No. 08-1194

IN THE

Supreme Court of the United States

ARKANSAS CARPENTERS HEALTH AND WELFARE FUND, PAPER, A.F. OF L., ET AL.,

Petitioners,

v.

BAYER AG AND BAYER CORP., ET AL.,

Respondents.

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

RESPONDENTS BAYER AG & BAYER CORP.'S BRIEF IN OPPOSITION

PHILLIP A. PROGER
KEVIN D. MCDONALD
LAWRENCE D. ROSENBERG
JONES DAY
51 Louisiana Ave., N.W.
Washington, D.C. 20001
(202) 879-3939

FRED H. BARTLIT, JR.
Counsel of Record
PETER B. BENSINGER, JR.
MICHAEL J. VALAIK
PAUL J. SKIERMONT
BARTLIT BECK HERMAN
PALENCHAR & SCOTT LLP
54 West Hubbard St.
Suite 300
Chicago, IL 60654
(312) 494-4400

Counsel for Respondents Bayer AG & Bayer Corp.

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QUESTION PRESENTED

Whether a settlement of patent litigation that excludes no more competition than the exclusionary effect of the patent gives rise to antitrust liability where there was no fraud in procuring the patent, and where the underlying patent litigation was not objectively baseless?

CORPORATE DISCLOSURE STATEMENT

Bayer Corporation is a wholly-owned subsidiary of Bayer AG. There is no publicly-held company that owns more than 10% of the stock of Bayer AG.

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INTRODUCTION

This case arises out of payments by Bayer AG and Bayer Corporation (collectively, "Bayer") to Barr Laboratories, Inc. ("Barr") to settle patent litigation over Barr's generic challenge to the validity of Bayer's patent on its blockbuster antibiotic, Cipro. The patent claimed Cipro's active ingredient, ciprofloxacin, which also must be the active ingredient in any "generic" version of the drug. Hence, all versions of generic Cipro, however formulated, infringed Bayer's patent. By excluding this infringing competition, the Bayer-Barr settlement was within the Cipro patent's exclusionary effect.

After the settlement, Bayer voluntarily re-submitted its patent to the Patent and Trademark Office ("PTO") for reexamination. The PTO confirmed the patentability of the relevant claim to ciprofloxacin. Bayer then defeated three later generic challenges to the validity of the Cipro patent, with the Federal Circuit affirming judgment in Bayer's favor in the two cases involving an appeal. In the case at issue, the Federal Circuit affirmed the district court's finding that there was no fraud on the PTO. The Petition does not challenge this finding.

The Court should deny certiorari for three principal reasons. *First*, there is no conflict among the circuits on the legal issue in this case. Rather, the circuits have uniformly held, as the Federal Circuit did below, that absent fraud on the PTO or "sham" litigation, a settlement within the exclusionary scope of a patent does not give rise to antitrust liability.

Second, this case presents a poor vehicle for this Court's review. As indirect purchasers, Petitioners present no live federal claims for review, creating a vehicle problem that the Solicitor General has emphasized in opposing certiorari in similar cases. In addition, after the settlement, Congress amended the regulatory scheme governing this case. Finally, Petitioners have made no attempt to articulate a rule of decision that should govern antitrust claims arising out of patent settlements. This Court thus has no assurance that any alternative standard it might adopt has been considered by *any* court of appeals, or would make a difference in the result reached by the courts below.

Third, the legal rule that the circuits have adopted is correct and workable, and the courts below applied it correctly to the facts of this case. The Court should therefore deny the Petition.

COUNTERSTATEMENT OF THE CASE

1. Bayer holds U.S. Patent No. 4,670,444 (the "'444 patent"), a compound patent that claims the molecule ciprofloxacin hydrochloride. Pet. App. 4a. This molecule is the sole active ingredient in Bayer's Cipro product. *Id.* Because '444 covers Cipro's active ingredient, it covers all ciprofloxacin formulations by definition, and any generic version of Cipro would infringe Bayer's patent. *Id.* at 43a-44a.

The '444 patent issued on June 2, 1987 and expired on December 9, 2003. *Id.* at 4a. The FDA granted Bayer an additional six months of "pediatric exclusivity" because Bayer tested and verified the

drug's effectiveness for children. *Id.* Thus, no generic ciprofloxacin could lawfully enter the market until June 9, 2004. Since that date, generic Cipro has been widely available. *See* FDA, Center for Drug Evaluation and Research, *First-Time Generics – June 2004*, http://www.fda.gov/cder/ogd/approvals/1stgen0604.htm (last visited May 20, 2009).

2. On December 6, 1991, Barr gave notice that it had filed a "Paragraph IV" Abbreviated New Drug Application ("ANDA") under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("Hatch-Waxman"),[1] by which it sought FDA approval to market a generic version of Cipro before '444's expiration. *See* Pet App. 4a; 21 U.S.C. § 355(j)(2)(A)(vii)(IV). To support its Paragraph IV submission, Barr alleged that '444 was invalid and unenforceable. Pet. App. 4a. But "[b]ecause the '444 Patent claims the active ingredient in Cipro and because Barr was required in its ANDA to certify that its generic version of Cipro was bioequivalent to Bayer's Cipro, there is no dispute that Barr's product would have infringed Bayer's patent." *Id.* at 43a-44a.

Pursuant to Hatch-Waxman, Bayer sued Barr for patent infringement in the United States District Court for the Southern District of New York. *Id.* at 5a. While the case was pending, The Rugby Group, Inc. ("Rugby"), a subsidiary of Hoechst Marion Roussel, Inc. ("HMR"), entered into a "Litigation

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[1] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended, 21 U.S.C. § 355).

Funding Agreement" with Barr. *Id.* In that agreement, Rugby promised "to help Barr fund its litigation against Bayer in exchange for half of any profits realized from Barr's sale of ciprofloxacin." *Id.* (HMR later sold Rugby to respondent Watson Pharmaceuticals, Inc.).

Bayer and Barr settled shortly before trial. *Id.* at 5a-6a. Barr agreed to a Consent Judgment affirming '444's validity. *Id.* at 6a. Barr also agreed to change its ANDA certification from a Paragraph IV to a Paragraph III, such that Barr could market generic Cipro only after '444 expired. *Id.* Bayer agreed to license Barr to sell a competing ciprofloxacin product at least six months before Bayer's patent expired, and Barr in fact commenced marketing on June 9, 2003. Bayer also agreed to make settlement payments that ultimately totaled $398.1 million. *Id.* at 7a n.5. This sum constituted 6.5% of Bayer's U.S. gross sales of oral Cipro tablets for the payment period ($6.1 billion). Aff. of Raymond Rasimas ¶ 3, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, No. 1:00-MDL-1383 (E.D.N.Y. May 26, 2004) ("*Cipro* MDL") (Supplemental Appendix ("Supp. App.") at 2a).

