FEB 4 - 2011

No. 10-762

IN THE

Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., *ET AL.*,
Petitioners,

v.

BAYER AG, *ET AL.*,
Respondents.

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

BRIEF IN OPPOSITION OF RESPONDENTS BARR LABORATORIES, INC., HOECHST MARION ROUSSEL, INC., WATSON PHARMACEUTICALS, INC., and THE RUGBY GROUP, INC.

DAVID E. EVERSON
HEATHER S. WOODSON
VICTORIA L. SMITH
STINSON MORRISON HECKER LLP
1201 Walnut Street
Kansas City, MO 64106
(816) 842-8600

CHRISTOPHER LANDAU, P.C.
Counsel of Record
KAREN N. WALKER, P.C.
EDWIN JOHN U
GREGORY L. SKIDMORE
KIRKLAND & ELLIS LLP
655 Fifteenth St., N.W.
Washington, DC 20005
(202) 879-5000
clandau@kirkland.com

February 4, 2011

Blank Page

TABLE OF CONTENTS

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, respondents state as follows:

1. Respondent Barr Laboratories, Inc. was wholly owned by Barr Pharmaceuticals, Inc. In December 2008, Barr Pharmaceuticals, Inc. was merged into a wholly owned subsidiary of Teva Pharmaceuticals USA, Inc., which itself is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., a publicly held company. After the merger, the surviving company changed its name to Barr Pharmaceuticals LLC. No publicly held company other than Teva Pharmaceutical Industries Ltd. directly or indirectly owns 10% or more of the stock of Barr Pharmaceuticals LLC.

2. Respondent Hoechst Marion Roussel, Inc. has been merged and its pertinent assets and liabilities now reside with sanofi-aventis U.S. LLC. Sanofi-aventis U.S. LLC is owned by Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals Inc., which are not publicly held. No other publicly held corporation owns 10% or more of its stock. Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals Inc. are ultimately owned by sanofi-aventis, which is publicly held.

3. Respondent Watson Pharmaceuticals, Inc. is a publicly held corporation. No publicly held corporation owns 10% or more of its stock.

4. Respondent The Rugby Group, Inc. is a subsidiary of respondent Watson Pharmaceuticals, Inc. No other publicly held corporation owns 10% or more of its stock.

TABLE OF AUTHORITIES

Page(s)

Cases

Constitution, Statutes, and Rules

Other Authorities

INTRODUCTION

This is at least the sixth petition to urge this Court to resolve an alleged conflict among the federal courts of appeals that does not exist. According to petitioners, "[t]he circuits are split three ways" on whether there can be an unlawful restraint of competition entirely within a patent's exclusionary zone. Pet. 13. That assertion is incorrect, which may explain why this Court has denied each of the previous petitions alleging this same conflict—including a petition arising out of the very same district court decision at issue here. *See Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, No. 08-1194, 129 S. Ct. 2828 (2009) (declining to review *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), which affirmed the district court decision at issue here); *Joblove v. Barr Labs., Inc.*, No. 06-830, 551 U.S. 1144 (2007) (declining to review *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006)); *FTC v. Schering-Plough Corp.*, No. 05-273, 548 U.S. 919 (2006) (declining to review *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005)); *Valley Drug Co. v. Geneva Pharms., Inc.*, No. 03-1175, 543 U.S. 939 (2004) (declining to review *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003)); *Andrx Pharms., Inc. v. Kroger Co.*, No. 03-779, 543 U.S. 939 (2004) (declining to review *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003)). This Court should follow the same path here. Nothing has changed since this Court denied the previous petitions, except that the Second Circuit has declined to disturb the very same district court decision at issue here and its own *Tamoxifen* decision, both of which this Court has previously declined to review.

The ruling below, moreover, is manifestly correct. The whole point of a patent is to encourage and reward invention by giving inventors a monopoly over their inventions for a limited time. The owner of a valid patent is thus *entitled* to restrain competition within the patent's scope, and does not violate the antitrust laws by doing so, at least where the patent litigation was not an objective sham and the patent was not procured by fraud. There is simply no basis for courts to impose antitrust liability by second-guessing the settlement of legitimate patent litigation. That straightforward point is the beginning and the end of the matter.

