.12 (citing J.A.50-53 ¶¶81-85).

Direct payments to delay generic entry are a thing of the past, and concerned *interim*-settlements for generics not to launch "at risk" during litigation. *E.g.*, *Cardizem*, 332 F.3d at 902 (CA6 2003); *Andrx*, 256 F.3d at 803 (CADC 2001); see U.S.Br.17, *Andrx*, *supra* ("The distinction is important because the calculus of competitive costs and benefits is

substantially different for interim settlements and final settlements."). Certainly post-MMA, the FTC has not reported (much less prosecuted) any direct-payment-for-delay settlements.

At bottom, the FTC's presumption is about courts appraising the "economic sense" of business transactions contemporaneous with settlement. What does not making "economic sense" mean? Does it mean that Solvay lost money in its co-marketing agreements with Watson and Par? If so, the FTC does *not* allege that; it alleges instead that Solvay had cheaper co-marketing alternatives. J.A.51 ¶82; see U.S.Br.15-20, *Trinko* (No.02-682) (filed May 23, 2002) (unsuccessfully advocating for an "economic sense" standard).

Under the FTC's rule, brand-names entering into profitable transactions could be subject to potential antitrust liability merely because *more*-profitable alternatives existed. Would the FTC's rule likewise oblige generics to earn only a "fair" profit on such transactions? See *Trinko*, 540 U.S. at 415 ("No court should impose a duty to deal that it cannot explain or adequately and reasonably supervise. The problem should be deemed irremediable by antitrust law ***.") (citations and internal quotation marks omitted); *Brooke Group* v. *Brown & Williamson Tobacco*, 509 U.S. 209, 223 (1993) (describing above-cost predation as "beyond the practical ability of a judicial tribunal to control").

The rudderless appraisal litigation that the FTC proposes would burden courts and parties alike without necessarily leading to reliable antitrust conclusions. See FTC-Br.37 (describing parties'

"heavy burden" to rebut presumption). In *Schering-Plough*, the FTC failed to convince its ALJ after a 40-day trial that the IP-licenses contemporaneous with settlement were a payment-for-delay (which did not deter the FTC from pursuing the case until denial of certiorari). *In re Schering-Plough*, No.9297, 2002 WL 1488085 (F.T.C. June 27, 2002); see also R. Hewitt Pate, Assistant Attorney General, DOJ Antitrust Division, *Antitrust and Intellectual Property* 12 (Jan. 24, 2003) ("The problem is that we have no way definitively to know which situation applies without evaluating the underlying IP rights, a task that is outside our core expertise as antitrust enforcers.").

The FTC concedes that circumscribing financial consideration will result in fewer settlements, FTC-Br.40, compelling parties to forgo settlements "to pursue the course that maximizes competition and consumer welfare," FTC-Br.51, when "competing considerations suggest that the mere presence of a reverse payment in the Hatch-Waxman context is not sufficient to establish that the settlement is unlawful." U.S.Br.11, *Schering-Plough*, *supra*.

D. Consequences

The contention that affirmance "would likely embolden manufacturers to enter into more such agreements, on more harmful terms," FTC-Br.46, presumes that patent-shortening settlements, like those here enabling generic entry five-years before patent expiration, are "harmful." That contention is undermined by the FTC's concession that predicting the but-for outcome would be "doctrinally anomalous and likely unworkable in practice." FTC-Br.53.

The FTC also *ignores* the MMA's remedial amendments. See pp.14-18, *supra*. In particular, due to exclusivity-forfeiture, first-filer settlements can no longer forestall subsequent generic entry. Due to shared-exclusivity, multiple generics can now line up with challenges qualifying for 180-day exclusivity. These changes incentivize *multiple* challengers, particularly given the FTC's finding that once a drug's sales reach $130 million, generics need only a 4% chance of winning to make challenges worthwhile. See p.15, *supra*.

The MMA Amendments have reduced incentives for reverse-payments (as the United States predicted in CVSGs), resulting in declining rates throughout the years when circuits unanimously applied the scope-of-the-patent approach. See pp.21-22, *supra*. Congress chose to reduce incentives for reverse-payments, rather than to prohibit reverse-payments or enact a "presumption" against them.

