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NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.*, 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

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FEDERAL TRADE COMMISSION *v.* ACTAVIS, INC., ET AL.

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

No. 12–416. Argued March 25, 2013—Decided June 17, 2013

The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act or Act) creates special procedures for identifying and resolving patent disputes between brand-name and generic drug manufacturers, one of which requires a prospective generic manufacturer to assure the Food and Drug Administration (FDA) that it will not infringe the brand-name's patents. One way to provide such assurance (the "paragraph IV" route) is by certifying that any listed, relevant patent "is invalid or will not be infringed by the manufacture, use, or sale" of the generic drug. 21 U. S. C. §355(j)(2)(A)(vii)(IV).

Respondent Solvay Pharmaceuticals obtained a patent for its approved brand-name drug AndroGel. Subsequently, respondents Actavis and Paddock filed applications for generic drugs modeled after AndroGel and certified under paragraph IV that Solvay's patent was invalid and that their drugs did not infringe it. Solvay sued Actavis and Paddock, claiming patent infringement. See 35 U. S. C. §271(e)(2)(A). The FDA eventually approved Actavis' generic product, but instead of bringing its drug to market, Actavis entered into a "reverse payment" settlement agreement with Solvay, agreeing not to bring its generic to market for a specified number of years and agreeing to promote AndroGel to doctors in exchange for millions of dollars. Paddock made a similar agreement with Solvay, as did respondent Par, another manufacturer aligned in the patent litigation with Paddock.

The Federal Trade Commission (FTC) filed suit, alleging that respondents violated §5 of the Federal Trade Commission Act by unlawfully agreeing to abandon their patent challenges, to refrain from

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launching their low-cost generic drugs, and to share in Solvay's monopoly profits. The District Court dismissed the complaint. The Eleventh Circuit concluded that as long as the anticompetitive effects of a settlement fall within the scope of the patent's exclusionary potential, the settlement is immune from antitrust attack. Noting that the FTC had not alleged that the challenged agreements excluded competition to a greater extent than would the patent, if valid, it affirmed the complaint's dismissal. It further recognized that if parties to this sort of case do not settle, a court might declare a patent invalid. But since public policy favors the settlement of disputes, it held that courts could not require parties to continue to litigate in order to avoid antitrust liability.

Held: The Eleventh Circuit erred in affirming the dismissal of the FTC's complaint. Pp. 8–21.

(a) Although the anticompetitive effects of the reverse settlement agreement might fall within the scope of the exclusionary potential of Solvay's patent, this does not immunize the agreement from antitrust attack. For one thing, to refer simply to what the holder of a valid patent could do does not by itself answer the antitrust question. Here, the paragraph IV litigation put the patent's validity and preclusive scope at issue, and the parties' settlement—in which, the FTC alleges, the plaintiff agreed to pay the defendants millions to stay out of its market, even though the defendants had no monetary claim against the plaintiff—ended that litigation. That form of settlement is unusual, and there is reason for concern that such settlements tend to have significant adverse effects on competition. It would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, and not against procompetitive antitrust policies as well. Both are relevant in determining the scope of monopoly and antitrust immunity conferred by a patent, see, *e.g.*, *United States* v. *Line Material Co.*, 333 U. S. 287, 310, 311, and the antitrust question should be answered by considering traditional antitrust factors. For another thing, this Court's precedents make clear that patent-related settlement agreements can sometimes violate the antitrust laws. See, *e.g.*, *United States* v. *Singer Mfg. Co.*, 374 U. S. 174; *United States* v. *New Wrinkle, Inc.*, 342 U. S. 371; *Standard Oil Co. (Indiana)* v. *United States*, 283 U. S. 163. Finally, the Hatch-Waxman Act's general procompetitive thrust—facilitating challenges to a patent's validity and requiring parties to a paragraph IV dispute to report settlement terms to federal antitrust regulators—suggests a view contrary to the Eleventh Circuit's. Pp. 8–14.

(b) While the Eleventh Circuit's conclusion finds some support in a general legal policy favoring the settlement of disputes, its related

underlying practical concern consists of its fear that antitrust scrutiny of a reverse payment agreement would require the parties to engage in time-consuming, complex, and expensive litigation to demonstrate what would have happened to competition absent the settlement. However, five sets of considerations lead to the conclusion that this concern should not determine the result here and that the FTC should have been given the opportunity to prove its antitrust claim. First, the specific restraint at issue has the "potential for genuine adverse effects on competition." *FTC* v. *Indiana Federation of Dentists*, 476 U. S. 447, 460–461. Payment for staying out of the market keeps prices at patentee-set levels and divides the benefit between the patentee and the challenger, while the consumer loses. And two Hatch-Waxman Act features—the 180-day exclusive-right-to-sell advantage given to the first paragraph IV challenger to win FDA approval, §355(j)(5)(B)(iv), and the roughly 30-month period that the subsequent manufacturers would be required to wait out before winning FDA approval, §355(j)(5)(B)(iii)—mean that a reverse settlement agreement with the first filer removes from consideration the manufacturer most likely to introduce competition quickly. Second, these anticompetitive consequences will at least sometimes prove unjustified. There may be justifications for reverse payment that are not the result of having sought or brought about anticompetitive consequences, but that does not justify dismissing the FTC's complaint without examining the potential justifications. Third, where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely has the power to bring about that harm in practice. The size of the payment from a branded drug manufacturer to a generic challenger is a strong indicator of such power. Fourth, an antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed. It is normally not necessary to litigate patent validity to answer the antitrust question. A large, unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the patent's validity. Fifth, the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuits. As in other industries, they may settle in other ways, *e.g.,* by allowing the generic manufacturer to enter the patentee's market before the patent expires without the patentee's paying the challenger to stay out prior to that point. Pp. 14–20.

(c) This Court declines to hold that reverse payment settlement agreements are presumptively unlawful. Courts reviewing such agreements should proceed by applying the "rule of reason," rather than under a "quick look" approach. See *California Dental Assn.* v.

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FTC, 526 U. S. 756, 775, n. 12. Pp. 20–21.

677 F. 3d 1298, reversed and remanded.

BREYER, J., delivered the opinion of the Court, in which KENNEDY, GINSBURG, SOTOMAYOR, and KAGAN, JJ., joined. ROBERTS, C. J., filed a dissenting opinion, in which SCALIA and THOMAS, JJ., joined. ALITO, J., took no part in the consideration or decision of the case.

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SUPREME COURT OF THE UNITED STATES

No. 12–416

FEDERAL TRADE COMMISSION, PETITIONER *v.* ACTAVIS, INC., ET AL.

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

[June 17, 2013]

JUSTICE BREYER delivered the opinion of the Court.

Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars. Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a "reverse payment" settlement agreement. And the basic question here is whether such an agreement can sometimes unreasonably diminish competition in violation of the antitrust laws. See, *e.g.,* 15 U. S. C. §1 (Sherman Act prohibition of "restraint[s] of trade or commerce"). Cf. *Palmer* v. *BRG of Ga., Inc.*, 498 U. S. 46 (1990) (*per curiam*) (invalidating agreement not to compete).

In this case, the Eleventh Circuit dismissed a Federal Trade Commission (FTC) complaint claiming that a particular reverse payment settlement agreement violated the antitrust laws. In doing so, the Circuit stated that a reverse payment settlement agreement generally is "im-

mune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *FTC* v. *Watson Pharmaceuticals*, *Inc.*, 677 F. 3d 1298, 1312 (2012). And since the alleged infringer's promise not to enter the patentee's market expired before the patent's term ended, the Circuit found the agreement legal and dismissed the FTC complaint. *Id.,* at 1315. In our view, however, reverse payment settlements such as the agreement alleged in the complaint before us can sometimes violate the antitrust laws. We consequently hold that the Eleventh Circuit should have allowed the FTC's lawsuit to proceed.

