No. 12-416

In the Supreme Court of the United States

FEDERAL TRADE COMMISSION, PETITIONER

v.

ACTAVIS, INC., ET AL.

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

REPLY BRIEF FOR THE PETITIONER

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A. The "Quick Look" Approach Identifies And Condemns Collusive Behavior That Destroys The Competitive Relationship Between Drug Manufacturers

1. The antitrust rule of reason—which even respondents profess to apply—must "take into account * * * 'specific information about the relevant business' and 'the [challenged] restraint's history, nature, and effect.'" *Leegin Creative Leather Prods., Inc.* v. *PSKS, Inc.*, 551 U.S. 877, 885 (2007) (citation omitted); see *United States* v. *American Tobacco Co.*, 221 U.S. 106, 179 (1911) (looking to the "inherent nature or effect" and "evident purpose" of a restraint). If a particular restraint "give[s] rise to an intuitively obvious inference of anticompetitive effect," a court should "place the burden of procompetitive justification on those who agree [to the restraint]." *California Dental Ass'n* v. *FTC*, 526 U.S. 756, 781, 771 (1999).

As the government's opening brief explains (Br. 8-9, 21-24), the practical economics of paragraph IV litigation in the pharmaceutical industry are these: When parties to paragraph IV litigation settle a case by simply agreeing on a compromise date of generic entry, the generic manufacturer's incentive is to negotiate the earliest possible entry date to maximize its own profits. That incentive ensures that consumer interests will receive significant protection in the negotiating process, and it provides reason for confidence that the agreed-upon entry date reflects the parties' own assessment of the likely litigation outcome. By contrast, a Hatch-Waxman settlement that includes a reverse payment allows the brand-name manufacturer to co-opt its rival by sharing the monopoly profits that result from an artificially prolonged period of market exclusivity. That result maximizes the manufacturers' profits at consumers' expense.

Respondents and their amici do not dispute those basic economic realities, which bear an unmistakable resemblance to those surrounding other payments not to compete. See *Palmer* v. *BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990) (per curiam); Pet. Br. 20. Respondents and their amici similarly do not dispute that a plaintiff's making large cash payments to a defendant—here, tens of millions of dollars—is an extraordinary and peculiar way to settle a lawsuit. Such a payment from a patentee to an accused infringer provides the defendant an important economic benefit that it could not hope to obtain even by prevailing in the litigation, and it has no apparent analogue in traditional settlement practice. Taken together, those circumstances warrant "a confident conclusion" that "the principal tendency" (*California Dental*, 526 U.S. at 781) of a reverse-payment agree-

ment is anticompetitive, so that the burden of identifying a procompetitive justification is properly placed on the agreeing parties.

2. Respondents' efforts to distinguish reverse-payment settlements from other agreements not to compete are unpersuasive.

a. Respondents suggest that reverse-payment agreements should be regarded as procompetitive because they can provide for generic competition before the patent expires (*i.e.*, before generic entry would have been permitted if the brand-name manufacturer had won the lawsuit). See, *e.g.*, Solvay Br. 26-27. In this case, for example, the agreements allowed generic entry in 2015, while the relevant patent was scheduled to expire in 2020. Under respondents' own theory, however, the presence or absence of such procompetitive potential is irrelevant to the proper antitrust analysis. Absent sham litigation or fraud on the PTO, the scope-of-the-patent rule would treat as legitimate a settlement under which the generic manufacturer agreed to defer entry until the date of patent expiration—*i.e.*, accepted the least amount of generic competition that could result from judicial disposition of the infringement suit—in return for a substantial cash payment. See Pet. Br. 43 n.10.

By definition, moreover, reverse-payment settlements of paragraph IV litigation are agreements between competitors who have previously taken conflicting positions as to the proper disposition of the infringement suit. Such suits are triggered by the generic manufacturer's paragraph IV certification that the relevant patent is invalid and/or not infringed. Although the respondents in this case agreed to a generic entry date earlier than the date of patent expiration, the agreed-

upon date was considerably later than the date generic competition would have begun if Watson or Par/Paddock had prevailed in its lawsuit. In determining the agreement's effect on competition, there is no logical reason to use as the benchmark the date that generic entry could have occurred if Solvay had won the infringement suit.