3. After settling, Bayer submitted '444 for reexamination by the PTO, Pet. App. 7a, providing the examiner with a roadmap of Barr's invalidity arguments. The PTO issued a reexamination certificate confirming the validity of the remaining claims of the '444 patent. *Id.* "In particular, the patentability of claim 12, directed to ciprofloxacin hydrochloride, was confirmed." *Id.*

Subsequently, four other generic companies, Ranbaxy, Mylan, Schein, and Carlsbad, filed ANDA Paragraph IV certifications seeking to market generic Cipro. *Id.* Bayer sued each for infringement of the '444 patent. *Id.* at 7a-8a. The Ranbaxy challenge was dismissed as moot following Ranbaxy's withdrawal of its ANDA IV certification. *Id.* at 8a. Bayer defeated Schein and Mylan on summary judgment, and the Federal Circuit affirmed. *Id.* at 7a-8a. Bayer prevailed after a bench trial in the Carlsbad case, *id.* at 8a, and Carlsbad did not appeal.

4. Starting in 2000, direct and indirect purchasers of Cipro filed federal and state antitrust challenges to the settlement. *Id.* The MDL Panel consolidated those cases before Judge David G. Trager in the Eastern District of New York. *Id.* In 2003, Judge Trager denied all plaintiffs' motions for partial summary judgment, and refused to find the settlement per se unlawful under the antitrust laws. *Id.*; *see In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003) ("*Cipro I*"). The indirect purchaser plaintiffs—Petitioners here—then amended their complaint to add a purported *state law* antitrust claim against Bayer (Count V) alleging that Bayer engaged in "sham" litigation and fraud on the PTO in procuring the '444 patent. Petitioners thus sought to allege a state-law claim based on *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S.

172 (1965).[2] Pet. App. 9a. The direct purchaser plaintiffs did not amend their complaints to include such a claim.

On March 31, 2005, Judge Trager granted judgment for Defendants on all claims attacking the settlement. *Id.* at 113a-114a; *see In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005) ("*Cipro II*") (Pet. App. 39a), *aff'd*, 544 F.3d 1323 (Fed. Cir. 2008) (Pet. App. 1a). Judge Trager applied the legal rule that has been endorsed by every circuit to have considered the legality of a patent settlement within the exclusionary scope of the patent: "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. 83a. Because "plaintiffs ha[d] not shown that the [Settlement] Agreements had anti-competitive effects beyond the scope of the '444 Patent," their claims failed. *Id.* at 96a. Judge Trager also dismissed Petitioners' Count V (directed at Bayer only) as preempted by federal patent law and noted that no fraud on the PTO had occurred. *Id.* at 113a.

All Plaintiffs appealed to the Second Circuit. On November 7, 2007, the Second Circuit granted

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[2] In *Walker Process*, this Court held "that the enforcement of a patent procured by fraud on the Patent Office may be violative of § 2 of the Sherman Act provided the other elements necessary to a § 2 case are present." 382 U.S. at 174.

Defendants' motion to transfer with respect to the appeal of Petitioners (the indirect purchaser plaintiffs), due to their state-law *Walker Process* claim. *Id.* at 36a-38a. The Second Circuit denied the motion as to the appeals of the direct purchasers, *id.*, which remain pending in the Second Circuit.

On October 15, 2008, a unanimous panel of the Federal Circuit affirmed Judge Trager's ruling in favor of Defendants. *Id.* at 3a; *see In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008). The court rejected Petitioners' argument that Judge Trager had treated the settlement as "per se legal." Pet. App. 16a. Rather, the court reaffirmed the legal rule applied by Judge Trager and adopted by the other circuits:

> We conclude that in cases such as this, wherein all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent. The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent. This analysis has been adopted by the Second and the Eleventh Circuits and by the district court below and we find it to be completely consistent with Supreme Court precedent. *See Walker*

> *Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 175-77 (1965) (holding that there may be a violation of the Sherman Act when a patent is procured by fraud, but recognizing that a patent is an exception to the general rule against monopolies).

Pet. App. 23a-24a (parallel citations omitted).

The Federal Circuit rejected Petitioners' arguments to the contrary. First, the court disagreed that other circuits applied "greater antitrust scrutiny than" Judge Trager did. *Id.* at 19a. Rather, the court held that Judge Trager's approach was consistent with that of the Second and Eleventh Circuits, and that the Sixth Circuit's ruling in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896 (6th Cir. 2003), was legally consistent and factually distinguishable because "the agreement [in that case] clearly had anticompetitive effects outside the exclusion zone of the patent." Pet. App. 21a. Second, the Federal Circuit held that, absent fraud 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 24a. Third, the court concluded that Petitioners failed to show that Defendants' conduct created a "bottleneck," or otherwise excluded further generic entry. *Id.* at 33a.

Petitioners filed a Petition for Panel Rehearing and Rehearing En Banc. The Federal Circuit denied that petition on December 23, 2008. *Id.* at 117a-118a. This Petition followed.

REASONS FOR DENYING THE PETITION

I. THERE IS NO CONFLICT AMONG THE CIRCUITS ON THE QUESTION PRESENTED

"A principal purpose for which [this Court] use[s] [its] certiorari jurisdiction . . . is to resolve conflicts among the United States courts of appeals and state courts concerning the meaning of provisions of federal law." *Braxton v. United States*, 500 U.S. 344, 347 (1991); *accord Bunting v. Mellen*, 541 U.S. 1019, 1021 (2004) (Stevens, J.). Petitioners attempt to manufacture a split in the circuits by raising a straw man: the false assertion that the Federal Circuit below held Hatch-Waxman settlements to be "per se legal" and "immune" from antitrust scrutiny. As the Federal Circuit explained, however, no court has so held. Rather, the decisions of the courts of appeals are in harmony, and there is no conflict to resolve.

A. The Circuits Have Developed A Uniform Standard For Assessing Hatch-Waxman Settlements And Have Applied It Consistently

The circuits have uniformly held that settlements within the scope of a patent do not give rise to antitrust liability so long as the patent was not procured by fraud or enforced through litigation that is "objectively baseless." Every court of appeals decision, including the one that Petitioners rely on most heavily to manufacture a conflict (*Cardizem*), cited Judge Trager's reasoning in this case with approval. *See In re Tamoxifen Citrate Antitrust*

Litig., 466 F.3d 187, 213 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1068 (11th Cir. 2005); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003); *Cardizem*, 332 F.3d at 908 n.13. As we show below, in each case, the United States has represented to this Court that no conflict warranting review existed. In each case, this Court denied certiorari.

