No. 12-416

IN THE
Supreme Court of the United States

FEDERAL TRADE COMMISSION,
Petitioner,
v.
ACTAVIS, INC., ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF FOR RESPONDENT SOLVAY PHARMACEUTICALS, INC.

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February 21, 2013

QUESTION PRESENTED

Whether the settlement of bona fide Hatch-Waxman patent litigation in which the accused generic infringer is licensed to come to market before the expiration of the innovator drug company's patent and which does not exceed the exclusionary potential of the patent is rendered presumptively illegal merely because it also includes a business deal that is alleged to provide additional value to the accused infringer.

RULE 29.6 STATEMENT

The corporate disclosure statement included in the brief filed at the certiorari stage is amended as follows:

Respondent Solvay Pharmaceuticals, Inc., now known as AbbVie Products LLC, is a wholly owned subsidiary of AbbVie Inc. and is no longer a wholly owned subsidiary of Abbott Laboratories. AbbVie Inc. is a publicly traded company, and no person beneficially owns 10% or more of its outstanding shares.

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INTRODUCTION

For a century, this Court has analyzed antitrust challenges to patent-related restraints by evaluating whether the restraint exceeds the scope of the patent. The FTC now asks the Court to abandon that precedent in favor of a new, untested rule focusing on the existence of a so-called "reverse payment" in pharmaceutical settlements arising from patent litigation under the Hatch-Waxman Act. Although the FTC characterizes its new rule as a "quick-look" analysis, its brief makes clear that the test amounts to a rule of *per se* illegality. Either way, the rule is unwarranted. *Per se* or quick-look treatment under the antitrust laws would be available only if long judicial experience or persuasive evidence showed "reverse-payment" settlements to be almost always anticompetitive. There is no such long judicial experience, and the FTC has no persuasive evidence that reverse payments delay generic entry or protect "weak" patents. In fact, there is substantial reason to believe the opposite.

Perhaps because its new rule finds no support in this Court's precedents, the FTC primarily invokes policy arguments. But policy considerations weigh heavily against the FTC's rule, which would be hopelessly unmanageable for courts and litigants alike. The FTC admits that a rule that would require relitigating the underlying patent case in any antitrust action it brought would be unworkable—but then concedes that this task may be necessary in private cases, which far outnumber FTC enforcement actions. In addition, because the concept of a "reverse payment" lacks any principled limitations, the FTC's rule would render suspect a wide swath of patent settlements far beyond the Hatch-Waxman context.

Finally, to the extent Hatch-Waxman has created any undesirable policies, the solution is for Congress—and not the courts—to weigh costs against benefits and formulate any potential industry-specific rules.

STATEMENT OF THE CASE

A. Statutory Background

Until 1984, a company seeking to market a generic drug needed to submit a New Drug Application (NDA) that included safety and efficacy data specific to its generic version of the drug. If a patent covered the drug, the generic company's development effort would usually infringe the patentee's legal monopoly on "making" and "using" the drug. *See Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 861 (Fed. Cir. 1984). As a result, the generic development work generally could not begin until patent expiration.

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly known as the Hatch-Waxman Act. Under Hatch-Waxman, a generic drug company can obtain FDA approval by filing an Abbreviated New Drug Application (ANDA), which relies on the brand-name (or "innovator") drug's clinical trial data to establish safety and efficacy. The generic company need show only that its proposed generic has the same active ingredient as and is bioequivalent to the innovator's drug. 21 U.S.C. § 355(j)(2)(A); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 (2011).[1] The Act also

[1] Unless otherwise specified, citations of the United States Code refer to the 2000 edition in effect during the events relevant to this case. *See* FTC Br. 2 n.1.

abrogates the innovator drug company's traditional patent right to preclude the "making" and "using" of its patented drug in a generic company's efforts to develop a copy of that drug. 35 U.S.C. § 271(e)(1). Generic drug companies can now copy drugs much more quickly and cheaply and can do so before patent expiration. In addition, Hatch-Waxman allows generic companies to file a "paragraph IV" certification when they contend the patent covering the drug is invalid or not infringed, and creates a framework for litigation of resulting patent disputes. This framework is described in detail in the FTC's brief and the decision below. FTC Br. 4-6; Pet. App. 6a-9a.

Congress again legislated in this area when it passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108-173, 117 Stat. 2066. Under the MMA, agreements settling Hatch-Waxman litigation must be submitted to the FTC and the Department of Justice. *Id.* § 1112, 117 Stat. at 2461-62 (codified as amended at 21 U.S.C. § 355 note (2006)). Nothing in the MMA substantively regulates such agreements.

B. Factual Background

1. The AndroGel invention

In 1995, Unimed Pharmaceuticals, Inc., now a subsidiary of respondent Solvay Pharmaceuticals, Inc., began collaborating with Besins Healthcare, S.A. to develop a new drug for treating men with chronically low testosterone. After years of clinical trials, Unimed and Besins determined that their drug, AndroGel, was safe and effective. Unimed began selling AndroGel in 2000. JA 36-37, ¶¶ 31-33.

AndroGel represented a significant advance over previously approved testosterone formulations, which were mostly delivered by injections or skin patches. It met the need for a convenient dosage form that produces a steady level of testosterone in the bloodstream.

Unimed and Besins applied for a patent on AndroGel, disclosing the formulation to the public. The U.S. Patent and Trademark Office granted the application as U.S. Patent No. 6,503,894 ('894 patent) in January 2003. The patent will expire in 2020. JA 38-39, ¶¶ 39-43. AndroGel has since become a medical and commercial success, improving the lives of millions of patients.

2. Applications for generic versions of AndroGel and ensuing litigation

In May 2003, Watson Pharmaceuticals, Inc. (now Actavis, Inc.) and Paddock Laboratories, Inc. each filed an ANDA seeking approval for a generic version of AndroGel that contained a paragraph IV certification against the '894 patent. Unimed and Besins promptly filed Hatch-Waxman patent-infringement lawsuits against Watson and Paddock. JA 39-40, ¶¶ 44, 47.

The parties litigated the cases for three years, produced hundreds of thousands of pages of documents, took nearly 40 depositions, and retained numerous scientific experts. Pet. App. 33a. Paddock ultimately sought litigation funding from a larger generic drug company, Par Pharmaceutical Companies, Inc., which received the exclusive right to distribute Paddock's generic version of AndroGel if

and when the product could come to market. JA 40, ¶ 46.

The '894 patent was specifically intended to cover AndroGel and disclosed AndroGel's composition. Neither Watson nor Paddock disputed that its proposed generic product used the same ingredients as AndroGel in very nearly the same amounts. But each defendant raised numerous defenses, including that the patent did not cover AndroGel because of an alleged technical error in claim drafting and that the patent was invalid. They filed partial summary judgment motions, but those motions addressed only some of the patent claims and could not have defeated Unimed's entire suit.

The district court has since held, in the context of antitrust class actions filed by private plaintiffs, that Unimed had an objectively reasonable expectation of success in the patent litigation. *In re AndroGel Antitrust Litig. (No. II)*, --- F. Supp. 2d ---, 2012 WL 5352986 (N.D. Ga. Oct. 30, 2012), *appeal docketed*, No. 12-15562-BB (11th Cir. Oct. 30, 2012). Although Watson received final approval for its product in January 2006, it chose not to come to market and risk facing damages liability if it lost the patent case. JA 46, ¶ 65.

In September 2006, before the district court decided any substantive motions, the parties settled. In separately negotiated agreements, Solvay (Unimed's parent company) agreed to license Watson and Paddock to launch their respective generic versions of AndroGel in August 2015—five years before the '894 patent will expire. JA 46, 49, ¶¶ 65, 76. In exchange, each generic company agreed to respect the patent by not marketing its generic drug before August 2015. Watson, Paddock, and Par also agreed

to provide services to Solvay before 2015—Watson to promote AndroGel to urologists, Paddock to provide manufacturing capacity for the drug, and Par to promote it to primary care physicians—and Solvay agreed to pay for those services. JA 46, 48, ¶¶ 66, 74. There has been no allegation that any party did not provide its agreed-upon services or that those services were not valuable, though the FTC alleges that Solvay overpaid for them.[2] Solvay's payments represented less than 10% of AndroGel's revenues at the time. *See* JA 28, ¶ 2.

C. Proceedings Below

1. The FTC investigated the settlements for two years and then filed this case. Shortly thereafter, several private plaintiffs brought follow-on putative class actions.

In its operative complaint, the FTC did not allege that the '894 patent was fraudulently procured, that Unimed's patent suits were "sham" litigation, or that the settlements constituted patent misuse. It alleged

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[2] The FTC makes the further allegations that: (1) an internal Solvay document shows that Solvay believed it would need to make payments to Watson and Par/Paddock to induce their agreement to a 2015 entry date; and (2) Watson knew Solvay planned to introduce a new AndroGel formulation by 2015, and this would decrease the value of generic AndroGel. FTC Br. 11; JA 45, ¶¶ 62-63. Even if true, these allegations would show at most that the business deals were necessary to bridge the gap between the entry dates to which the parties respectively would have been willing to agree. *See infra* § IV.C (explaining that the FTC's test would prevent many cases from settling). Moreover, the allegation about a new formulation concerns only the settlement between Solvay and Watson; it has no bearing on the settlement among Solvay and Par and Paddock.

only that Solvay's business agreements with Watson, Par, and Paddock were not "independent business transactions," that Solvay overpaid for the services, and that the agreements induced Watson, Par, and Paddock to accept a later entry date for their generic versions of AndroGel. JA 50-53, ¶¶ 81-85. The complaint also alleged that Unimed was "not likely to prevail" in its lawsuits against Watson and Paddock. JA 53, ¶ 86.

2. The district court dismissed the complaint, rejecting the FTC's theory that "it should be presumptively unlawful for companies to settle a patent dispute with reverse payments." Pet. App. 51a. It observed that the only alleged "exclusion" ended five years before the close of the '894 patent's term. *Id.* at 48a-49a. The alleged exclusion was therefore within the lawful "environment of exclusion" of the patent. *Id.* at 48a (quotation marks omitted).