I

A

Apparently most if not all reverse payment settlement agreements arise in the context of pharmaceutical drug regulation, and specifically in the context of suits brought under statutory provisions allowing a generic drug manufacturer (seeking speedy marketing approval) to challenge the validity of a patent owned by an already-approved brand-name drug owner. See Brief for Petitioner 29; 12 P. Areeda & H. Hovenkamp, Antitrust Law ¶2046, p. 338 (3d ed. 2012) (hereinafter Areeda); Hovenkamp, Sensible Antitrust Rules for Pharmaceutical Competition, 39 U. S. F. L. Rev. 11, 24 (2004). We consequently describe four key features of the relevant drug-regulatory framework established by the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, as amended. That Act is commonly known as the Hatch-Waxman Act.

First, a drug manufacturer, wishing to market a new prescription drug, must submit a New Drug Application to the federal Food and Drug Administration (FDA) and undergo a long, comprehensive, and costly testing process, after which, if successful, the manufacturer will receive

marketing approval from the FDA. See 21 U. S. C. §355(b)(1) (requiring, among other things, "full reports of investigations" into safety and effectiveness; "a full list of the articles used as components"; and a "full description" of how the drug is manufactured, processed, and packed).

Second, once the FDA has approved a brand-name drug for marketing, a manufacturer of a generic drug can obtain similar marketing approval through use of abbreviated procedures. The Hatch-Waxman Act permits a generic manufacturer to file an Abbreviated New Drug Application specifying that the generic has the "same active ingredients as," and is "biologically equivalent" to, the already-approved brand-name drug. *Caraco Pharmaceutical Laboratories, Ltd.* v. *Novo Nordisk A/S*, 566 U. S. ___, ___ (2012) (slip op., at 2) (citing 21 U. S. C. §§355(j)(2)(A)(ii), (iv)). In this way the generic manufacturer can obtain approval while avoiding the "costly and time-consuming studies" needed to obtain approval "for a pioneer drug." See *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U. S. 661, 676 (1990). The Hatch-Waxman process, by allowing the generic to piggy-back on the pioneer's approval efforts, "speed[s] the introduction of low-cost generic drugs to market," *Caraco*, *supra*, at ___ (slip op., at 2), thereby furthering drug competition.

Third, the Hatch-Waxman Act sets forth special procedures for identifying, and resolving, related patent disputes. It requires the pioneer brand-name manufacturer to list in its New Drug Application the "number and the expiration date" of any relevant patent. See 21 U. S. C. §355(b)(1). And it requires the generic manufacturer in its Abbreviated New Drug Application to "assure the FDA" that the generic "will not infringe" the brand-name's patents. See *Caraco*, *supra*, at___ (slip op., at 3).

The generic can provide this assurance in one of several ways. See 21 U. S. C. §355(j)(2)(A)(vii). It can certify that the brand-name manufacturer has not listed any rele-

vant patents. It can certify that any relevant patents have expired. It can request approval to market beginning when any still-in-force patents expire. Or, it can certify that any listed, relevant patent "is invalid or will not be infringed by the manufacture, use, or sale" of the drug described in the Abbreviated New Drug Application. See §355(j)(2)(A)(vii)(IV). Taking this last-mentioned route (called the "paragraph IV" route), automatically counts as patent infringement, see 35 U. S. C. §271(e)(2)(A) (2006 ed., Supp. V), and often "means provoking litigation." *Caraco*, *supra,* at___ (slip op., at 5). If the brand-name patentee brings an infringement suit within 45 days, the FDA then must withhold approving the generic, usually for a 30-month period, while the parties litigate patent validity (or infringement) in court. If the courts decide the matter within that period, the FDA follows that determination; if they do not, the FDA may go forward and give approval to market the generic product. See 21 U. S. C. §355(j)(5)(B)(iii).

Fourth, Hatch-Waxman provides a special incentive for a generic to be the first to file an Abbreviated New Drug Application taking the paragraph IV route. That applicant will enjoy a period of 180 days of exclusivity (from the first commercial marketing of its drug). See §355(j)(5)(B)(iv) (establishing exclusivity period). During that period of exclusivity no other generic can compete with the brand-name drug. If the first-to-file generic manufacturer can overcome any patent obstacle and bring the generic to market, this 180-day period of exclusivity can prove valuable, possibly "worth several hundred million dollars." Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N. Y. U. L. Rev. 1553, 1579 (2006). Indeed, the Generic Pharmaceutical Association said in 2006 that the "'vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period.'"

Brief for Petitioner 6 (quoting statement). The 180-day exclusivity period, however, can belong only to the first generic to file. Should that first-to-file generic forfeit the exclusivity right in one of the ways specified by statute, no other generic can obtain it. See §355(j)(5)(D).

B

1

In 1999, Solvay Pharmaceuticals, a respondent here, filed a New Drug Application for a brand-name drug called AndroGel. The FDA approved the application in 2000. In 2003, Solvay obtained a relevant patent and disclosed that fact to the FDA, 677 F. 3d, at 1308, as Hatch-Waxman requires. See §355(c)(2) (requiring, in addition, that FDA must publish new patent information upon submission).

Later the same year another respondent, Actavis, Inc. (then known as Watson Pharmaceuticals), filed an Abbreviated New Drug Application for a generic drug modeled after AndroGel. Subsequently, Paddock Laboratories, also a respondent, separately filed an Abbreviated New Drug Application for its own generic product. Both Actavis and Paddock certified under paragraph IV that Solvay's listed patent was invalid and their drugs did not infringe it. A fourth manufacturer, Par Pharmaceutical, likewise a respondent, did not file an application of its own but joined forces with Paddock, agreeing to share the patent litigation costs in return for a share of profits if Paddock obtained approval for its generic drug.

Solvay initiated paragraph IV patent litigation against Actavis and Paddock. Thirty months later the FDA approved Actavis' first-to-file generic product, but, in 2006, the patent-litigation parties all settled. Under the terms of the settlement Actavis agreed that it would not bring its generic to market until August 31, 2015, 65 months before Solvay's patent expired (unless someone else marketed a generic sooner). Actavis also agreed to promote AndroGel

to urologists. The other generic manufacturers made roughly similar promises. And Solvay agreed to pay millions of dollars to each generic—$12 million in total to Paddock; $60 million in total to Par; and an estimated $19–$30 million annually, for nine years, to Actavis. See App. 46, 49–50, Complaint ¶¶66, 77. The companies described these payments as compensation for other services the generics promised to perform, but the FTC contends the other services had little value. According to the FTC the true point of the payments was to compensate the generics for agreeing not to compete against AndroGel until 2015. See *id.*, at 50–53, Complaint ¶¶81–85.

2

On January 29, 2009, the FTC filed this lawsuit against all the settling parties, namely, Solvay, Actavis, Paddock, and Par. The FTC's complaint (as since amended) alleged that respondents violated §5 of the Federal Trade Commission Act, 15 U. S. C. §45, by unlawfully agreeing "to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years." App. 29, Complaint ¶5. See generally *FTC* v. *Indiana Federation of Dentists*, 476 U. S. 447, 454 (1986) (Section 5 "encompass[es] . . . practices that violate the Sherman Act and the other antitrust laws"). The District Court held that these allegations did not set forth an antitrust law violation. *In re Androgel Antitrust Litigation (No. II)*, 687 F. Supp. 2d 1371, 1379 (ND Ga. 2010). It accordingly dismissed the FTC's complaint. The FTC appealed.

The Court of Appeals for the Eleventh Circuit affirmed the District Court. It wrote that "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclu-

sionary potential of the patent." 677 F. 3d, at 1312. The court recognized that "antitrust laws typically prohibit agreements where one company pays a potential competitor not to enter the market." *Id.,* at 1307 (citing *Valley Drug Co.* v. *Geneva Pharmaceuticals, Inc.,* 344 F. 3d 1294, 1304 (CA11 2003)). See also *Palmer*, 498 U. S., at 50 (agreement to divide territorial markets held "unlawful on its face"). But, the court found that "reverse payment settlements of patent litigation presen[t] atypical cases because one of the parties owns a patent." 677 F. 3d, at 1307 (internal quotation marks and second alteration omitted). Patent holders have a "lawful right to exclude others from the market," *ibid.* (internal quotation marks omitted); thus a patent "conveys the right to cripple competition." *Id.,* at 1310 (internal quotation marks omitted). The court recognized that, if the parties to this sort of case do not settle, a court might declare the patent invalid. *Id.,* at 1305. But, in light of the public policy favoring settlement of disputes (among other considerations) it held that the courts could not require the parties to continue to litigate in order to avoid antitrust liability. *Id.,* at 1313–1314.