Congress's intervention with remedial changes and enactment of an antitrust-specific penalty and an antitrust-savings clause are reason for the Court to adhere to, *not* depart from, the common-law precedents that were the backdrop for Hatch-Waxman and the MMA.

These interventions (and pending legislation proposing an antitrust "presumption" *for FTC actions*) indicate higher likelihood for legislative backstop on the Hatch-Waxman settlement issue than is typical in antitrust cases. Congress can enact policy preferences that are not in judges' antitrust toolkits.

The FTC's contention that the scope-of-the-patent approach is a rule of *per se* lawfulness overlooks the FTC's own pending *Provigil* enforcement action, the *AndroGel* private suits, *K-Dur*, and numerous other challenges to Hatch-Waxman settlements that survived dismissal under the scope-of-the-patent approach. See Par/Paddock-B.I.O.20-21.

Far from toothless, this Court has applied the scope-of-the-patent approach both to uphold and to condemn patent-based restraints of trade.

II. The Complaint Fails To State A Claim Against Par/Paddock Under Any Antitrust Standard.

A. The district court order restraining Par/Paddock's generic entry confers *Noerr-Pennington* immunity.

Respondents' private settlement agreements (between Solvay and Watson on one hand, and Solvay and Par/Paddock on the other) could *not* of their own force end the patent litigations:

Solvay and Watson dismissed their litigation "without prejudice" by filing a stipulation of dismissal "without a court order." Fed.R.Civ.P.41(a)(1)(A)(ii).

Solvay and Par/Paddock successfully petitioned the court to enter the Consent Judgment and Order of Permanent Injunction, which: (i) terminated Solvay and Par/Paddock's litigation "with prejudice"; (ii) enjoins Par/Paddock from selling its generic AndroGel® until 2015 at the latest; (iii) guarantees Par/Paddock's right to practice the patent after that date; and (iv) retains continuing jurisdiction to enforce these terms. J.A.99-101.

The order binds Solvay and Par/Paddock to their generic-entry compromise in ways that a settlement agreement alone cannot. *United States* v. *Swift*, 286 U.S. 106, 115 (1932) ("We reject the argument *** that a decree entered upon consent is to be treated as a contract and not as a judicial act."); *SEC* v. *Randolph*, 736 F.2d 525, 528 (CA9 1984) ("A consent decree offers more security to the parties than a settlement agreement where the only penalty for failure to abide by the agreement is another suit."); see *Schering-Plough*, 402 F.3d at 1072 ("Veritably, the Commission's opinion would leave settlements, including those endorsed and facilitated by a federal court, with little confidence.").

Because Solvay and Par/Paddock successfully *petitioned* the court for an order enforcing their compromise generic-entry terms, they are immune from antitrust liability under *Noerr-Pennington*:

> We conclude that it would be destructive of rights of association and of petition to hold that groups with common interests may not, without violating the antitrust laws, use the channels and procedures of state and federal agencies *and courts* to advocate their causes and points of view respecting *resolution of their business and economic interests* vis-à-vis *their competitors*.

California Motor Transport, 404 U.S. at 510-511 (emphasis added); see *Andrx*, 421 F.3d at 1234 (CA11 2005) ("[A]s the Supreme Court has noted, engaging in litigation to seek an anticompetitive outcome from a court is First Amendment activity that is immune from antitrust liability."); *PRE*, 944 F.2d at 1528 (CA9 1991) ("A decision to accept or reject an offer of

settlement is conduct incidental to the prosecution of the suit and not a separate and distinct activity which might form the basis for antitrust liability."), aff'd, 508 U.S. 49 (1993); see also *Valley Drug*, 344 F.3d at 1309 ("The failure to produce the competing [generic] drug, rather than the payment of money, is the exclusionary effect ***.").

Noerr-Pennington immunity trumps the question presented as to the Solvay and Par/Paddock settlement. The FTC cannot undo Solvay and Par/Paddock's petitioned-for consent judgment, entered by the court as a continuing-injunction enforcing their compromise terms on Par/Paddock's generic entry.