To be sure, it would be equally inappropriate to use as the antitrust benchmark the date of entry that would have resulted from judgment for the generic competitor. That approach would unduly constrain the ability of paragraph IV litigants to engage in traditional settlement practices since it would effectively condemn agreements that use compromise dates of generic entry *without* reverse payments. See Pet. Br. 27-28. For different (but equally weighty) reasons, it would likewise be inappropriate for the antitrust court to attempt to determine (and to use as a benchmark) the date when generic entry likely would have occurred if the infringement suit had been litigated to judgment. See *id.* at 53-55.

Thus, rather than effectively presuming that either the brand-name or generic manufacturer would have won the infringement suit, or requiring the antitrust court to assess the likely outcome of that suit, the government's approach focuses on the presence or absence of a settlement term that distorts the integrity of the *process* through which the settlement was negotiated. Because "the antitrust laws were passed for 'the protection of *competition*,'" *Brooke Grp. Ltd.* v. *Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993) (citation omitted), the rule of reason condemns not only agreements that in a particular instance are conclusively shown to have raised price or lowered output (the test

respondents suppose), but also "actions that harm the competitive process," *Clamp-All Corp.* v. *Cast Iron Soil Pipe Inst.*, 851 F.2d 478, 486 (1st Cir. 1988) (Breyer, J.), cert. denied, 488 U.S. 1007 (1989). Thus, this Court has condemned restraints because they "impede[d] the ordinary give and take of the marketplace," *National Soc'y of Prof'l Eng'rs* v. *United States*, 435 U.S. 679, 692 (1978) (citation omitted), or because they were "likely enough to disrupt the proper functioning of the price-setting mechanism of the market * * * even absent proof that [they] resulted in higher prices," *FTC* v. *Indiana Fed'n of Dentists*, 476 U.S. 447, 461-462 (1986). Of particular relevance here—where Solvay was facing willing and able would-be generic competitors—"[t]he anti-trust laws are as much violated by the prevention of competition as by its destruction." *United States* v. *Griffith*, 334 U.S 100, 107 (1948); see Pet. Br. 20-21. Reverse-payment agreements raise the central concern of antitrust law: that the competitive process that benefits consumers will be thwarted because a potential competitor finds it most profitable to preserve and share in the rewards of the incumbent firm's monopoly.

b. Respondents identify some economists who conclude that it is possible for a reverse-payment agreement to result in generic entry earlier than the "expected" outcome of the litigation (*i.e.*, a theoretical middle-ground date of generic entry that reflects the relative probabilities of the generic manufacturer prevailing and entering immediately or losing and being excluded until patent expiration). See Solvay Br. 32-33; Actavis Br. 24-25. But there is no reason to believe that sort of early entry is the norm when "a rudimentary understanding of [pharmaceutical] economics," *California Dental*, 526 U.S. at 770, suggests otherwise: Ra-

tional manufacturers would not choose those settlements when it is more profitable for them to agree instead to preserve the brand-name manufacturer's monopoly and share the profits, a point those same economists effectively concede.[1] Moreover, the "quick look" approach permits settling parties to show that their reverse-payment agreement is an exceptional case. Pet. Br. 38-39. And none of the economist amici defends respondents' scope-of-the-patent approach.

c. Respondents argue that, for antitrust purposes, "there are no 'weak' patents" (Par/Paddock Br. 8) and "there is no meaningful way to define [such] categories" (Solvay Br. 30). We agree that the antitrust analysis of a Hatch-Waxman settlement should not turn on a judicial assessment of the strength or scope of the *particular* patent involved in the case. In fashioning an appropriate antitrust rule, however, this Court can and should take account of the facts that some patents are stronger and more encompassing than others; that the patents involved in paragraph IV litigation are not likely to be representative of pharmaceutical patents generally (since such litigation occurs only when a generic manufacturer certifies that the patent is invalid and/or will not be infringed by generic competition); and that the parties' own assessment of patent validity and scope will

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[1] See, *e.g.*, Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements That Settle Patent Litigation*, 49 Antitrust Bull. 655, 657 (2004) ("It is plain that some settlement agreements would profitably perpetuate monopoly, to the harm of social and consumer welfare."); Bret Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Ann. Health L. 367, 399 (2010) ("Patent settlements between brand-name and generic pharmaceutical manufacturers can be anticompetitive and should continue to be closely scrutinized.").

affect their litigation behavior, including their choice of settlement terms.