The FTC sought certiorari. Because different courts have reached different conclusions about the application of the antitrust laws to Hatch-Waxman-related patent settlements, we granted the FTC's petition. Compare, *e.g., id.,* at 1312 (case below) (settlements generally "immune from antitrust attack"); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F. 3d 1323, 1332–1337 (CA Fed. 2008) (similar); *In re Tamoxifen Citrate Antitrust Litigation*, 466 F. 3d 187, 212–213 (CA2 2006) (similar), with *In re K-Dur Antitrust Litigation*, 686 F. 3d 197, 214–218 (CA3 2012) (settlements presumptively unlawful).

II

A

Solvay's patent, if valid and infringed, might have permitted it to charge drug prices sufficient to recoup the reverse settlement payments it agreed to make to its potential generic competitors. And we are willing to take this fact as evidence that the agreement's "anticompetitive effects fall within the scope of the exclusionary potential of the patent." 677 F. 3d, at 1312. But we do not agree that that fact, or characterization, can immunize the agreement from antitrust attack.

For one thing, to refer, as the Circuit referred, simply to what the holder of a valid patent could do does not by itself answer the antitrust question. The patent here may or may not be valid, and may or may not be infringed. "[A] *valid* patent excludes all except its owner from the use of the protected process or product," *United States* v. *Line Material Co.*, 333 U. S. 287, 308 (1948) (emphasis added). And that exclusion may permit the patent owner to charge a higher-than-competitive price for the patented product. But an *invalidated* patent carries with it no such right. And even a valid patent confers no right to exclude products or processes that do not actually infringe. The paragraph IV litigation in this case put the patent's validity at issue, as well as its actual preclusive scope. The parties' settlement ended that litigation. The FTC alleges that in substance, the plaintiff agreed to pay the defendants many millions of dollars to stay out of its market, even though the defendants did not have any claim that the plaintiff was liable to them for damages. That form of settlement is unusual. And, for reasons discussed in Part II–B, *infra*, there is reason for concern that settlements taking this form tend to have significant adverse effects on competition.

Given these factors, it would be incongruous to determine antitrust legality by measuring the settlement's

anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well. And indeed, contrary to the Circuit's view that the only pertinent question is whether "the settlement agreement . . . fall[s] within" the legitimate "scope" of the patent's "exclusionary potential," 677 F. 3d, at 1309, 1312, this Court has indicated that patent and antitrust policies are both relevant in determining the "scope of the patent monopoly"—and consequently antitrust law immunity—that is conferred by a patent.

Thus, the Court in *Line Material* explained that "the improper use of [a patent] monopoly," is "invalid" under the antitrust laws and resolved the antitrust question in that case by seeking an accommodation "between the lawful restraint on trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act." 333 U. S., at 310. To strike that balance, the Court asked questions such as whether "the patent statute specifically gives a right" to restrain competition in the manner challenged; and whether "competition is impeded to a greater degree" by the restraint at issue than other restraints previously approved as reasonable. *Id.*, at 311. See also *United States* v. *United States Gypsum Co.*, 333 U. S. 364, 390–391 (1948) (courts must "balance the privileges of [the patent holder] and its licensees under the patent grants with the prohibitions of the Sherman Act against combinations and attempts to monopolize"); *Walker Process Equipment, Inc.* v. *Food Machinery & Chemical Corp.*, 382 U. S. 172, 174 (1965) ("[E]nforcement of a patent procured by fraud" may violate the Sherman Act). In short, rather than measure the length or amount of a restriction solely against the length of the patent's term or its earning potential, as the Court of Appeals apparently did here, this Court answered the antitrust question by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially

offsetting legal considerations present in the circumstances, such as here those related to patents. See Part II–B, *infra*. Whether a particular restraint lies "beyond the limits of the patent monopoly" is a *conclusion* that flows from that analysis and not, as THE CHIEF JUSTICE suggests, its starting point. *Post*, at 3, 8 (dissenting opinion).

For another thing, this Court's precedents make clear that patent-related settlement agreements can sometimes violate the antitrust laws. In *United States* v. *Singer Mfg. Co.*, 374 U. S. 174 (1963), for example, two sewing machine companies possessed competing patent claims; a third company sought a patent under circumstances where doing so might lead to the disclosure of information that would invalidate the other two firms' patents. All three firms settled their patent-related disagreements while assigning the broadest claims to the firm best able to enforce the patent against yet other potential competitors. *Id.,* at 190–192. The Court did not examine whether, on the assumption that all three patents were valid, patent law would have allowed the patents' holders to do the same. Rather, emphasizing that the Sherman Act "imposes strict limitations on the concerted activities in which patent owners may lawfully engage," *id.,* at 197, it held that the agreements, although settling patent disputes, violated the antitrust laws. *Id.,* at 195, 197. And that, in important part, was because "the public interest in granting patent monopolies" exists only to the extent that "the public is given a novel and useful invention" in "consideration for its grant." *Id.,* at 199 (White, J., concurring). See also *United States* v. *New Wrinkle, Inc.*, 342 U. S. 371, 378 (1952) (applying antitrust scrutiny to patent settlement); *Standard Oil Co. (Indiana)* v. *United States*, 283 U. S. 163 (1931) (same).

Similarly, both within the settlement context and without, the Court has struck down overly restrictive patent licensing agreements—irrespective of whether those

agreements produced supra-patent-permitted revenues. We concede that in *United States* v. *General Elec. Co.*, 272 U. S. 476, 489 (1926), the Court permitted a single patentee to grant to a single licensee a license containing a minimum resale price requirement. But in *Line Material*, *supra*, at 308, 310–311, the Court held that the antitrust laws forbid a group of patentees, each owning one or more patents, to cross-license each other, and, in doing so, to insist that each licensee maintain retail prices set collectively by the patent holders. The Court was willing to presume that the single-patentee practice approved in *General Electric* was a "reasonable restraint" that "accords with the patent monopoly granted by the patent law," 333 U. S., at 312, but declined to extend that conclusion to multiple-patentee agreements: "As the Sherman Act prohibits agreements to fix prices, any arrangement between patentees runs afoul of that prohibition and is outside the patent monopoly." *Ibid.* In *New Wrinkle*, 342 U. S., at 378, the Court held roughly the same, this time in respect to a similar arrangement in settlement of a litigation between two patentees, each of which contended that its own patent gave it the exclusive right to control production. That one or the other company (we may presume) was right about its patent did not lead the Court to confer antitrust immunity. Far from it, the agreement was found to violate the Sherman Act. *Id.,* at 380.

Finally in *Standard Oil Co. (Indiana)*, the Court upheld cross-licensing agreements among patentees that settled actual and impending patent litigation, 283 U. S., at 168, which agreements set royalty rates to be charged third parties for a license to practice all the patents at issue (and which divided resulting revenues). But, in doing so, Justice Brandeis, writing for the Court, warned that such an arrangement would have violated the Sherman Act had the patent holders thereby "dominate[d]" the industry and "curtail[ed] the manufacture and supply of an unpatented

product." *Id.,* at 174. These cases do not simply ask whether a hypothetically valid patent's holder would be able to charge, *e.g.*, the high prices that the challenged patent-related term allowed. Rather, they seek to accommodate patent and antitrust policies, finding challenged terms and conditions unlawful unless patent law policy offsets the antitrust law policy strongly favoring competition.