B. Under pre-MMA rules, second ANDA filer Par/Paddock could not have obtained an earlier settlement-entry date.

Par/Paddock's settlement is pro-competitive. The FTC's theory is that but-for alleged reverse-payments, each generic would have obtained an earlier settlement-entry date. FTC-Br.23-24; J.A.56 ¶¶93-94. That theory is inapplicable to second-filer Par/Paddock, whose settlement enabled entry on the *same day* as Watson, 180-days earlier than Watson's pre-MMA exclusivity period otherwise would have permitted. Pet.App.12a.

Even under the FTC's theory that a settlement enabling generic entry before patent expiration may nonetheless cause anticompetitive "delay," a purported delay could only exist if the second-filer entered more than 180-days *after* the first-filer. In the three reverse-payment cases litigated by the FTC (all involving pre-MMA ANDAs), Par/Paddock is the

only second-filer that obtained the same entry date as the first-filer.[8]

Because Par/Paddock could *not* have obtained an earlier settlement-entry date than Watson even *without* any alleged reverse-payment, the FTC can only allege: "If Solvay had settled with Watson only, Par had ample financial incentive to continue to challenge Solvay's patent." J.A.56 ¶95.

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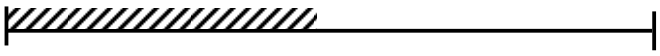
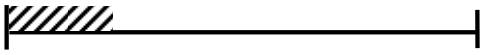
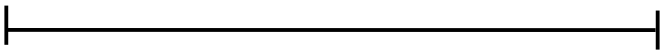
[8]

	Sept. 1, 2001	Jan. 1, 2004	Sept. 5, 2006
	1st-filer entry	2nd-filer entry	patent expiry
K-Dur			

"Delay" between first- and second-filer entry = 28 months

	Apr. 6, 2012	Oct. 3, 2012	Apr. 6, 2015
	1st-filer entry	2nd-filer entry	patent expiry
Provigil			

"Delay" between first- and second-filer entry = 180 days

	Aug. 31, 2015	
	1st-filer entry (Watson)	Aug. 30, 2020
	2nd-filer entry (Par/Paddock)	patent expiry
AndroGel		

"Delay" between first- and second-filer entry = zero

From FTC complaints susceptible of judicial notice. See *Tellabs* v. *Makor Issues & Rights*, 551 U.S. 308, 322 (2007).

That bears repeating: the FTC acknowledges that due to the pre-determined settlement between Solvay and first-filer Watson, Par/Paddock could *not* have obtained the FTC's theoretical earlier settlement-entry date even *absent* any alleged reverse-payment. The FTC's case against the Solvay and Par/Paddock settlement is based on a purported *duty* by second-filer Par/Paddock to have continued litigating after first-filer Watson settled.

Under pre-MMA rules for subsequent ANDA-filers, success in a continued litigation by Par/Paddock would have required winning "a final decision of a court from which no appeal *** has been or can be taken." 21 U.S.C. 355 note (explaining pre-MMA rule). In other words, Par/Paddock would have been required to win in the district court *and* sustain that victory through the Federal Circuit's infamous coin-flip reversal rate. Even then, under pre-MMA rules, *Watson* would have reaped the reward of Par/Paddock's Herculean efforts—with Par/Paddock still having to wait dutifully to enter 180-days later.

The FTC's complaint against Par/Paddock thus dangles by an allegation of "ample financial incentive" for continued-litigation when Congress enacted the MMA's remedial changes precisely because such incentives were *lacking* under pre-MMA law. *Mova Pharm.* v. *Shalala*, 140 F.3d 1060, 1073 (CADC 1998) ("One difficulty is that the 180-day exclusivity period will seemingly always go to the *first* applicant, no matter whose suit satisfies the court-decision trigger ***. It seems odd to reward the first applicant if some later applicant was the party that actually prevailed in the patent-infringement litigation.").

As a Hatch-Waxman practice manual observes:

> If the generic is not a first-filer, it will obtain no exclusivity even if the patent is held invalid or not infringed. Thus, there is little to gain by remaining a party to the litigation and continuing to pay litigation costs and endure discovery burdens. Nonlitigation alternatives should, therefore, be considered all the more seriously to avoid unnecessary litigation costs.

ANDA Litigation, *supra*, at 138.