Petitioners' policy arguments about the supposed adverse effects of patent settlements are thus directed to the wrong forum. Those who wish to subject such settlements to antitrust scrutiny are free to ask Congress to craft such a regime. And in fact they *have* asked Congress to craft such a regime, but Congress has declined to do so. Regardless of whether patent settlements are "controversial" as policy matter, Pet. 2, they are not "controversial" as a legal matter, as evidenced by petitioners' inability to identify any conflict among the circuits on this score. Accordingly, as in the previous cases raising this precise issue, this Court should once again deny *certiorari*.

COUNTERSTATEMENT OF THE CASE

A. Factual Background

This case involves a challenge to a settlement of patent litigation. Respondents Bayer AG and Bayer Corp. owned and licensed the patent to the active ingredient in the prescription antibiotic ciprofloxacin hydrochloride, commonly known as Cipro. Pet. App.

13a, 36-37a, 39-40a. When respondent Barr Laboratories, a generic drug manufacturer, sought FDA approval to introduce a competing generic version of the drug pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355, Bayer brought a patent infringement action, Pet. App. 15-16a, 40-41a. Because the Cipro patent covered the drug's active ingredient, Barr did not deny that the proposed generic would infringe the patent, but instead challenged the patent's validity. Given that Barr did not contest infringement and had not yet made any infringing sales, Barr's challenge to the patent's validity was the central issue in the litigation. Thus, for all intents and purposes, Barr was the plaintiff and Bayer the defendant in the lawsuit. Barr and Bayer litigated these patent issues against each other for five years. Pet. App. 15-16a, 41a.

In 1997, on the eve of trial, the parties settled the case. Pet. App. 16-17a, 41-42a. As part of the settlement agreement, Barr and its litigation partners received both monetary consideration and a license to sell a competing ciprofloxacin product at least six months before the Cipro patent expired. Pet. App. 16-17a, 41-42a. Nothing in that agreement purported to preclude other parties from challenging the validity of the Cipro patent, and indeed several other generic drug manufacturers proceeded to do so—unsuccessfully. *See, e.g., Bayer AG v. Schein Pharms., Inc.*, 301 F.3d 1306, 1312-23 (Fed. Cir. 2002) (upholding validity of Bayer's Cipro patent); *see also Bayer AG v. Carlsbad Tech., Inc.*, No. 01 CV0867-B (S.D. Cal. June 7, 2002 & Aug. 7, 2002) (same); Pet. App. 43a. Bayer itself also sought re-examination of the Cipro patent by the U.S. Patent & Trademark Office (PTO), which reaffirmed its

validity. Pet. App. 42-43a. The Cipro patent expired in 2003. Pet. App. 13a & n.1, 42a.

B. Procedural History

Petitioners are direct purchasers of Cipro. Starting in 2000, both direct and indirect purchasers began filing lawsuits against respondents challenging the 1997 Cipro settlement agreement as unlawfully anticompetitive. Pursuant to 28 U.S.C. § 1407, the lawsuits were transferred to the U.S. District Court for the Eastern District of New York.

After extended discovery, the district court (Trager, J.) granted summary judgment in respondents' favor, holding that the Cipro settlement agreement was lawful because it did not "constrain[] competition beyond the scope of the patent claims." Pet. App. 91a. "Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." Pet. App. 79a. In analyzing a challenge to the settlement agreement, the district court emphasized, "it would be inappropriate to engage in an after-the-fact analysis of the patent's likely validity." Pet. App. 89-90a.

Petitioners appealed to the Second Circuit. While the appeal was pending, that court decided *Tamoxifen*, in which it endorsed the district court's analysis in this case. *See* 466 F.3d at 211-13. Writing for the court, Judge Sack (joined by Judge Raggi) explained that "[w]hatever damage is done to competition by settlement is done pursuant to the monopoly extended to the patent holder by patent

law unless the terms of the settlement enlarge the scope of that monopoly." *Id.* at 212-13. The court block-quoted the legal standard established by the district court in this case: "'Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.'" *Id.* at 213 (quoting Pet. App. 79a). Judge Pooler dissented, arguing that courts can and should engage in "a more searching inquiry" into patent settlements challenged under the antitrust laws. *Id.* at 228 (dissenting opinion). This Court declined to review *Tamoxifen*. *See Joblove*, 551 U.S. 1144 (2007).

The Second Circuit thereafter transferred to the Federal Circuit one of the appeals arising out of the district court's decision in this case. *See* Order (11/7/07). As the Second Circuit explained, that appeal (by the indirect-purchaser plaintiffs) included a claim arising under the patent laws, and therefore fell within the Federal Circuit's exclusive appellate jurisdiction. *See id.*; *see generally* 28 U.S.C. § 1295(a)(1).