Thus, contrary to the dissent's suggestion, *post*, at 4–6, there is nothing novel about our approach. What *does* appear novel are the dissent's suggestions that a patent holder may simply "pa[y] a competitor to respect its patent" and quit its patent invalidity or noninfringement claim without any antitrust scrutiny whatever, *post*, at 3, and that "such settlements . . . are a well-known feature of intellectual property litigation," *post*, at 10. Closer examination casts doubt on these claims. The dissent does not identify any patent statute that it understands to grant such a right to a patentee, whether expressly or by fair implication. It would be difficult to reconcile the proposed right with the patent-related policy of eliminating unwarranted patent grants so the public will not "continually be required to pay tribute to would-be monopolists without need or justification." *Lear, Inc.* v. *Adkins*, 395 U. S. 653, 670 (1969). And the authorities cited for this proposition (none from this Court, and none an antitrust case) are not on point. Some of them say that when Company A sues Company B for patent infringement and demands, say, $100 million in damages, it is not uncommon for B (the defendant) to pay A (the plaintiff) some amount less than the full demand as part of the settlement—$40 million, for example. See Schildkraut, Patent-Splitting Settlements and the Reverse Payment Fallacy, 71 Antitrust L. J. 1033, 1046 (2004) (suggesting that this hypothetical settlement includes "an implicit net payment" from A to B of $60 million—*i.e.,* the amount of the settlement discount). The

cited authorities also indicate that if B has a counterclaim for damages against A, the original infringement plaintiff, A might end up paying B to settle B's counterclaim. Cf. *Metro-Goldwyn Mayer, Inc.* v. *007 Safety Prods., Inc.*, 183 F. 3d 10, 13 (CA1 1999) (describing trademark dispute and settlement). Insofar as the dissent urges that settlements taking these commonplace forms have not been thought for that reason alone subject to antitrust liability, we agree, and do not intend to alter that understanding. But the dissent appears also to suggest that reverse payment settlements—*e.g.*, in which A, the plaintiff, pays money to defendant B purely so B will give up the patent fight—should be viewed for antitrust purposes in the same light as these familiar settlement forms. See *post,* at 9–10. We cannot agree. In the traditional examples cited above, a party with a claim (or counterclaim) for damages receives a sum equal to or less than the value of its claim. In reverse payment settlements, in contrast, a party with no claim for damages (something that is usually true of a paragraph IV litigation defendant) walks away with money simply so it will stay away from the patentee's market. That, we think, is something quite different. Cf. *Verizon Communications, Inc.* v. *Law Offices of Curtis V. Trinko, LLP*, 540 U. S. 398, 408 (2004) ("[C]ollusion" is "the supreme evil of antitrust").

Finally, the Hatch-Waxman Act itself does not embody a statutory policy that supports the Eleventh Circuit's view. Rather, the general procompetitive thrust of the statute, its specific provisions facilitating challenges to a patent's validity, see Part I–A, *supra*, and its later-added provisions requiring parties to a patent dispute triggered by a paragraph IV filing to report settlement terms to the FTC and the Antitrust Division of the Department of Justice, all suggest the contrary. See §§1112–1113, 117 Stat. 2461–2462. Those interested in legislative history may also wish to examine the statements of individual Mem-

bers of Congress condemning reverse payment settlements in advance of the 2003 amendments. See, *e.g.,* 148 Cong. Rec. 14437 (2002) (remarks of Sen. Hatch) ("It was and is very clear that the [Hatch-Waxman Act] was not designed to allow deals between brand and generic companies to delay competition"); 146 Cong. Rec. 18774 (2000) (remarks of Rep. Waxman) (introducing bill to deter companies from "strik[ing] collusive agreements to trade multimillion dollar payoffs by the brand company for delays in the introduction of lower cost, generic alternatives").

B

The Eleventh Circuit's conclusion finds some degree of support in a general legal policy favoring the settlement of disputes. 677 F. 3d, at 1313–1314. See also *Schering-Plough Corp.* v. *FTC*, 402 F. 3d 1056, 1074–1075 (2005) (same); *In re Tamoxifen Citrate*, 466 F. 3d, at 202 (noting public's "'strong interest in settlement'" of complex and expensive cases). The Circuit's related underlying practical concern consists of its fear that antitrust scrutiny of a reverse payment agreement would require the parties to litigate the validity of the patent in order to demonstrate what would have happened to competition in the absence of the settlement. Any such litigation will prove time consuming, complex, and expensive. The antitrust game, the Circuit may believe, would not be worth that litigation candle.

We recognize the value of settlements and the patent litigation problem. But we nonetheless conclude that this patent-related factor should not determine the result here. Rather, five sets of considerations lead us to conclude that the FTC should have been given the opportunity to prove its antitrust claim.

First, the specific restraint at issue has the "potential for genuine adverse effects on competition." *Indiana Federation of Dentists*, 476 U. S., at 460–461 (citing 7

Areeda ¶1511, at 429 (1986)). The payment in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product. Suppose, for example, that the exclusive right to sell produces $50 million in supracompetitive profits per year for the patentee. And suppose further that the patent has 10 more years to run. Continued litigation, if it results in patent invalidation or a finding of noninfringement, could cost the patentee $500 million in lost revenues, a sum that then would flow in large part to consumers in the form of lower prices.

We concede that settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumer's benefit. But settlement on the terms said by the FTC to be at issue here—payment in return for staying out of the market—simply keeps prices at patentee-set levels, potentially producing the full patent-related $500 million monopoly return while dividing that return between the challenged patentee and the patent challenger. The patentee and the challenger gain; the consumer loses. Indeed, there are indications that patentees sometimes pay a generic challenger a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market. See Hemphill, 81 N. Y. U. L. Rev., at 1581. See also Brief for 118 Law, Economics, and Business Professors et al. as *Amici Curiae* 25 (estimating that this is true of the settlement challenged here). The rationale behind a payment of this size cannot in every case be supported by traditional settlement considerations. The payment may instead provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive

market.

But, one might ask, as a practical matter would the parties be able to enter into such an anticompetitive agreement? Would not a high reverse payment signal to other potential challengers that the patentee lacks confidence in its patent, thereby provoking additional challenges, perhaps too many for the patentee to "buy off?" Two special features of Hatch-Waxman mean that the answer to this question is "not necessarily so." First, under Hatch-Waxman only the first challenger gains the special advantage of 180 days of an exclusive right to sell a generic version of the brand-name product. See Part I–A, *supra*. And as noted, that right has proved valuable—indeed, it can be worth several hundred million dollars. See Hemphill, *supra*, at 1579; Brief for Petitioner 6. Subsequent challengers cannot secure that exclusivity period, and thus stand to win significantly less than the first if they bring a successful paragraph IV challenge. That is, if subsequent litigation results in invalidation of the patent, or a ruling that the patent is not infringed, that litigation victory will free not just the challenger to compete, but all other potential competitors too (once they obtain FDA approval). The potential reward available to a subsequent challenger being significantly less, the patentee's payment to the initial challenger (in return for not pressing the patent challenge) will not necessarily provoke subsequent challenges. Second, a generic that files a paragraph IV after learning that the first filer has settled will (if sued by the brand-name) have to wait out a stay period of (roughly) 30 months before the FDA may approve its application, just as the first filer did. See 21 U. S. C. §355(j)(5)(B)(iii). These features together mean that a reverse payment settlement with the first filer (or, as in this case, *all* of the initial filers) "removes from consideration the most motivated challenger, and the one closest to introducing competition." Hemphill, *supra,* at 1586. The dissent may

doubt these provisions matter, *post*, at 15–17, but scholars in the field tell us that "where only one party owns a patent, it is virtually unheard of outside of pharmaceuticals for that party to pay an accused infringer to settle the lawsuit." 1 H. Hovenkamp, M. Janis, M. Lemley, & C. Leslie, IP and Antitrust §15.3, p. 15–45, n. 161 (2d ed. Supp. 2011). It may well be that Hatch-Waxman's unique regulatory framework, including the special advantage that the 180-day exclusivity period gives to first filers, does much to explain why in this context, but not others, the patentee's ordinary incentives to resist paying off challengers (*i.e.,* the fear of provoking myriad other challengers) appear to be more frequently overcome. See 12 Areeda ¶2046, at 341 (3d ed. 2010) (noting that these provisions, no doubt unintentionally, have created special incentives for collusion).