Additionally, the district court dismissed the private plaintiffs' claims concerning the settlements. *Id.* at 47a-52a. It has since granted summary judgments to respondents on the private plaintiffs' further claims (not asserted by the FTC) that Unimed's patent litigation was a sham. *AndroGel*, 2012 WL 5352986. Appeals from that judgment are stayed.

3. The Eleventh Circuit affirmed. It observed that the usual antitrust rules prohibiting agreements not to compete or divide markets do not apply in the patent context because a patent is "a lawful right to exclude others from the market." Pet. App. 17a (quotation marks omitted). The court held that there cannot be antitrust liability for an "exclusionary" effect that is within the bona fide exclusionary potential of the patent. *See id.*

The court of appeals rejected the FTC's proposal that antitrust liability turn on relitigating the merits of the patent case to determine whether Solvay was "likely to prevail." *Id.* at 30a. This "retrospective predict-the-likely-outcome-that-never-came" inquiry would be unmanageable, requiring courts to undertake the "turducken task" of "attempt[ing] to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to [a] judgment" that was never rendered. *Id.* at 33a, 36a. The court expressed that this "retrospective" approach was "unlikely to be reliable," would be burdensome for the parties and the court, would "undo much of the benefit of settling," and would "discourage settlements." *Id.* at 33a.[3]

4. After the court of appeals denied the FTC's petition for rehearing en banc, Pet. App. 62a, this Court granted certiorari.

SUMMARY OF THE ARGUMENT

I. The FTC argues that the scope-of-the-patent rule is flawed because it presumes validity and infringement when considering antitrust challenges to patent settlements. But more than a century of this Court's precedents have taken that approach.

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[3] As Par and Paddock argue, their settlement is immune from liability for two independent reasons regardless of the outcome of this appeal: (1) the district court's consent injunction that currently restrains Par and Paddock's generic entry provides *Noerr-Pennington* immunity; and (2) when Par and Paddock entered into their settlement, they believed that, as pre-MMA second filers, they could not have obtained an earlier agreed-upon entry date even absent any alleged payment. The court of appeals did not reach either of these arguments.

Only if a restraint falls outside the scope of a patent, or the patent was obtained through fraud or asserted in a sham manner, is there a basis for antitrust scrutiny. The Court has expressly refused to discount the patent's exclusionary scope because of the possibility that the patent someday might be found invalid or not infringed.

Like every previous federal-court decision confronting an antitrust challenge to this kind of Hatch-Waxman settlement, the Eleventh Circuit properly applied these precedents and considered whether the terms of the settlements here fell within the scope of the patent at issue. The court upheld the settlements as lawful because the FTC did not allege that Solvay's patent claims were sham or that the patent was fraudulently obtained; and, as the FTC admits, the settlements here provide for generic competition in 2015, five years earlier than the result if Solvay had prevailed in the litigation.

II. The FTC seeks to jettison the established scope-of-the-patent analysis. It urges the Court to adopt a new, untested antitrust rule that turns on whether a settlement includes a so-called "reverse payment" from the patentee to the accused infringer, and treats every settlement featuring such a "payment" as presumptively illegal under the antitrust laws. Only one federal court has embraced this standard, and only within the last eight months.

Although the FTC describes its novel rule as a "quick-look" analysis, the rule would function as a *per se* prohibition of "reverse-payment" settlements, because no "rebuttal" to the presumption of anticompetitive effect is realistically possible under the FTC's test. *Per se* condemnation is appropriate only after "courts have had considerable experience"

with a category of restraint and that experience demonstrates that the restraint is almost always anticompetitive. *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 886 (2007). Here, there is no such judicial experience. "Quick-look" analysis has been applied only to arrangements that resemble practices that are *per se* illegal, and for which the "anticompetitive effects can easily be ascertained." *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 770-71 (1999). But there is no resemblance between the patent restraint at issue in this case and any practice that is *per se* illegal, and it is far from obvious that "reverse-payment" settlements have anticompetitive effects.

At bottom, the FTC's argument ignores the existence of the patent. The FTC falsely analogizes to agreements by competitors to divide markets where no patents are involved—agreements that unquestionably harm competition and are *per se* illegal. But a patent represents a Congressional grant of the power to exclude. A settlement within the scope of a valid and infringed patent has no anticompetitive effect, regardless of any payments between the parties. Continuing to litigate instead of settling would keep the generic off the market for even longer if the patentee prevailed. This Court's precedents teach, moreover, that unless and until a patent is adjudicated invalid or not infringed, good-faith claims of validity and infringement must be assumed true for antitrust purposes.

The FTC responds by suggesting that pharmaceutical patents are generally "weak," and so should not be presumed valid or infringed for antitrust purposes. This argument is not only legally irrelevant, but also contrary to empirical data. A study

conducted by the FTC's own amici, for example, shows that pharmaceutical patents have been held valid in nearly three-quarters of cases litigated to judgment.

While the FTC's position is predicated entirely on the assumption that "reverse-payment" settlements cause later generic entry dates, the FTC has not come close to supporting this assumption. It relies primarily on its characterization of a non-public FTC analysis. Even setting aside that its study has not been subjected to public scrutiny, it does not show that reverse payments cause later entry dates. More importantly, the FTC ignores the risk that any short-term benefit of its rule would be swamped by a decrease in long-term consumer welfare from weakening the incentives for pharmaceutical innovation.

III. The FTC's rule also would be unworkable. *First*, the FTC concedes that any standard that requires relitigating the underlying patent dispute would be unmanageable and would create a "powerful disincentive to settlement." FTC Br. 54. Yet the FTC also concedes that its rule would require relitigating the underlying patent dispute in private antitrust lawsuits, which constitute most of the challenges to Hatch-Waxman settlements. Moreover, under a true "quick-look" (or rule-of-reason) analysis, relitigation of the patent case would occur even in FTC actions because a patent settlement has no anti-competitive effect if the patent is valid and infringed.

Second, the FTC's rule would render many non-Hatch-Waxman patent settlements presumptively illegal. The FTC does not define "reverse payment" in its brief here, but its public statements acknowledge that the concept necessarily would extend to many common settlement terms, and would not be limited

to a transfer of money. Indeed, a "payment" could extend even to a provision that does no more than release a settling party's damage claim.

Third, the "rebuttal" opportunity the FTC rule would permit is not the traditional one under the quick-look approach; the FTC would not permit rebuttal of the presumption of illegality by showing that a settlement is actually procompetitive. Instead the rebuttal would be limited to an ill-defined and unmanageable *five-factor test* that a court would need to consider to determine whether the "value" given to the generic was reasonable consideration for something other than a later entry date. Parties could spend years litigating this issue.

IV. The policy arguments invoked by the FTC are either factually unsupported, demonstrably incorrect, or inconclusive. They do not justify creating an untested new approach to antitrust law and patent settlements.

The scope-of-the-patent test, which has been the governing legal standard for a decade, has not harmed generic competition. Generic companies have aggressively challenged patents under this test. Although the FTC suggests that patentees might engage in seriatim "reverse-payment" settlements with would-be generic competitors, that scenario is economically infeasible and contrary to experience.

Neither do considerations of legislative history and statutory purpose support the FTC's rule. The Hatch-Waxman Act did not favor early generic entry at all costs, as the FTC and its amici suggest. To the contrary, the Act recognized the importance of strong patent rights to innovation: it *extended* many patent terms, while creating "the opportunity for competition in generic drugs to be on the market after

that patent has expired." 130 Cong. Rec. 24,430 (1984) (Rep. Waxman). When providing for litigation of disputes regarding patent validity and infringement, Congress did not intend to substantively modify the patent laws at all.

Ultimately, the FTC's test would have pernicious consequences for the courts and consumers. If settlement discussions are confined to the "single dimension" of splitting the patent term, differing expectations about a case's settlement value and differing resource constraints and business interests will frequently make settlement impossible. This would contravene the strong public policy in favor of settlement and undermine incentives for brand manufacturers to invent new drugs.

ARGUMENT

I. THE SCOPE-OF-THE-PATENT RULE CORRECTLY REFLECTS PATENT AND ANTITRUST PRECEDENTS

The court below, consistent with many other courts, concluded that patent settlements are subject to antitrust scrutiny only if (1) the patent was procured by fraud, (2) the assertion of the patent was a sham, or (3) the settlement's exclusionary restraint exceeds the exclusionary scope of the patent. Pet. App. 28a. The FTC complains that this scope-of-the-patent rule accepts the exclusionary scope of a duly issued patent even though the patent claim might not be upheld if the case were fully litigated. But the scope-of-the-patent test follows precisely the approach this Court's precedents take.

A. Only Restraints Outside The Scope Of A Patent Have Been Subjected To Antitrust Scrutiny

There is no dispute that "patent grants [are] an exception" to antitrust restrictions. *United States v. Line Material Co.*, 333 U.S. 287, 309 (1948). The antitrust analysis of patent-related restraints differs from that of other restraints because the purpose of patents is to enable patentees to exclude competition and charge supra-competitive prices for the life of the patent. *See* U.S. Const. art I, § 8, cl. 8. This Court has reconciled patentees' exclusionary rights with antitrust scrutiny in two ways.

First, antitrust law may be implicated where the patent was improperly acquired or asserted, *i.e.*, for fraud on the PTO or sham litigation. *See Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 178 (1965); *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 51 (1993) (*PRE*).

Second, the Court's precedents focus on whether patent-related restraints exceed the substantive or temporal scope of the patent, an idea arising both in antitrust cases and in the related doctrine of patent misuse. Restraints that exceed the patent's scope are subject to traditional antitrust analysis, such as *per se* condemnation or the rule of reason. A patentee may, for example, implicate the antitrust laws by using its patent to control the sale of unpatented products, *see Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 491 (1942), or to seek royalties beyond the patent term, *see Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964). Similarly, a patentee may implicate the antitrust laws by restricting the resale of patented products, *see United States v. Masonite Corp.*, 316

U.S. 265, 310-11 (1942), which is beyond the scope of a patent because the initial sale terminates all patent rights, *see Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 625 (2008). Antitrust law may apply also to patent pools, where multiple patentees jointly restrain trade beyond what a single patentee could achieve with its own patents. *See Line Material*, 333 U.S. at 288-89; *United States v. New Wrinkle, Inc.*, 342 U.S. 371, 376-79 (1952); *see also United States v. Singer Mfg. Co.*, 374 U.S. 174, 189 (1963) (patent pool used to implement concerted refusal to deal). Patent misuse is likewise evaluated with reference to the "physical or temporal scope of the patent." *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 343 (1971) (discussing *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 666 (1944)).