The Federal Circuit decided the transferred indirect-purchaser case before the Second Circuit even heard oral argument in this direct-purchaser case. *See Ciprofloxacin*, 544 F.3d 1323. The Federal Circuit affirmed the grant of summary judgment in respondents' favor, and endorsed the Second Circuit's reasoning in *Tamoxifen*. In particular, the Federal Circuit held that "the essence of the inquiry is whether the [settlement] agreements restrict competition beyond the exclusionary zone of the

patent," and that "in the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment." *Id.* at 1336. Because the plaintiffs raised no genuine issue of material fact regarding any restraint on competition beyond the exclusionary zone of the Cipro patent, and failed to establish either fraud on the PTO or sham litigation, defendants were entitled to summary judgment. *See id.* at 1331-37. This Court declined to review that decision. *See Arkansas Carpenters*, 129 S. Ct. 2828 (2009).

In a *per curiam* opinion, a panel of the Second Circuit (which included Judge Pooler, the dissenter in *Tamoxifen*) also affirmed the district court's decision in this case under *Tamoxifen*. *See* Pet. App. 9-35a. Because petitioners "do not argue that the patent infringement lawsuit was a sham or that the Cipro patent was procured by fraud, ... the only reasonable basis for distinguishing *Tamoxifen* would be if [petitioners] demonstrated that the settlement agreement here, unlike in *Tamoxifen*, exceeded the scope of the Cipro patent." Pet. App. 26a. But petitioners "cannot establish this because a generic version of Cipro would necessarily infringe Bayer's patent," which covered the drug's active ingredient. *Id.* "Thus, Barr's agreement to refrain from manufacturing generic Cipro encompasses only conduct that would infringe Bayer's patent rights," *id.*, and petitioners' antitrust claims necessarily fail as a matter of law. Although the panel recognized that the result in this case was dictated by *Tamoxifen*, the panel "invite[d]" petitioners "to petition for rehearing in banc." Pet. App. 35a.

Not surprisingly, petitioners accepted that invitation. The Second Circuit, however, denied the petition for rehearing *en banc* over the lone dissent of Judge Pooler. *See* Pet. App. 1-8a.

REASONS FOR DENYING THE WRIT

I. The Decision Below Is Correct.

The U.S. Constitution expressly authorizes Congress "[t]o promote the Progress of Science and useful Arts" by granting inventors "the exclusive Right" to their inventions "for limited Times." U.S. Const. Art. I § 8 cl. 8. Congress has exercised that authority by enacting the federal patent laws, which expressly grant patent holders "the right to exclude others from making, using, offering for sale, or selling the invention" for a limited period of time. 35 U.S.C. § 154(a)(1). "[T]he essence of a patent grant," as this Court has explained, "is the right to exclude others from profiting by the patented invention." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980); *see also Precision Instrument Mfg. Co. v. Automobile Maint. Mach. Co.*, 324 U.S. 806, 816 (1945) ("[A] patent is an exception to the general rule against monopolies and to the right to access to a free and open market."); *E. Bement & Sons v. National Harrow Co.*, 186 U.S. 70, 91 (1902) ("The very object of [the patent] laws is monopoly.").

Because a patent confers the right to restrain competition within its exclusionary zone, by definition there can be no unlawful restraint of competition within that zone. "It is only when [a patent holder] steps *out* of the scope of his patent rights ... that he comes within the operation of the Anti-Trust Act." *United States v. General Elec. Co.*, 272 U.S. 476, 485 (1926) (emphasis added); *see also*

Schering-Plough, 402 F.3d at 1067 ("A patent holder does not incur antitrust liability when it chooses to exclude others from producing its patented work."); *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992) ("Should the restriction [on competition] be found to be reasonably within the patent grant, *i.e.*, that it relates to subject matter within the scope of the patent claims, that ends the [antitrust] inquiry."); *cf. United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963) ("[A] valid patent ... does not give the patentee any exemption from the provisions of the Sherman Act *beyond* the limits of the patent monopoly.") (emphasis added).

These points, as the Second Circuit recognized, dispose of this case. Petitioners "cannot establish" that the settlement agreement at issue here exceeded the scope of the Cipro patent "because a generic version of Cipro would necessarily infringe" the patent, which covered the active ciprofloxacin compound itself. Pet. App. 26a; *see also id.* ("Barr's agreement to refrain from manufacturing generic Cipro encompasses *only* conduct that would infringe Bayer's patent rights.") (emphasis added). Nor do petitioners contend that "the patent infringement lawsuit was a sham or that the Cipro patent was procured by fraud." *Id.* Accordingly, petitioners' challenge to the Cipro settlement agreement is necessarily a challenge to the monopoly granted by the Cipro patent, and fails as a matter of law.