Second, these anticompetitive consequences will at least sometimes prove unjustified. See 7 *id.*, ¶1504, at 410–415 (3d ed. 2010); *California Dental Assn.* v. *FTC*, 526 U. S., 756, 786–787 (1999) (BREYER, J., concurring in part and dissenting in part). As the FTC admits, offsetting or redeeming virtues are sometimes present. Brief for Petitioner 37–39. The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement. That payment may reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item. There may be other justifications. Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement. In such cases, the parties may have provided for a reverse payment without having sought or brought about the anticompetitive consequences

we mentioned above. But that possibility does not justify dismissing the FTC's complaint. An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason. See, *e.g., Indiana Federation of Dentists*, *supra*, at 459; 7 Areeda ¶¶1504a–1504b, at 401–404 (3d ed. 2010).

Third, where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice. See *id.*, ¶1503, at 392–393. At least, the "size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power"—namely, the power to charge prices higher than the competitive level. 12 *id.*, ¶2046, at 351. An important patent itself helps to assure such power. Neither is a firm without that power likely to pay "large sums" to induce "others to stay out of its market." *Ibid.* In any event, the Commission has referred to studies showing that reverse payment agreements are associated with the presence of higher-than-competitive profits—a strong indication of market power. See Brief for Petitioner 45.

Fourth, an antitrust action is likely to prove more feasible administratively than the Eleventh Circuit believed. The Circuit's holding does avoid the need to litigate the patent's validity (and also, any question of infringement). But to do so, it throws the baby out with the bath water, and there is no need to take that drastic step. That is because it is normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham, see 677 F. 3d, at 1312). An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, suggests that the payment's objective is to main-

tain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness. The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm. In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself. 12 Areeda ¶2046, at 350–352.

Fifth, the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit. They may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point. Although the parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust question is: What are those reasons? If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.

In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it; such a firm or individual may well possess market power derived from the patent; a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of

the patent; and parties may well find ways to settle patent disputes without the use of reverse payments. In our view, these considerations, taken together, outweigh the single strong consideration—the desirability of settlements—that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements.

III

The FTC urges us to hold that reverse payment settlement agreements are presumptively unlawful and that courts reviewing such agreements should proceed via a "quick look" approach, rather than applying a "rule of reason." See *California Dental*, 526 U. S., at 775, n. 12 ("Quick-look analysis in effect" shifts to "a defendant the burden to show empirical evidence of procompetitive effects"); 7 Areeda ¶1508, at 435–440 (3d ed. 2010). We decline to do so. In *California Dental*, we held (unanimously) that abandonment of the "rule of reason" in favor of presumptive rules (or a "quick-look" approach) is appropriate only where "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets." 526 U. S., at 770; *id.,* at 781 (BREYER, J., concurring in part and dissenting in part). We do not believe that reverse payment settlements, in the context we here discuss, meet this criterion.

That is because the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification. The existence and degree of any anticompetitive consequence may also vary as among industries. These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason

cases.

To say this is not to require the courts to insist, contrary to what we have said, that the Commission need litigate the patent's validity, empirically demonstrate the virtues or vices of the patent system, present every possible supporting fact or refute every possible pro-defense theory. As a leading antitrust scholar has pointed out, "'[t]here is always something of a sliding scale in appraising reasonableness,'" and as such "'the quality of proof required should vary with the circumstances.'" *California Dental*, *supra*, at 780 (quoting with approval 7 Areeda ¶1507, at 402 (1986)).

As in other areas of law, trial courts can structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences. See 7 *id.,* ¶1508c, at 438–440. We therefore leave to the lower courts the structuring of the present rule-of-reason antitrust litigation. We reverse the judgment of the Eleventh Circuit. And we remand the case for further proceedings consistent with this opinion.

It is so ordered.

JUSTICE ALITO took no part in the consideration or decision of this case.

SUPREME COURT OF THE UNITED STATES

No. 12–416

FEDERAL TRADE COMMISSION, PETITIONER *v.* ACTAVIS, INC., ET AL.

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

[June 17, 2013]

CHIEF JUSTICE ROBERTS, with whom JUSTICE SCALIA and JUSTICE THOMAS join, dissenting.

Solvay Pharmaceuticals holds a patent. It sued two generic drug manufacturers that it alleged were infringing that patent. Those companies counterclaimed, contending the patent was invalid and that, in any event, their products did not infringe. The parties litigated for three years before settling on these terms: Solvay agreed to pay the generics millions of dollars and to allow them into the market five years before the patent was set to expire; in exchange, the generics agreed to provide certain services (help with marketing and manufacturing) and to honor Solvay's patent. The Federal Trade Commission alleges that such a settlement violates the antitrust laws. The question is how to assess that claim.

A patent carves out an exception to the applicability of antitrust laws. The correct approach should therefore be to ask whether the settlement gives Solvay monopoly power beyond what the patent already gave it. The Court, however, departs from this approach, and would instead use antitrust law's amorphous rule of reason to inquire into the anticompetitive effects of such settlements. This novel approach is without support in any statute, and will discourage the settlement of patent litigation. I respectfully dissent.

I

The point of antitrust law is to encourage competitive markets to promote consumer welfare. The point of patent law is to grant limited monopolies as a way of encouraging innovation. Thus, a patent grants "the right to exclude others from profiting by the patented invention." *Dawson Chemical Co.* v. *Rohm & Haas Co.*, 448 U. S. 176, 215 (1980). In doing so it provides an exception to antitrust law, and the scope of the patent—*i.e.*, the rights conferred by the patent—forms the zone within which the patent holder may operate without facing antitrust liability.

This should go without saying, in part because we've said it so many times. *Walker Process Equipment, Inc.* v. *Food Machinery & Chemical Corp.*, 382 U. S. 172, 177 (1965) ("'A patent . . . is an exception to the general rule against monopolies'"); *United States* v. *Line Material Co.*, 333 U. S. 287, 300 (1948) ("[T]he precise terms of the grant define the limits of a patentee's monopoly and the area in which the patentee is freed from competition"); *United States* v. *General Elec. Co.*, 272 U. S. 476, 485 (1926) ("It is only when . . . [the patentee] steps out of the scope of his patent rights" that he comes within the operation of the Sherman Act); *Simpson* v. *Union Oil Co. of Cal.*, 377 U. S. 13, 24 (1964) (similar). Thus, although it is *per se* unlawful to fix prices under antitrust law, we have long recognized that a patent holder is entitled to license a competitor to sell its product on the condition that the competitor charge a certain, fixed price. See, *e.g., General Elec. Co.*, *supra*, at 488–490.

We have never held that it violates antitrust law for a competitor to refrain from challenging a patent. And by extension, we have long recognized that the settlement of patent litigation does not by itself violate the antitrust laws. *Standard Oil Co. (Indiana)* v. *United States*, 283 U. S. 163, 171 (1931) ("Where there are legitimately conflicting claims or threatened interferences, a settlement by

agreement, rather than litigation, is not precluded by the [Sherman] Act"). Like most litigation, patent litigation is settled all the time, and such settlements—which can include agreements that clearly violate antitrust law, such as licenses that fix prices, or agreements among competitors to divide territory—do not ordinarily subject the litigants to antitrust liability. See 1 H. Hovenkamp, M. Janis, M. Lemley, & C. Leslie, IP and Antitrust §7.3, pp. 7–13 to 7–15 (2d ed. 2003) (hereinafter Hovenkamp).

