No. 06-830

IN THE

Supreme Court of the United States

In Re: TAMOXIFEN CITRATE ANTITRUST LITIGATION

JOBLOVE, ALLIED SERVS., DIV WELFARE FUND, BENNISH, KOONAN, GREAT LAKES HEALTH PLAN INC., LACAVA, DONEGA, SMITH, LOVINGER, WOOLLACOTT, WHITESIDE, PLATT, UNDERWOOD, TEAMSTERS LOCAL 237, LYNCH, CALLAWAY, MALONEY, MECHANICAL CONTRACT, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, A.F. OF L. – A.G.C. BUILDING TRADES WELFARE FUND, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, LOCAL 1199 NAT'L BENEFIT FUND FOR HEALTH AND HUMAN SERVICES, NEW YORK STATEWIDE SENIOR ACTION COUNCIL, MARKS, BLONSTEIN,

Petitioners,

v.

BARR LABS., INC., ASTRAZENCA PHARMACEUTICALS LP, ZENECA INC., ASTRAZENECA PLC,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

REPLY BRIEF

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STATEMENT PURSUANT TO RULE 29.6

Petitioners' corporate disclosure statement was set forth at page *ii* of the Petition for a Writ of Certiorari, and there are no amendments to that statement.

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1. This case puts into sharp focus an issue that is fundamental to antitrust doctrine in the Hatch-Waxman context: whether a branded drug seller can buy protection from potential generic competition so long as the competition excluded falls within the nominal scope of a non-sham patent claim. Petitioners (plaintiffs below) show that certiorari is warranted to reconcile the inconsistent standards applied by courts of appeals. Pet. 12-15; *accord* Brief of *Amicus Curiae* National Association of Chain Drug Stores in Support of Petitioners ("NACDS Br.") 3-9; Brief of *Amicus Curiae* the American Antitrust Institute in Support of Petitioners ("AAI Br.") 14-16;[1] Brief Amici Curiae of 41 Professors of Economics, Business and Law in Support of Granting the Petition ("41 Profs. Br.") 1-3. In their opposition, Respondents (defendants below) attempt to isolate unique facts of each court of appeals case to conjure up some baseline, hypothetical consistency. Resp. Br. 9-13.

Even if the ultimate outcomes of these cases could somehow be reconciled on the basis of individual facts — and they cannot[2] — the *standards* employed by the Second, Sixth and Eleventh Circuits are purposely inconsistent. In *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), the Eleventh Circuit *expressly* disagreed with the Sixth Circuit. 344 F.3d at 311 n.26 ("To the extent that the Sixth Circuit [in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003)] suggests that a settlement of patent litigation was a per se violation of the antitrust laws merely because it involves a generic's agreement to delay marketing until resolution of the patent infringement case in exchange for exit payments, *we respectfully disagree*. We believe that the potential exclusionary power of the patent must first be considered.")

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1. The AAI Brief also describes a division between the three branches of government. *See* AAI Br. 10-13.

2. *See*, *e.g.*, 1 Herbert Hovenkamp, Mark D. Janis, and Mark A. Lemley, *IP and Antitrust*, *An Analysis of Antitrust Principles Applied to Intellectual Property Law* § 7.4, at p. 7-41 (2007 Supp.) ("Courts and agency decisions evaluating exclusion payments have led to widely different outcomes."); *see also id.* at 7-41 - 7-51 (addressing *Cardizem*, *Schering*, *Valley Drug*, *Tamoxifen*).

(emphasis added); *accord Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).[3] In this case the Second Circuit went even further, deeming exclusion payments (regardless of amount) immune from antitrust liability so long as (1) the patent, even if "fatally weak," is not a sham, and (2) the exclusion does not exceed the patent's facial scope. Pet. App. 48a-49a; *see also* 1 *IP and Antitrust*, § 7.4, at p. 7-48 ("The Second Circuit has shown even more lenient treatment toward exclusion payments than the Eleventh Circuit."). This Court should grant certiorari to eliminate the stark divergences that exist between the legal standards adopted by the circuit courts.