The FTC dismisses "the competitive consequences of [Par/Paddock's] status as a second filer (as compared to Watson's status as a first filer)" as "an intricate argument." FTC-Cert.Reply-9. That intricacy derives from the FTC contending that it states an antitrust claim solely by alleging that Par/Paddock "had ample financial incentive to continue to challenge Solvay's patent." J.A.56 ¶95. Our antitrust laws do not compel firms to litigate.

CONCLUSION

The judgment below should be affirmed.

Respectfully submitted,

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J. MARK GIDLEY
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WHITE & CASE LLP

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FEBRUARY 2013

APPENDIX

APPENDIX A

113TH CONGRESS
1ST SESSION **S. 214**

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market.

IN THE SENATE OF THE UNITED STATES

Ms. KLOBUCHAR (for herself, Mr. GRASSLEY, Mr. DURBIN, Mr. FRANKEN, and Mr. JOHNSON of South Dakota) introduced the following bill; which was read twice and referred to the Committee on the Judiciary.

A BILL

To prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Preserve Access to Affordable Generics Act".

SEC. 2. CONGRESSIONAL FINDINGS AND DECLARATION OF PURPOSES.

(a) FINDINGS.—Congress finds the following:

(1) In 1984, the Drug Price Competition and Patent Term Restoration Act (Public Law 98–417) (referred to in this Act as the "1984 Act"), was enacted with the intent of facilitating the early entry of generic drugs while preserving incentives for innovation.

(2) Prescription drugs make up 10 percent of the national health care spending but for the past decade have been one of the fastest growing segments of health care expenditures.

(3) Until recently, the 1984 Act was successful in facilitating generic competition to the benefit of consumers and health care payers—although 67 percent of all prescriptions dispensed in the United States are generic drugs, they account for only 20 percent of all expenditures.

(4) Generic drugs cost substantially less than brand name drugs, with discounts off the brand price sometimes exceeding 90 percent.

(5) Federal dollars currently account for an estimated 35 percent of the $263,000,000,000 spent on prescription drugs, and this share is expected to rise to 42 percent by 2021.

(6)(A) In recent years, the intent of the 1984 Act has been subverted by certain settlement agreements between brand companies and their potential generic competitors that make "reverse payments" which are payments by the brand company to the generic company.

(B) These settlement agreements have unduly delayed the marketing of low-cost generic drugs contrary to free competition, the interests of consumers, and the principles underlying antitrust law.

(C) Because of the price disparity between brand name and generic drugs, such agreements are more profitable for both the brand and generic manufacturers than competition, and will become increasingly common unless prohibited.

(D) These agreements result in consumers losing the benefits that the 1984 Act was intended to provide.

(b) PURPOSES.—The purposes of this Act are—

(1) to enhance competition in the pharmaceutical market by stopping anticompetitive agreements between brand name and generic drug manufacturers that limit, delay, or otherwise prevent competition from generic drugs; and

(2) to support the purpose and intent of antitrust law by prohibiting anticompetitive practices in the pharmaceutical industry that harm consumers.

SEC. 3. UNLAWFUL COMPENSATION FOR DELAY.

The Federal Trade Commission Act (15 U.S.C. 44 et seq.) is amended by—

(1) redesignating section 28 as section 29; and

(2) inserting before section 29, as redesignated, the following:

"SEC. 28. PRESERVING ACCESS TO AFFORDABLE GENERICS.

"(a) IN GENERAL.—

"(1) ENFORCEMENT PROCEEDING.—The Federal Trade Commission may initiate a proceeding to enforce the provisions of this section against the parties to any agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a drug product.

"(2) PRESUMPTION.—

"(A) IN GENERAL.—Subject to subparagraph (B), in such a proceeding, an agreement shall be presumed to have anticompetitive effects and be unlawful if—

"(i) an ANDA filer receives anything of value; and

"(ii) the ANDA filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the ANDA product for any period of time.

"(B) EXCEPTION.—The presumption in subparagraph (A) shall not apply if the parties to such agreement demonstrate by clear and convincing evidence that the procompetitive

benefits of the agreement outweigh the anti-competitive effects of the agreement.