The key, of course, is that the patent holder—when doing anything, including settling—must act within the scope of the patent. If its actions go beyond the monopoly powers conferred by the patent, we have held that such actions are subject to antitrust scrutiny. See, *e.g.*, *United States* v. *Singer Mfg. Co.*, 374 U. S. 174, 196–197 (1963). If its actions are within the scope of the patent, they are not subject to antitrust scrutiny, with two exceptions concededly not applicable here: (1) when the parties settle sham litigation, cf. *Professional Real Estate Investors, Inc.* v. *Columbia Pictures Industries, Inc.*, 508 U. S. 49, 60–61 (1993); and (2) when the litigation involves a patent obtained through fraud on the Patent and Trademark Office. *Walker Process Equipment, supra*, at 177.

Thus, under our precedent, this is a fairly straightforward case. Solvay paid a competitor to respect its patent—conduct which did not exceed the scope of its patent. No one alleges that there was sham litigation, or that Solvay's patent was obtained through fraud on the PTO. As in any settlement, Solvay gave its competitors something of value (money) and, in exchange, its competitors gave it something of value (dropping their legal claims). In doing so, they put an end to litigation that had been dragging on for three years. Ordinarily, we would think this a good thing.

II

Today, however, the Court announces a new rule. It is willing to accept that Solvay's actions did not exceed the scope of its patent. *Ante,* at 8. But it does not agree that this is enough to "immunize the agreement from antitrust attack." *Ibid.* According to the majority, if a patent holder settles litigation by paying an alleged infringer a "large and unjustified" payment, in exchange for having the alleged infringer honor the patent, a court should employ the antitrust rule of reason to determine whether the settlement violates antitrust law. *Ante*, at 19.

The Court's justifications for this holding are unpersuasive. First, the majority explains that "the patent here may or may not be valid, and may or may not be infringed." *Ante*, at 8. Because there is "uncertainty" about whether the patent is actually valid, the Court says that any questions regarding the legality of the settlement should be "measur[ed]" by "procompetitive antitrust policies," rather than "patent law policy." *Ante,* at 9. This simply states the conclusion. The difficulty with such an approach is that a patent holder acting within the scope of its patent has an obvious defense to any antitrust suit: that its patent allows it to engage in conduct that would otherwise violate the antitrust laws. But again, that's the whole point of a patent: to confer a limited monopoly. The problem, as the Court correctly recognizes, is that we're not quite certain if the patent is actually valid, or if the competitor is infringing it. But that is always the case, and is plainly a question of patent law.

The majority, however, would assess those patent law issues according to "antitrust policies." According to the majority, this is what the Court did in *Line Material—i.e.*, it "accommodat[ed]" antitrust principles and struck a "balance" between patent and antitrust law. *Ante,* at 9. But the Court in *Line Material* did no such thing. Rather, it explained that it is "well settled that the possession of a

valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act *beyond the limits of the patent monopoly*." 333 U. S., at 308 (emphasis added). It then, in the very next sentence, stated that "[b]y aggregating patents in one control, the holder of the patents cannot escape the prohibitions of the Sherman Act." *Ibid.* That second sentence follows only if such conduct—the aggregation of multiple patents—goes "beyond the limits of the patent monopoly," which is precisely what the Court concluded. See *id.,* at 312 ("There is *no suggestion in the patent statutes* of authority to combine with other patent owners to fix prices on articles covered by the respective patents" (emphasis added)). The Court stressed, over and over, that a patent holder does not violate the antitrust laws when it acts within the scope of its patent. See *id.,* at 305 ("Within the limits of the patentee's rights under his patent, monopoly of the process or product by him is authorized by the patent statutes"); *id.,* at 310 ("price limitations on patented devices *beyond the limits of a patent monopoly* violate the Sherman Act" (emphasis added)).

The majority suggests that "[w]hether a particular restraint lies 'beyond the limits of the patent monopoly' is a *conclusion* that flows from" applying traditional antitrust principles. *Ante*, at 10. It seems to have in mind a regime where courts ignore the patent, and simply conduct an antitrust analysis of the settlement without regard to the validity of the patent. But a patent holder acting within the scope of its patent does not engage in any unlawful anticompetitive behavior; it is simply exercising the monopoly rights granted to it by the Government. Its behavior would be unlawful only if its patent were invalid or not infringed. And the scope of the patent—i.e., what rights are conferred by the *patent*—should be determined by reference to *patent law*. While it is conceivable to set up a legal system where you assess the validity of patents

or questions of infringement by bringing an antitrust suit, neither the majority nor the Government suggests that Congress has done so.

Second, the majority contends that "this Court's precedents make clear that patent-related settlement agreements can sometimes violate the antitrust laws." *Ante*, at 10. For this carefully worded proposition, it cites *Singer Manufacturing Co.*, *United States* v. *New Wrinkle, Inc.*, 342 U. S. 371 (1952), and *Standard Oil Co. (Indiana).* But each of those cases stands for the same, uncontroversial point: that when a patent holder acts *outside* the scope of its patent, it is no longer protected from antitrust scrutiny by the patent.

To begin, the majority's description of *Singer* is inaccurate. In *Singer*, several patent holders with competing claims entered into a settlement agreement in which they cross-licensed their patents to each other, and did so in order to disadvantage Japanese competition. See 374 U. S., at 194–195 (finding that the agreement had "a common purpose to suppress the Japanese machine competition in the United States" (footnote omitted)). According to the majority, the Court in *Singer* "did not examine whether, on the assumption that all three patents were valid, patent law would have allowed the patents' holders to do the same." *Ante,* at 10. Rather, the majority contends, *Singer* held that this agreement violated the antitrust laws because "in important part . . . 'the public interest in granting patent monopolies' exists only to the extent that 'the public is given a novel and useful invention' in 'consideration for its grant.' " *Ibid.* (quoting *Singer*, 374 U. S., at 199 (White, J., concurring)). But the majority in *Singer* certainly *did* ask whether patent law permitted such an arrangement, concluding that it did not. See *id.*, at 196–197 (reiterating that it "is equally well settled that the possession of a valid patent or patents does not give the patentee any exemption from the provisions of the

Sherman Act *beyond the limits of the patent monopoly*" and holding that "those limitations have been exceeded in this case" (emphasis added; internal quotation marks omitted)); see also Hovenkamp §7.2b, at 7–8, n. 15 (citing *Singer* as a quintessential case in which patent holders were subject to antitrust liability *because* their settlement agreement went beyond the scope of their patents and thus conferred monopoly power beyond what the patent lawfully authorized). Even Justice White's concurrence, on which the majority relies, emphasized that the conduct at issue in *Singer*—collusion between patent holders to exclude Japanese competition and to prevent disclosure of prior art—was not authorized by the patent laws. 374 U. S., at 197, 200.

New Wrinkle is to the same effect. There, the Court explained that because "[p]rice control through cross-licensing [is] *barred as beyond the patent monopoly*," an "arrangement . . . made between patent holders to pool their patents and fix prices on the products for themselves and their licensees . . . plainly violate[s] the Sherman Act." 342 U. S., at 379, 380 (emphasis added). As the Court further explained, a patent holder may not, "'acting in concert with all members of an industry . . . issue substantially identical licenses to all members of the industry under the terms of which the industry is completely regimented, the production of competitive unpatented products suppressed, a class of distributors squeezed out, and prices on unpatented products stabilized.'" *Id.,* at 379–380 (quoting *United States* v. *United States Gypsum Co.*, 333 U. S. 364, 400 (1948)). The majority here, however, ignores this discussion, and instead categorizes the case as "applying antitrust scrutiny to [a] patent settlement." *Ante,* at 10.

Again, in *Standard Oil Co. (Indiana)*, the parties settled claims regarding "competing patented processes for manufacturing an unpatented product," which threatened to

create a monopoly over the unpatented product. 283 U. S., at 175. The Court explained that "an exchange of licenses for the purpose of curtailing the . . . supply of an unpatented product, is beyond the privileges conferred by the patents." *Id.,* at 174.

