No. 12-265

IN THE
Supreme Court of the United States

UPSHER-SMITH LABORATORIES INC.,
Petitioner,

v.

LOUISIANA WHOLESALE DRUG CO., INC. ET AL.,
Respondents.

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

REPLY TO BRIEF IN OPPOSITION

CHRISTOPHER M. CURRAN
J. MARK GIDLEY
JAIME M. CROWE
WHITE & CASE LLP
701 Thirteenth St., N.W.
Washington, DC 20005
(202) 626-3600
Counsel for Petitioner Upsher-Smith Labs., Inc.

JAY P. LEFKOWITZ, P.C.
Counsel of Record
CHRISTOPHER LANDAU, P.C.
KAREN N. WALKER, P.C.
JOHN C. O'QUINN
GREGORY L. SKIDMORE
JOSEPH R. OLIVERI
KIRKLAND & ELLIS LLP
655 Fifteenth St., N.W.
Washington, DC 20005
(202) 879-5000
jlefkowitz@kirkland.com
Counsel for Petitioner Upsher-Smith Labs., Inc.

November 19, 2012

TABLE OF CONTENTS

Page

INTRODUCTION 1

REASONS FOR GRANTING THE WRIT 3

I. This Case Presents A Universally Acknowledged Circuit Split On A Question Of Tremendous Significance. 3

II. This Case Provides An Ideal Vehicle For Review. 7

CONCLUSION 12

TABLE OF AUTHORITIES

Page(s)

Cases

Andrx Pharm. Inc. v. Biovail Corp. Int'l,
256 F.3d 799 (D.C. Cir. 2001).....3

Arkansas Carpenters Health & Welfare Fund v. Bayer AG,
604 F.3d 98 (2d Cir. 2010).....2

Asahi Glass Co. v. Pentech Pharm., Inc.,
289 F. Supp. 2d 986 (N.D. Ill. 2003) 6

Bell Atl. Corp. v. Twombly,
550 U.S. 544 (2007).....9

Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.,
402 U.S. 313 (1971).....6

FTC v. Watson Pharm., Inc.,
677 F.3d 1298 (11th Cir. 2012) 2

In re Auto. Refinishing Paint Antitrust Litig.,
358 F.3d 288 (3d Cir. 2004).....5

In re Cardizem CD Antitrust Litig.,
332 F.3d 896 (6th Cir. 2003) 3

In re Ciprofloxacin Hydrochloride Antitrust Litig.,
544 F.3d 1323 (Fed. Cir. 2008).....2

In re Tamoxifen Citrate Antitrust Litig.,
466 F.3d 187 (2d Cir. 2006).....2, 7, 12

Schering-Plough Corp. v. FTC,
402 F.3d 1056 (11th Cir. 2005) 2

United States v. Gen. Motors Corp.,
323 U.S. 373 (1945).....9

Valley Drug Co. v. Geneva Pharm., Inc.,
344 F.3d 1294 (11th Cir. 2003) 2, 6

Statutes

15 U.S.C. § 22 4

Other Authorities

Cynthia A. Jackevicius et al.,
Generic Atorvastatin and Health Care Costs,
366 New Eng. J. Med. 201 (2012) 7

Eugene Gressman et al.,
Supreme Court Practice § 4:18
(9th ed. 2007) 9, 10

Jon Leibowitz, Chairman, FTC,
Remarks Prepared for Delivery at the Sixth Annual Georgetown Law Global Antitrust Enforcement Symposium 4 (Sept. 19, 2012), *available at*
http://www.ftc.gov/speeches/leibowitz/120919jdlgeorgetownspeech.pdf.....5

RBC Capital Markets,
Pharmaceuticals: Analyzing Litigation Success Rates 6 ex. 6 (Jan. 15, 2010), *available at*
http://www.amlawdaily.typepad.com/pharmareport.pdf 6

INTRODUCTION

The brief in opposition confirms that if ever there were a clear-cut case where this Court's review is warranted, this is it: "Respondents agree that the lawfulness of reverse payment agreements is a very important question on which the courts of appeals have divided." Opp. 9. Indeed, there is a Circuit split on the very settlement agreement at issue in this case.