In the case at issue, the Federal Circuit affirmed Judge Trager's opinion in *Cipro II* and agreed that the key inquiry is "whether the agreements restrict competition beyond the exclusionary zone of the patent." Pet. App. 24a. The Second Circuit adopted the same test in *Tamoxifen*: "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." 466 F.3d at 213 (internal quotation marks omitted). In reaching its conclusion, the Second Circuit in *Tamoxifen* expressly agreed with the reasoning of Judge Trager in *Cipro II*—the very same decision that the Federal Circuit affirmed in this case below.

In *Schering-Plough* and *Valley Drug*, the Eleventh Circuit also held that the "exclusionary effect of the patent" is the starting point for the antitrust analysis. *Valley Drug*, 344 F.3d at 1306 (internal quotation marks omitted); *Schering-Plough*, 402 F.3d at 1068. Thus, according to the Eleventh Circuit, the antitrust analysis requires evaluation of "(1) the scope of the exclusionary potential of the patent; (2)

the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." *Schering-Plough*, 402 F.3d at 1066 (citing *Valley Drug*, 344 F.3d at 1312). In *Schering-Plough*, the Eleventh Circuit applied this analysis as follows: "[T]here has been no allegation that the '743 patent itself is invalid or that the resulting infringement suits against Upsher and ESI were 'shams.' . . . Therefore, the proper analysis now turns to whether . . . the challenged agreements restrict competition beyond the exclusionary effects of the '743 patent." *Id.* at 1068.

In addition to Judge Trager, all of these courts have relied upon the reasoning of Judge Richard Posner, sitting by designation, in *Asahi Glass Co. v. Pentech Pharmaceuticals, Inc.*:

> A firm that has received a patent from the patent office (and not by fraud . . .) . . . is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them . . . unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it . . . .

289 F. Supp. 2d 986, 992-93 (N.D. Ill. 2003); *see* Pet. App. 27a; *Tamoxifen*, 466 F.3d at 210; *Schering-Plough*, 402 F.3d at 1067, 1074-75. Thus, the rule of the circuit courts ensures that worthless or "objectively baseless" patents cannot be used to create actual adverse effects on competition.

B. There Is No Conflict Among The Circuits Warranting Certiorari

Petitioners allege two conflicts between the Federal Circuit's ruling below and the decisions of the other circuits: (1) a conflict with the Sixth Circuit's holding in *Cardizem*, and (2) a conflict with the Eleventh Circuit's purported evaluation of the size of the payments and strength of the patent. Neither alleged conflict exists.

1. *Cardizem.* Contrary to Petitioners' assertion, Pet. 20-21, *Cardizem* did not hold that reverse payments are per se illegal. Instead, the Sixth Circuit found that the terms of that settlement agreement imposed restraints *beyond* the exclusionary effect of the patent. In the very passage that Petitioners rely upon, the Sixth Circuit in *Cardizem* cited *with approval* Judge Trager's opinion below in *Cipro I*, in which he observed that the Cardizem agreement had imposed restraints beyond the patent's scope. *See Cardizem*, 332 F.3d at 908 n.13 ("As the court in *In re Ciprofloxacin* observed, '[w]hen the *Cardizem* [district] court condemned the HMR/Andrx Agreement, it emphasized that the agreement [there] restrained Andrx from marketing other bioequivalent or generic versions of Cardizem that were not at issue in the pending litigation[.] Thus, the court found that the agreement's restrictions extended to noninfringing and/or potentially noninfringing versions of generic Cardizem.'") (first three alterations in original).

The United States also recognized in its briefs to this Court in *Cardizem*, *Schering-Plough*, and

Tamoxifen that *Cardizem* is distinguishable. In response to the petition for certiorari in *Cardizem*, the FTC and the Solicitor General jointly explained that *Cardizem* and the Eleventh Circuit's decision in *Valley Drug* "*do not present a square conflict* that necessitates this Court's review at this time." Brief for United States as Amicus Curiae at 11, *Andrx Pharms., Inc. v. Kroger Co.*, No. 03-779 (U.S. July 9, 2004), 2004 WL 1562075 ("*Cardizem* Br.") (emphasis added). Relying expressly on *Cardizem*'s citation to Judge Trager's *Cipro* decision, *id.* at 14-15, the United States explained that the Cardizem agreement was found "to cover petitioner's marketing not only of allegedly infringing products but also of non-infringing or potentially non-infringing products that were not at issue in the patent litigation." *Id.* at 7; *see also id.* at 13-15. The United States rejected the reading of *Cardizem* that Petitioners advance here, noting that if *Cardizem* were construed to "require application of a per se rule" for "every settlement agreement that includes a reverse payment in exchange for the exclusion from the market of an allegedly infringing product," "the court of appeals' decision would be *erroneous*." *Id.* at 12 (emphasis added).

The United States in *Schering-Plough* and *Tamoxifen* reaffirmed its position that there is no conflict between *Cardizem* and subsequent court of appeals decisions. *See* Brief for United States as Amicus Curiae at 16 n.7, *Joblove v. Barr Labs., Inc.*, No. 06-830 (U.S. May 23, 2007), 2007 WL 1511527 ("*Tamoxifen* Br.") ("*Cardizem* involved payments to

exclude competition in drugs that did not fall within the scope of the allegedly infringed patent . . . .") (emphasis omitted) (citing Brief for United States as Amicus Curiae at 16-17, *FTC v. Schering-Plough Corp.*, No. 05-273 (U.S. May 17, 2006), 2006 WL 1358441).

Every circuit that has discussed *Cardizem* has recognized that the *Cardizem* court found that the settlement at issue there went beyond the exclusionary effect of the patent. The Federal Circuit noted below that "the [Cardizem] agreement provided that the generic manufacturer would not market non-infringing versions of the generic drug," and thus, "clearly had anticompetitive effects outside the exclusion zone of the patent." Pet. App. 21a. The Second Circuit also distinguished the Tamoxifen settlement from the Cardizem settlement, emphasizing that under the Cardizem agreement, "the generic manufacturer would not market non-infringing products." *Tamoxifen*, 466 F.3d at 214. Likewise, the Eleventh Circuit emphasized that some provisions of the Cardizem agreements "seem to exceed the potential exclusionary power of the patent." *Valley Drug*, 344 F.3d at 1311 n.26.