The principle applied in each of these cases is the same: exclusionary effects are subject to antitrust scrutiny when they reach "beyond the limits of the patent monopoly," *i.e.*, the challenged restraint's exclusionary effect is greater than the patent potentially provides. *Line Material*, 333 U.S. at 308; *see also United States v. Gen. Elec. Co.*, 272 U.S. 476, 485 (1926) (antitrust laws implicated "only when" the patentee "steps out of the scope of his patent rights"); *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 456-57 (1940) (patentee may not "control conduct by the licensee not embraced in the patent monopoly"); 6 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 1427c, at 216-17 (3d ed. 2012) (Masonite "exceeded" the patent "privilege"). That the restraints exceed the scope of the patent can be demonstrated by showing that the restraint on competition is greater than what could have been achieved through litigation. *See, e.g.*,

United States v. Univis Lens Co., 316 U.S. 241, 250 (1942) (relying on fact that a "patentee cannot control the resale price of patented articles which he has sold . . . by resort to an infringement suit").

By contrast, this Court has not applied antitrust scrutiny or the patent misuse doctrine to restraints within the scope of a patent. For example, the Court has held that antitrust law does not prohibit a patentee from dividing the market for its invention through exclusive licenses with territorial or field-of-use restrictions, *see Gen. Talking Pictures Corp. v. W. Elec. Co.*, 304 U.S. 175, 179-81 (1938), even though, absent a patent, such vertical restraints are subject to antitrust scrutiny—at one time, *per se* condemnation, *see Cont'l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 43 (1977) (replacing *per se* rule against non-price vertical restraints with rule of reason).

B. Antitrust Analysis Is Unaffected By The Possibility A Patent Could Be Held Invalid Or Not Infringed

In evaluating patent-related restraints under the antitrust laws, this Court has neither required adjudication of the underlying patent's scope nor validity or discounted the patent merely because it was challenged in litigation. Unless and until a patent claim is judicially rejected, antitrust law assumes its validity. *See Masonite*, 316 U.S. at 280 (antitrust courts are not "warranted in assuming, in absence of a definite adjudication, that one grant by the Patent Office is more valid than another").

In *Standard Oil Co. v. United States*, 283 U.S. 163 (1931), the Court's antitrust analysis of patent settlements treated the patents as valid and infringed, despite the expressly recognized contrary possibility.

There, four competing licensors of gasoline cracking technology had sued each other for patent infringement. Each claimed the others' patents were invalid and not infringed by its own technology. The parties settled by cross-licensing the patents and agreeing to share profits from licensing their technologies—with a fixed royalty price to their respective downstream licensee customers. *See id.* at 167-68.

The government contended that the licensors' agreements "constitute[d] an unlawful combination under [section 1 of] the Sherman Act." *Id.* at 171. This Court rejected that contention, holding that "[w]here there are legitimately conflicting [patent] claims or threatened interferences, a settlement by agreement, rather by litigation, is not precluded by the Act." *Id.*

The government had argued that the patents were invalid and not infringed, and that the patents' "infringement had been asserted merely as a means of" making the profit-pooling contracts seem legal. *Id.* at 180. Although it "confirmed the finding of presumptive validity," the district court had questioned whether the patents were actually infringed, ruling that each patent's claims "should be interpreted narrowly" and that "the respective inventions might be practiced without infringement of the adversely owned patents." *Id.* at 180-81. Nevertheless, the district court held that the infringement claims were "sufficient to justify the threats and fear of litigation," *i.e.*, had been asserted in "good faith." *Id.* at 180. Those findings were not appealed, so this Court accepted them for purposes of its analysis. *Id.* at 181. That analysis explained that the agreements to fix and share license royalties were within the rights granted by their patents. Critically, this was

true even though it appeared the patent-infringement claims may well have failed if litigated to conclusion.[4] In other words, this Court implicitly concluded that the antitrust analysis—which specifically found that the conduct was not anticompetitive because of the patents—did not require it to "consider any of the issues concerning the validity or scope of the cracking patents," because the patents had been asserted in "good faith." *Id.* at 181.

Likewise, *Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176 (1980), concerned whether a tying arrangement between a patented process and a non-staple good constituted patent misuse. Again, the Court analyzed the patent misuse issue without regard to the petitioners' "assert[ion of] the invalidity of Rohm & Haas' patent on a variety of grounds," which had not yet been decided in the district court. *Id.* at 185 & n.5. The possibility that the patent might ultimately be found invalid—as it later was, *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556 (Fed. Cir. 1983)—did not affect whether the challenged restraint was within the scope of the patent. (Once the patent was invalidated, obviously, any existing patent licenses became void, and any subsequent tying arrangement would have been subject to normal antitrust scrutiny.)

Similarly, in *United States v. United States Gypsum Co.*, 333 U.S. 364 (1948), the United States challenged patent licenses related to gypsum boards.

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[4] *Standard Oil* also considered whether the licensors had used their profit-pooling and royalty-fixing agreement to obtain a monopoly in gasoline itself (which would have been beyond the scope of their patents on gasoline cracking processes), and held that they had not. 283 U.S. at 174-79.

There was no dispute that, "in the absence of whatever protection is afforded by valid patents[,] the licensing arrangements described would" violate the antitrust laws. *Id.* at 386. Although the Court held that the government had standing on remand to challenge the patents' validity and thus void the licenses, the Court also held that unless and until the government proved that "the asserted shield of patentability does not exist," the antitrust analysis "must be considered on a record that assumes the validity of all the patents." *Id.* at 388. The licenses were held to violate the antitrust laws because they imposed restrictions "beyond any patent privilege," not because the patents might have been invalid or not infringed. *Id.* at 391.

C. The Scope-Of-The-Patent Rule Follows This Court's Precedents

The lower courts' scope-of-the-patent rule is a direct application of the principles embodied in these precedents. Antitrust scrutiny is limited to patent settlements involving restraints exceeding the scope of the patent, fraudulently obtained patents, or sham patent assertion.

1. The FTC insists that the proper antitrust analysis must discount the patent's exclusionary force to account for the possibility that it might be held invalid or not infringed. But the FTC cites no case of this Court discounting a patent's exclusionary scope merely because the patent later might be found invalid or not infringed. Such an approach would effectively eliminate every patent's exclusionary power because every patent, even a patent that has already been found valid in one case, *might* be found invalid in another case involving a different accused infringer.

Rather, this Court's precedents show that it is irrelevant if an antitrust challenge to a patent settlement arises against the backdrop of a patent whose validity and infringement was contested but undecided. Although the Court's precedents have addressed a diverse variety of alleged restraints, they all indicate that the antitrust analysis "must be considered on a record that assumes the validity of all the patents involved," unless and until the patent claim is rejected. *Gypsum*, 333 U.S. at 388.

2. The FTC is wrong in contending that the scope-of-the-patent rule treats Hatch-Waxman settlements as "per se lawful." FTC Br. i. First, the rule does not protect settlements involving fraudulently acquired patents or sham litigation, so it safeguards the public from being "repressed by worthless patents." *Id.* at 48.

Second, the rule does not protect settlements that restrain competition beyond the potential impact of the patent litigation. For example, courts condemn patent settlements that seek to control obviously non-patented products. *See, e.g.*, *King Drug Co. of Florence v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 534 (E.D. Pa. 2010) (denying motion to dismiss because the complaints alleged that the settlements excluded "products not covered by any of Cephalon's patents"). In the Hatch-Waxman context, courts subject settlements to antitrust scrutiny to ensure they do not go beyond the patent's scope by including terms that block future ANDA filers in a manner that exceeds the restrictions adopted by Congress. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1311-12 (11th Cir. 2003) (generic company's agreement never to waive its 180-day exclusivity period made settlement potentially anticompetitive); *King Drug*, 702 F.

Supp. 2d at 532-33 (denying motion to dismiss because complaints alleged "creation of a bottleneck" through generics' "agree[ment] not to give up their 180-day exclusivity").[5]

3. The FTC is also incorrect when it suggests (FTC Br. 36, 48) that the scope-of-the-patent rule conflicts with the rule permitting licensees to challenge patents notwithstanding contrary license terms. *See, e.g.*, *Lear, Inc. v. Adkins*, 395 U.S. 653, 673-74 (1969). Any policy favoring the testing of patents does not apply to litigation settlements, which, to be meaningful, must include a release by the accused infringer. *See, e.g.*, *Hemstreet v. Spiegel, Inc.*, 851 F.2d 348, 350 (Fed. Cir. 1988). *Lear* does not displace the strong public policy favoring finality of litigation and private resolution of disputes.

4. Under the scope-of-the-patent rule, the FTC's complaint fails to state a claim. It does not allege sham litigation or *Walker Process* fraud, and the FTC concedes that the challenged agreements "contemplated a greater degree of generic competition than might have occurred if the case had been litigated to judgment and the patentee (Solvay) had prevailed"—which would have excluded Watson's and Paddock's products for five additional years, until 2020. FTC Br. 43 n.10. The challenged restraint is thus within the scope of Solvay's patent.

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[5] Here, Watson expressly relinquished its 180-day exclusivity as part of the settlement.

II. THE FTC'S PROPOSED TEST IS UNPRECEDENTED AND UNJUSTIFIED

A. The FTC Is Asking For A Rule Of *Per Se* Illegality

The FTC largely ignores the law discussed above and instead asks the Court to treat any patent settlement with a "reverse payment" as presumptively illegal. It asserts that the presumption of illegality can be rebutted by only one of three showings: (1) the reverse payment was "bona fide fair consideration" for something "unrelated to the brand name manufacturer's monopoly"; (2) the "reverse payment" was less than "avoided litigation costs"; or (3) other "rare" circumstances of "unusual business or litigation justifications," such as a "modest cash payment that enables a cash-starved generic manufacturer to avoid bankruptcy and begin marketing a generic." FTC Br. 37-38.