Respondents' agreement that the criteria for granting certiorari are satisfied is hardly surprising. After all, the Third Circuit below expressly acknowledged that, prior to its decision, every court of appeals to have considered the antitrust implications of an agreement settling Hatch-Waxman patent litigation has used the "scope of the patent test" and concluded that such a settlement cannot, as a matter of law, sustain antitrust liability as long as it does not restrain competition beyond the exclusionary potential of the patent. *See* Pet. App. 28a, 31a-32a. Nonetheless, the Third Circuit "[took] issue with" this uniformly applied test firmly grounded in this Court's settled antitrust and patent-law precedent, and "reject[ed]" it in favor of a novel rule that patent litigation settlements are presumptively unlawful based solely on the form of consideration exchanged, even if they restrain no more competition than the patent itself can legally restrain. *See id.* at 33a, 39a-41a. In so doing, the court unsettled the legal landscape governing the generic pharmaceutical industry.

The Third Circuit's divergence from the uniform holdings of its sister Circuits warrants this Court's review. *Compare* Pet. App. 32a-33a, 39a, *with FTC*

v. Watson Pharm., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012); *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 105 (2d Cir. 2010); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003).

And this case not only presents the ideal vehicle for that review, it compels it. Not only is the decision below the only court of appeals decision to reject the scope of the patent test, but that decision held presumptively unlawful the *very same settlement agreement* already upheld as lawful under the Sherman Act by the Eleventh Circuit. *See Schering-Plough*, 402 F.3d at 1076. It goes without saying that the same settlement agreement cannot be lawful in one Circuit but presumptively unlawful in another. Allowing Petitioners to be subject to different liability regimes under federal law for the very same agreement is intolerable and requires this Court's intervention.

The parties obviously disagree on the merits of this case—indeed, Respondents devote nearly half of their opposition to prematurely arguing the merits. But that provides no basis for this Court to deny review. This Court should grant certiorari to resolve this universally acknowledged Circuit split on a universally acknowledged issue of national significance.

REASONS FOR GRANTING THE WRIT

I. This Case Presents A Universally Acknowledged Circuit Split On A Question Of Tremendous Significance.

It is a rare occasion on which all parties to a case acknowledge the need for this Court's review of an issue. Yet, this is precisely the situation with the issue presented: whether an agreement settling patent litigation that does not restrict competition outside the scope of the exclusionary right granted by the patent itself may presumptively violate the antitrust laws. Every court of appeals to address the issue prior to the decision below has held, unsurprisingly and in nearly identical language, that it cannot. *See, supra*, at 1-2; Pet. 13-14 (citing six cases from three Circuits spanning nearly a decade).[1] Although acknowledging the importance of the issue and the division among the lower courts, Respondents nominally oppose certiorari on the theory that a better vehicle for review might come along someday.

Yet, at the same time, they devote nearly six pages of their opposition to explaining why this case

---

[1] Respondents contend that the decisions of the Sixth Circuit in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), and the D.C. Circuit in *Andrx Pharm. Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001), support the Third Circuit's rule of presumptive illegality. Petitioner disagrees, *see* Pet. 15-16 n.1, but even were Respondents correct, it would only reflect an even deeper circuit split warranting this Court's review.

presents a *good* candidate for certiorari and nearly half of their brief to arguing the merits of the case.

The Solicitor General, in petitioning for certiorari in a case presenting the same issue, also agrees with Petitioner and Respondents here, explaining that the question of the proper standard for resolving antitrust challenges to Hatch-Waxman patent settlements is "a recurring question of great economic importance that has divided the courts of appeals." FTC Petition for Certiorari ("FTC *Watson* Pet.") 2, *FTC v. Watson Pharm., Inc.*, No. 12-416 (U.S. filed Oct. 4, 2012).

And thirty-one states, in a brief *amicus curiae* in support of the Solicitor General's petition, have likewise observed that the issue presented is "a legal question of exceptional nationwide importance on which the courts of appeals are sharply divided" and that "[t]he persistence of this circuit split ... has serious adverse consequences." Br. for Thirty-One States as *Amicus Curiae* in Supp. of Pet'r ("States' *Watson* Amicus Br.") 6, 8, *FTC v. Watson Pharm., Inc.*, No. 12-416 (U.S. filed Nov. 5, 2012).