Petitioners insist, however, that the Cipro settlement agreement violated the antitrust laws because the Cipro patent *might have been* invalid. *See* Pet. 2, 14-15, 22-23, 25-26. According to petitioners, the statutory presumption of patent

validity, *see* 35 U.S.C. § 282, is rebutted by a settlement agreement that includes a payment by the patent holder to the party challenging the patent's validity. *See* Pet. 4-5; *see also id.* at 23 ("[T]he fact that the brand made an exclusion payment is, at a minimum, sufficient evidence to satisfy the antitrust plaintiff's initial burden under the rule of reason."). A patent holder, petitioners assert, "would not have made the payment" if the patent were valid. Pet. 5.

That assertion is baseless. There are many reasons why parties settle litigation even if they believe they should and will prevail. For one thing, parties cannot know in advance if they will prevail; given the inherent uncertainty of litigation, "[n]o one can be *certain* that he will prevail in a patent suit." *Asahi Glass Co. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003) (Posner, J., by designation) (emphasis in original). Indeed, "[d]ue to the 'asymmetrics of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.'" *Schering-Plough*, 402 F.3d at 1075 (quoting *Valley Drug*, 344 F.3d at 1310). Petitioners' contrary approach essentially asks this Court to adopt a presumption of patent *invalidity* unknown, and contrary, to the law. Thus, whether the terms of a patent settlement agreement include a license, a payment, or both, such an agreement cannot subject the settling parties to treble-damages antitrust liability where (as here) the settlement does not exceed the scope of the patent, the patent litigation was not an objective sham, and the patent was not procured by fraud.

Prohibiting a lawsuit over patent validity—in contrast to any other type of lawsuit—from being settled for monetary consideration would discourage not only patent settlements but also challenges to patent validity. "A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive." *Asahi Glass*, 289 F. Supp. 2d at 994; *see also Tamoxifen*, 466 F.3d at 203 ("Rules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation.") (citing *Valley Drug*, 344 F.3d at 1308); *Schering-Plough*, 402 F.3d at 1075 ("[T]he caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product.").

Petitioners complain, however, that this regime allows patent holders to "muzzle" any challenge to the validity of their patents, *see* Pet. 26 (internal quotation omitted), and "buy a shield from judicial examination of the legitimacy of their patents," *id.* at 30. Again, petitioners are incorrect. The settlement of patent litigation resolves claims between the settling parties, but does not preclude *other* parties from challenging the patent's validity. Indeed, this case underscores the point: after the patent settlement at issue here, the patent's validity was challenged by other generic drugmakers—*unsuccessfully*. *See, e.g., Schein Pharms.*, 301 F.3d

at 1312-23; *Carlsbad Tech.*, No. 01 CV0867-B (S.D. Cal. June 7, 2002 & Aug. 7, 2002). Petitioners argue that a patent settlement "delays" any such additional challenges, Pet. 26, but such challenges can be brought at any time. Indeed, the Second Circuit rejected as "unpersuasive" petitioners' argument that the settlement agreement at issue here "caused other generic manufacturers to delay subsequent challenges." Pet. 27a. Moreover, under certain circumstances, the Government may even sue to cancel or annul a patent. *See, e.g.*, *United States v. Glaxo Group Ltd.*, 410 U.S. 52, 57-59 (1973). Petitioners' fundamental premise that a patent settlement allows a patent holder to "forgo judicial testing of the patent's validity," Pet. 2, is simply untrue.

II. The Decision Below Does Not Conflict With Decisions Of Other Courts Of Appeals.

Petitioners argue that this Court "should grant review because the circuit courts are divided over the standard for evaluating whether exclusion payments are anticompetitive." Pet. 13 (capitalization modified). In particular, petitioners allege that "[t]he circuits are split three ways" on this issue, *id.*, with (1) the Sixth and D.C. Circuits applying a "patent strength" standard, *id.* at 14-18 (citing *Cardizem*, 332 F.3d 896, and *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001)), (2) the Eleventh Circuit applying a "patent relitigation" approach, *see id.* at 18-20 (citing *Valley Drug*, 344 F.3d 1294), and (3) the Second and Federal Circuits applying the presumption of patent validity to settlement agreements within the scope of a patent, unless the patent was obtained by fraud or

the patent claim was a sham, *see id.* at 20-23 (citing, in addition to the decision below, *Tamoxifen*, 466 F.3d 187, and *Ciprofloxacin*, 544 F.3d 1323).

