turer to assure the Food and Drug Administration (FDA) that it will not infringe the brand-name's patent s. One way to provide such assurance (the "paragraph IV" route) is by certifying that any listed, relevant patent "is invalid or w ill 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 in fringement. 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

#### Syllabus

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 inva lid. 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 simp ly to what the holder of a valid patent could do does not by itself answer the anti trust question. Here, the paragraph IV litigation put the patent's validity and preclusive scope at issue, and the part ies' settlement-in which, the FTC alleges, the plaintiff agreed to pay the defendants millions to stay out of its market, even though the de fendants 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 settle ment's anticompetitive effects sole ly against patent law policy, and not against procompetitive antitrust policies as well. Both are rele

FTC 4

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# SUPREME COURT OF THE UNITED STATES

## No. 12–416

## FEDERAL TRADE COMMI SSION, 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-

## FTC v. ACTAVIS, INC.

## Opinion of the Court

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 cont ext 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.

## FTC v. ACTAVIS, INC.

## Opinion of the Court

vant patents. It can certify that any relevant patents have expired. It can request ap proval to market beginning when any still-in-force patents expire. Or, it can certify that any listed, relevant pate nt "is invalid or will not be infringed by the manufacture, use, or sale" of the drug

4

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).

В 1

#### FTC v. ACTAVIS, INC.

### Opinion of the Court

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 compet e 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 Litiga tion (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-

## 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 quest ion. 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 ou t 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, ma rket power, and potentially

#### FTC v. ACTAVIS, INC.

## Opinion of the Court

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 T HE 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 (1952I-18.ht a pateny lawful4 (1963), r78 e potential y18fderT0 1 Tn 14hndatenOil Tw Sin

agreements produced supra-pa tent-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-paten tee 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." lbid. 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) not lead the Court to confer was right about its patent did antitrust immunity. Far from it, the agreement was found to violate the Sherman Act. ld., 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

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 fightshould 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 counte rclaim) 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 guite 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 facilitat ing 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-

## FTC v. ACTAVIS, INC.

## Opinion of the Court

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 Cite as: 570 U. S. \_\_\_\_ (2013)

#### FTC v. ACTAVIS, INC.

#### Opinion of the Court

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 valuableindeed, it can be worth several hundred million dollars. See Hemphill, supra, at 1579; Brief for Petitioner 6. Subsequent challengers cannot secu re 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 c hallenger 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 ne cessarily provoke subsequent challenges. Second, a generic that files a paragraph IV after learning that the first f iler 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

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 unintent ionally, 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 compensati on 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 cost s 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 in dicator 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-thancompetitive 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 pay-

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 unlaw-The owner of a particularly valuable patent fulness. 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 conseguence 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-g enerated 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 240CTAVIS, INC.0 FTC

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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, "

## SUPREME COURT OF THE UNITED STATES

## No. 12–416

# FEDERAL TRADE COMMI SSION, 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 J USTICE 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 guestion 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.

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

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agreement, rather than litigation, is not precluded by the

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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 ex plains 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 poli cies," 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

4

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 Ibid. That second sentence follows only if such Act." 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 anti-Ante, at 10. It seems to have in mind a trust principles. 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 un lawful 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 pr otected 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

create a monopoly over the unpat ented 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 prece dents. 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 remarka ble, 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 pr imary 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 procom petitive thrust," in its words—and uses that policy to unsettle the established relationship between patent and antitrust law.

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 beyo nd 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.

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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 expira tion, 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 "n ecessary 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

Cite as: 570 U. S. \_\_\_\_ (2013)

R

13

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 correctne ss 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 problemcannot possibly be limited to reverse-payment agreements, or those that are "large." Ibid. The Government's brief acknowledges as much, suggesting that if antitrust scru tiny 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 prod uct 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.

Cite as: 570 U. S. \_\_\_\_ (2013)

17