"(b) COMPETITIVE FACTORS.—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall consider—

"(1) the length of time remaining until the end of the life of the relevant patent, compared with the agreed upon entry date for the ANDA product;

"(2) the value to consumers of the competition from the ANDA product allowed under the agreement;

"(3) the form and amount of consideration received by the ANDA filer in the agreement resolving or settling the patent infringement claim;

"(4) the revenue the ANDA filer would have received by winning the patent litigation;

"(5) the reduction in the NDA holder's revenues if it had lost the patent litigation;

"(6) the time period between the date of the agreement conveying value to the ANDA filer and

the date of the settlement of the patent infringement claim; and

"(7) any other factor that the fact finder, in its discretion, deems relevant to its determination of competitive effects under this subsection.

"(c) LIMITATIONS.—In determining whether the settling parties have met their burden under subsection (a)(2)(B), the fact finder shall not presume—

"(1) that entry would not have occurred until the expiration of the relevant patent or statutory exclusivity; or

"(2) that the agreement's provision for entry of the ANDA product prior to the expiration of the relevant patent or statutory exclusivity means that the agreement is pro-competitive, although such evidence may be relevant to the fact finder's determination under this section.

"(d) EXCLUSIONS.—Nothing in this section shall prohibit a resolution or settlement of a patent infringement claim in which the consideration granted by the NDA holder to the ANDA filer as part

of the resolution or settlement includes only one or more of the following:

"(1) The right to market the ANDA product in the United States prior to the expiration of—

"(A) any patent that is the basis for the patent infringement claim; or

"(B) any patent right or other statutory exclusivity that would prevent the marketing of such drug.

"(2) A payment for reasonable litigation expenses not to exceed $7,500,000.

"(3) A covenant not to sue on any claim that the ANDA product infringes a United States patent.

"(e) REGULATIONS AND ENFORCEMENT.—

"(1) REGULATIONS.—The Federal Trade Commission may issue, in accordance with section 553 of title 5, United States Code, regulations implementing and interpreting this section. These regulations may exempt certain types of agreements described in subsection (a) if the Commission determines such agreements will

further market competition and benefit consumers. Judicial review of any such regulation shall be in the United States District Court for the District of Columbia pursuant to section 706 of title 5, United States Code.

"(2) ENFORCEMENT.—A violation of this section shall be treated as a violation of section 5.

"(3) JUDICIAL REVIEW.—Any person, partnership or corporation that is subject to a final order of the Commission, issued in an administrative adjudicative proceeding under the authority of subsection (a)(1), may, within 30 days of the issuance of such order, petition for review of such order in the United States Court of Appeals for the District of Columbia Circuit or the United States Court of Appeals for the circuit in which the ultimate parent entity, as defined at 16 CFR 801.1(a)(3), of the NDA holder is incorporated as of the date that the NDA is filed with the Secretary of the Food and Drug Administration, or the United States Court of Appeals for the circuit in which the ultimate parent entity of the ANDA filer is incorporated as of the date that the ANDA is filed with the Secretary of the Food and Drug

Administration. In such a review proceeding, the findings of the Commission as to the facts, if supported by evidence, shall be conclusive.

"(f) ANTITRUST LAWS.—Nothing in this section shall be construed to modify, impair or supersede the applicability of the antitrust laws as defined in subsection (a) of the 1st section of the Clayton Act (15 U.S.C. 12(a)) and of section 5 of this Act to the extent that section 5 applies to unfair methods of competition. Nothing in this section shall modify, impair, limit or supersede the right of an ANDA filer to assert claims or counterclaims against any person, under the antitrust laws or other laws relating to unfair competition.

"(g) PENALTIES.—

"(1) FORFEITURE.—Each person, partnership or corporation that violates or assists in the violation of this section shall forfeit and pay to the United States a civil penalty sufficient to deter violations of this section, but in no event greater than 3 times the value received by the party that is reasonably attributable to a violation of this section. If no such value has been received by the

NDA holder, the penalty to the NDA holder shall be sufficient to deter violations, but in no event greater than 3 times the value given to the ANDA filer reasonably attributable to the violation of this section. Such penalty shall accrue to the United States and may be recovered in a civil action brought by the Federal Trade Commission, in its own name by any of its attorneys designated by it for such purpose, in a district court of the United States against any person, partnership or corporation that violates this section. In such actions, the United States district courts are empowered to grant mandatory injunctions and such other and further equitable relief as they deem appropriate.