According to petitioners, the decision below "cannot be squared with those of other circuits." Pet. 2. Petitioners are wrong, and the "clear and wide" circuit conflict they allege, *id.* at 23, is illusory.

A. The Sixth and D.C. Circuits

Petitioners first assert that the decision below conflicts with *Cardizem*, in which the Sixth Circuit upheld a grant of partial summary judgment to plaintiffs challenging a patent settlement agreement. *See* Pet. 15-16. That assertion is incorrect; indeed, the Second Circuit in *Tamoxifen*, the Federal Circuit in *Ciprofloxacin*, and the district court in this case expressly negated any such conflict.

The settlement agreement at issue in *Cardizem* went *beyond* the scope of the patent monopoly; it "included not only a substantial reverse payment but also an agreement that the generic manufacturer would not market *non*-infringing products." *Tamoxifen*, 466 F.3d at 213-14 (emphasis added). It was thus "unlike the agreement" at issue in *Tamoxifen* (and here) which "did *not* extend the patent monopoly by restraining the introduction or marketing of unrelated or non-infringing products." *Id.* at 213 (emphasis added; citing *Cardizem*, 332 F.3d at 902, 908 & n.13); *see also* Pet. App. 59a ("The agreement at issue in [*Cardizem*] ... contained provisions that clearly exceeded any competitive restrictions accruing to the defendants under patent law."); *Ciprofloxacin*, 544 F.3d at 1335 (explaining that *Cardizem* is "distinguishable from this case" because the settlement agreement at issue there

"clearly had anticompetitive effects *outside* the exclusion zone of the patent") (emphasis added). Indeed, the United States has made this point repeatedly in recommending against review of the very circuit conflict alleged here. *See* Br. for the U.S. as Amicus Curiae, *Joblove v. Barr Labs., Inc.*, No. 06-830 (U.S. May 23, 2007), 2007 WL 1511527, at 16 n.7 ("*Cardizem* involved payments to exclude competition in drugs that did *not* fall within the scope of the allegedly infringed patent, and thus it is uncertain whether the per se rule employed by the Sixth Circuit extends beyond the unique circumstances of that case.") (emphasis in original); Br. for the U.S. as Amicus Curiae, *FTC v. Schering-Plough Corp.*, No. 05-273 (U.S. May 17, 2006), 2006 WL 1358441, at 16-17 (same); *see also id.* at 19 ("[T]he Second Circuit's decision [in *Tamoxifen*] did not involve drugs outside the patent claim and it thus does not create any split with the Sixth Circuit's *Cardizem* decision."); Br. for the U.S. as Amicus Curiae, *Andrx Pharms., Inc. v. Kroger Co.*, No. 03-779 (U.S. July 9, 2004), 2004 WL 1562075, at 11-15 (same).

Petitioners' argument that the decision below conflicts with the D.C. Circuit's decision in *Andrx* fails for the same reason. That case, as petitioners concede, involved "the same agreement that was at issue in *Cardizem*." Pet. 16. Because that agreement restrained competition *beyond* a patent's scope, it is readily distinguishable from the settlement agreement at issue here. *See Tamoxifen*,

466 F.3d at 213-14; *Ciprofloxacin*, 544 F.3d at 1335; Pet. App. 59-60a.[1]

B. The Eleventh Circuit

Petitioners next assert that the decision below conflicts with *Valley Drug*, in which the Eleventh Circuit reversed a grant of partial summary judgment to plaintiffs challenging a patent settlement agreement. *See* Pet. 18-20. Again, that assertion is incorrect.