2.a. The 2003 Medicare Amendments require the submission of Hatch-Waxman settlement agreements to the FTC (Pet. App. 154a-156a), reflecting congressional concern over the anticompetitive effects of these agreements. Respondents, ignoring the purpose of this legislation, find it notable that "after the dismissal of petitioners' claims by the district court in this case," Congress required parties who settled infringement actions to file copies of their settlements with the FTC, "but took no action to limit the terms of settlement." Resp. Br. 22-23 (footnote omitted).

Respondents' claim to congressional blessing of the result in the case is specious. It is more significant that Congress passed the 2003 Medicare Amendments *after* the circuit court rulings in *Cardizem* and *Andrx Pharms., Inc. v. Biovail Corp.*, 256 F.3d 799, 801 (D.C. Cir. 2001). These prominent rulings reflected the prevailing interpretation of antitrust law at the time Congress acted. *See also* AAI Br. 11-12 (noting that a representative of the brand manufacturers' trade association testified in Congress that a reporting requirement was all that was needed because exclusion payments violate the Sherman Act). Thus, the *antitrust*

3. *See also In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp.2d 1279, 1315 n.36 (S.D. Fla. 2005) ("The Eleventh Circuit [in *Valley Drug*] disagreed with the Sixth Circuit's approach in *Cardizem*, because that Court did not conduct an analysis of the exclusionary potential of the patent and also placed considerable reliance on the size of the exit payments.").

laws "limit the terms of settlement" between horizontal competitors and, by requiring that pharmaceutical companies submit their settlement agreements to the FTC, Congress sought to further the FTC's ability to enforce those laws. *See* S. Rep. No. 167, 107 Cong., 2d Sess., 2002 WL 1350511 (June 20, 2002) at 4 (Congress sought to stamp out the "abuse of the Hatch-Waxman law" resulting from "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower-cost drugs off the market."). If the decision below stands, however, the FTC will be left with precious little to enforce, at least in the Second Circuit. *See* 1 *IP and Antitrust*, § 7.4, at p. 7-49 ("The result is that in the Second Circuit, exclusion payments are legal per se unless the lawsuit is not only weak but a sham, a standard that is virtually impossible to surmount.") (footnote omitted).

Based upon the agreements submitted to the FTC, Commissioner Jon Leibowitz commented on April 26, 2006 about the apparent increase in the number of exclusion payments. Pet. 16-17; *see also* NACDS Br. 9-13; 41 Profs. Br. 10-11. On January 17, 2007, the FTC released its final report on agreements filed with the FTC during fiscal year 2006.[4]

> In FY 2006, fourteen of the twenty-eight final settlements that the Commission received (50%) included provisions in which the generic manufacturer received some form of compensation from the manufacturer of the brand product at issue in the litigation and restrictions on the generic manufacturer's ability to enter with its product. By comparison, in FY 2005 only 3 of the 11 final settlements (27%) included both the compensation to the generic and a restriction on the generic's ability to enter, and, in FY 2004, no agreements involved both compensation and restriction.

4. Federal Trade Commission, *Agreements Filed With the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in Fiscal Year 2006: A Report by the Bureau of Competition* (filed Jan. 17, 2007), *available at*: http://www.ftc.gov/opa/2007/01/drugsettlements.htm.

> The fourteen agreements received in FY 2006 settled patent litigation on eight different branded pharmaceutical products. *Each of the agreements involved a product with 2005 U.S. annual sales exceeding $125 million; eight of the agreements involved products with 2005 U.S. annual sales of more than $450 million*.

Id. at 4 (emphasis added); *see also id.* Figure III (Reply App. 1a).

The Eleventh Circuit's decision in *Schering* and the Second Circuit's initial decision in this case, 429 F.3d 270, are largely (if not exclusively) responsible for the disturbing increase in anticompetitive settlements. *See* Jon Leibowitz, *Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-ack!* (April 24, 2006) at 7-8[5] ("If the *Schering* and *Tamoxifen* decisions are not reversed — that is, if branded firms are empowered by the courts to pay the generic more than it would have made by competing — these rivals will have *carte blanche* to avoid competition and share resulting profits, and we will see minimal competition before patent expiration."); C. Scott Hemphill, *Drug Patent Settlements*, *1993-2006*, Columbia Law School Working Paper (2007), at 2[6] (*Schering* and *Tamoxifen* rulings "have led to a flood of new settlements . . . [in which] the generic firm agrees to abandon its patent challenge and delay entry in exchange for payment from the innovator.")

b. Respondents also find comfort in the FTC's discussion in its *Schering* opinion of the district court's opinion below. Resp. Br. 25-26 (quoting *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2003 FTC LEXIS 187, at *71 (FTC Dec. 8, 2003), *rev'd*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005)). According to Respondents, the FTC "did not retract its endorsement of the result in this case." *Id.* at 26. The FTC's comment was not an "endorsement" of the result in the

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5. *Available at* http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf.