Although the FTC describes its proposed rule as an application of "quick-look" analysis, it would actually impose *per se* illegality. The FTC's first two forms of permitted "rebuttal" require showing that, in fact, there was no reverse payment—the first by showing that there was no net "payment" because the exchange was at fair market value, and the second by showing that any "payment" was de minimis. The third permitted form of rebuttal is both "rare" (by the FTC's admission) and undefined; it certainly is not "clear enough for lawyers to explain to clients," *Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. 438, 453 (2009), or for courts to apply. The FTC's only example—saving a generic company from bankruptcy—is unrealistic; rational patentees would not fund such a potential competitor.

While the FTC says it does not support a *per se* rule of illegality for reverse-payment patent settlements, the inability to rebut the presumption of illegality by showing there likely would be no anticompetitive effect is the very essence of *per se* analysis.

B. The FTC's Test Is Not Supported By Precedent

1. Especially when viewed as the rule of *per se* condemnation that it is, the FTC's rule cannot be supported. The Court adopts *per se* rules only after "courts have had considerable experience with the restraint" and that experience shows the restraint is always or almost always anticompetitive. *Leegin*, 551 U.S. at 886. The FTC has not shown any judicial experience, much less "considerable" experience, finding "reverse-payment" settlements anticompetitive. To the contrary, until the Third Circuit's decision last year in *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012), every circuit to consider the issue had found "reverse-payment" settlements to be lawful unless they contained exclusionary terms that exceeded the scope of the patent. *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 104-08 (2d Cir. 2010) (per curiam); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336-37 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 205-09 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005); *Valley Drug*, 344 F.3d at 1312.[6]

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[6] The Sixth Circuit had previously held a Hatch-Waxman settlement *per se* illegal, *see In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), but that settlement contained

2. Even treated as a "quick-look" analysis, the FTC's proposed rule cannot be supported. This Court has only applied a "quick-look" analysis to arrangements that "resemble[] practices" that are *per se* unlawful. *E.g.*, *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 458 (1986); *see also* 11 Areeda & Hovenkamp, *supra*, ¶ 1911c, at 335. The FTC argues that a "reverse-payment" patent settlement "closely resembles" a *per se* illegal horizontal agreement, citing cases concerning horizontal price-fixing and market allocation in the absence of a patent. FTC Br. 20-24, 35. But the patent cannot simply be ignored. *See supra* § I; *see also E. Bement & Sons v. Nat'l Harrow Co.*, 186 U.S. 70, 88 (1902) ("The first important and most material fact in considering this question [antitrust analysis of patent-related agreements] is that the agreements concern articles protected by letters patent of the government of the United States."). This Court has never treated a patent-related restraint as a market allocation that can be condemned under a *per se* or quick-look analysis, rather than examining whether the restraint is within the scope of the patent. Cases such as *General Electric*, *Standard Oil*, and *Gypsum* show that conventional antitrust analysis does not apply where, as here, the challenged restraints are within the scope of the patent.

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competitive restraints that exceeded the scope of the patent, *see Tamoxifen*, 466 F.3d at 213-15 (distinguishing *Cardizem*); U.S. Br. at 11-15, *Andrx Pharms., Inc. v. Kroger Co.*, 540 U.S. 1160 (2004) (No. 03-779) (filed July 9, 2004) (explaining that the *Cardizem* settlement "extended beyond the legitimate scope of the patent claims").

Even the FTC implicitly recognizes this by endorsing patent-term split settlements, where the accused infringer agrees to stay off the market for some period. FTC Br. 27-28. Such an agreement would be a *per se* illegal horizontal market allocation in the absence of the patent but is indisputably legal in settlement of a bona fide patent dispute.

The FTC relies heavily on *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990). But nothing in *Palmer* suggests that antitrust law should ignore the potential exclusionary force of a patent or other intellectual property. That issue did not even arise in the case. *Palmer* concerned two competing bar-exam course providers that agreed not to compete in their respective geographies. The only property right mentioned was one defendant's trademark, but the defendants did not and could not claim that excluding all bar-exam preparation services, even those using a different mark, was within the scope of that trademark. Thus, the restriction was a naked market division, unsupported by a claim that it was within the scope of any intellectual property right. *Cf.* 12 Areeda & Hovenkamp, *supra*, ¶ 2044e2, at 317 (discussing how the restraint in *Palmer* was not "commensurate with the property right").

The error in the FTC's analysis is evidenced by the prior views of the United States itself, which previously argued to this Court that "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. at 11, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273) (filed May 17, 2006).

C. The FTC's Assumption Of Anticompetitive Effect Ignores That Many Patents Are Valid And Infringed

1. Neither a quick-look nor a *per se* rule is appropriate here because many "reverse-payment" settlements will have procompetitive effects. *See Leegin*, 551 U.S. at 886 (2007); *Cal. Dental*, 526 U.S. at 770-71 (quick-look analysis appropriate only when "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect" and when the "anticompetitive effects can easily be ascertained"). If a patent is actually adjudicated valid and infringed, for example, a settlement that provides for entry before patent expiration will *increase* generic competition, regardless of any "reverse payment."

This is hardly a theoretical criticism. Two of the leading reverse-payment antitrust cases of the past decade, *Tamoxifen* and *Ciprofloxacin*, involved settlements in which the generic company agreed to stay off the market and the patentee paid it tens of millions of dollars. *Tamoxifen*, 466 F.3d at 193; *Ciprofloxacin*, 544 F.3d at 1328-29. The FTC's rule would quickly condemn these settlements as illegal. But, in each instance, multiple additional generic applicants challenged the patent, the later patent litigation was not settled, and the patent was upheld. *See Tamoxifen*, 466 F.3d at 195; *Ciprofloxacin*, 544 F.3d at 1329.

The FTC acknowledges that a settlement allowing generic entry before the expiration of a valid and infringed patent *increases* competition. *See* FTC Br. 43 n.10. Under the FTC's approach, however, the

Tamoxifen and *Ciprofloxacin* settlements would be condemned as illegal notwithstanding that in each case courts held the patentee had an absolute legal right to exclude all infringing products. This cannot be correct. Neither the infringer nor consumers have the right to competition that violates a valid patent.

2. This central tension in the FTC's rule—that a "reverse-payment" settlement will be condemned even though the patent might be valid and infringed—may explain the government's inconsistent positions about whether antitrust analysis requires relitigating the patent dispute. The FTC first argued that antitrust courts should not determine the merits of the patent dispute because doing so would create "serious uncertainties" for "parties who seek to settle patent litigation." *In re Schering-Plough Corp.*, 136 F.T.C. 956, 993-98 (2003). In the same case, however, the United States argued before this Court that "an appropriate legal standard should take into account the relative likelihood of success of the parties' claims." U.S. Br. at 11, *Schering, supra.*

In 2009, the United States switched positions and argued that it was "not appropriate" to inquire into the likelihood of success on the merits. U.S. Br. at 24, *Ark. Carpenters*, 604 F.3d 98 (No. 05-2851) (filed July 6, 2009). But that same year, the FTC brought this case, arguing that antitrust analysis should turn on whether "it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date." Pet. App. 29a; *see also FTC v. Watson Pharms., Inc.*, 611 F. Supp. 2d 1081, 1088 (C.D. Cal. 2009) (noting that the FTC admitted "it could not litigate this case without also including

a theory of competitive harm that would necessitate looking to the merits of the patent cases").

Although the FTC and the United States now agree (as do all parties) that the patent merits should not be part of the antitrust analysis, the FTC's proposed rule still cannot avoid the paradox of condemning settlements as anticompetitive even if they result in generic entry earlier than the patent otherwise provides.

3. The FTC's response is to disparage patents and the PTO, suggesting most pharmaceutical patents are invalid. The sole support for this proposition is the FTC's own decade-old study concluding that, during the period 1992-2002, more than 70% of fully litigated pharmaceutical patent claims were defeated, and a more recent academic study concluding that 46% of patents are held invalid. FTC Br. 4, 6, 26. But the FTC's statistics are outdated and unreliable. *See* Br. of Antitrust Economists as Amici Curiae in Supp. of Resp'ts. Moreover, the academic study that the FTC cites—conducted by one of its amici—also found that 72% of *pharmaceutical* patents had been held *valid*. John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 217 (1998). And a more recent study with a larger sample shows that patentees win Hatch-Waxman cases more than half the time. RBC Capital Mkts., *Analyzing Litigation Success Rates* 1 (2010).

More fundamentally, statistics about patent cases litigated to conclusion are beside the point here, where the issue involves patent cases that are *not* litigated to conclusion. The FTC offers no data or analysis of the supposed "strength" of the patents in those cases. Indeed, the government itself has

previously recognized that the "gross disparities in the litigants' respective risks may . . . make reverse payments more likely, even when the patentee's legal claims are strong." U.S. Br. at 10, *Schering*, *supra*.

4. The FTC also derides many pharmaceutical patents as "secondary" or "trivial" because they cover improvements to or new formulations of a drug, rather than the active ingredient. FTC Br. 7, 44. There is no legal or factual basis for a rule that is premised on ranking some patentable inventions as more worthy of protection than others. The relief specified in Hatch-Waxman for patent infringement—exclusion of the generic drug for the entire patent term, 21 U.S.C. § 355(j)(5)(B)(iii)(II); 35 U.S.C. § 271(e)(4)(A)—applies regardless of whether the patent covers an improvement or formulation rather than the active ingredient, as do the patent laws generally. *See* 35 U.S.C. § 101. *Standard Oil*, *Dawson*, and *Gypsum* all involved "secondary" patents on new formulations or new processes for using or obtaining well-known chemicals. The Court did not suggest that these patents were entitled to less antitrust deference. Rather, the Court explained in *Dawson* that "[d]evelopment of new uses for existing chemicals" is a "major component of practical chemical research," with immense social value. 448 U.S. at 220-21.

AndroGel itself demonstrates how important a new formulation can be. Although testosterone has been known for decades, no one before Solvay had developed a dosage form that both was convenient and ensured a steady level of testosterone in the blood. This new formulation dramatically expanded the population of afflicted patients treated for their condition. It is for physicians and the marketplace,

not the FTC, to determine whether an invention is important or trivial.