Valley Drug, like the decision below, held that a settlement agreement resolving a challenge to patent validity does not violate the antitrust laws to the extent such an agreement does not exceed the patent's scope, at least insofar as the underlying patent litigation was not a sham and the patent was not procured by fraud. *See* 344 F.3d at 1308-10 & nn.21, 22. The Eleventh Circuit thus reversed a grant of partial summary judgment in the plaintiffs'

---

[1] Curiously, petitioners also argue that this Court should grant review on the ground that the decision below conflicts with an administrative decision by the Federal Trade Commission. *See* Pet. 17-18 (citing *In re Schering-Plough Corp.*, F.T.C. Docket No. 9297, 2003 WL 22989651 (F.T.C. Dec. 8, 2003), *vacated*, 402 F.3d 1056 (11th Cir. 2005)). That argument is, to put it mildly, a stretch. This Court has never identified an asserted conflict between an administrative enforcement agency and a court as a basis for review. *See* S. Ct. R. 10. That is not surprising, because administrative enforcement decisions are subject to judicial review in their own right. Indeed, the administrative decision on which petitioners rely was not only challenged but also *vacated* by the Eleventh Circuit on precisely the ground at issue here. *See Schering-Plough*, 402 F.3d at 1075-76. The FTC unsuccessfully sought this Court's review of the Eleventh Circuit's decision. *See* 548 U.S. 919 (2006).

favor, and remanded for the district court to determine whether the challenged agreements "have effects *beyond* the exclusionary effect of [the disputed] patent," in which case they "may then be subject to traditional antitrust analysis to assess their probable anticompetitive effects." *Id.* at 1312 (emphasis added); *see also id.* ("We recognize the patent exception to antitrust liability, but also recognize that the exception is limited by the terms of the patent and the statutory rights granted the patentee.").

That approach is entirely consistent with the approach followed by the Second and Federal Circuits, and indeed both of those courts (as well as the district court in this case) followed the Eleventh Circuit's approach. *See Ciprofloxacin*, 544 F.3d at 1335-37; *Tamoxifen*, 466 F.3d at 212-13; Pet. App. 24a, 54-58a. Again, the United States made this point in recommending against review of the very circuit conflict alleged here. *See* Br. for the U.S. as Amicus Curiae, *FTC v. Schering-Plough Corp.*, No. 05-273 (U.S. May 17, 2006), 2006 WL 1358441, at 19 ("Far from expressing any disagreement with the Eleventh Circuit's decision below, ... the Second Circuit explicitly approved of the Eleventh Circuit's focus on whether 'the exclusionary effects of the agreement exceed the scope of the patent's protection.'") (quoting *Tamoxifen*, 466 F.3d at 212).

Petitioners caricature *Valley Drug* as holding that "the lawfulness of an exclusion payment is determined by relitigating the patent issues as part of the antitrust case." Pet. 5; *see also id.* at 18 (asserting that the Eleventh Circuit requires courts to "engag[e] in an *ex-post* judicial determination of

the patent issues as part of the antitrust case"). The Eleventh Circuit held nothing of the sort, except insofar as it recognized—as have the Second and Federal Circuits—that a patent's scope is relevant to the antitrust analysis because a patent holder does not unlawfully restrain competition when acting within that scope. *See Valley Drug*, 344 F.3d at 1307-08; *see also Schering-Plough*, 402 F.3d at 1076 ("What we must focus on is the extent to which the exclusionary effects of the [settlement] agreement fall within the scope of the patent's protection.").

Contrary to petitioners' suggestion, *see* Pet. 18, the Eleventh Circuit did *not* hold that it is necessary or appropriate for courts to assess a patent's validity in resolving an antitrust challenge to a settlement agreement. Not surprisingly, petitioners cite nothing in *Valley Drug* so holding, and other courts have recognized that the Eleventh Circuit has *rejected* that approach. *See Ciprofloxacin*, 544 F.3d at 1336 ("[W]e agree with the Second and Eleventh Circuits and with the district court that, in the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment."); *id.* at 1336 n.12 ("[T]he Eleventh Circuit did *not* consider or rely on evidence of patent invalidity in ... *Valley Drug*.") (emphasis added); Pet. App. 54a ("The Eleventh Circuit in *Valley Drug* ... held that to the extent the effects of the subject settlement agreements are within the scope of the exclusionary potential of the patent, such effects are not subject to ... antitrust condemnation, *even where the patent is later held invalid*.") (emphasis added); *id.* at 56a ("[*Valley Drug*] reserved any *post hoc* validity analysis for

those cases in which the patent was procured by fraud or known by the patentee to be invalid.").

And even assuming that *Valley Drug* left any ambiguity on this score, the Eleventh Circuit dispelled any such ambiguity in *Schering-Plough*. As the Eleventh Circuit explained in that case, a patent's "validity" *vel non* has no bearing in the antitrust inquiry, as long as the agreement does not exceed the patent's scope. 402 F.3d at 1075.