6. *Available at* http://www2.law.columbia.edu/contracteconomics/papers/papers.html.

district court, but merely an effort to distinguish that decision from the facts before it. The comment derives from the district court's misconstruction of Petitioners' complaint, as it does not even mention that the tamoxifen patent had been held invalid and unenforceable *at the time of the agreements.* The *status quo* at the time of agreement was an important aspect of the FTC's rationale. Moreover, the FTC's amicus brief in support of rehearing in this case states that "the panel majority opinion conflicts with basic principles of antitrust law in numerous respects, the most egregious example of which is condoning agreements that harm competition and consumers on the ground that they make 'economic sense' to the parties who profit from them." Brief of Amicus Curiae Federal Trade Commission (Nov. 30, 2005) at 2.[7] The FTC has not retracted its endorsement of this view.

3. Petitioners show that the Second Circuit decision misapplied settled antitrust law in a number of crucial respects. Pet. 17-27; *see also* NACDS Br. 13-20; AAI Br. at 16-20; 41 Profs. Br. 4-10. In opposition, Respondents reiterate, as the Second Circuit held, that so long as they did not restrain generic entry beyond the facial scope of the '516 patent, they were free to resolve the patent infringement litigation on virtually any terms that they wished. Resp. Br. 13-26. While exceeding the scope of the patent would obviously raise antitrust concerns, it is not the only inquiry. *See* NACDS Br. 16-17.[8] Even holders of valid patents are liable for antitrust violations when they combine with horizontal competitors to exclude competition. *See*, *e.g.*,

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7. *Available at:* http://www.ftc.gov/os/2005/12/051202 amicus tamoxifen.pdf.

8. *See Blonder-Tongue Labs. Inc. v. University of Illinois Found.*, 402 U.S. 313, 343 (1971) ("The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeking that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope") (quoting *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945)).

Andrx, 256 F.3d at 813 n.15 ("[E]ven a patent-right holder is not immune from antitrust liability."); *United States v. Microsoft Corp.*, 253 F.3d 34, 63 (D.C. Cir. 2001) (*en banc*) ("Intellectual property rights do not confer a privilege to violate the antitrust laws.") (citation omitted).

a. Respondents contend that it is immaterial whether Barr received consideration in excess of the profits it could have made by marketing its own generic product, Resp. Br. 21-22, but this shows that Respondents negotiated an allocation of the expected consumer surplus, rather than a compromise of the patent infringement litigation.[9] *See* AAI Br. at 6-7. There was no "compromise" or "settlement" of the infringement litigation — a successful challenge to the patent was *eliminated* by exclusion payments to the alleged infringer.[10] If litigants in

9. *See* FTC Commissioner Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes*, *Part II* (May 17, 2001) at p 5 ("The inference that the parties really intend to share monopoly profits for the period of deferred entry — however long it may be — would be particularly strong if the payments exceed the projected profits of the generic firm for that period.") (footnote omitted), *available at:* http://www.ftc.gov/speeches/leary/learypharmaceutical settlement.htm.

10. Barr (and its supplier) received $56.9 million in cash and Barr secured a lucrative distribution arrangement, through which it enjoyed nine years of tamoxifen sales at "branded" prices without generic competition. For the fiscal year ended June 30, 2001, for example, Barr reported tamoxifen sales of more that $332 million. Barr Form 10-K405, filed August 24, 2001 at 3 ("Tamoxifen accounted for approximately 65%, 68% and 66% of our product sales during fiscal 2001, 2000, and 1999, respectively."), *available at*: http://phx.corporate-ir.net/phoenix.zhtml?c=60908&p=irol-sec&secCat01.1_rs=431 &secCat01.1_rc=10. Barr maintained these sales in a market that Barr helped shelter from generic competition. With the emergence of true generic competition in 2003, Barr's tamoxifen sales plummeted. *See* Barr's November 6, 2003 financial press release ("As expected, sales of Tamoxifen, an anti-cancer agent that the Company distributed until November 2002 and launched as a manufactured product in February 2003, declined to *$3.1 million* in first quarter of fiscal 2004 from *$76.0 million* in the first quarter of fiscal 2003.") (emphasis added), *available at*: http://phx.corporate-ir.net/phoenix.zhtml?c=60908&p=irol-newsArticle&ID=467263&highlight=.