Generic drug manufacturers concentrate their resources on challenging patents that are particularly likely to be held invalid or not infringed by the generic manufacturer's product, a practice that is highly beneficial to competition. See C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. Health Econ. 327, 334-335 (2012) (finding "strong evidence that patent challenges target low quality patents and those that extend market life, as opposed to basic patents"). The frequency with which generic manufacturers have prevailed in fully litigated paragraph IV cases (see Pet. Br. 6-7) suggests, not that a large percentage of all pharmaceutical patents are invalid, but that generic manufacturers have chosen their targets astutely and aimed to develop noninfringing products. When the parties to paragraph IV litigation negotiate settlement terms, moreover, "the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity." *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 211 (2d Cir. 2006) (citation omitted), cert. denied, 551 U.S. 1144 (2007). In assessing the anticompetitive potential of reverse-payment agreements, it therefore would be particularly unsound to use as a benchmark the assumption that the patent is both valid and infringed.

B. Respondents And Their Amici Mischaracterize The "Quick Look" Approach And Ignore Important Limits On Its Application

Respondents' principal criticisms of the "quick look" approach consist of mischaracterizations of that approach's operation and assertions that it lacks limiting

principles. Those criticisms are unfounded. The "quick look" approach is a structured application of the rule of reason that affords respondents a full opportunity to advance legitimate justifications for their apparently anticompetitive agreements. It is appropriately applied where, as here, "a confident conclusion about the principal tendency of [the] restriction" at issue may be drawn, *California Dental*, 526 U.S. at 781.

1. Respondents describe the "quick look" approach as "a rule of *per se* illegality." Solvay Br. 1. That is incorrect. Under the government's approach, the use of a reverse payment to settle paragraph IV litigation raises a strong presumptive inference that the generic manufacturer has agreed to delay entry beyond the date that would otherwise reflect the parties' assessment of likely litigation outcomes. The agreeing parties can rebut that presumption, however, by showing that the payment was consideration for something other than delay; that it was commensurate with the brand-name manufacturer's expected litigation savings; or, in rare cases, that unusual business or litigation circumstances supply a procompetitive justification for the agreement.[2]

2. Respondents are likewise wrong in describing the government's approach as "an antitrust analysis for patent litigation settlements that disregards the patent." Actavis Br. 19. Under our approach, the parties

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[2] Par/Paddock's fact-specific arguments—that its agreement with Solvay (1) is immunized by being embodied in a consent decree and (2) was not anticompetitive because it delayed generic competition no more than Solvay's agreement with Watson (Br. 63-68)—could be aired within the "quick look" framework. The FTC explained in district court why those arguments fail (see Dkt. 137, at 31-44), but the lower courts should have the opportunity to pass on those issues in the first instance.

to paragraph IV litigation have broad freedom to settle by agreeing upon a compromise date of generic entry. See Pet. Br. 27-28. Although a potential competitor's agreement not to compete for a defined period would ordinarily be a per se violation of the antitrust laws, see *Palmer*, *supra*, a compromise date of market entry is a natural and generally lawful term of an agreement to settle *patent* litigation. The justification for that settlement term, however, depends on the premise that the compromise date chosen reflects the outcome of arm's-length bargaining in which the generic manufacturer seeks to obtain the earliest entry date that the perceived strength of its litigating position allows. A reverse payment undermines that premise by giving the generic manufacturer an evident incentive to accept an entry date later than it could otherwise achieve. Cf. *Tumey* v. *Ohio*, 273 U.S. 510, 532 (1927) (Due Process Clause was violated where judicial officer had financial incentive to convict).