III. The Decision Below Does Not Conflict With This Court's Decisions.

Petitioners further contend that "this Court should grant review because the Second Circuit's standard conflicts with this Court's precedents." Pet. 23 (capitalization modified). That is so, they assert, because "[t]he Second Circuit has elevated the rebuttable presumption of validity into an *ironclad right* of patentees to exclude competition." *Id.* (emphasis added). That assertion is manifestly incorrect, and the alleged conflict with this Court's patent and antitrust cases is fanciful.

A. Patent cases

Petitioners first argue that the decision below conflicts with a line of this Court's cases "emphasiz[ing] that judicial testing of patent validity is essential precisely because the issuance of a patent by the PTO was not intended to have—and does not have—the *conclusive significance* accorded by the Second Circuit." Pet. 25 (emphasis added).

The premise of that argument is incorrect: the Second Circuit never suggested that the statutory presumption of validity was "conclusive." *Id.* Rather, the Second Circuit recognized only that a

patent settlement, regardless of its terms, does not create a presumption of invalidity. *See Tamoxifen*, 466 F.3d at 203-04, 210; *see also Ciprofloxacin*, 544 F.3d at 1337; *Schering-Plough*, 402 F.3d at 1066-68; *Valley Drug*, 344 F.3d at 1306-08; Pet. App. 69-93a. Indeed, the Second Circuit has emphasized that the statutory presumption of patent validity is *not* the cornerstone of the analysis, and that "irrespective of whether there was a presumption," a patent holder is "entitled to protect its ... patent monopoly through settlement." *Tamoxifen*, 466 F.3d at 209 n.22.

Contrary to petitioners' assertion, there is no federal "policy in favor of judicial examination of patent validity," Pet. 30, that precludes parties from settling a challenge to patent validity. The federal patent laws neither compel anyone to challenge a patent's validity in the first place nor prohibit anyone from settling such a challenge on whatever terms the parties see fit, as long as such a settlement does not exceed the patent's scope. Contrary to petitioners' suggestion, *see* Pet. 9-10; *id.* at 25 n.9, there is no basis in law or logic for distinguishing between settlements that give a patent challenger a license and settlements that give a patent challenger a payment—*all* settlements involve consideration, and the form of that consideration has no bearing on the lawfulness of the settlement. *See, e.g.*, *Asahi Glass*, 289 F. Supp. 2d at 994 ("*[A]ny* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement.") (emphasis in original).

The cases on which petitioners rely are wholly inapposite. The issue in both *Edward Katzinger Co.*

v. Chicago Metallic Mfg. Co., 329 U.S. 394 (1947), and *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), was whether a patent licensee was estopped from challenging the patent's validity. This Court held in both cases that the federal patent laws did not create any such estoppel, *see* 329 U.S. at 399-401, 395 U.S. at 669-70, but did not remotely suggest that a licensee (or anyone else) is either compelled to launch such a challenge or precluded from settling it on terms the parties see fit.

The issue in *Cardinal Chem. Co. v. Morton Int'l Inc.*, 508 U.S. 83 (1993) was whether a determination of patent non-infringement precluded a court from reaching the issue of patent validity. In holding that courts were entitled to reach the validity issue, this Court noted that the enforcement of invalid patents is undesirable, *see id.* at 101-02 & n.24, but did not suggest that this unremarkable point either compels anyone to challenge patent validity or precludes anyone from settling such a challenge on terms the parties see fit.

The issue in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006), was whether a patent holder is automatically entitled to enjoin an infringer, or must satisfy the traditional standard for obtaining such equitable relief. By holding that the patent laws do not obviate the need to meet the traditional standard, *see id.* at 391-92, this Court did not call into question the statutory presumption of patent validity, or suggest that anyone is either compelled to challenge patent validity or precluded from settling such a challenge on terms the parties see fit.

And the issue in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), was whether a licensee had

standing to challenge a patent's validity without terminating or breaching the license agreement. In holding that a licensee did have such standing, *see id.* at 130-36, the Court again did not suggest that anyone is compelled to challenge patent validity or precluded from settling such a challenge on terms the parties see fit.

It is thus not true that the decision below "conflicts with this Court's patent cases." Pet. 24. Petitioners simply wrench snippets of language out of context and describe those cases at a level of generality that has no bearing on the issue presented here.

B. Antitrust cases

Petitioners next argue that the decision below "violates this Court's fundamental antitrust principles," insofar as "this Court has held that it is anticompetitive for a firm to pay a competitor to exit or stay out of the market." Pet. 30.