The consequences of this Circuit split will be especially pronounced and the effect dramatic. Because of the permissive venue provisions of the federal antitrust laws, without this Court's intervention, the ruling of one panel of the Third Circuit will become the *de facto* law of the land, essentially displacing nearly a decade of holdings by every other court of appeals to address this issue. Under the Sherman Act, a plaintiff may lay venue in any judicial district in which a defendant may be found or transacts business, *see* 15 U.S.C. § 22, and under Third Circuit law, "personal jurisdiction in

federal antitrust litigation is assessed on the basis of a defendant's aggregate contacts with the United States as a whole," not with the forum state. *In re Auto. Refinishing Paint Antitrust Litig.*, 358 F.3d 288, 298 (3d Cir. 2004). Thus, plaintiffs in *every* nationwide antitrust class action will be able to—and no doubt will—sue in the Third Circuit. As a result, Petitioner and others like it will be forced to abide by the Third Circuit's lowest common denominator standard, even when entering settlement agreements in those Circuits which reject its presumptively unlawful test in favor of the long-standing the scope of the patent test.

This result is not merely speculative. Since the Third Circuit's decision below, numerous private antitrust suits have been filed in the Third Circuit,[2] and the FTC Chairman has announced that if this Court does not address this issue, "we'll simply be forced to bring [these antitrust] cases in the Third Circuit for years to come." Jon Leibowitz, Chairman, FTC, Remarks Prepared for Delivery at the Sixth Annual Georgetown Law Global Antitrust Enforcement Symposium 4 (Sept. 19, 2012), *available at* http://www.ftc.gov/speeches/leibowitz/120919jdlgeorgetownspeech.pdf. In any event, the Third Circuit's holding will have a disproportionate impact for the simple reason that more Hatch-Waxman patent

---

[2] *See, e.g.*, *Rochester Drug Co-Op., Inc. v. AstraZeneca AB*, No. 12-cv-4911 (E.D. Pa. filed Aug. 27, 2012) (and related cases); *Int'l Bhd. of Elec. Workers Local 595 Health & Welfare Fund v. GlaxoSmithKline LLC*, No. 12-cv-6721 (D.N.J. filed Oct. 25, 2012).

cases are brought in the Third Circuit than all other Circuits combined. *See* RBC Capital Markets, *Pharmaceuticals: Analyzing Litigation Success Rates* 6 ex. 6 (Jan. 15, 2010), *available at* http://www.amlawdaily.typepad.com/pharmareport.pdf.

Moreover, the economic incentive effects of the Third Circuit's outlier holding will be dramatic. Patent litigation is notoriously expensive and time-consuming. *See Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 336 (1971). The ability to settle provides Petitioner and other generic pharmaceutical manufacturers—the defendants in Hatch-Waxman patent cases—the necessary ability to control those costs. But now, following the decision below, generic companies will be faced with the prospect of presumptive antitrust liability (and the spectre of treble damages) in the Third Circuit for settling Hatch-Waxman patent litigation anywhere in the country—even in Circuits that would uphold the legality of those settlements. The result would be that settling patent litigation just creates antitrust litigation, with all the costs and exposure to presumptive liability that go with it. Settlements will thus be chilled, and, as a result, generic companies will not be as willing to file Paragraph IV challenges in the first place. *See Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation) ("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."); *see also Valley Drug*, 344 F.3d at 1308 ("By restricting settlement options,

which would effectively increase the cost of patent enforcement, the proposed rule would impair the incentives for disclosure and innovation.").

The upshot will be fewer patent challenges and less competition, not more. And this will happen even though such settlements have enabled the entry of low-cost generic pharmaceuticals onto the market *years* before the asserted patents expire, resulting in billions of dollars in consumer savings. For example, one such settlement enabled entry of generic tamoxifen onto the market nine years prior to the expiry of a patent that was later upheld in three separate cases. *See Tamoxifen*, 466 F.3d at 195. Because of another settlement, generic Lipitor entered the market five years prior to patent expiry, which is projected to save consumers over $10 billion. *See* Cynthia A. Jackevicius et al., *Generic Atorvastatin and Health Care Costs*, 366 New Eng. J. Med. 201, 202 (2012). The settlement at issue in this case resulted in generic entry five years prior to patent expiry. Pet. App. 14a.