3. Respondents contend that the government has failed to identify "a workable boundary around what constitutes a 'reverse payment,'" Solvay Br. 43, so that the "quick look" approach would in effect presumptively condemn nearly any settlement of patent litigation. That argument is misconceived.

a. For present purposes, it would suffice to understand "payment" as cash, since that is what Solvay agreed to pay Watson and Par/Paddock. See Complaint ¶¶ 66, 73-74, J.A. 46, 48. More generally, the defining characteristics of a reverse payment are that it (1) is consideration from the patentee that the accused infringer could not obtain by prevailing in the litigation, and (2) allows the patentee to co-opt its rival by sharing monopoly profits that align the accused infringer's in-

terests with the patentee's interest in preserving its monopoly. Thus, the logic of the government's position would extend to a settlement involving non-cash consideration if—but only if—those characteristics are present. See Pet. Br. 36 n.7. That would surely be true of "payment" made in gold bullion; it may be true of other business arrangements that have yet to be fully litigated; and it is decidedly not true of a wide range of ordinary settlement practices.

b. Respondents place particular emphasis on the supposed implications of the government's position for ordinary settlement of traditional patent-infringement suits. In such settlements, the patentee accepts a lower amount of damages for alleged past infringement than it might have been awarded in litigation, and the accused infringer accedes to the patent. Respondents assert that this forgiveness of alleged accrued damages is a "payment" no different from the cash payments from a patentee to accused infringer in a reverse-payment agreement. See Solvay Br. 42-45; Actavis Br. 54-55 (citing *Asahi Glass Co.* v. *Pentech Pharms., Inc.*, 289 F. Supp. 2d 986 (N.D. Ill. 2003), appeal dismissed, 104 Fed. Appx. 178 (7th Cir. 2004)).

Respondents' analogy is flawed. See Pet. Br. 30; Nat'l Ass'n of Chain Drug Stores (NACDS) Amicus Br. 8-9; States Amicus Br. 25-27. When the plaintiff in a suit for monetary relief forgoes a portion of its claimed damages, it provides the defendant part (though not all) of the benefit the defendant would have realized by winning the lawsuit. Such an agreement is analogous to a settlement of paragraph IV litigation in which no payment is exchanged and the parties compromise on a date when the generic will enter the market. In both scenarios, the compromise result falls where one would natu-

rally expect it—between the dispositions that could result from litigated judgments in favor of the plaintiff and defendant respectively. See Pet. Br. 27-28.

Where either of those settlement terms is used, all else being equal, weaker patent infringement claims will lead to settlements with lower damages (or royalties) and shorter periods of exclusion than will stronger infringement claims. In neither instance will the accused infringer predictably have an economic incentive to accede to an agreement that preserves the patentee's monopoly (at the expense of consumers' interests). See Pet. Br. 28. Reverse-payment agreements, by contrast, give the generic manufacturer an economic benefit that it could not obtain even by winning the lawsuit, and they provide an evident incentive for the generic to accept a later entry date than the strength of its bargaining position would otherwise allow it to obtain.[3]

4. Some respondents and amici (Solvay Br. 33-34, 57-59; Actavis Br. 23-26) express concern that adopting the "quick look" approach may frustrate attempts to settle paragraph IV litigation. (Par/Paddock presumably thinks otherwise, because it contends that the pharmaceutical industry's use of reverse-payment agreements is "sharply declining." Par/Paddock Br. in Opp. 13.) Although some additional Hatch-Waxman suits may be litigated to judgment if reverse-payment agreements

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[3] In a $1 million damages action, a settlement under which the defendant agrees to pay the plaintiff $500,000 would be routine; a settlement under which the plaintiff agrees to pay the defendant $500,000 would be extraordinary. To be sure, the plaintiff's willingness to compromise its damages claim and the plaintiff's cash payment could both be described as forms of "consideration" to the defendant. Practicing lawyers would have no difficulty recognizing, however, that the former type of consideration is regularly used to settle litigation while the latter is not.

are deemed presumptively unlawful, that prospect is not a sufficient reason to reject the "quick look" approach.

If this Court agrees with the government that reverse-payment agreements should be disfavored, suits that would otherwise be settled with such agreements can be resolved in either of two ways. In most such cases, the parties can be expected to negotiate alternative settlement terms, agreeing on a compromise date of generic entry, with or without a licensing royalty paid by the generic manufacturer to the patentee.[4] To the extent the "quick look" approach prompts the parties to paragraph IV litigation to settle on those terms, it is an unalloyed good. To induce the generic manufacturer to accept a settlement without a reverse payment, the brand-name manufacturer will need to agree to an earlier entry date, thereby benefiting consumers. The settlement process will involve non-collusive arm's-length negotiations, in which the brand-name manufacturer seeks the latest entry date that it can achieve and the generic manufacturer seeks the earliest, and the date actually chosen will likely reflect the parties' perceptions of the strength of the infringement claim.