It is equally misguided to suggest that antitrust law should categorize some pharmaceutical patents as "weak." The courts are not "warranted in assuming, in absence of a definite adjudication, that one grant by the Patent Office is more valid than another." *Masonite*, 316 U.S. at 280. Although the terms "strong" and "weak" may be bandied about in casual discussions of patents, there is no meaningful way to define these categories, or any reliable method of sorting patents into such categories.

In any event, Congress is the proper branch of government to address any perceived concerns about the patent system. *See Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2251-52 (2011). Congress has done so repeatedly, providing *ex parte* reexamination and *inter partes* review procedures that any person or entity can invoke to challenge a patent's validity. *See* 35 U.S.C. §§ 302-307; Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 6(a), 125 Stat. 284, 299 (2011).[7]

D. The FTC Cannot Demonstrate That "Reverse-Payment" Settlements Are Generally Anticompetitive

1. The FTC insists that the antitrust analysis should disregard the potential or actual exclusionary scope of patents and instead focus on a single supposed fact: that "reverse payments" are exchanged

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[7] Likewise, the United States itself has standing to challenge a patent's validity by bringing an antitrust challenge to a patent-related restraint. *Gypsum*, 333 U.S. at 386-88.

for later entry dates. Remarkably, the FTC has no persuasive evidence that establishes this proposition, despite studying "reverse payments" for almost 15 years and possessing detailed information on almost every Hatch-Waxman settlement since 2003. *See supra* p. 3. A demand that longstanding precedent be shunted aside in favor of a new presumption of illegality should require a very persuasive showing. *See Times-Picayune Publ'g Co. v. United States*, 345 U.S. 594, 621 (1953) (government cannot show "deleterious effects on competition" in Section 1 case with inconclusive evidence because "guilt cannot rest on speculation").

2. While the FTC characterizes its assumption that settlements delay entry as "natural" and "presumptive," FTC Br. 36, 38, the only evidence it provides is an FTC study concluding that the average settlement with a "reverse payment" provided for generic entry 17 months later than settlements without reverse payments. But the FTC has chosen not to release the study or any of the underlying data for independent evaluation, and instead relies in this Court on a public summary of its undisclosed analysis. *See* FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 7 (2010).[8] The Court should not give weight to any litigant's characterization of the results of its own private study.

Moreover, the FTC's report is flawed on its own terms. *See* Bret Dickey, Jonathan Orszag & Robert Willig, *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on 'Reverse*

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[8] www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

Payment' Settlements (2010).[9] The FTC study observes that agreements with what it characterizes as "reverse payments" have, on average, entry dates 17 months later than those with just a patent-term split. But this hardly proves the point the FTC is trying to make, because it assumes *causation* (that reverse payments cause entry delays) from purported evidence of nothing more than *correlation. Id.* Moreover, the FTC's analysis does not even control for the length of each patent's remaining term. A patent with 15 years remaining (as Solvay's patent had) is treated the same as one with one year remaining, even though the former is obviously much more likely to result in an agreement with later generic entry measured from the date of settlement. *See id.*

It may well be that the FTC has it exactly backwards. Instead of "reverse payments" causing longer entry delays, as the FTC assumes, it may be that "reverse payments" are caused by potential entry dates (based on the parties' estimates of the likely litigation outcome and the remaining length of the patent term) that are far into the future. For example, if the generic company has to wait 10 years before entry, it might require additional compensation given the risks that the market might shift to another drug in that time, or that it would no longer be operating under the same corporate ownership by then, or because its management compensation is based on short-term profits. Absent compensation, a generic company might prefer to play the litigation lottery based on a small possibility of a big victory,

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[9] www.compasslexecon.com/highlights/Documents/Dickey%20Orszag%20Willig%20CBO.pdf.

rather than wait for an agreed entry date that fairly reflects its chances in the litigation. Economists recognize that companies do not make decisions simply by multiplying probabilities by potential payoffs. *See* Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. 367, 392-93 (2010); Willard K. Tom & Alexis J. Gilman, *U.S. and E.C. Antitrust Approaches to Patent Uncertainty*, 34 Law & Pol'y Int'l Bus. 859, 878-79 (2003).[10]

Thus, reverse payments may be necessary to achieve settlements that actually reflect what the FTC calls the "strength" of the patent, by compensating for the unique interests of accused infringers that are separate and apart from the patent merits. Certainly the FTC has presented no evidence otherwise. And the Government itself has previously recognized this possibility: that the "gross disparities in the litigants' respective risks may . . . make reverse payments more likely, even when the patentee's legal claims are strong." U.S. Br. at 10, *Schering*, *supra*.

Placing a scarlet letter on "reverse-payment" settlements could thus harm not only long-term consumer welfare (by weakening the incentives to

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[10] In addition, the 17 month calculation appears to assume that cases that settled with "reverse payments" could have settled without them and with an earlier entry date for the generic. But without reverse payments, many cases likely would not settle at all. *See infra* § IV.C. In those circumstances, if the patentee would succeed through litigation in keeping the generic off the market for the remainder of the patent term, the payment would have sped, not slowed, generic entry.

innovate, *infra* pp. 35-36) but also short-term consumer welfare (by eliminating settlements with earlier generic entry than the likely outcome of full litigation). *See* Dickey, Orszag & Willig, *supra*, at 4-5 (explaining this point and numerous other criticisms of the FTC's study).

The true relationship among "reverse payments," agreed-upon entry dates, and consumer welfare is not obvious, and the possibility that "reverse payments" enhance competition precludes *per se* or presumptive condemnation of such settlements. *See Cal. Dental*, 526 U.S. at 771, 775 n.12 (quick-look analysis is inappropriate where restraint "might plausibly be thought to have a net procompetitive effect, or possibly no effect at all on competition" or where "[a]s a matter of economics [the procompetitive] view may or may not be correct, but it is not implausible"); *Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 340 n.10 (2d Cir. 2008) (Sotomayor, J., concurring in the judgment) (quick-look analysis is inappropriate when "empirical analysis is required to determine a challenged restraint's net competitive effect").

3. The FTC criticizes reverse payments as giving accused infringers something "they could not hope to obtain even if they prevailed in the litigation." FTC Br. 30. But this is beside the point. For example, no litigation outcome would have produced the cross-licenses and royalty-sharing provisions in the *Standard Oil* settlements. The relevant issue for purposes of assessing anticompetitive effect is whether the *exclusion* obtained by the patent holder is beyond what could have been obtained in the litigation. *See Valley Drug*, 344 F.3d at 1309 ("The failure to produce [a generic], rather than the payment of money,

is the exclusionary effect, and litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement.").

E. The FTC Ignores The Critical Benefits Of Innovation

A key premise of the FTC's arguments is that a presumption of unlawfulness will "enhance consumer welfare." FTC Br. 39. This argument rests on a flawed, myopic understanding of consumer welfare. It focuses exclusively on alleged short-term pricing effects (static efficiency), and disregards long-term innovation effects (dynamic efficiency). The reality is that the FTC's rule will make it harder to settle Hatch-Waxman cases, which will in turn decrease incentives for pharmaceutical research and also new generics. The FTC has not even attempted to show that its rule would have a net positive effect on consumer welfare.

1. The FTC admits that some cases that have settled with reverse payments would not otherwise have settled. FTC Br. 40. Indeed, the FTC has concluded that settlement rates doubled after the lower courts rejected the FTC's rule and adopted the scope-of-the-patent rule. *See* FTC, *Pay-for-Delay*, *supra*, at 9-10 (concluding that Hatch-Waxman settlement rates increased from 7% to 18% after the Eleventh Circuit's *Schering* decision).

If patent cases are harder to settle and patentees must more often roll the dice in litigation, the value of patents will decline. The ability to derive value from patents by bringing and settling litigation in good faith necessarily factors into business decisions to invest hundreds of millions of dollars or more to develop new drugs. *See Valley Drug*, 344 F.3d at

1308 ("restricting settlement options, which would effectively increase the cost of patent enforcement, . . . would impair the incentives . . . and innovation").

Strong patent rights are a prerequisite to continued pharmaceutical innovation. A reduction in the value of patents will lead to a reduction in investment. *See* Hon. Richard D. Cudahy & Alan Devlin, *Anticompetitive Effect*, 95 Minn. L. Rev. 59, 79-80 (2010) (noting that the pharmaceutical industry "would largely cease to exist but for patent protection"). The FTC's rule therefore would decrease investment in pharmaceutical innovation. Moreover, if it is harder to settle cases, such that expected Hatch-Waxman litigation costs are much higher, the cost of attempting to bring a generic version of a patented drug to market will increase, thereby disincentivizing development of generic products. *See* Br. for Generic Manufacturers as Amici Curiae in Supp. of Resp'ts.

2. Antitrust analysis must consider both static and dynamic procompetitive benefits, rather than privileging one over the other. *See* Thomas O. Barnett, Assistant Attorney Gen., Antitrust Div., U.S. Dep't of Justice, Recent Development in Antitrust and Intellectual Property Law 5-6 (May 16, 2007) ("[Because] technical change (dynamic efficiency) accounts for a large share of efficiency, growth, and welfare gains, antitrust enforcers should seek to ensure that their actions promote—and not inadvertently reduce—the forces that lead to technical change in the long term.");[11] *see also* Joseph E. Stiglitz & Carl E. Walsh, *Economics* 457 (4th ed.

[11] www.justice.gov/atr/public/speeches/223390.pdf.

2006) (the "overall efficiency of the economy requires harmonizing" both short-term and long-term effects). A *per se* or quick-look rule is appropriate only where either past judicial experience or compelling empirical evidence decisively shows that a practice is always or nearly always anticompetitive. Thus, even if the FTC's rule would accelerate generic entry in some particular instances (which is speculative), that benefit would have to be shown to exist in nearly all cases and also weighed against the degree to which "*future* consumers will be harmed by reducing the flow of new pharmaceuticals to the market." James W. Hughes et al., *'Napsterizing' Pharmaceuticals: Access, Innovation, and Consumer Welfare* 2 (Nat'l Bureau of Econ. Research, Working Paper No. 9229, 2002) (emphasis added).