Thus, there can be no doubt that this Court's intervention is not only prudent, but necessary.

II. This Case Provides An Ideal Vehicle For Review.

The clear and acknowledged Circuit split over the standard by which to assess the antitrust implications of Hatch-Waxman patent settlements unquestionably warrants this Court's review. But *this case* in particular demands it: not only did the court below diverge from the uniform legal standard adopted and applied by its sister Circuits, but in so doing it held presumptively unlawful under the Sherman Act *the exact same settlement agreement*

that the Eleventh Circuit had already held lawful under that same Act.

Even though the Eleventh Circuit had already considered and rejected an antitrust challenge to the very settlement agreement at issue here, different plaintiffs, solely by virtue of laying venue in a different forum, were able to avoid that holding—and the finality it should have brought—and have the same settlement agreement held presumptively unlawful under the same statute. It simply cannot be that Petitioner's rights under the federal antitrust laws depend entirely on the forum in which plaintiffs choose to sue. This case is a poster child for certiorari.

Respondents, although agreeing that the question presented here is "a very important question on which the courts of appeals have divided," Opp. 9, nonetheless offer two reasons that this Court might deny certiorari here. Neither represents a factor this Court uses in deciding whether to grant certiorari, and neither is persuasive.

Respondents first suggest that the Court "may find it more appropriate to await a final judgment and a complete record" before granting certiorari. Opp. 10. Their suggestion is curious at best. Although the decision below reversed summary judgment and is thus technically not final, this Court "has unquestioned jurisdiction to review interlocutory judgments of federal courts of appeal," and review is appropriate where, as here, "the opinion of the court has decided an important issue, otherwise worthy of review, and Supreme Court intervention may serve to hasten or finally resolve the litigation." Eugene Gressman et al., *Supreme*

Court Practice § 4:18, at 280, 282 (9th ed. 2007); *see, e.g.*, *United States v. Gen. Motors Corp.*, 323 U.S. 373, 377 (1945) (granting certiorari to review non-final ruling "fundamental to the further conduct of the case"). The settlement agreement challenged here has already been upheld under the scope of the patent test—by both the Eleventh Circuit and the district court below—and, if the Court adopts that standard here, its holding will be dispositive of this case. *Cf. Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559, 570 (2007) (reviewing and reversing non-final judgment of court of appeals and noting the "potentially enormous expense of discovery" if case were remanded for continued litigation).

Respondents' related assertion that the Court should deny certiorari to await a more developed record is equally unconvincing. As Respondents repeatedly observe elsewhere in their opposition, this case has "a substantial record" developed through discovery, replete with "extensive" fact and expert testimony. Opp. 7, 14. Indeed, Respondents cite the quality of the record here as a factor that *supports* granting certiorari: "[T]he record in this case would assist the Court in considering the question in context...." *Id.* at 12. In light of these frank admissions, Respondents' half-hearted argument against certiorari on this ground rings hollow.

Respondents also assert that this Court should deny certiorari because other Hatch-Waxman patent settlement cases are pending in the lower courts. Respondents' reasoning, however, has it exactly backwards: the existence of numerous lower court cases that turn, in whole or in significant part, on the legal standard to be applied *supports* granting

certiorari in this case. *See* Gressman, *supra*, § 4.13, at 269. Indeed, multiple lower courts with cases presenting this issue have stayed those cases pending this Court's resolution of the Petition and any subsequent proceedings here. *See In re Effexor XR Antitrust Litig.*, No. 11-cv-5479, dkt. #191 (D.N.J. Oct. 23, 2012) (staying seven cases); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, No. 06-cv-1797, dkt. #479 (E.D. Pa. Aug. 29, 2012) (staying four cases). These courts would unquestionably benefit from, and are awaiting, this Court's guidance.