2. *Valley Drug* and *Schering-Plough.* Petitioners also contend that the Eleventh Circuit's decisions are "irreconcilable" with the Federal Circuit's decision here. They argue that the Eleventh Circuit requires evaluation of the size of the payments and the strength of the patent. Pet. 21-22 & nn. 9-10. The Eleventh Circuit, however, emphasized in both cases that the key is whether the settlement exceeds the

scope of the patent. *Schering-Plough*, 402 F.3d at 1068; *Valley Drug*, 344 F.3d at 1309 n.21, 1311. *Valley Drug*'s reference to assessing the "likelihood" of an injunction, 344 F.3d at 1312, had to do with provisions that went *beyond* the scope of the patent. *See id.* at 1311 ("[T]he instant Agreements are not confined to matters involving restrictions on infringing products . . . ."). The Court confirmed in the same section that "effects of the Agreements . . . within the scope" of the patent could not be condemned under any antitrust theory. *Id.* at 1311 & n.27.

Schering-Plough's reference to the "need to evaluate the strength of the patent," 402 F.3d at 1076, did not mean conducting a *post hoc* review of the likelihood of a generic victory at trial. In fact, the Eleventh Circuit expressly equated the patent's exclusionary effect with the scope of the patent claims. *Id.* at 1073 ("The '743 patent claims a 'controlled release [microencapsulated] potassium chloride tablet.' The language in the Schering-Upsher agreement covers the identical reach of the '743 patent."). The Eleventh Circuit also stated on the same page as the "strength" reference that "the agreements fell well within the protections of the '743 patent, and were therefore not illegal." *Id.* at 1076. The district court in *Cipro II* properly rejected Petitioners' misreading of these cases, concluding that "this admonition [in *Schering-Plough*] is more fairly read as requiring an evaluation of the scope of the patent's claims, and not a *post hoc* analysis of the patent's validity." Pet. App. 93a. Indeed, even the

FTC—in *Schering-Plough* itself—conceded in a brief to this Court that any "suggestion that a *post hoc* inquiry into the patent merits would satisfy the court of appeals is *disingenuous*, because *Valley Drug* precludes a conclusion of liability on that basis." Reply Brief for Petitioner at 2, *FTC v. Schering-Plough Corp.*, No. 05-273 (U.S. Oct. 13, 2005), 2005 WL 2652617 (emphasis added; citation omitted).

In sum, the case law is in harmony, in part because the circuit decisions discussed above adopted the reasoning of the district court in its *Cipro I* and *Cipro II* decisions. As a result, this Court has denied certiorari in four prior cases on the same issue. These denials underscore the *absence* of any circuit split or reason to grant certiorari in this case. *See Miroyan v. United States*, 439 U.S. 1338, 1338-39 (1978) (Rehnquist, J., denying application for stay) ("[U]nless applicants can demonstrate a conflict among the Courts of Appeals of which this Court was unaware at the time of the previous denials of certiorari, or which has developed since then, applicants' petition for certiorari will not [be granted] . . . ."). Thus, there is no conflict warranting this Court's review.[3]

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[3] Petitioners also suggest that the Federal Circuit opinion conflicts with scholarly commentary because "[s]ome academic scholars have written that reverse payment settlements of Hatch-Waxman patent litigation with large payoffs to the alleged infringer should be presumptively anti-competitive." Pet. 23 n.11. However, numerous professors, former enforcement officials, and commentators have rejected Petitioners' position. *See, e.g.*, Kent S. Bernard & Willard K.

II. THIS CASE IS A POOR VEHICLE TO ADDRESS THE QUESTION PRESENTED

This case is a poor vehicle to address the question presented due to (1) the lack of federal claims in this case, (2) changes in the regulatory regime, (3) Petitioners' failure to articulate a legal rule that the Court should adopt, and (4) the repeated vindication of the Cipro patent before the PTO and in the courts, making this a poor test case for imposing antitrust constraints based on the "strength" of the underlying patent.

(continued...)

Tom, *Antitrust Treatment Of Pharmaceutical Patent Settlements: The Need For Context And Fidelity To First Principles*, 15 FED. CIRCUIT B.J. 617, 632 (2005-2006) ("Our proposed standard is the sham standard Judge Posner set forth in . . . *Asahi*."); Marc G. Schildkraut, *Patent-Splitting Settlements And The Reverse Payment Fallacy*, 71 ANTITRUST L.J. 1033, 1067 (2004); Daniel A. Crane, *Ease Over Accuracy In Assessing Patent Settlements*, 88 MINN. L. REV. 698, 704 (2004); Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements That Settle Patent Litigation*, 49 ANTITRUST BULL. 655, 677-78 (2004); James Langenfeld & Wenqing Li, *Intellectual Property And Agreements To Settle Patent Disputes: The Case Of Settlement Agreements With Payments From Branded To Generic Drug Manufacturers*, 70 ANTITRUST L.J. 777, 784-85 (2003); Richard J. Gilbert & Willard K. Tom, *Is Innovation King At The Antitrust Agencies? The Intellectual Property Guidelines Five Years Later*, 69 ANTITRUST L.J. 43, 78 (2001).

1. Just as in *Tamoxifen*, there are no live federal claims here. Petitioners are indirect purchasers of Cipro. Because indirect purchasers cannot recover damages under federal antitrust law, *see Ill. Brick Co. v. Illinois*, 431 U.S. 720 (1977), Petitioners have sued under numerous *state* antitrust and consumer protection statutes. Pet. App. 42a. They have no damages claims under federal law. Moreover, Petitioners' claims for injunctive relief under federal antitrust law are moot because the '444 patent has expired and generic Cipro has been widely available since 2004. As the Solicitor General explained in *Tamoxifen*, after patent expiration, "the settlement ceased to have any effect" and "an injunction prohibiting compliance with the settlement would have no operative force." *Tamoxifen* Br. at 17.

Although it is true that some state courts look to federal law as a source for interpreting state antitrust law, as the Solicitor General noted previously, "petitioners have not identified even a single state statute (of the many on which the complaint relied) that has been construed as being coterminous in all respects with federal antitrust law." *Id.* at 18. Accordingly, "it would certainly be unusual, and potentially undesirable, for the Court to determine the scope of federal antitrust liability in a context in which the relevance of that determination to the state laws at issue is entirely uncertain." *Id.*

2. As the Solicitor General noted in *Tamoxifen*, Congress "altered the regulatory dynamic" under which the settlement here is to be evaluated when it amended the Hatch-Waxman Act in 2003. *Id.* at 19.