"(2) CEASE AND DESIST.—

"(A) IN GENERAL.—If the Commission has issued a cease and desist order with respect to a person, partnership or corporation in an administrative adjudicative proceeding under the authority of subsection (a)(1), an action brought pursuant to paragraph (1) may be commenced against such person, partnership or corporation at any time before the

expiration of one year after such order becomes final pursuant to section 5(g).

"(B) EXCEPTION.—In an action under subparagraph (A), the findings of the Commission as to the material facts in the administrative adjudicative proceeding with respect to such person's, partnership's or corporation's violation of this section shall be conclusive unless—

"(i) the terms of such cease and desist order expressly provide that the Commission's findings shall not be conclusive; or

"(ii) the order became final by reason of section 5(g)(1), in which case such finding shall be conclusive if supported by evidence.

"(3) CIVIL PENALTY.—In determining the amount of the civil penalty described in this section, the court shall take into account—

"(A) the nature, circumstances, extent, and gravity of the violation;

"(B) with respect to the violator, the degree of culpability, any history of violations, the

ability to pay, any effect on the ability to continue doing business, profits earned by the NDA holder, compensation received by the ANDA filer, and the amount of commerce affected; and

"(C) other matters that justice requires.

"(4) REMEDIES IN ADDITION.—Remedies provided in this subsection are in addition to, and not in lieu of, any other remedy provided by Federal law. Nothing in this paragraph shall be construed to affect any authority of the Commission under any other provision of law.

"(h) DEFINITIONS.—In this section:

"(1) AGREEMENT.—The term 'agreement' means anything that would constitute an agreement under section 1 of the Sherman Act (15 U.S.C. 1) or section 5 of this Act.

"(2) AGREEMENT RESOLVING OR SETTLING A PATENT INFRINGEMENT CLAIM.—The term 'agreement resolving or settling a patent infringement claim' includes any agreement that is entered into within 30 days of the resolution or

the settlement of the claim, or any other agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim.

"(3) ANDA.—The term 'ANDA' means an abbreviated new drug application, as defined under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)).

"(4) ANDA FILER.—The term 'ANDA filer' means a party who has filed an ANDA with the Food and Drug Administration.

"(5) ANDA PRODUCT.—The term 'ANDA product' means the product to be manufactured under the ANDA that is the subject of the patent infringement claim.

"(6) DRUG PRODUCT.—The term 'drug product' means a finished dosage form (e.g., tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with 1 or more other ingredients, as defined in section 314.3(b) of title 21, Code of Federal Regulations.

"(7) NDA.—The term 'NDA' means a new drug application, as defined under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)).

"(8) NDA HOLDER.—The term 'NDA holder' means—

"(A) the party that received FDA approval to market a drug product pursuant to an NDA;

"(B) a party owning or controlling enforcement of the patent listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the 'FDA Orange Book') in connection with the NDA; or

"(C) the predecessors, subsidiaries, divisions, groups, and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (A) and (B) (such control to be presumed by direct or indirect share ownership of 50 percent or greater), as well as the licensees, licensors, successors, and assigns of each of the entities.

"(9) PATENT INFRINGEMENT.—The term 'patent infringement' means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patents of addition and extensions thereof.

"(10) PATENT INFRINGEMENT CLAIM.—The term 'patent infringement claim' means any allegation made to an ANDA filer, whether or not included in a complaint filed with a court of law, that its ANDA or ANDA product may infringe any patent held by, or exclusively licensed to, the NDA holder of the drug product.

"(11) STATUTORY EXCLUSIVITY.—The term 'statutory exclusivity' means those prohibitions on the approval of drug applications under clauses (ii) through (iv) of section 505(c)(3)(E) (5- and 3-year data exclusivity), section 527 (orphan drug exclusivity), or section 505A (pediatric exclusivity) of the Federal Food, Drug, and Cosmetic Act.".

SEC. 4. NOTICE AND CERTIFICATION OF AGREEMENTS.