The FTC has not begun to make such a showing. Rather, it urges the Court to adopt its untested rule while ignoring the drag it could have on long-term consumer welfare. But innovation—and investment in innovation—can be more important to long-term consumer welfare than are lower prices. As Judge Easterbrook has put it:

> 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.

Frank H. Easterbrook, *Ignorance and Antitrust, in* Antitrust, Innovation, and Competitiveness 119, 122-23 (Thomas M. Jorde & David J. Teece eds., 1992).

The FTC estimates that "reverse-payment" settlements cost American consumers "$3.5 billion annually." FTC, *Pay-for-Delay*, *supra*, at 8. Even taking that estimate as true,[12] it would only amount to less than 2% of the $245 billion spent domestically on pharmaceuticals in 2011. FTC Br. 7. So even if all of the supposed "costs" of reverse payments were eliminated, the savings might be swamped by the resulting harm from even a tiny decrease in pharmaceutical investment and innovation.

III. THE FTC'S RULE IS NOT ADMINISTRABLE AND WOULD RADICALLY EXPAND ANTITRUST LIABILITY

A. Under The FTC's Rule, Parties To Antitrust Suits Would Need To Relitigate The Patent Merits

1. All parties agree that the antitrust standard for evaluating Hatch-Waxman settlements must not require relitigating the underlying patent dispute. After years of taking conflicting positions, including in the court below, the FTC now concedes that relitigating would be "likely unworkable in practice." FTC Br. 53. This accords with the conclusion of the court below that "'deciding a patent case within an antitrust case about the settlement of the patent case'" is an "'[un]palatable' 'turducken task.'" FTC Br. 54 (quoting Pet. App. 36a). No amicus in support of the FTC argues otherwise.

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[12] There are many reasons to think this $3.5 billion figure is exaggerated. It is entirely based, for example, on the faulty assumption that "reverse payments" delay generic entry by 17 months on average. *See supra* pp. 31-33.

As the FTC also now concedes, forcing relitigation of the patent case in a subsequent antitrust suit not only would be unworkable, but also would create a "powerful disincentive to settlement" because litigants would know that, in "settling" the patent dispute, they were likely just moving that entire dispute into one or more inevitable antitrust cases. FTC Br. 54.[13] Perhaps more importantly, forcing relitigation would magnify the risk of settlement by having treble-damage liability turn on a subsequent court's analysis of what the outcome of highly technical, uncertain patent litigation might have been. That is precisely the approach to antitrust scrutiny of patents that this Court rejected in *Walker Process*, 382 U.S. at 180 (Harlan, J., concurring) (antitrust liability should not turn on "one or more of the numerous technicalities" of patent law).

In addition to these undesirable effects, the "retrospective predict-the-likely-outcome-that-never-came" approach would be judicially unmanageable and unreliable. Pet. App. 33a. "It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case." *Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990). This is particularly true in patent litigation, the unpredictability of which is well documented.[14]

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[13] Forcing relitigation of the patent dispute would also increase the expense of antitrust litigation, which this Court has recognized as already quite significant. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007).

[14] U.S. Court of Appeals for the Fed. Circuit, *Affirmance and Reversal Rates for District Court Patent Infringement Appeals*, www.patentlyo.com/files/caseload_patent_infringement_affirmance_and_reversal_rates_2001-2010.pdf (showing that over 40% of patent appeals result in reversal or vacatur at least in part).

2. Despite agreeing that it would be undesirable and unworkable to relitigate the patent merits in a subsequent antitrust case, the FTC candidly acknowledges, as it must, that its rule *would* require such relitigation for "[q]uantification of damages" in private antitrust actions. FTC Br. 55 n.11. The significance of this admission cannot be overstated. Private antitrust actions far outnumber those brought by the FTC and will be subject to whatever test the Court adopts in this case. Every "reverse-payment" challenge the FTC has initiated has been followed by droves of private-plaintiff lawsuits. This case alone gave rise to *thirteen* follow-on private-plaintiff cases. And private plaintiffs have brought dozens of "reverse-payment" challenges to settlements that the FTC never pursued, for drugs including Tamoxifen, Cipro, Effexor, Lipitor, Lamictal, and Nexium.[15] The FTC's proposed rule would thus mire the federal courts in years of litigation over the merits of patent disputes that were supposedly settled.

Moreover, this is not just an issue of the "quantification of damages." Under a genuine quick-look rule (or full rule-of-reason analysis), relitigating the patent case would need to occur even in cases brought by the FTC because no conclusion about a patent settlement's effect on competition could logically be reached without determining if the patent was likely valid and infringed. *See Cal. Dental*, 526 U.S. at 775 n.12 (under "quick-look" approach, defendant must have an opportunity to show "empirical

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[15] See, respectively, MDL No. 1408; MDL No. 1384; No. 11-cv-5590 (D.N.J); MDL No. 2332; No. 12-cv-5 (D.N.J); and MDL No. 2409.

evidence of procompetitive effects" that "offset anti-competitive effects").

Worse, under a true "quick-look" (or full rule-of reason) analysis, the patent merits would be relevant to determining not just who would have won, but the *odds*, at the time of settlement, that the patent claims would have been upheld. *See Tamoxifen*, 466 F.3d at 227 (Pooler, J., dissenting) (suggesting that liability would turn on assessment of "the ex ante likelihood of prevailing in [the] infringement lawsuit"). Those odds would then need to be compared with the patent-term split to see if the split fairly reflects the actual patent "strength." But it is obviously impossible for a jury to determine the "strength of the patent" reliably, particularly years after the fact.

In contrast, the scope-of-the-patent rule does not implicate relitigating the underlying patent dispute at all. If *Walker Process* (fraud on the PTO) or *PRE* (sham litigation) is alleged, the damages would be calculated from a baseline "but-for" world in which the patent litigation was never filed. *See* 2A Areeda & Hovenkamp, *supra*, ¶ 392e, at 336-37. If a restraint exceeds the scope of the patent, damages would be based on the market impact of that restraint, which (being outside the patent scope) should have little to do with the merits of the patent claims.

B. The FTC's Rule Will Render Many Ordinary Settlements Presumptively Illegal

Another problem with the FTC's proposed rule is that it is not possible to apply the concept of "reverse payments" in a principled, predictable manner. It is

striking that the FTC's and its amici's briefs fail to precisely define the term "reverse payments," even though the concept lies at the core of the FTC's theory. The reality is that there are no principled limits to that term, so the FTC's rule would condemn many typical settlements both inside and outside the pharmaceutical context. At bottom, the rule would give the FTC roving authority to challenge almost any settlement it believed could have been structured to provide more consumer benefits. Moreover, the FTC's rule would give *private* plaintiffs the same unbridled authority, with the added incentive of the potential for recovering treble damages and attorneys' fees.

1. The concept of "reverse payments" cannot be limited to specific types of transactions

Despite the FTC's use of "reverse payment" nomenclature, it is not seeking to condemn only naked cash payments. FTC Br. 27 (referring to "money or similar consideration"). No naked cash payments are present in either the settlements in this case or those challenged in several other cases. Rather, each settlement here includes a business deal in which Solvay, at the time a relatively small pharmaceutical company with a small sales force, paid the respective generic company to market AndroGel using its own sales forces or to provide manufacturing capacity to Solvay. Pet. App. 44a. Settlements in complex commercial cases routinely involve these kinds of cooperative business dealings to bridge the difference in the parties' respective litigation positions. The FTC alleges that these business deals constituted "reverse payments" because they delivered "value" to

the generics in one form or another, such as because Solvay "overpaid" for the services it received.

But if "reverse payments" include more than naked cash payments—if they include any "value" delivered to the accused infringer—then the FTC's rule cannot reasonably be limited. Over the past decade, neither the FTC nor any amicus has proposed a workable boundary around what constitutes a "reverse payment." *See* FTC Br. 36 n.7 (discussing "alternative form[s] of consideration" that would be subject to the same analysis).

Although not explicit in its briefs here, the FTC publicly advocates that a "reverse payment" cannot be limited to a monetary payment. If, for example, the patentee agrees as part of the settlement to supply the drug at issue or license another drug to the generic company—both seemingly procompetitive agreements—the FTC says those would be "reverse payments" and condemned. *See* FTC, Summary of Agreements Filed in FY 2009, at 4 (brand supplied generic with unrelated drug);[16] FTC, Summary of Agreements Filed in FY 2008, at 4 (license to sell authorized generic version of other drugs).[17] Even if the accused infringer paid for the license or the drug supply, it would be just as possible that the accused infringer was "underpaying" for those benefits as it is that Solvay "overpaid" for the services it obtained in this case.

Indeed, in half of the settlements that the FTC last year classified as involving a "reverse payment," the

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[16] www.ftc.gov/reports/mmact/MMAreport2009.pdf.

[17] www.ftc.gov/os/2010/01/100113mpdim2003rpt.pdf.

patentee merely agreed that its license to the generic infringer as part of a patent-term split would be exclusive as against the patentee—*i.e.*, the patentee would not market its own drug as a generic. FTC, Overview of Agreements Filed in FY 2012, at 1.[18] Such "no-authorized-generic" provisions merely ensure that the brand-name firm does not undercut the 180-day exclusivity period that Hatch-Waxman provides to the first generic, which the FTC itself touts as one way Congress sought to encourage patent challenges. FTC Br. 31. The FTC has asserted, however, that the exclusivity of the license is "value" to the generic infringer and therefore constitutes a presumptively illegal "reverse payment." As one Commissioner explained, "[w]hether a branded firm offers a [no-authorized-generic] commitment, its own stock, a license to an unrelated product, or an overt cash payment, *the economic reality is the same*: a generic receives compensation for delayed entry." J. Thomas Rosch, Comm'r, FTC, Remarks at CBI's 2nd Annual Life Scis. Compliance, Legal & Regulatory Congress 19-20 (Sept. 21, 2012) (emphasis added).[19]

If a "reverse payment" includes "anything of value" then even a standard royalty-bearing license with a deferred entry date would be a presumptively illegal "payment." After all, the generic company might have paid a higher royalty if the entry date had been earlier. For example, if an accused infringer chooses a $1-per-pill royalty with a 2017 entry date instead of a $2-per-pill royalty with a 2014 entry date,

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[18] www.ftc.gov/os/2013/01/130117mmareport.pdf.