But the cases on which petitioners rely in support of that argument are inapposite, because they do not involve competition within the scope of a patent. As noted above, this Court has long recognized that the patent laws "are in pari materia with the antitrust laws and modify them pro tanto." *Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964). Antitrust cases outside the patent context thus shed no light on the issue presented here, and certainly do not give rise to the "conflict" alleged by petitioners.

Not surprisingly, therefore, petitioners beat a hasty retreat from that alleged "conflict" to the more modest assertion that "this Court has never afforded patentees antitrust immunity for paying competitors

not to try to overcome them." Pet. 31. But that assertion proves nothing, as it is equally true that this Court has never held that a settlement agreement renders a patent presumptively invalid. Leaving patent holders subject to antitrust liability even for a settlement that does not exceed the patent's scope, does not involve sham litigation, or does not involve a patent procured by fraud would upset the balance between the patent and antitrust laws that has always been the polestar of this Court's jurisprudence in this area. *See, e.g., Glaxo*, 410 U.S. at 58; *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 179-80 (1965) (Harlan, J., concurring); *Singer*, 374 U.S. at 189, 196-97; *General Electric*, 272 U.S. at 485.

IV. The Decision Below Does Not Warrant This Court's Review In The Absence Of A Conflict.

Because the decision below does not conflict with any decision of another court of appeals or this Court, petitioners are ultimately left with nothing more than an argument that patent settlements of the type at issue here represent bad public policy. In essence, petitioners contend that the public policy favoring competition (which underlies the antitrust laws) should trump the public policy favoring innovation (which underlies the patent laws) so as to allow antitrust claims within the scope of a patent. In our democratic system, however, such far-reaching policy arguments must be directed to Congress, not the courts.

And such policy arguments *have* been directed to Congress—repeatedly. Numerous bills have been introduced in recent years that would have altered

the law governing patent settlements. *See, e.g.*, S. 27, 112th Cong. (2011); S. 3677 (amend.), 111th Cong. (2010); S. 369, 111th Cong. (2009); H.R. 3962, 111th Cong. (2009); H.R. 1706, 111th Cong. (2009); S. 316, 110th Cong. (2007); H.R. 1432, 110th Cong. (2007); S. 3582, 109th Cong. (2005). None of these bills, however, has passed. Needless to say, in the absence of a conflict, there is no basis for the judicial branch to take up policy arguments on which the political branches are fully engaged.

Indeed, legislative action taken during the pendency of this case makes this a poor vehicle to address petitioners' arguments. Congress amended the Hatch-Waxman Act in 2003 in ways that addressed some of petitioners' theories of competitive harm. *See* Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. As the United States noted in recommending against *certiorari* in *Tamoxifen* (another case governed by the pre-2003 regime), the 2003 amendments "altered the regulatory dynamic" in relevant ways, and thereby make it "preferable" to address the question presented in *Tamoxifen* (and here), if at all, "in a case that arises under the current regulatory regime." Br. for the U.S. as Amicus Curiae, *Joblove v. Barr Labs., Inc.*, No. 06-830 (U.S. May 23, 2007), 2007 WL 1511527, at 19-20.

And petitioners' insistence that patent settlements of the type at issue here are "routine[]" and "not abating," Pet. 2, 35, only underscores that it would be imprudent for this Court to grant review at this juncture. If indeed patent settlement agreements are as "controversial" as petitioners suggest, Pet. 2, then a conflict can be expected to

develop as the issue percolates among the lower courts. It is neither necessary nor appropriate for this Court now to jump into the fray.

CONCLUSION

For the foregoing reasons, this Court should deny the petition for writ of certiorari.

Respectfully submitted,

DAVID E. EVERSON
HEATHER S. WOODSON
VICTORIA L. SMITH
STINSON MORRISON HECKER LLP
1201 Walnut Street
Kansas City, MO 64106
(816) 842-8600

Counsel for Respondents Hoechst Marion Roussel, Inc., Watson Pharmaceuticals, Inc., and The Rugby Group, Inc.

CHRISTOPHER LANDAU, P.C.
Counsel of Record
KAREN N. WALKER, P.C.
EDWIN JOHN U
GREGORY L. SKIDMORE
KIRKLAND & ELLIS LLP
655 Fifteenth St., N.W.
Washington, DC 20005
(202) 879-5000

Counsel for Respondent Barr Laboratories, Inc.

February 4, 2011

Blank Page