Hatch-Waxman patent infringement litigation are immunized from antitrust liability by a general policy favoring "settlement," as the Second Circuit held (Pet. App. 48a-49a), it must be expected that generic manufacturers will "settle" on terms that they deem most profitable. No rational generic company could refuse a "settlement offer" of more money than it could earn by invalidating the patent and marketing a competing product. "Instead of racing to file ANDAs to compete, [generic manufacturers] will be racing to file ANDAs to be first to settle — the first to be paid not to compete."[11] Such a prospect is antithetical to the antitrust laws. *See United States v. Citizens & S. Nat'l Bank*, 422 U.S. 86, 116 (1975) ("The central message of the Sherman Act is that a business entity must find new customers and higher profits through internal expansion — that is, by competing successfully rather than by arranging treaties with its competitors.").

b. In addition, Respondents argue that crediting allegations concerning the initial ruling of patent invalidity[12] would "wrongly ascribe preclusive significance to a vacated judgment" and that "any inference that might be drawn from the initial patent ruling is undermined by AstraZeneca's later successes defending the '516 patent." Resp. Br. 18 (citing Pet. App. 34a & n.17). The district court, in fact, afforded dispositive weight to subsequent patent challenges, initiated by relatively unmotivated generic challengers,[13] that failed to prove the '516

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11. Jon Leibowitz, *How Settlements Make Strange Bedfellows: Or How the Federal Trade Commission has Managed to Unite the Entire Pharmaceutical Industry (but only in Opposition to the FTC's Position on Exclusion Payment Settlements* (Sept. 29, 2006) at 10, *available at*: http://www.ftc.gov/speeches/leibowitz/060929GPHApubvers.pdf.

12. *Imperial Chem. Indus.*, *PLC v. Barr Labs.*, *Inc.*, 795 F. Supp. 619 (S.D.N.Y. 1992), *vacated pursuant to settlement sub nom. Imperial Chem. Indus.*, *PLC v. Heumann Pharma GmbH & Co.*, 991 F.2d 811 (Fed. Cir. 1993) (table).

13. *See* Pet. 24-27 (citing C. Scott Hemphill, *Paying for Delay*, 81 N.Y.U. L. Rev. 1553, 1586 (Nov. 2006) ("Generic firms other than the

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patent invalid or unenforceable. The Second Circuit held that it "was appropriate for the district court to take these decisions into account for the limited purpose of rebutting the plaintiffs' conclusory allegation that the Federal Circuit would have affirmed Judge Broderick's decision invalidating the tamoxifen patent." Pet. App. 34a n.17 (citations omitted). The apparent crux of the courts' reliance on the subsequent determinations is that the judgment in *ICI v. Barr* must have been "wrong," and, therefore, Respondents' private agreements could not harm Petitioners.

This approach is erroneous, especially on a motion to dismiss, because (1) the agreements must be evaluated on the basis of the facts that existed at the time they were entered (*see*, *e.g.*, *Valley Drug*, 344 F.3d at 1306 ("We begin with the proposition that the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into.")), which in this case was at a time when the patent had been held to be invalid and unenforceable, and (2) it ignores the standard of appellate review that would have applied in *ICI v. Barr*. A trial judge's findings of fact are reviewed for clear error only. Fed. R. Civ. P. 52(a). *See Shelcore*, *Inc. v. Durham Indust.*, *Inc.*, 745 F.2d 621, 624-25 (Fed. Cir. 1984) ("The presumption of validity does not guide our analysis on appeal."). "If the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently." *Anderson v. City of Bessemer*, 470 U.S. 564, 573-74 (1985). Moreover, "special deference" is paid to findings of fact where the trial court bases its determinations on assessments of witnesses' credibility. *Id.* at 574. This is particularly true where, as here, the trial court's findings of

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first filer will be behind in the approval process, if they have bothered to file at all; they will also be less motivated to initiate or vigorously pursue the challenge.")).

fraudulent conduct were expressly based on clear and convincing evidence. *See ICI v. Barr*, 795 F. Supp. at 621.