[19] www.ftc.gov/speeches/rosch/120921cbipharmaspeech.pdf.

plaintiffs will argue that consumers would have been better off with the latter choice.

Almost no settlement term—certainly no business deal—appears to be immune from potential classification as a "reverse payment." Enterprising plaintiffs could argue even that agreeing to a generic company's preferred terms regarding damage caps, attorneys' fees, and the like—provisions with real economic value—presumptively violates the antitrust laws because the generic company could have been induced to accept a slightly later entry date in exchange for those settlement terms.

It is not that the FTC has chosen an overbroad definition of "reverse payments," but that there is no principled limit to the concept of a "reverse payment" because it logically includes "economic value to the challenger in any form." FTC C.A. *En Banc* Pet. 13. That logic forces the rule to condemn *any* business deal or settlement term favorable to the generic company.

2. The FTC's rule could not be limited to the Hatch-Waxman context

The concept of presumptively illegal "reverse payments" would outlaw even routine settlements—including outside the Hatch-Waxman context—in which a patentee compromises a damage claim in exchange any market exit by the accused infringer. Releasing a party from potential liability is, from a legal and economic perspective, just as much the provision of "value" as cash or a business deal. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003) ("in the traditional context, implicit consideration flows from

the patent holder to the alleged infringer"); Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1033 (2004) ("the patent holder 'pays' to settle by accepting less in damages from the infringer than it expects to get from litigating").

Although the FTC declines to address the issue explicitly, even the FTC's supporters acknowledge this. For example, the only source the FTC cites to explain the scope of "reverse payment" is an article by counsel for one of its certiorari-stage amici who also served as a consultant to the FTC on pharmaceutical issues. *See* FTC Br. 36 n.7 (citing C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Competition*, 109 Colum. L. Rev. 629, 633-66 (2009)). This article explains that a patent-term split with an agreement to compromise damages must be treated as presumptively illegal. The article offers several examples of such "payments," including the Lipitor settlement, in which Pfizer forgave the damages it claimed in a different patent lawsuit. Hemphill, *supra*, at 683. The article also discusses a settlement relating to the drug Solodyn, in which the generic company agreed to cease sales for two years in exchange for the patentee's agreeing to waive damages in the same case.[20] The article argues that this standard settlement structure constitutes a "reverse payment." *Id.* at 683-84 & n.228.

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[20] Damages had accrued in that case because the generic entered "at risk" after it received FDA approval but before the patent litigation had reached conclusion.

This is not a hypothetical but a live issue in litigation brought by the plaintiffs' antitrust bar. Antitrust actions have already been filed alleging that Pfizer's forgiveness of damages was a "reverse payment" to delay the entry of generic Lipitor. Direct Purchasers' Consolidated Am. Compl. ¶ 316, *In re Lipitor Antitrust Litig.*, No. 12-cv-2389 (D.N.J. filed Sept. 10, 2012).

The FTC asserts that "reverse-payment" settlements "appear to be essentially unknown outside the Hatch-Waxman context," FTC. Br. 18, but it presents no support for that assertion. Private patent settlements are confidential, so it is impossible to study them systematically. But there is no reason to assume that private patent settlements in other contexts never include "value" beyond the patent license itself. Rather, it stands to reason that they include compromises of damages and other business deals that confer value on the alleged infringer. The FTC's proposed rule would presumptively condemn these patent settlements.

3. The FTC's purported "rebuttal" opportunity is impractical

To make its rule more palatable, the FTC states that defendants could "rebut" the presumption of illegality by showing that exchanges were of commensurate value. FTC Br. 37. But settlement agreements rarely quantify in dollars the various elements or concessions provided each side, and, even if they did, such a quantification could itself be disputed in later antitrust litigation under the FTC's rule. The end result is that the "rebuttal" opportunity would spur years of litigation in essentially every case about what the value was given "for."

Indeed, the FTC states that courts would need to consider at least *five factors* in the rebuttal analysis, including "whether the payment reflected bona fide fair consideration," whether the "other terms of the side transaction comported with industry standards," and the previous dealings between the parties. FTC Br. 37-38. At least the first two of these factors would involve testimony by experts, whose inevitable disagreements could preclude summary judgment and require high-stakes, expensive, and unpredictable litigation all the way through jury trial.

Moreover, the standard to be applied to these often one-of-a-kind transactions is unclear. The FTC says the property or services would have to be "unrelated to the brand name manufacturer's monopoly." FTC Br. 37. But the FTC nowhere explains what "unrelated" means or why it would make the deal less likely to be "for delay," in the FTC's parlance. And even if the consideration provided by the patentee in a contemporaneous business deal could be shown to exceed the consideration provided by other companies for similar products or services in other circumstances, that would not necessarily mean the deal was a disguised payment. For example, Solvay could have concluded that Watson would make a more concerted effort to develop the AndroGel market than a third party because Watson will inherit that market in 2015. *Cf. Town of Concord v. Boston Edison Co.*, 915 F.2d 17, 25 (1st Cir. 1990) (Breyer, C.J.) (explaining why antitrust law should not depend on a test involving determination of a "fair price" when no "other suppliers of the primary product" exist, and asking "how is a judge or jury to determine a 'fair price?'").

C. Congress, Not The Courts, Should Address Any Proposals For Industry-Specific Rules

Perhaps concerned about the difficulty of applying the FTC's rule broadly, the Third Circuit tried to limit this new antitrust rule to the pharmaceutical industry. *K-Dur*, 686 F.3d at 216. (The FTC's brief appears to take no position on such a limitation.) But the problems posed by the boundless concept of "reverse payment" cannot properly be addressed by artificially limiting the proposed new rule to the pharmaceutical industry. Antitrust statutes are "law[s] of general application." *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 640 (1994). In providing the "substantive content" of antitrust law, the Court has been careful to "adher[e] to rules that are justified in their general application." *Arizona v. Maricopa County Med. Soc'y*, 457 U.S. 332, 354 (1982).

Whether the FTC's new rule is understood as a *per se* rule or a "quick-look" analysis, any effort to confine it to a single industry would be in tension with this Court's precedents. *Per se* rules have "general application," *id.* at 344, and are designed to "treat[] *categories* of restraints as necessarily illegal." *Leegin*, 551 U.S. at 886 (emphasis added). The Court has similarly not confined its "quick-look" decisions to particular industries. *See Cal. Dental*, 526 U.S. at 770-71 (describing prior "quick-look" cases). Even in *National Collegiate Athletic Ass'n v. Board of Regents of the University of Oklahoma*, 468 U.S. 85 (1984), the Court did not create a "quick-look" rule limited to football or college sports, but rather framed its holding in broad terms, as applicable to an "industry in which horizontal restraints on competition are

essential if the product is to be available at all." *Id.* at 101.

This Court's reluctance to create industry-specific antitrust rules reflects "a recognition of the respective roles of the Judiciary and the Congress in regulating the economy." *Maricopa*, 457 U.S. at 354; *cf. United States v. Topco Assocs., Inc.*, 405 U.S. 596, 611-12 (1972). "By articulating the rules of law with some clarity and by adhering to rules that are justified in their general application," the courts "enhance the legislative prerogative to amend the law." *Maricopa*, 457 U.S. at 354. Parties seeking industry-specific rules "are better directed to the Legislature," which "may consider the exception[s] that [courts] are not free to read into the statute." *Id.* at 354-55; *see also Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 689-90 (1978) (arguments for special antitrust rules "for specific industries" are "properly addressed to Congress").[21]

When the Third Circuit relied on *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004), to support an industry-specific rule, it mistook the import of that case. *K-Dur*, 686 F.3d at 216. *Trinko* involved an antitrust challenge relating to breaches of express regulatory provisions. Instead of inventing a new antitrust rule specific to that regulated industry, the Court applied "pre-existing antitrust standards" to find that no violation had occurred. 540 U.S. at 407. When *Trinko*

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[21] *See generally* 1A Areeda & Hovenkamp, *supra*, ¶ 240a, at 272 (where a particular market is "thought to require more restriction on competition than others[,] Congress may then respond by enacting special statutes that modify, complement, or displace the competitive premises and rules of antitrust").

stated that antitrust analysis should "recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies," *id.* at 411, *quoted in* FTC Br. 30, it was merely a call for considering context when applying "pre-existing antitrust standards," *id.* at 407.

To the extent Congress views Hatch-Waxman settlements as raising unique or particular problems, it can adopt specific legislation to address those concerns. That Congress has repeatedly considered legislation in this area, *see infra* pp. 56-57, is powerful evidence that the FTC is better directed to Congress than to this Court in seeking to codify its preferred rule.

IV. POLICY CONSIDERATIONS DO NOT SUPPORT THE FTC'S RULE

In the absence of any precedent that genuinely supports its position, the FTC and its amici rely primarily on rhetorical policy arguments. These arguments are incorrect and unsupported.

A. The Scope-Of-The-Patent Test Does Not Diminish Generic Competition

The FTC and its amici warn that the scope-of-the-patent rule impedes generic entry because (1) later generic applicants without 180-day first-filer exclusivity lack incentives to pursue patent challenges, *e.g.*, FTC Br. 51-52; Apotex Br. 11-16; and (2) the scope-of-the-patent test allows innovator companies to "buy off" each generic company that comes along with a payment equal the generic company's potential profit, *e.g.*, FTC Br. 21. These arguments are inconsistent with experience and logic.

1. As an initial matter, the generic drug industry has been flourishing, including under the scope-of-the-patent rule that has prevailed for the last decade. When Hatch-Waxman was enacted in 1984, generic drugs accounted for 19% of all U.S. prescriptions; as of 2011, generics represented 80% of prescriptions, a fourfold increase. IMS Inst. for Healthcare Informatics, *The Use of Medicines in the United States: Review of 2010*, at 19 (2011);[22] Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 New Eng. J. Med. 1993, 1993 (2007).