To be sure, there will likely be some cases in which a rule disfavoring reverse payments will cause paragraph IV suits to be litigated to judgment rather than settled on alternative terms. Even in those cases, however, the rule has countervailing advantages. The date of generic entry in such cases will reflect the *actual* exclusionary force of the patent, as determined through the judicial

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[4] During the past decade, the large majority of Hatch-Waxman settlements have involved such terms. See FTC, *Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, at 2 (FY 2012), http://www.ftc.gov/os/2013/01/130117mmareport.pdf.

processes fashioned by Congress based on adversary presentations by the brand-name and generic manufacturers, rather than an artificially deferred date reflecting supposed competitors' collusive agreement to split monopoly profits. See Pet. Br. 20-33.

Moreover, it is unexceptional that a legal rule might prevent parties from settling, if settling entails harm to third parties. In cases where reverse payments facilitate settlements that might otherwise be unobtainable, the payments achieve that result by inducing the generic manufacturer to accept a deferred date of entry, increasing (at consumers' expense) the total pool of profits for the brand-name and generic manufacturers combined, and thereby enhancing the likelihood that each party will find its own portion of the pool satisfactory. See Pet. Br. 8-9, 22-23. Because the potential for reverse payments to facilitate settlement is inextricably linked to their tendency to harm consumers, there is no sound reason to treat that potential as a ground for relaxed antitrust scrutiny.

5. Finally, respondents object that the "quick look" approach will be difficult to administer. First, respondents and their amici fear that parties and courts will have difficulty resolving disputes over whether the payment was compensation not for delay but instead for the parties' supposed side deal. Solvay Br. 47-48; Merck Amicus Br. 9-19. In defending against antitrust challenges, however, manufacturers should have ready access to whatever evidence supplied a business justification for their multi-million dollar transactions. And the antitrust court's ultimate inquiry should be no more difficult than in other fields of the law where a factfinder is charged with reviewing a party's evaluation of a particular transaction or asset. See, *e.g.*, 11 U.S.C.

548(a)(1)(B)(i) (avoidance by bankruptcy trustee of certain transfers in which the debtor "received less than a reasonably equivalent value"); *Golden* v. *Cooper-Ellis*, 924 A.2d 19 (Vt. 2007) (valuation of assets in divorce); *Brehm* v. *Eisner*, 746 A.2d 244, 263 (Del. 2000) (corporate waste doctrine).

Second, respondents argue that, if this Court adopts the "quick look" approach, *private* antitrust suits challenging reverse-payment agreements will require a judicial inquiry into how the infringement suit would have been decided if it had been litigated to judgment. Solvay Br. 40; Actavis Br. 37-38. That is incorrect. To be sure, the plaintiff in such a suit can collect damages only by proving economic harm, which requires evidence as to the sequence of events that would likely have occurred if no reverse payment had been made. See Pet. Br. 55 n.11. The plaintiff might seek to discharge that burden, however, by instead showing that the brand-name and generic manufacturers would otherwise have settled the case with no reverse payment and an earlier entry date, rather than by attempting to prove that the case would have been litigated to judgment and the patentee would have lost.

In any event, respondents' argument conflates the question of whether the antitrust laws have been violated and the question of who may obtain what remedies for such a violation. See *Atlantic Richfield Co.* v. *USA Petroleum Co.*, 495 U.S. 328, 341-342 (1990) (distinguishing the two). Assumptions about the complexity of the damages phase of a private antitrust suit are no reason to abandon the prospective enforcement of core competition-law principles. That is particularly so because any remedial-phase difficulties would be largely transitional, since parties to paragraph IV suits can be

expected going forward to conform their settlements to whatever antitrust rule this Court adopts.