Like Respondents, the Solicitor General agrees that the question presented here is "a recurring question of great economic importance that has divided the courts of appeals," but asserts that his petition in *FTC v. Watson Pharmaceuticals, Inc.*, No. 12-416, presents a superior vehicle for review than this case. FTC *Watson* Pet. 2, 29-33. Not so.[3]

First, the Solicitor General contends that this Court would benefit from the "simpler" record in *Watson*, viz. the FTC's bald complaint. *Id.* at 30. Rather than take this issue in a vacuum, the Court would benefit from considering it in the context of a challenge to a settlement agreement that has twice

---

[3] Upsher-Smith agrees with Respondents that if this Court grants both this petition and the petition in *FTC v. Watson*, it would be beneficial for this Court to hear argument in both cases on the same day. However, Petitioner does not agree that any realignment of parties or consolidation of cases is appropriate, and does not agree with Respondents' proposed allotment of time for oral argument. Petitioner believes that this Court should hear each case separately, as is its normal practice.

been considered by courts of appeals on extensively-developed records rather than on one litigant's artfully-pleaded allegations.

Second, the Solicitor General asserts that the fact that Respondents here—private plaintiffs—have sought monetary damages somehow makes this case less suited for review. *Id.* at 31-32. However, there has been no suggestion that any damages issue—which would be wholly subsidiary to any liability decision—could moot or otherwise impact the necessity of determining liability in this case. Indeed, to the extent damages are relevant, the significant damages sought by Respondents in this case weigh in favor of certiorari. And, even more fundamentally, a case brought by private plaintiffs is especially suited for review given that such plaintiffs bring the overwhelming majority of these challenges.[4]

Third, the Solicitor General suggests that this case is somehow less suited for review than *Watson* because the patent challenge underlying this case focused on questions of infringement and not both infringement *and* patent validity. *Id.* at 32. But, as the Solicitor General correctly observes, the antitrust analysis does not change based on whether the underlying patent challenge involved allegations

---

[4] As Respondents' note, "Respondents in this case include some of the largest purchasers of pharmaceutical products in the country," and "[t]hey are represented by counsel who collectively have been involved in nearly every reverse payment case filed over the past decade and have developed substantial expertise in this area of the law." Opp. 12.

regarding patent validity (and the procedural presumption thereof) or infringement, and no court has ever held otherwise. *See id.*; *see also Tamoxifen*, 466 F.3d at 209 n.22 (explaining that the antitrust analysis is the same "irrespective of whether there was a presumption" of patent validity).

Finally, the Solicitor General suggests that *Watson* presents a superior vehicle for this Court's review because it was brought by the FTC. FTC *Watson* Pet. 29-30. But the government could still be heard here; indeed, both the FTC and United States have been active participants as *amici* in this case.

* * *

In the end, although the parties disagree on the merits of this case, all agree that the issue presented is one of tremendous significance on which the Circuit courts have fundamentally divided. And this case demonstrates the profound consequences of that division: Petitioner, after having been exonerated of antitrust liability arising from its settlement agreement by the Eleventh Circuit, now faces presumptive antitrust liability for the exact same agreement in the Third Circuit. This Court should intervene to resolve this intolerable conflict.

CONCLUSION

The Court should grant the petition for a writ of certiorari.

November 19, 2012

Respectfully submitted,

CHRISTOPHER M. CURRAN
J. MARK GIDLEY
JAIME M. CROWE
WHITE & CASE LLP
701 Thirteenth St., N.W.
Washington, DC 20005
(202) 626-3600
Counsel for Petitioner Upsher-Smith Labs., Inc.

JAY P. LEFKOWITZ, P.C.
Counsel of Record
CHRISTOPHER LANDAU, P.C.
KAREN N. WALKER, P.C.
JOHN C. O'QUINN
GREGORY L. SKIDMORE
JOSEPH R. OLIVERI
KIRKLAND & ELLIS LLP
655 Fifteenth St., N.W.
Washington, DC 20005
(202) 879-5000
jlefkowitz@kirkland.com
Counsel for Petitioner Upsher-Smith Labs., Inc.