The majority is therefore right to suggest that these "precedents make clear that patent-related settlement agreements can *sometimes* violate the antitrust laws." *Ante,* at 10 (emphasis added). The key word is sometimes. And those some times are spelled out in our precedents. Those cases have made very clear that patent settlements—and for that matter, any agreements relating to patents—are subject to antitrust scrutiny if they confer benefits beyond the scope of the patent. This makes sense. A patent exempts its holder from the antitrust laws only insofar as the holder operates within the scope of the patent. When the holder steps outside the scope of the patent, he can no longer use the patent as his defense. The majority points to *no* case where a patent settlement was subject to antitrust scrutiny merely because the validity of the patent was uncertain. Not one. It is remarkable, and surely worth something, that in the 123 years since the Sherman Act was passed, we have never let antitrust law cross that Rubicon.

Next, the majority points to the "general procompetitive thrust" of the Hatch-Waxman Act, the fact that Hatch-Waxman "facilitat[es] challenges to a patent's validity," and its "provisions requiring parties to [such] patent dispute[s] . . . to report settlement terms to the FTC and the Antitrust Division of the Department of Justice." *Ante,* at 13. The Hatch-Waxman Act surely seeks to encourage competition in the drug market. And, like every law, it accomplishes its ends through specific provisions. These provisions, for example, allow generic manufacturers to enter the market without undergoing a duplicative application process; they also grant a 180-day monopoly to

the first qualifying generic to commercially market a competing product. See 21 U. S. C. §§355(j)(2)(A)(ii), (iv), 355(j)(5)(B)(iv). So yes, the point of these provisions is to encourage competition. But it should by now be trite—and unnecessary—to say that "no legislation pursues its purposes at all costs" and that "it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute's primary objective must be the law." *Rodriguez* v. *United States*, 480 U. S. 522, 525–526 (1987) (*per curiam*). It is especially disturbing here, where the Court discerns from specific provisions a very broad policy—a "general procompetitive thrust," in its words—and uses that policy to unsettle the established relationship between patent and antitrust law. *Ante,* at 13. Indeed, for whatever it may be worth, Congress has repeatedly declined to enact legislation addressing the issue the Court takes on today. See Brief for Actavis, Inc. 57 (citing 11 such bills introduced in the House or Senate since 2006).

In addition, it is of no consequence that settlement terms must be reported to the FTC and the Department of Justice. Such a requirement does not increase the role of antitrust law in scrutinizing patent settlements. Rather, it ensures that such terms are scrutinized consistent with existing antitrust law. In other words, it ensures that the FTC and Antitrust Division can review the settlements to make sure that they do not confer monopoly power beyond the scope of the patent.

The majority suggests that "[a]pparently most if not all reverse payment settlement agreements arise in the context of pharmaceutical drug regulation." *Ante,* at 2. This claim is not supported empirically by anything the majority cites, and seems unlikely. The term "reverse payment agreement"—coined to create the impression that such settlements are unique—simply highlights the fact that the party suing ends up paying. But this is no anomaly,

nor is it evidence of a nefarious plot; it simply results from the fact that the patent holder plaintiff is a defendant against an invalidity counterclaim—not a rare situation in intellectual property litigation. Whatever one might call them, such settlements—paying an alleged infringer to drop its invalidity claim—are a well-known feature of intellectual property litigation, and reflect an intuitive way to settle such disputes. See *Metro-Goldwyn Mayer, Inc.* v. *007 Safety Prods., Inc.*, 183 F. 3d 10, 13 (CA1 1999); see also Schildkraut, Patent-Splitting Settlements and the Reverse Payment Fallacy, 71 Antitrust L. J. 1033, 1033, 1046–1049 (2004); Brief for Actavis 54, n. 20 (citing examples). To the extent there are not scores and scores of these settlements to point to, this is because such settlements—outside the context of Hatch-Waxman—are private agreements that for obvious reasons are generally not appealed, nor publicly available.

The majority suggests that reverse-payment agreements are distinct because "a party with no claim for damages . . . walks away with money simply so it will stay away from the patentee's market." *Ante,* at 13. Again a distinction without a difference. While the alleged infringer may not be suing for the patent holder's *money*, it is suing for the right to use and market the (intellectual) property, which is worth money.

Finally, the majority complains that nothing in "any patent statute" gives patent-holders the right to settle when faced with allegations of invalidity. *Ante,* at 12. But the right to settle generally accompanies the right to litigate in the first place; no one contends that drivers in an automobile accident may not settle their competing claims merely because no statute grants them that authority. The majority suggests that such a right makes it harder to "eliminat[e] unwarranted patent grants." *Ibid.* That may be so, but such a result—true of all patent settlements—is no reason to adjudicate questions of pa-

tent law under antitrust principles. Our cases establish that antitrust law has no business prying into a patent settlement so long as that settlement confers to the patent holder no monopoly power beyond what the patent itself conferred—unless, of course, the patent was invalid, but that again is a question of patent law, not antitrust law.

In sum, none of the Court's reasons supports its conclusion that a patent holder, when settling a claim that its patent is invalid, is not immunized by the fact that it is acting within the scope of its patent. And I fear the Court's attempt to limit its holding to the context of patent settlements under Hatch-Waxman will not long hold.

III

The majority's rule will discourage settlement of patent litigation. Simply put, there would be no incentive to settle if, immediately after settling, the parties would have to litigate the same issue—the question of patent validity—as part of a defense against an antitrust suit. In that suit, the alleged infringer would be in the especially awkward position of being for the patent after being against it.

This is unfortunate because patent litigation is particularly complex, and particularly costly. As one treatise noted, "[t]he median patent case that goes to trial costs each side $1.5 million in legal fees" alone. Hovenkamp §7.1c, at 7–5, n. 6. One study found that the cost of litigation in this specific context—a generic challenging a brand name pharmaceutical patent—was about $10 million per suit. See Herman, Note, The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation, 111 Colum. L. Rev. 1788, 1795, n. 41 (2011) (citing M. Goodman, G. Nachman, & L. Chen, Morgan Stanley Equity Research, Quantifying the Impact from Authorized Generics 9 (2004)).

The Court acknowledges these problems but nonetheless offers "five sets of considerations" that it tells us overcome

these concerns: (1) sometimes patent settlements will have "'genuine adverse effects on competition'"; (2) "these anticompetitive consequences will at least sometimes prove unjustified"; (3) "where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice"; (4) "it is normally not necessary to litigate patent validity to answer the antitrust question" because "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival," and using a "payment . . . to prevent *the risk* of competition . . . constitutes the relevant anticompetitive harm"; and (5) parties may still "settle in other ways" such as "by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Ante*, at 14–19 (emphasis added).

Almost all of these are unresponsive to the basic problem that settling a patent claim *cannot possibly* impose unlawful anticompetitive harm if the patent holder is acting within the scope of a valid patent and therefore permitted to do precisely what the antitrust suit claims is unlawful. This means that in any such antitrust suit, the defendant (patent holder) will want to use the validity of his patent as a defense—in other words, he'll want to say "I can do this because I have a valid patent that lets me do this." I therefore don't see how the majority can conclude that it won't normally be "necessary to litigate patent validity to answer the antitrust question," *ante*, at 18, unless it means to suggest that the defendant (patent holder) cannot raise his patent as a defense in an antitrust suit. But depriving him of such a defense—if that's what the majority means to do—defeats the point of the patent, which is to confer a *lawful* monopoly on its holder.

The majority seems to think that *even if* the patent is valid, a patent holder violates the antitrust laws merely

because the settlement took away some chance that his patent would be declared invalid by a court. See *ante,* at 18–19 ("payment . . . to prevent *the risk* of competition . . . constitutes the relevant anticompetitive harm" (emphasis added)). This is flawed for several reasons.

First, a patent is either valid or invalid. The parties of course don't know the answer with certainty at the outset of litigation; hence the litigation. But the same is true of any hard legal question that is yet to be adjudicated. Just because people don't know the answer doesn't mean there is no answer until a court declares one. Yet the majority would impose antitrust liability based on the parties' subjective uncertainty about that legal conclusion.