(a) NOTICE OF ALL AGREEMENTS.—Section 1112(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note) is amended by—

(1) striking "the Commission the" and inserting the following: "the Commission—

"(1) the";

(2) striking the period and inserting "; and"; and

(3) inserting at the end the following:

"(2) any other agreement the parties enter into within 30 days of entering into an agreement covered by subsection (a) or (b).".

(b) CERTIFICATION OF AGREEMENTS.—Section 1112 of such Act is amended by adding at the end the following:

"(d) CERTIFICATION.—The Chief Executive Officer or the company official responsible for negotiating any agreement required to be filed under subsection

(a), (b), or (c) shall execute and file with the Assistant Attorney General and the Commission a certification as follows: 'I declare that the following is true, correct, and complete to the best of my knowledge: The materials filed with the Federal Trade Commission and the Department of Justice under section 1112 of subtitle B of title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with respect to the agreement referenced in this certification: (1) represent the complete, final, and exclusive agreement between the parties; (2) include any ancillary agreements that are contingent upon, provide a contingent condition for, or are otherwise related to, the referenced agreement; and (3) include written descriptions of any oral agreements, representations, commitments, or promises between the parties that are responsive to subsection (a) or (b) of such section 1112 and have not been reduced to writing.'.".

SEC. 5. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.

Section 505(j)(5)(D)(i)(V) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(V)) is amended by inserting "section 28 of the Federal

Trade Commission Act or" after "that the agreement has violated".

SEC. 6. COMMISSION LITIGATION AUTHORITY.

Section 16(a)(2) of the Federal Trade Commission Act (15 U.S.C. 56(a)(2)) is amended—

(1) in subparagraph (D), by striking "or" after the semicolon;

(2) in subparagraph (E), by inserting "or" after the semicolon; and

(3) inserting after subparagraph (E) the following:

"(F) under section 28;".

SEC. 7. STATUTE OF LIMITATIONS.

The Commission shall commence any enforcement proceeding described in section 28 of the Federal Trade Commission Act, as added by section 3, except for an action described in section 28(g)(2) of the Federal Trade Commission Act, not later than 3 years after the date on which the parties to the agreement file the Notice of Agreement as provided

by sections 1112(c)(2) and (d) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (21 U.S.C. 355 note).

SEC. 8. SEVERABILITY.

If any provision of this Act, an amendment made by this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions of such Act or amendments to any person or circumstance shall not be affected thereby.

APPENDIX B

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FOIA EXEMPT
CONFIDENTIAL BUSINESS INFORMATION

BY HAND

November 22, 2010

Federal Trade Commission
Premerger Notification Office
Bureau of Competition
Room 303
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

U.S. Department of Justice
Director of Operations &
Civil Enforcement
Antitrust Division
950 Pennsylvania Avenue, N.W., #3335
Washington, DC 20530

Re: Filing Pursuant to Section 1112(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Dear Sir or Madam:

Pursuant to Section 1112(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Par Pharmaceutical Companies, Inc. ("Par") files the enclosed First Amendment to Co-Promotion Agreement entered into on November 10, 2010 with Abbott Laboratories f/k/a Solvay Pharmaceuticals, Inc. This First Amendment amends the September 13, 2006 Co-Promotion Agreement, which Par submitted to the FTC and DOJ pursuant to Section 1112(a) on September 25, 2006. We also include a November 19, 2010 letter from Par to Abbott Laboratories pursuant to the First Amendment. The effect of the First Amendment and the ensuing November 15, 2010 letter is to terminate the Co-Promotion Agreement. For your convenience, the September 13, 2006 Co-Promotion Agreement also is enclosed.

This letter and the copy of the First Amendment to the Co-Promotion Agreement enclosed herewith are being produced pursuant to the requirements of the Medicare Modernization Act, Pub. L. 108-173 Title XI, Subtitle B, §§ 1111-1118 (codified at 21 U.S.C. § 355 (note)). We request confidential treatment of all materials submitted pursuant to 15 U.S.C. § 18a(h), the Commission's and Division's regulations protecting confidential proprietary information from disclosure, and any other relevant confidentiality provisions under federal and state law.

Very truly yours,
/s/ Martin L. Wilson
Martin L. Wilson
Senior Director – Legal, Compliance
Par Pharmaceutical Companies, Inc.

Enclosures