C. The "Quick Look" Approach Best Respects Congress's Intended Balance Between Innovation And Competition

Respondents and their amici argue that adopting the "quick look" approach would result in both "fewer [p]aragraph IV ANDA challenges and reduced incentives [for brand-name manufacturers] to innovate" than under the scope-of-the-patent approach. Actavis Br. 40; see Solvay Br. 35-38; PhRMA Amicus Br. 6-13; GPhA Amicus Br. 21. That argument has considerable internal tension, inasmuch as a reduced threat of paragraph IV litigation would seem to *increase* a patent's value. Moreover, the argument proves too much on the brand-name side because offering blanket immunity from the antitrust laws to all patent holders would likewise increase the incentives to innovate, yet there is no general "innovator exemption" from those laws. And on the generic side, even assuming that the hope of receiving a reverse payment might create an incentive to file a paragraph IV certification, that incentive will not ultimately further the purposes of the Hatch-Waxman Amendments if the generic manufacturer allows itself to be co-opted in return for a share of monopoly profits.

More fundamentally, none of those arguments answers the critical question here, which is whether Congress intended to offer brand-name drug manufacturers the particular incentive of monopoly profits secured by a reverse-payment agreement. The Patent Act and the Hatch-Waxman Amendments indicate that it did not.

1. "From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to

invention itself and the very lifeblood of a competitive economy." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). Similarly, the Hatch-Waxman Amendments seek both to promote innovation and to speed generic drugs to market, and "the balance struck between these competing goals is quintessentially a matter for legislative judgment." *Teva Pharm. Indus. Ltd.* v. *Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005). As the government's opening brief explains (Br. 24-33, 43-44, 48), the "quick look" approach is consistent with the congressional balance struck in the Patent Act and the Hatch-Waxman Amendments, and the scope-of-the-patent approach is not. See also NACDS Amicus Br. 10-22; Law, Econ. & Bus. Professors Amicus Br. 8-9. In particular, neither of those laws legitimizes the use of reverse payments as a settlement term. And together they reflect a balance of benefits for generic manufacturers and protections from competition for brand-name manufacturers that would be upset by giving brand-name manufacturers the added opportunity to purchase still more protection by sharing their monopoly profits.

Solvay's reliance (Br. 35-36) on the risks of patent enforcement, as a justification for applying the scope-of-the-patent rule to reverse-payment agreements, is particularly misconceived. Those risks are a core part of the bargain in our system of judicially enforced patents, in which, *inter alia*, the presumption of validity is rebuttable (*Microsoft Corp.* v. *i4i Ltd. P'ship*, 131 S. Ct. 2238, 2245 (2011)), judgments adverse to patentees can have non-mutual collateral estoppel effect (*Blonder-Tongue Labs., Inc.* v. *University of Ill. Found.*, 402 U.S. 313, 350 (1971)), and infringement must be proved and is not simply presumed (*Railroad Co.* v. *Mellon*, 104 U.S. 112, 119 (1881)). Parties may settle to avoid those risks, but

they must take the bitter with the sweet; having contracted out of the risks of patent litigation, respondents are not entitled to the shield afforded to "[t]hose who petition the government for redress" through non-sham litigation, *Professional Real Estate Investors, Inc.* v. *Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56 (1993). See Pet. Br. 26.

2. Relying on unenacted legislative proposals, Solvay asserts that "recent evidence of legislative intent suggests that Congress does *not* view 'reverse-payment' settlements as presumptively unlawful." Solvay Br. 56; see Actavis Br. 56-57. But this Court does not rely on unenacted bills to interpret federal law, see *Central Bank* v. *First Interstate Bank*, 511 U.S. 164, 186 (1994), especially when it is exercising its common law authority under the antitrust laws, where congressional intervention has been the exception. And what Congress *has* enacted is more telling: Its 2003 revisions to the Hatch-Waxman Amendments presuppose meaningful antitrust review of Hatch-Waxman settlement agreements by (1) requiring that such agreements be reported to the FTC and Department of Justice, and (2) providing for the forfeiture of any generic exclusivity period if such an agreement is challenged by the government and held to "violate[] the antitrust laws." Medicare Prescription Drug, Modernization, and Improvement Act, Pub. L. No. 108-173, §§ 1102(a)(2), 1111-1118, 117 Stat. 2458, 2461-2464 (codified at 21 U.S.C. 355(j)(5)(D)(i)(V) and note).