Those amendments—as well as proposed legislation to ban reverse payments entirely—counsel against the Court resolving issues arising from a small set of settlements in an outdated regulatory context. *See* Eugene Gressman *et al.*, *Supreme Court Practice* 247 (9th ed. 2007) ("If the statute upon which the controversy rests has expired or been amended in a manner that will prevent the problem from arising in the future, certiorari may be denied . . . .").

a. This settlement, like the one in *Tamoxifen*, arose under the regulatory regime in place before Congress substantially amended the Hatch-Waxman Act in 2003. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. Those amendments included, among other things, an entirely new provision governing the first generic filer's right to 180 days of "exclusivity" before other generics may enter.

The amendments thus affect Petitioners' theories of competitive harm based on the *prior* statute's 180-day exclusivity provision. Petitioners and certain commentators on whom they rely claimed that settlement payments to first ANDA filers created "bottlenecks" preventing challenges by subsequent ANDA filers. Those theories misread the prior statute, and the courts—like the district court and court of appeals here—have rejected them. *See* Pet. App. 30a-33a; *Cipro I*, 261 F. Supp. 2d at 243. In this case in particular, the undisputed facts belie any "bottleneck" claim because multiple generic

challenges followed the settlement. *See* Pet. App. 7a-8a.

Nonetheless, the 2003 amendments are directly relevant to Petitioners' request that this Court fashion a new antitrust rule to limit Hatch-Waxman settlements. That is because Petitioners have argued from the outset that the "bottleneck" created by the prior statute was central to the antitrust analysis of settlements containing reverse payments. Thus, in the district court, Petitioners argued that, because a reverse payment agreement with a first ANDA IV filer "precludes new entry by other potential competitors, it is far more damaging to competition than the garden variety agreement not to compete." Indirect Purchasers' Opp. to Defs.' Mot. to Dismiss, *Cipro* MDL (May 22, 2002) (Supp. App. 6a). Both the Petitioners and the commentators on whom they rely emphasize that any evaluation of reverse payments must proceed from the premise that the 180-day exclusivity period "make[s] [Hatch-Waxman] patent settlements *fundamentally different* from other patent infringement settlements." [4] Indeed,

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[4] Herbert Hovenkamp, *et al.*, *IP and Antitrust* § 7.4, at 7-34 (2004) (emphasis added); *accord* Herbert Hovenkamp, *Sensible Antitrust Rules For Pharmaceutical Competition*, 39 U.S.F. L. REV. 11, 28 (2004) (exclusivity rights "sharply distinguish[] Hatch-Waxman settlement *payments* from other types of settlements") (emphasis added); David Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321, 332 (2000) (Hatch-Waxman exclusivity provisions make settlements "of deeper concern to antitrust policy"); *id.* at 331 ("Hatch-Waxman Act [exclusivity] provides one critical feature that makes a world of difference . . . .").

failure to enter. *See* 21 U.S.C. § 355(j)(5)(B)(iv), (D). It was then clear, in the words of those who drafted it, that the new statute would "ensure that the 180-day exclusivity period . . . cannot be used as a bottleneck to prevent additional generic competition."[6]

The Solicitor General has advised this Court on multiple occasions that the 2003 amendments to the Hatch-Waxman Act make cases decided under the prior statute poor vehicles for certiorari: "To the extent the Court is inclined to address the validity of that type of settlement in particular, it may be preferable to do so in a case that arises under the current regulatory regime." *Tamoxifen* Br. at 20; *accord Cardizem* Br. at 18-19. The advice is sound. If the Court were to grant certiorari here, it would have to consider questions relating to the prior statute that are of no prospective application. Such a decision could lead to confusion under the different language of the current regime.

b. Congress is currently considering a new statute that could render moot the entire debate over

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[6] 149 CONG. REC. S15670-03, S15746 (Nov. 24, 2003) (Remarks of Sen. Schumer); 149 CONG. REC. S15882-03, S15884 (Nov. 25, 2003) (Remarks of Sen. Kennedy) ("The Hatch-Waxman provisions in this bill are intended to prevent parking of the exclusivity."). *See generally* Natalie M. Derzko, *The Impact Of Recent Reforms Of The Hatch-Waxman Scheme On Orange Book Strategic Behavior And Pharmaceutical Innovation*, 45 IDEA 165, 245 (2005) ("In particular, the new 180-day exclusivity provision should prevent anticompetitive settlement agreements from being entered into.").

reverse payments. This legislative session, Senator Kohl introduced the "Preserve Access to Affordable Generics Act," S. 369, 111th Cong. (2009). The bill would make it

> unlawful . . . for any person, in connection with the sale of a drug product, to directly or indirectly be a party to any agreement resolving or settling a patent infringement claim in which—(1) an ANDA filer receives anything of value; and (2) the ANDA filer agrees not to research, develop, manufacture, market, or sell the ANDA product for any period of time.

Id. § 3. The Act cites as the impetus for the proposed legislation the Second Circuit's decision in *Tamoxifen* and the Eleventh Circuit's decision in *Schering-Plough*. *See id.* § 2(a)(8). On March 25, 2009, Congressman Rush introduced a similar bill in the House, H.R. 1706, 111th Cong., the "Protecting Consumer Access to Generic Drugs Act of 2009."

The proposed legislation would prohibit settlements with "reverse payments" and therefore render academic further judicial discussion of the issue.

3. This case is also a poor vehicle because Petitioners have not set forth the legal rule that they wish the Court to adopt, and have not made any attempt to show that the outcome of this case would change under a legal rule different from that applied by the courts below. Here, as below, Petitioners rely exclusively on the false assertion that the lower

courts held settlements to be per se *legal*. As to what the correct rule may be, however, they take no position. Thus, they told the Federal Circuit that "[t]he precise nature and scope of the antitrust inquiry should be addressed by the district court on remand." Non-Confidential Brief for Plaintiffs-Appellants at 35, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, No. 2008-1097 (Fed. Cir. Jan. 18, 2008), 2008 WL 937441.

Nor are Petitioners any more helpful here. This Court, they argue, "*could* adopt the standard articulated by one of the Courts of Appeals *or* government agencies, *or* possibly establish another, such as those suggested by antitrust scholars." Pet. 15 n.7 (emphases added).