The Court does so on the assumption that offering a "large" sum is reliable evidence that the patent holder has serious doubts about the patent. Not true. A patent holder may be 95% sure about the validity of its patent, but particularly risk averse or litigation averse, and willing to pay a good deal of money to rid itself of the 5% chance of a finding of invalidity. What is actually motivating a patent holder is apparently a question district courts will have to resolve on a case-by-case basis. The task of trying to discern whether a patent holder is motivated by uncertainty about its patent, or other legitimate factors like risk aversion, will be made all the more difficult by the fact that much of the evidence about the party's motivation may be embedded in legal advice from its attorney, which would presumably be shielded from discovery.

Second, the majority's position leads to absurd results. Let's say in 2005, a patent holder sues a competitor for infringement and faces a counterclaim that its patent is invalid. The patent holder determines that the risk of losing on the question of validity is low, but after a year of litigating, grows increasingly risk averse, tired of litigation, and concerned about the company's image, so it pays the competitor a "large" payment, *ante,* at 18, in exchange

for having the competitor honor its patent. Then let's say in 2006, a different competitor, inspired by the first competitor's success, sues the patent holder and seeks a similar payment. The patent holder, recognizing that this dynamic is unsustainable, litigates this suit to conclusion, all the way to the Supreme Court, which unanimously decides the patent was valid. According to the majority, the first settlement would violate the antitrust laws even though the patent was ultimately declared valid, because that first settlement took away some chance that the patent would be invalidated in the first go around. Under this approach, a patent holder may be found liable under antitrust law for doing what its perfectly valid patent allowed it to do in the first place; its sin was to settle, rather than prove the correctness of its position by litigating until the bitter end.

Third, this logic—that taking away any *chance* that a patent will be invalidated is itself an antitrust problem—cannot possibly be limited to reverse-payment agreements, or those that are "large." *Ibid.* The Government's brief acknowledges as much, suggesting that if antitrust scrutiny is invited for such cash payments, it may also be required for "other consideration" and "alternative arrangements." Brief for Petitioner 36, n. 7. For example, when a patent holder licenses its product to a licensee at a fixed monopoly price, surely it takes away some chance that its patent will be challenged by that licensee. According to the majority's reasoning, that's an antitrust problem that must be analyzed under the rule of reason. But see *General Elec. Co.*, 272 U. S., at 488 (holding that a patent holder may license its invention at a fixed price). Indeed, the Court's own solution—that patent holders should negotiate to allow generics into the market sooner, rather than paying them money—also takes away some chance that the generic would have litigated until the patent was invalidated.

Thus, although the question posed by this case is fundamentally a question of patent law—*i.e.*, whether Solvay's patent was valid and therefore permitted Solvay to pay competitors to honor the scope of its patent—the majority declares that such questions should henceforth be scrutinized by antitrust law's unruly rule of reason. Good luck to the district courts that must, when faced with a patent settlement, weigh the "likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances." *Ante,* at 9–10; but see *Pacific Bell Telephone Co.* v. *linkLine Communications, Inc.*, 555 U. S. 438, 452 (2009) ("We have repeatedly emphasized the importance of clear rules in antitrust law").

IV

The majority invokes "procompetitive antitrust policies," *ante*, at 9, but misses the basic point that patent laws promote consumer interests in a different way, by providing protection against competition. As one treatise explains:

> "The purpose of the rule of reason is to determine whether, on balance, a practice is reasonably likely to be anticompetitive or competitively harmless—that is, whether it yields lower or higher marketwide output. By contrast, patent policy encompasses a set of judgments about the proper tradeoff between competition and the incentive to innovate over the *long* run. Antitrust's rule of reason was not designed for such judgments and is not adept at making them." Hovenkamp §7.3, at 7–13 (footnote omitted).

The majority recognizes that "a high reverse payment" may "signal to other potential challengers that the patentee lacks confidence in its patent, thereby provoking additional challenges." *Ante,* at 16. It brushes this off, how-

ever, because of two features of Hatch-Waxman that make it "'not necessarily so.'" *Ibid.* First, it points out that the first challenger gets a 180-day exclusive period to market a generic version of the brand name drug, and that subsequent challengers cannot secure that exclusivity period—meaning when the patent holder buys off the first challenger, it has bought off its most motivated competitor. There are two problems with this argument. First, according to the Food and Drug Administration, all manufacturers who file on the first day are considered "first applicants" who share the exclusivity period. Thus, if ten generics file an application to market a generic drug on the first day, all will be considered "first applicants." See 21 U. S. C. §355(j)(5)(B)(iv)(II)(bb); see also FDA, Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day 4 (July 2003). This is not an unusual occurrence. See Brief for Generic Pharmaceutical Association as *Amicus Curiae* 23–24 (citing FTC data indicating that some drugs "have been subject to as many as *sixteen* first-day" generic applications; that in 2005, the average number of first-day applications per drug was 11; and that between 2002 and 2008, the yearly average never dropped below three first-day applications per drug).

Second, and more fundamentally, the 180 days of exclusivity simply provides *more* incentive for generic challenges. Even if a subsequent generic would not be entitled to this additional incentive, it will have as much or nearly as much incentive to challenge the patent as a potential challenger would in any other context outside of Hatch-Waxman, where there is no 180-day exclusivity period. And a patent holder who gives away notably large sums of money because it is, as the majority surmises, concerned about the strength of its patent, would be putting blood in water where sharks are always near.

The majority also points to the fact that, under Hatch-

Waxman, the FDA is enjoined from approving a generic's application to market a drug for 30 months if the brand name sues the generic for patent infringement within 45 days of that application being filed. *Ante*, at 16 (citing 21 U. S. C. §355(j)(5)(B)(iii)). According to the majority, this provision will chill subsequent generics from challenging the patent (because they will have to wait 30 months before receiving FDA approval to market their drug). But this overlooks an important feature of the law: the FDA may approve the application before the 30 months are up "if before the expiration of [the 30 months,] the district court decides that the patent is invalid or not infringed." §355(j)(5)(B)(iii)(I). And even if the FDA did not have to wait 30 months, it is far from clear that a generic would want to market a drug prior to obtaining a judgment of invalidity or noninfringement. Doing so may expose it to ruinous liability for infringement.

The irony of all this is that the majority's decision may very well discourage generics from challenging pharmaceutical patents in the first place. Patent litigation is costly, time consuming, and uncertain. See *Cybor Corp.* v. *FAS Techs., Inc.*, 138 F. 3d 1448, 1476, n. 4 (CA Fed. 1998) (opinion of Rader, J.) (en banc) (discussing study showing that the Federal Circuit wholly or partially reversed in almost 40 percent of claim construction appeals in a 30-month period); Brief for Generic Pharmaceutical Association as *Amicus Curiae* 16 (citing a 2010 study analyzing the prior decade's cases and showing that generics prevailed in 82 cases and lost in 89 cases). Generics "enter this risky terrain only after careful analysis of the potential gains if they prevail and the potential exposure if they lose." *Id.*, at 19. Taking the prospect of settlements off the table—or limiting settlements to an earlier entry date for the generic, which may still be many years in the future—puts a damper on the generic's expected value going into litigation, and decreases its incentive to sue in

the first place. The majority assures us, with no support, that everything will be okay because the parties can settle by simply negotiating an earlier entry date for the generic drug manufacturer, rather than settling with money. *Ante*, at 17. But it's a matter of common sense, confirmed by experience, that parties are more likely to settle when they have a broader set of valuable things to trade. See Brief for Mediation and Negotiation Professionals as *Amici Curiae* 6–8.

V

The majority today departs from the settled approach separating patent and antitrust law, weakens the protections afforded to innovators by patents, frustrates the public policy in favor of settling, and likely undermines the very policy it seeks to promote by forcing generics who step into the litigation ring to do so without the prospect of cash settlements. I would keep things as they were and not subject basic questions of patent law to an unbounded inquiry under antitrust law, with its treble damages and famously burdensome discovery. See 15 U. S. C. §15; *Bell Atlantic Corp.* v. *Twombly*, 550 U. S. 544, 558–559 (2007). I respectfully dissent.