D. Adopting The Scope-Of-The-Patent Approach Would Immunize And Encourage Collusive Behavior

Pharmaceutical manufacturers can be expected to conform their primary conduct to whatever rule the Court adopts in this case. And, as the government's

opening brief explains, antitrust law seeks to achieve its goals by channeling companies' pursuit of their own self-interest into conduct that is likely to benefit consumers. See Pet. Br. 28, 39; *Premier Elec. Constr. Co.* v. *National Elec. Contractors Ass'n*, 814 F.2d 358, 369-370 (7th Cir. 1987) (Easterbrook, J.).

Adopting the "quick look" approach will discourage use of a particular settlement term (a reverse payment) that appears to be essentially unknown outside the Hatch-Waxman context. Parties will remain free, however, to settle paragraph IV litigation on other terms, or to litigate their disputes to judgment in the (likely rare) cases in which the parties are willing to settle if, but only if, a reverse payment can be used. Although the prospect of some additional litigation is appropriately viewed as a cost of the "quick look" approach, the approach has countervailing advantages even in that category of cases, since the ultimate date of generic entry will reflect the *actual* exclusionary force of the patent. See pp. 12-13, *supra*.

By contrast, this Court's adoption of the scope-of-the-patent approach would encourage collusive behavior that harms consumers. As even respondents' preferred economists acknowledge, "a safe harbor for agreements that settle patent disputes would foster anticompetitive outcomes that benefit the parties to the patent disputes but that harm consumers." John P. Bigelow & Robert D. Willig, *"Reverse Payments" in Settlements of Patent Litigation:* Schering-Plough, K-Dur, *and the FTC (2005)*, in *The Antitrust Revolution* 248, 274 (John E. Kwoka, Jr. & Lawrence J. White eds., 5th ed. 2009). Given the pharmaceutical industry's economics, the scope-of-the-patent approach would create a powerful incentive for generic manufacturers in paragraph IV

litigation to agree to deferred dates of entry (*i.e.*, dates significantly later than the strength of their negotiating positions would otherwise enable them to obtain), since both the brand-name and generic manufacturers' profits can be increased if the brand-name's monopoly can be extended and the monopoly profits can be shared. See Pet. Br. 22-23.

That sort of collusive behavior is antithetical to the federal competition laws, and it would systematically disserve consumer interests. Treating such agreements as legitimate would be especially untoward in light of Congress's effort, through the 180-day exclusivity period available to a successful first filer of a paragraph IV certification, to increase the incentives for generic competition. See Pet. Br. 31; 21 U.S.C. 355(j)(5)(B)(iv). A generic first filer who accepts a reverse payment to defer market entry does not simply fail to compete vigorously; its overall course of conduct impedes the competitive potential of other generic manufacturers as well, since second and later filers are not entitled to the exclusivity period and therefore have diminished incentives to bear the costs and regulatory burdens of seeking market entry before the patent expires. See Apotex Amicus Br. 11-20.

E. This Court's Patent-Licensing Precedents Do Not Justify Respondents' Scope-Of-The-Patent Approach

Respondents' affirmative support for their scope-of-the-patent approach principally consists of decisions of this Court addressing the antitrust limits on the exercise of patent rights. Solvay Br. 14-19; Actavis Br. 47-51; Par/Paddock Br. 31-46. Respondents' reliance on those precedents is misplaced.

1. Respondents contend that under this Court's decisions, setting aside frauds and shams, "antitrust scruti-

ny" is appropriate "[o]nly if a restraint falls outside the scope of a patent." Solvay Br. 9. The scope-of-the-patent approach plays a useful role in antitrust analysis by identifying agreements that are per se unlawful (*viz.*, agreements not to compete unconnected with any colorable patent right). It does not logically follow, however, that a patentee enjoys an exemption from antitrust scrutiny for every possible action—whether unilateral or by agreement—that would achieve the same exclusionary effect as a court injunction.

By "scope of the patent," moreover, respondents do not refer to the *actual* exclusionary effect of the patent, as determined through judicial proceedings resolving contested issues of validity and infringement. Rather, they refer to the "exclusionary effect * * * the patent *potentially* provides," Solvay Br. 15 (emphasis added), *i.e.*, the exclusionary force that the patentee *alleges* it to have (so long as the patent was not procured through fraud and the allegations of infringement are not a sham). Use of that baseline would be particularly unsound when addressing the antitrust implications of an agreement between potential competitors who have asserted inconsistent positions on the pertinent issues of patent validity and/or infringement. See Pet. Br. 43-44; pp. 3-4, *supra*.