Thus, other generic manufacturers' failure, at least four years later, to demonstrate that the '516 patent is invalid has no bearing on the status quo at the time of the agreements or the appellate prospects of *ICI v Barr*. In *Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144, 1997 WL 168318 (Fed. Cir. 1997) (table), for example, the subsequent ANDA-IV filer (Novopharm Ltd.) appealed the finding that Zeneca had not acted with deceptive intent in connection with the '516 patent:

> We do not agree that the district court committed clear error in failing to find that deceptive intent on the part of Zeneca has been proven by clear and convincing evidence. At best, the evidence cited by Novopharm *reveals the existence of two permissible views of the evidence*. Based on the entire record, we are not left with the definite and firm conviction that the district court committed a mistake; its findings are clearly plausible. *They cannot be clearly erroneous just because contrary findings would also be plausible*. . . .

1997 WL 168318, at *3 (emphasis added). In contrast, the factual findings in *ICI v. Barr* adhered to Barr's view of the evidence — that clear and convincing proofs demonstrated that Zeneca *had* acted with deceptive intent. Zeneca avoided this judgment not on the strength of the '516 patent, but by combining with its competitor Barr to preserve its tamoxifen monopoly and share the monopoly rents. It was erroneous for the lower courts to rely upon subsequent decisions as a basis to brand Petitioners' well-pleaded allegations as "conclusory."[14] As Judge Pooler's dissent correctly recognized, those subsequent victories could not have existed but for the deal with Barr. *See* Pet. App. 131a

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14. Moreover, Petitioners here are strangers to the infringement actions against generic manufacturers and the requirements of due process preclude giving "conclusive effect to a prior judgment against one who is neither a party nor in privity with a party therein." *Richards v. Jefferson County*, 517 U.S. 793, 797, n.4 (1996) (citation omitted).

("[T]here is a certain unfairness in using the subsequent litigation, which would not have existed had Barr prevailed on appeal, to demonstrate that plaintiffs cannot establish that Barr would have prevailed on appeal.").[15]

4. Petitioners further show that this case presents an ideal opportunity for the Court to address the practice of pharmaceutical exclusion payments, in part because it arises from a dismissal motion that is uncomplicated by factual findings such as those that the Solicitor General found troubling in *Schering*. Pet. 9-11. Respondents counter that this case is a "poor vehicle" to address these issues because of intervening changes in the law, including the 2003 Medicare Amendments. Resp. Br. 26-28.[16] Although some of the peripheral factual circumstances may have been addressed by subsequent court decisions or legislation, no one has suggested that the central issue of the litigation — exclusion payments to manufacturers of generic pharmaceuticals — is unlikely to recur. Indeed, it *is* recurring at an alarming rate. *See* FTC FY 2006 Report, Jan. 17, 2007 (fn. 4, *supra*). Respondents' contention also ignores the Second Circuit's observation "the issues presented have been much litigated and appear to retain their vitality." Pet. App. 2a.

CONCLUSION

For the foregoing reasons and those stated in our petition, the petition for a writ of certiorari should be granted.

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15. With different presentations and different fact-finders, it is not unprecedented for one challenger to fail and another succeed. *See*, *e.g.*, *Dana Corp. v. NOK, Inc.*, 882 F.2d 505 (Fed. Cir. 1989); *Mississippi Chem. Corp. v. Swift Arg. Chem. Corp.*, 717 F.2d 1374 (Fed. Cir. 1983). Once a challenger succeeds in defeating the patent, however, all other potential entrants will benefit from collateral estoppel. *See Blonder-Tongue Labs., Inc. v. University of Illinois Found.*, 402 U.S. 313 (1971); *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1379 (Fed. Cir. 1999).

16. There is no dispute – not even from Respondents (Resp. Br. 28) – that state antitrust claims are interpreted in accordance with federal antitrust law pursuant to either an express harmonization provision or judicial decision. *See Cardizem*, 332 F.3d at 906 ("It is undisputed that the state antitrust statutes at issue either follow federal Sherman Act precedent or find federal case law persuasive.").

Respectfully submitted,

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