2. Experience also shows that blockbuster drugs often face swarms of ANDAs, "even without the prospect of the exclusivity period." John M. Rebman, *Dr. Strange Drug, Or: How I Learned to Stop Worrying and Love Authorized Generics*, 12 DePaul J. Health Care L. 159, 180-81 (2009); *see also, e.g.*, *Pfizer Inc. v. Apotex Inc.*, No. 12-cv-808 (D. Del.) (consolidated Hatch-Waxman litigation involving more than ten ANDAs for Pristiq); *Pfizer, Inc. v. Teva Pharms. U.S.A., Inc.*, 882 F. Supp. 2d 643, 657-62 (D. Del. 2012) (describing patent lawsuits arising from eight generic companies' ANDAs for Lyrica); Bristol-Myers Squibb Co., Annual Report (Form 10-K), at 101 (Feb. 17, 2012) (describing Hatch-Waxman litigation against seven generic companies regarding Abilify). All of these examples took place at a time when *every* federal appellate court to have addressed the issue embraced the scope-of-the-patent test.

3. Nor is there any basis for the FTC's assertion that the scope-of-the-patent test encourages pharmaceutical companies to pay off every generic

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[22] www.rxobserver.com/?p=506.

challenger. If a brand-name company were willing—or even perceived as willing—to pay generic challengers "more than they could hope to earn if they entered the market," FTC Br. 21, it would attract a multitude of generic challengers, particularly if, as the FTC supposes, the patent were seen as unlikely to be upheld. Such a brand-name company would also invite economic holdup, as each generic company demanded payment exceeding its potential profits because the brand-name company stands to lose so much more.

Although the FTC cites instances in which there were two or three "reverse-payment" settlements involving generic versions of the same drug, FTC Br. 52, it does not offer a single example in which every generic applicant was paid all its profits, let alone data showing this to be a common practice. To the contrary, the FTC's own data show that a substantial majority of the Hatch-Waxman settlements in the last decade did not involve any kind of payment, even while the courts of appeals were uniformly adopting the scope-of-the-patent test. FTC Br. 47. Nor do its own data support the idea that filers subsequent to the first filer have been paid off. Instead, the FTC itself recently reported that "[s]ince 2004, 44 branded products have been involved in a potential [reverse-payment] settlement followed by at least one settlement containing no compensation to the generic. As many as nine generic companies have settled for no compensation following a potential [reverse-payment] deal on the same branded product." FTC, Overview of Agreements Filed in FY 2012, at 1 n.1.[23]

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[23] www.ftc.gov/os/2013/01/130117mmareport.pdf.

Innovator companies also have been known to litigate with second and later filers instead of settling. For example, after settling a Hatch-Waxman case with the respective first generic filer, the ciprofloxacin and tamoxifen patent holders each litigated numerous subsequent cases to judgment—and won them all. *See Ciprofloxacin*, 544 F.3d at 1328-29; *Tamoxifen*, 466 F.3d at 193-95.

B. The Hatch-Waxman Act Does Not Support The FTC's Rule

Like the Third Circuit, the FTC seeks support for its rule in the text and supposed purpose of the Hatch-Waxman Act. FTC Br. 30-33; *K-Dur*, 686 F.3d at 217. But the statute says nothing about settlement of paragraph IV litigation, and it certainly does not treat "reverse-payment" settlements as presumptively unlawful. Moreover, this Court must consider Hatch-Waxman "in the light of the purposes which led to the enactment of the entire legislation." *Southland Gasoline Co. v. Bayley*, 319 U.S. 44, 47 (1943). In that light, the Act cannot reasonably be construed as evincing a singular "goal . . . to increase the availability of low cost generic drugs." *K-Dur*, 686 F.3d at 217; *see also* FTC Br. 30-31.

Hatch-Waxman "respond[ed] to two unintended distortions of the 17-year patent term." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990). First, there was a concern that, as a result of the review process for new drugs, patentees were not being sufficiently rewarded because they could not "reap any financial rewards during the early years of the term." *Id.* Congress responded by extending the patent term by up to five years for certain products, 35 U.S.C. § 156, to "create a new incentive for increased expenditures for research and development,"

H.R. Rep. No. 98-857, pt. 1, at 15 (1984) (House Report).

Second, because generic companies could not "conduct[] tests and develop[] information necessary to apply for regulatory approval" during the life of the patent without infringing it, the development of generic drugs was delayed for many years after patent expiration. *Lilly*, 496 U.S. at 670. Congress responded by (1) adopting the expedited ANDA process, *see* 21 U.S.C. § 355(j); and (2) creating a safe harbor for generic manufacturers' research and development during the patent term, *see* 35 U.S.C. § 271(e)(1).

Thus, the primary goals of the bill were to strengthen patent rights while encouraging earlier development of generic drugs, so that the generics would be available soon after patent expiration. As Congressman Waxman explained:

> [T]he whole conceptuality of this bill is to give more time for the firm developing the patented drug, to give them a further incentive for research and development. There is a public good in that. The other side of it is to give the opportunity for competition in generic drugs to be on the market *after that patent has expired.*

130 Cong. Rec. 24,430 (emphasis added).[24] And when Congress provided procedures for litigating patent

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[24] To the extent that the FTC and Congressman Waxman attempt to "create[] legislative history through the *post hoc* statements of interested onlookers," they are "entitled to no

disputes, it did not intend to alter the patent laws or to inhibit settlements.[25] *See, e.g.*, House Report, *supra*, at 28 ("[P]rovisions of this bill relating to the litigation of disputes involving patent validity and infringement are not intended to modify existing patent law . . . .").

The FTC's characterization of Hatch-Waxman cannot be squared with this history. The FTC contends that the Act, including the 180-day exclusivity period, reflects a "policy" of "realizing the benefits of generic competition at the earliest appropriate time." FTC Br. 30-31. But that would come as a surprise to the 1984 Congress, which not only provided for extra years of patent protection, but also amended the bill before final passage to *lengthen* the stay on final approval of ANDAs that are subject to paragraph IV litigation from 18 months to 30 months. *See* 130 Cong. Rec. 24,430 (Rep. Waxman) (describing change and arguing in favor of it). While Congressman Waxman now asserts that an overriding purpose of the law was to encourage paragraph IV litigation, *see* Rep. Waxman Br. 15, he described the paragraph IV procedures at the time as "a side issue to the overall importance of this bill." 130 Cong. Rec. 24,430.

More recent evidence of legislative intent suggests that Congress does *not* view "reverse-payment" settlements as presumptively unlawful. Every Congress

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weight." *W. Air Lines, Inc. v. Bd. of Equalization*, 480 U.S. 123, 130 n.* (1987); *see* FTC Br. 31 & n.5; Rep. Waxman Br. 2.

[25] Similarly, nothing in the 2003 MMA legislation suggests that agreements featuring "reverse payments" are presumptively unlawful.

since 2006 has declined to pass bills that would address such settlements, including bills establishing a "presumption" of illegality. *See, e.g.*, S. 369, 111th Cong. § 3 (2009). Where Congress has "considered but rejected legislation that would endorse" an interpretation of a statute, it lends "support to [the] conclusion" that the statute should not be interpreted in that way. *Till v. SCS Credit Corp.*, 541 U.S. 465, 480 n.19 (2004). For example, the fact that Congress "repeatedly" introduced remedial legislation to respond to the antitrust exemption for professional baseball, but that "none has ever been enacted," rightly caused this Court to "conclude[] that Congress as yet has had no intention to subject baseball's reserve system to the reach of the antitrust statutes." *Flood v. Kuhn*, 407 U.S. 258, 283 (1972).

C. The FTC's Rule Will Preclude Settlements

Although the FTC imagines a world where "the parties to a Hatch-Waxman settlement simply agree upon a compromise date of generic entry," FTC Br. 27, basic principles of dispute resolution establish that a "straightforward settlement that simply splits the remaining patent term may not be available," Kent S. Bernard & Willard K. Tom, *Antitrust Treatment of Pharmaceutical Patent Settlements: The Need for Context and Fidelity to First Principles*, 15 Fed. Cir. B.J. 617, 629 (2006). When parties "negotiat[e] along a single dimension" and are prohibited from introducing other sources of value into the negotiation, there may be "no way to split the pie that leaves both parties satisfied." Roger Fisher et al., *Getting to Yes* 58 (3d ed. 2011); *see also* Br. of Mediation & Negotiation Professionals as Amici Curiae in Supp. of Resp'ts.

For example, a simple patent-term split may be impossible where the parties have different views about the likely outcome of the case, which is a common occurrence. Empirical studies demonstrate that "lawyers are poor predictors of the outcomes of their cases and tend to be over-confident concerning their chances of winning." Peter H. Schuck & E. Donald Elliott, *To the Chevron Station: An Empirical Study of Federal Administrative Law*, 1990 Duke L.J. 984, 1013 n.72. Where each side entertains inflated expectations about its chance of prevailing, there may be "a gap between the latest date at which the generic is willing to accept entry in order to settle litigation and the earliest date at which the innovator is willing to permit entry"—a gap rendering the case "impossible to settle within the [FTC's] patent-term-splitting paradigm." Bernard & Tom, *supra*, at 630.

Other factors may also make settling solely on a patent-term split impossible. For example, if a generic company sets its management's compensation based on short-term profits or stock price increases, or is considering selling the company, it may reject a patent-term split that provides no revenue in the short term, even if that split reflects the parties' expectations of success. If so, collateral terms, such as the licensing of other products, co-promotion agreements, or supply arrangements "may allow the brand-name and generic manufacturers to bridge the settlement gap" between their otherwise irreconcilable bargaining positions. Dickey, Orszag & Tyson, *supra*, at 394. But *all* of these terms would be treated as presumptively unlawful "reverse payments" under the FTC's rule.

The FTC downplays the significance of the fact that its rule will inhibit settlement. *See* FTC Br. 47-48. But "[t]here is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation." *Tamoxifen*, 466 F.3d at 202 (quotation marks omitted). More importantly, by increasing the cost and uncertainty of patent litigation, the FTC's rule would undermine incentives for brand manufacturers to develop new drugs and would also limit the incentive of generic manufacturers to pursue new generic challenges.

CONCLUSION

The Court should affirm the judgment of the court of appeals.

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February 21, 2013