Similarly, the academic amici concede that they "differ in their views on precisely what standard should be applied to judge the legality of exclusionary settlements." Brief Amici Curiae of 54 Professors, *et al.* at 6 (Apr. 24, 2009). But without a clear definition of the legal rule that Petitioners seek, and some attempt to apply that rule to the facts of this case, it is unclear what tangible effect the Court's application of a standard other than the one affirmed below would have on the outcome of this case.

This Court does not issue advisory opinions. *See Preiser v. Newkirk*, 422 U.S. 395, 401 (1975). Nor is the Court required to guess at the proper rule to apply without help from the party seeking review, nor to apply for the first time an analysis that, as far as this Petition indicates, no court may have considered. *See The Monrosa v. Carbon Black*

Export, Inc., 359 U.S. 180, 184 (1959) ("Resolution here of the [issue presented] can await a day when the issue is posed less abstractly.").

4. Finally, the Petition presents a poor test case for imposing antitrust limitations on patent settlements within the scope of a valid patent. Time and again, the PTO, the district courts, and the Federal Circuit have confirmed the validity of Bayer's '444 patent. As Judge Trager stated, "there is something anomalous about the notion that plaintiffs could collect treble damages for settlement of a litigation involving a patent that has been subsequently upheld by the Federal Circuit." Pet. App. 70a n.14. Petitioners make no argument that any test based on the "strength" or possible invalidity of the patent, *see* Pet. 14-15, 21-22, would change the result in this case. As the courts below concluded, "a *post hoc* assessment of the validity of the ciprofloxacin patent would likely do plaintiffs little good." Pet. App. 70a.[7]

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[7] Moreover, contrary to Petitioners' suggestion, Pet. 5; Pet. App. 79a-80a, the settlement amount itself is not evidence of '444's vulnerability. Bayer's settlement payments ($398.1 million) represented only 6.5% of U.S. gross sales of oral Cipro tablets for the payment period. Supp. App. 2a. Thus, as the district court recognized, the settlement amount here "indicate[s] that Bayer was relatively confident of its chances of winning at trial." Pet. App. 80a.

III. THE COURTS OF APPEALS HAVE ADOPTED A UNIFORM RULE, WHICH IS CORRECT AND MANDATED SUMMARY JUDGMENT FOR DEFENDANTS

Certiorari is also unwarranted because the rule adopted by the courts of appeals (including the Federal Circuit below) is consistent with well-established principles of antitrust and patent law, and because the courts below correctly applied these legal principles to the facts of this case.

A. The "Scope Of The Patent" Rule Is Correct

1. As the Court has recognized, "the essence of the patent grant 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) (emphasis added); *accord E. Bement & Sons v. Nat'l Harrow Co.*, 186 U.S. 70, 91 (1902) ("The very object of [the patent laws] is monopoly."); 35 U.S.C. § 154. When patents are involved, therefore, "the protection of the patent laws and the coverage of the antitrust laws are not separate issues." *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981) (citing *E. Bement & Sons*, 186 U.S. at 91).

Because antitrust law recognizes the patentee's right to exclude, it is also clear that "the public [is] not entitled to profit by competition among infringers." *Rubber Tire Wheel Co. v. Milwaukee Rubber Works Co.*, 154 F. 358, 364 (7th Cir. 1907). The antitrust plaintiff therefore bears the burden of showing that the "excluded" competition was lawful

competition. *See, e.g.*, *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 790-92 (8th Cir. 2006) (no antitrust liability for conspiring to preclude the importation of illegal drugs); *Access Telecom, Inc. v. MCI Telecommc'ns Corp.*, 197 F.3d 694, 712 (5th Cir. 1999).

To carry that burden in a case, such as this, where the agreement attacked is no broader than the claims of the patent, the plaintiff faces numerous obstacles. They include (1) the presumption of patent validity, 35 U.S.C. § 282, which applies at "at every stage of the litigation," *Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc.*, 134 F.3d 1085, 1088 (Fed. Cir. 1998); (2) the refusal of courts to speculate on the outcome of a patent case that was never tried (discussed below); and (3) the long-standing judicial policy in favor of settlements, including patent settlements, *see, e.g.*, *Standard Oil Co. 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."); *see also* Pet. App. 18a (citing *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1368 (Fed. Cir. 2001)). As the Solicitor General told the Court in *Tamoxifen*, "the public policy favoring settlements, and the right of a patent holder to exclude competition within the scope of its *valid* patent, would be frustrated by adoption of a legal standard that subjected patent settlements involving reverse payments to automatic or near-automatic invalidation." *Tamoxifen* Br. at 11 (emphasis in original).

For these reasons, it is well-settled that agreements within the lawful exclusionary scope of a valid patent do not violate the antitrust laws. *Studiengesellschaft*, 670 F.2d at 1128 ("[T]he conduct at issue is illegal if it threatens competition in areas other than those protected by the patent, and is otherwise legal."); *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992) ("Should the restriction 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."); *USM Corp. v. SPS Techs., Inc.*, 694 F.2d 505, 513 (7th Cir. 1982) (holding that antitrust liability may lie "only upon proof of an anticompetitive effect beyond that implicit in the grant of the patent"); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981) ("[W]here a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws."); *see also supra* Part I.A.

The courts below correctly applied these principles to settlements of Hatch-Waxman litigation, holding that such settlements can give rise to antitrust liability only if their effects exceed the patent's scope *or* if the defendant engaged in "fraud before the PTO or sham litigation." Pet. App. 24a.

The fraud and sham litigation exceptions are wholly consistent with the Court's decisions in *Walker Process* and *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49 (1993) ("*PRE*"). In *Walker Process*, the

Court held that patent enforcement may violate the antitrust laws if, *inter alia*, "the relevant patent is shown to have been procured by knowing and willful fraud practiced by the defendant on the Patent Office." 382 U.S. at 179 (Harlan, J., concurring). Similarly, *PRE* demonstrates that antitrust law may impose limits on the assertion of a patent when a claim of infringement is "objectively baseless." 508 U.S. at 60-62. Beyond that, however, in the words of the *Walker Process* Court, "[the patentee's] good faith would furnish a complete defense." 382 U.S. at 177.

The bright-line "scope of the patent" rule is also one that lower courts can apply practically. The courts need only review the claims of the patent to determine their scope, a task they regularly undertake, *see Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), and determine whether the competitive effects of the settlement fall within that scope. The courts must also consider whether the patent was procured by fraud or enforced in sham litigation, but these are also questions that federal district courts regularly must answer under *PRE* and *Walker Process*.