2. None of the decisions respondents cite from this Court compels the rule they advocate, and adoption of the government's "quick look" approach to reverse-payment agreements would not call any of those decisions into question. Most of the decisions addressed challenges to particular terms of agreements under which a patent was licensed (or a patented product was

sold).[5] A licensor and its licensee stand in a vertical relationship as to the license agreement's terms, and licensing arrangements are generally procompetitive because they tend to present opportunities for increased output. The scope-of-the-patent approach, by contrast, would apply to a horizontal agreement between a brand-name manufacturer and its would-be generic competitor; that approach would immunize agreements regardless of whether they involve a license, and indeed would permit agreements not to compete until patent expiration. Such agreements by definition cannot result in increased output. See 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2046c, at 337-338 (3d ed. 2012) (distinguishing on this ground between licensing agreements and reverse-payment settlements).

The procompetitive effect of a license may be most evident when it is undisputed that the licensed conduct would otherwise infringe a valid patent. But even when a license is used to resolve an actual or potential dispute about patent validity or infringement, the license may be procompetitive, particularly if its terms reflect a negotiating dynamic in which consumers' interests are adequately protected. By contrast, a reverse payment severs the alignment of interests that would otherwise exist between the generic manufacturer and consumers when the parties to paragraph IV litigation negotiate a set-

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[5] See, *e.g.*, *United States* v. *Line Material Co.*, 333 U.S. 287 (1948) (addressing validity under antitrust laws of terms of sublicenses of multiple cross-licensed patents); *United States* v. *United States Gypsum Co.*, 333 U.S. 364 (1948) (addressing validity under antitrust laws of terms on which patent was licensed); *United States* v. *General Elec. Co.*, 272 U.S. 476 (1926) (same); *General Talking Pictures Corp.* v. *Western Elec. Co.*, 304 U.S. 175 (1938) (patent-infringement suit addressing sale by patent licensee of patented article in violation of license).

tlement, and realigns the generic manufacturer's interests with the brand-name manufacturer's desire to preserve its monopoly.

In a somewhat different category is *Dawson Chemical Co.* v. *Rohm & Haas Co.*, 448 U.S. 176 (1980), in which the patentee had refused to license to sellers of an unpatented chemical its patent on a method of using that chemical, a practice the sellers claimed in their defense was patent misuse. As Solvay points out (Br. 18), this Court assumed the validity of the patent for purposes of the misuse defense. The Court adopted that assumption, however, simply because the courts below had not yet passed on the sellers' challenges to the validity of the patent. *Dawson Chem.*, 448 U.S. at 185 n.5. The Court's decision clearly assumed that the sellers, who had been sued for patent infringement, would ultimately be heard on their invalidity challenge. This case, by contrast, involves generic manufacturers' receipt of cash payments in exchange for their promise *not* to contest patent validity or infringement.

Finally, Solvay's reliance (Br. 16-18) on *Standard Oil Co.* v. *United States*, 283 U.S. 162 (1931), is particularly misplaced. That case likewise involved licensing agreements rather than an agreement not to compete. And Solvay is wrong in contending that the permissible cross-licensing of patents in the challenged settlement agreement, like a reverse payment, "g[ave] accused infringers something 'they could not hope to obtain even if they prevailed in litigation.'" Br. 34 (quoting Pet. Br. 30). Those cross-licenses mirrored a judicial decree of infringement with a remedy of a compulsory license with prospective running royalties rather than an injunction (an established form of remedy in patent cases, see, *e.g.*, *Innogenetics, N.V.* v. *Abbott Labs.*, 512 F.3d 1363, 1379-

1381 (Fed. Cir. 2008)). In any event, if the scope-of-the-patent approach were correct, this Court in *Standard Oil* should not have bothered to analyze the arrangements under the rule of reason (see 283 U.S. at 170-179), but instead should have simply disposed of the case on the ground that the government had failed to prove at trial (and did not contend on appeal) that the patent litigation was pretextual or the settlements were entered in bad faith, see *id.* at 180.

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For the foregoing reasons and those stated in our opening brief, the judgment of the court of appeals should be reversed and the case remanded for further proceedings.

Respectfully submitted.

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Solicitor General

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