Petitioners' efforts to condemn reverse payments are especially misguided in the Hatch-Waxman context. Under the statute, an ANDA filer infringes simply by filing its Paragraph IV certification. *See* 35 U.S.C. § 271(e). But because the ANDA filer has not yet made any sales subjecting it to possible infringement damages, the patent challenger bears no risk in the ensuing infringement litigation beyond its litigation costs. *See Cipro I*, 261 F. Supp. 2d at

252. The innovator, on the other hand, bears the same risk as in any infringement suit: losing its lawful patent monopoly. *See Tamoxifen*, 466 F.3d at 207. Thus, as the Federal Circuit concluded below, "a sizable exclusion payment from the patent holder to the generic manufacturer is not unexpected under the Hatch-Waxman Act, where the relative risks of litigation are redistributed." Pet. App. 18a n.11. Because Hatch-Waxman has fostered litigation in which the innovator has everything to lose and the generic challenger has everything to gain, payments from an innovator to a generic challenger in settlement of that litigation are simply "a natural by-product of the Hatch-Waxman process." *Cipro I*, 261 F. Supp. 2d at 252; *accord Schering-Plough*, 402 F.3d at 1074-76; *Valley Drug*, 344 F.3d at 1310.

Finally, the recent and pending Congressional legislation provides telling evidence that the antitrust laws do not currently prohibit a patent holder from paying an ANDA filer to settle Hatch-Waxman litigation. Among other changes enacted in the 2003 amendments to the Hatch-Waxman Act, Congress required that parties settling Hatch-Waxman litigation give notice of their settlement agreements to the FTC. *See* 21 U.S.C. § 355(j)(5)(D)(i)(V). But Congress did not change the *existing* law on antitrust liability for Hatch-Waxman settlements. In fact, Congressman Waxman explained that the new requirement of FTC review would "ensure that *existing* antitrust and drug approval laws are enforced to the letter." 146 CONG.

REC. E1538-02, E1538 (Sept. 20, 2000) (emphasis added).

Moreover, for several years, the FTC has supported bills to ban reverse-payment settlements. *See* S. 369, H.R. 1706, 111th Cong. (2009); S. 316, H.R. 1432, 110th Cong. (2007); S. 3582, 109th Cong. (2006); *see also supra* Part II.2.b. The FTC is correct to resort to Congress to seek the change in the law that it advocates. As Judge Trager noted in *Cipro II*, "[a]ny readjustment of the competing interests affected by exclusion payments is a matter better addressed by Congress than the courts." Pet. App. 113a.

2. In the courts below, Petitioners offered various theories of competitive injury to evade the settled rule of antitrust immunity for agreements within a patent's scope. But these theories have no support in this Court's case law or the factual record. The courts below correctly rejected them.

First, Petitioners have alleged that, but for the settlement, Barr "could have won" its case against Bayer and generic Cipro could have come to market earlier. *See Cipro I*, 261 F. Supp. 2d at 199. However, this Court has held that a theory of injury based on the predicted outcome of a specific lawsuit is "too speculative" to support Article III jurisdiction, *Whitmore v. Arkansas*, 495 U.S. 149, 157 (1990), reasoning that "[i]t is just not possible for a litigant to prove . . . that the judicial system will lead to any particular result in his case," *id.* at 159-60; *see also Christianburg Garment Co. v. EEOC*, 434 U.S. 412,

422 (1978); *Boehm v. Comm'r*, 146 F.2d 553, 555 (2d Cir. 1945).

The courts below correctly applied this authority. The district court noted that "without a showing of patent invalidity, all that the complaints contain is conjecture" about possible injury to Petitioners, and held that the allegation that Barr "would have won" was "too speculative" and "insufficient to state a claim under the antitrust laws." *Cipro I*, 261 F. Supp. 2d at 201 (citing *Whitmore*). Moreover, as the Federal Circuit noted, Bayer successfully defended the validity of its patent before the PTO on reexamination and in three subsequent infringement suits, Pet. App. 7a-8a, further highlighting the "speculative nature" of Petitioners' theory, *Cipro I*, 261 F. Supp. 2d at 201; *accord Tamoxifen*, 466 F.3d at 204 n.17 ("[T]hese decisions [in favor of the patent] . . . rebut[] the plaintiffs' conclusory allegation that the Federal Circuit would have affirmed [the trial court's] decision invalidating the tamoxifen patent.").

Second, Petitioners have claimed that, but for the settlement, Bayer would have entered a "more pro-competitive settlement" of the patent litigation, for example, one granting a license with an earlier entry date than the license granted to Barr. Pet. App. 85a. However, in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, this Court rejected the argument that a firm must conduct its affairs so as to permit the "most" competition. The Court stated that the Sherman Act is "the Magna Carta of free enterprise but it does not give judges *carte blanche* to insist that a monopolist alter its way of

doing business whenever some other approach might yield greater competition." 540 U.S. 398, 415-16 (2004) (internal quotation marks and citation omitted). Here, the district court correctly held that, "if defendants were within their [patent] rights . . . in reaching the settlement they did, consumers have no right to second-guess whether some different agreement would have been more palatable." Pet. App. 85a (citing *Trinko*). Plaintiffs' rule would force patent holders to continue infringement litigation "as unwilling private attorneys general," *id.* at 75a (internal quotation marks omitted), bearing unwanted costs and risks of litigation, and undermining the "long-standing policy in the law in favor of settlements," *id.* at 18a (citing *Standard Oil Co.*, 283 U.S. at 171 & n.5).

Third, Petitioners have challenged the settlement on the theory that "every patent has a chance of being held invalid," *id.* at 76a, and that the Agreements "unfairly foreclosed" this "potential for open competition," *id.* at 73a; *see also id.* at 25a (Federal Circuit discussing the FTC's "probabilistic" argument). Essentially, Petitioners assert that antitrust liability is a function of a patent's *potential* invalidity, and that consumers have a "property right" in the chance that any patent may be defeated. *Id.* at 73a-74a.

But the theory "that every patent is 'a little bit invalid,'" *id.* at 77a, eviscerates the statutory presumption of patent *validity*, *id.* at 26a, 77a; *see* 35 U.S.C. § 282, and has no support in the law: "This concept of a public property right in the outcome of

private lawsuits does not translate well into the realities of litigation, and there is no support in the law for such a right." Pet. App. 75a. To the contrary, this Court has emphasized that a patentee has no duty to use its patent in a way that imposes the lowest possible competitive burden on consumers. *See Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964) ("A patent empowers the owner to exact royalties as high as he can negotiate with the leverage of that monopoly."); *see also Nestle Co. v. Chester's Mkt., Inc.*, 756 F.2d 280, 284 (2d Cir. 1985) (forcing settling parties to litigate for the benefit of the public would be "a ruling without precedent").

Furthermore, because *any* given patent could potentially be held invalid in litigation, Petitioners' probabilistic-invalidity theory could subject *all* patent license agreements—whose "high" royalty rates or geographic restrictions do not give consumers the full value of their "probabilistic" property—to the threat of treble antitrust damages. Pet. App. 78a. As the courts below correctly noted, however, to open all "license agreements to antitrust scrutiny simply because patents are often held invalid . . . would undermine the settled expectations of patentees and potential infringers/licensees across countless industries." *Id.* Finally, Petitioners' probabilistic-invalidity theory contravenes Justice Harlan's warning in *Walker Process* that an antitrust claim cannot be based on a showing of "no more than invalidity of the patent." 382 U.S. at 179 (Harlan, J., concurring).

B. The Record Below Mandated Summary Judgment In Defendants' Favor

The courts below correctly applied the law to the facts of this case.

First, the settlement did not exceed the scope of the patent because *all* generic competition fell within the scope of '444. To obtain FDA approval of generic Cipro, an ANDA applicant must show, *inter alia*, "that the active ingredient of the new drug is the same as that of the [branded] drug." 21 U.S.C. § 355(j)(2)(A)(ii)(I). But Bayer's patent *claimed* the active ingredient of ciprofloxacin, so all generic versions infringed it by definition. Accordingly, Petitioners cannot show that any of the generic competition it claims the settlement excluded was *lawful* competition. *See, e.g.*, *Rubber Tire Wheel Co.*, 154 F. at 364. The settlement therefore excluded no more competition than did the patent itself.

Second, Petitioners have not attempted to argue that Bayer's enforcement of the Cipro patent was objectively baseless, nor could they credibly do so. As noted, the PTO confirmed the patentability of the claims to the ciprofloxacin molecule on reexamination, and Bayer successfully defended its patent against three other generic challengers who filed Paragraph IV ANDAs. Judge Trager therefore correctly held that "Bayer's success in its litigations against [subsequent challengers] forecloses any argument that its lawsuits were shams." Pet. App. 112a; *see PRE*, 508 U.S. at 60 n.5 ("A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham.").

Third, the settlement did not create a "bottleneck" that unlawfully delayed generic competition because Barr was never entitled to 180 days of generic market exclusivity under Hatch-Waxman. At the time of the settlement in 1997, the FDA had imposed a so-called "successful defense" requirement on ANDA IV-filers seeking 180 days of market exclusivity. *Cipro I*, 261 F. Supp. 2d at 243. That rule conditioned a generic challenger's right to market exclusivity on the challenger's "successful defense" against the patent holder's infringement suit. It is undisputed that Barr did not satisfy the successful defense requirement. The Federal Circuit correctly concluded that there was no Cipro bottleneck because "Barr had failed to satisfy the [FDA's] successful defense requirement . . . ." Pet. App. 31a.

Moreover, "under the Barr Settlement Agreement, Barr agreed to withdraw its Paragraph IV Certification [with the allegation that the patent was invalid] and to amend its ANDA to contain a Paragraph III Certification [generic entry only after patent expiration]." *Cipro I*, 261 F. Supp. 2d at 243. At the time of the January 1997 settlement, FDA regulations provided that such an amendment would preclude exclusivity. *See* 21 C.F.R. § 314.94(a)(12)(viii)(A) (1997). Hence, the Federal Circuit correctly determined that "even without the successful defense requirement, there [is] still no support for the claim that Barr retained the 180-day exclusivity period after amending from a Paragraph IV ANDA to a Paragraph III ANDA." Pet. App. 32a.

In addition, Petitioners produced no evidence that generic competition was foreclosed in any way due to Barr's exclusivity rights. Barr never asserted any exclusivity rights as to Cipro, nor did the FDA refuse to grant any later application on the ground of exclusivity. Indeed, four different generic applicants filed ANDA IVs after the settlement, as the courts below noted. *Id.* at 33a; *Cipro I*, 261 F. Supp. 2d at 247. Thus, the Federal Circuit correctly held that "there was no evidence that the Agreements created a bottleneck preventing generic challenges to the '444 patent." Pet. App. 29a.

CONCLUSION

The Petition should be denied.

Respectfully submitted,

PHILLIP A. PROGER
KEVIN D. MCDONALD
LAWRENCE D. ROSENBERG
JONES DAY
51 Louisiana Ave., N.W.
Washington, D.C. 20001
(202) 879-3939

FRED H. BARTLIT, JR.
Counsel of Record
PETER B. BENSINGER, JR.
MICHAEL J. VALAIK
PAUL J. SKIERMONT
BARTLIT BECK HERMAN
PALENCHAR & SCOTT LLP
54 West Hubbard St.
Suite 300
Chicago, IL 60654
(312) 494-4400

Counsel for Respondents
Bayer AG & Bayer Corp.

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Petitioners insisted below that the issue of reverse payments could not be separated from that of exclusivity, specifically denying that they were merely asking for "a new rule prohibiting the payment of cash to settle ANDA litigation." Indirect Purchasers' Opp. to Defs.' Mot. for Summ. J., *Cipro* MDL (July 9, 2004) (Supp. App. 8a) (internal quotation marks omitted). Petitioners complained that Defendants' arguments placed "exclusive focus on the reverse payment," and attempted to ignore Barr's "eligib[ility] for the Hatch-Waxman exclusivity period as the first generic manufacturer to challenge Bayer's patent." *Id.*

As noted, these arguments misunderstood the pre-2003 exclusivity provision, and were rejected.[5] The point for certiorari, however, is that the statute is fundamentally different from the one in place at the time of the settlement. The 2003 amendments introduced the term "first applicant" for purposes of exclusivity, changed the triggering mechanism, ensured that any entry under a settlement license would trigger the 180 days, and provided a series of mechanisms by which exclusivity could be forfeited, including a "use it or lose it" provision based on

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[5] For example, the assertion that, under the old statute, a first-filer was "the only part[y] legally in a position to challenge a patent," Hovenkamp, *supra*, 39 U.S.F. L. REV. at 28, was always incorrect, as was the assertion that, "until [the first filer] enters, no other generic firm can enter the market," Balto, *supra*, 55 FOOD & DRUG L.J. at 331; *contra* 21 U.S.C. § 355(j)(5)(B)(iv)(I) & (II) (2000), *repealed by* Medicare Prescription Drug, Improvement, and Modernization Act § 1102.