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 A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF

PATRICK E. CAFFERTY
CAFFERTY FAUCHER LLP
101 North Main Street
Suite 450
Ann Arbor, MI 48104
(734) 769-2144

J. DOUGLAS RICHARDS*
COHEN MILSTEIN SELLERS & TOLL PLLC
150 East 52nd Street
Thirtieth Floor
New York, NY 10022
(212) 838-7797

* *Counsel of Record*

Counsel for Petitioners

(Additional Counsel Listed on Signature Page)

223117

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1. This case puts into sharp focus a fundamental issue: whether a branded drug seller can lawfully buy protection from potential generic competition so long as the competition excluded falls within the nominal scope of a patent claim. The petition showed that review is required to reconcile the inconsistent standards applied by the courts of appeals. Pet. 19-23; *accord* Brief Amici Curiae of 54 Intellectual Property Law, Antitrust Law, Economics, and Business Professors, the American Antitrust Institute, the Public Patent Foundation, and the AARP in Support of the Petitioner, 2-7.[1] In their oppositions, respondents attempt to portray courts of appeals' decisions as consistent. Bayer Br. 9-17; Generic Def. Br. 8-10.

Even if the ultimate outcomes of these cases could be reconciled, the standards employed by the circuits are expressly inconsistent. In *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), the Sixth Circuit held that a generic manufacturer's agreement to delay market entry until resolution of the patent infringement case in exchange for exit payments was a per se violation of federal and state antitrust laws. In *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), the Eleventh Circuit expressly disagreed with the Sixth Circuit and held that the "exclusionary power" of the patent needed to be

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1. *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. 7-41-7-51 (2007 Supp.).

considered. *See* Pet. 21 n. 9.[2] In *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.2d 187 (2d Cir. 2006), *cert. denied sub nom. Joblove v. Barr Laboratories, Inc.*, 127 S.Ct. 3001 (2007), the Second Circuit went further than the Eleventh Circuit by deeming exclusion payments — regardless of the amount — immune from antitrust scrutiny 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. *Tamoxifen*, 466 F.3d at 208; *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."). In the case before the Court, the Federal Circuit has followed the Second Circuit's *Tamoxifen* decision.

As explained in the Petition, the Federal Trade Commission ("FTC") has conspicuously avoided challenging reverse payment agreements in district courts in the Second and Eleventh Circuits. *See* Pet. 27 (citing *FTC v. Watson Pharmaceuticals, Inc.*, No. 09-cv-598 (C.D. Cal.)). At the same time, pharmaceutical defendants are seeking to transfer cases involving reverse payment agreements to district courts within the Second and Eleventh Circuits. *See, e.g., FTC v. Watson Pharmaceuticals, Inc.*, __ F. Supp.2d __, 2009 WL 1116341 (C.D. Cal. April 8, 2009) (transferring actions challenging reverse payment agreement to the

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2. *See Valley Drug*, 344 F.3d at 311 n.26 ("To the extent that the Sixth Circuit 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.").

Northern District of Georgia); *Kroger Co. v. Sanofi-Aventis*, No. 1:06-cv-163, Opinion and Order (S.D. Ohio July 26, 2007) (denying motion to transfer to the Southern District of New York). These tactics are deliberate. Until this Court resolves the legality of pay-for-delay agreements, the behavior of plaintiffs and defendants in cases challenging such agreements shows clear recognition that the judicial circuit in which an action proceeds is likely to determine the outcome. This Court should grant the petition for a writ of certiorari in order to harmonize the inconsistent approaches taken by the circuit courts.[3]

2. a. Respondents also contend that the expiration of the Cipro patent has rendered petitioners' federal claim for injunctive relief moot. Bayer Br. 18; Generic Def. Br. 1, 11. Not so. *See* Pet. 16-17 & n.8. One of the objectives when these actions were filed was, indeed, to enjoin respondents' compliance with the challenged agreements and to facilitate commercial launches of generic ciprofloxacin. Nonetheless, broader relief to prohibit respondents (particularly respondent Barr Laboratories) from engaging in pay-for-delay

3. As the FTC recently noted to Congress, "Plaintiffs have asked the Supreme Court to review the *Cipro* decision, and we urge the Court to do so." Prepared Statement of the Federal Trade Commission Before the Subcommittee on Commerce, Trade, and Consumer Protection, Committee on Energy and Commerce, United States House of Representatives on "How Pay-for-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs" (March 31, 2009) at 6 (footnote omitted, citing Petition); *available at*: *http://www.ftc.gov/os/2009/03/P859910payfordelay.pdf*.

settlements remains appropriate. Barr is the foremost reverse payment recidivist, with agreements involving at least eight drugs, *see* Pet. 17 n.8, including tamoxifen (*see Tamoxifen*, 466 F.3d 187) and Ovcon 35® (*see FTC v. Warner Chilcott Holdings, Inc.*, No. 1:05-cv-021790CKK (D.D.C.)). Petitioners (especially third-party payors who reimburse for most prescription drugs) have a broad interest in ensuring that cost-saving, generic pharmaceuticals are available without collusively-imposed delays.

In *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100 (1969), the Court stated that

> [w]e see no reason that the federal courts, in exercising the traditional equitable powers extended to them by § 16 [of the Clayton Act, 15 U.S.C. § 26], should not respond to the salutary principle that when one has been found to have committed acts in violation of a law he may be restrained from committing *other related* unlawful acts.

Id. at 133 (citation omitted; emphasis added). Even before *Zenith*, courts recognized that the voluntary cessation of illegal conduct generally does not moot disputes over the legality of a challenged practice because "[t]he defendant is free to return to his old ways." *U.S. v. W. T. Grant Co.*, 345 U.S. 629, 632-33 (1953). Such reasoning applies with even greater force where, as here, the challenged practice has been expressly deemed *lawful* by the lower courts. In these circumstances, the natural expectation is that repetition is not only possible, *but likely*. *See* Pet. 25-27 (noting

recent increase in pay-for-delay payment agreements). Although courts cannot enjoin "all future violations of the antitrust laws," they can enjoin the continuation of repetitive practices, such as pay-for-delay settlements, that squelch generic competition. *Zenith*, 395 U.S. at 133 ("[W]hen the purpose to restrain trade appears from a clear violation of the law, it is not necessary that all of the untraveled roads to the end be left open and that only the worn one be closed.") (citation and quotation marks omitted).

In any event, the question presented relates to whether petitioners have alleged an antitrust violation in the first place, and not the scope of a potential injunction. The limited life span of patents, the ubiquity of pay-for-delay agreements and their impact on the national economy, the conflicting circuit court standards, and the strong public interest in antitrust enforcement, all militate strongly in favor of granting certiorari in this case.

b. In addition, the ciprofloxacin patent has been raised as a federal defense that immunizes conduct that would otherwise violate antitrust laws — federal or state. *See, e.g.*, *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1307 (11th Cir. 2003) ("The right of exclusion conferred by a patent has been characterized as a defense to an antitrust claim . . . ."); *In re Stock Exchanges Options Trading Antitrust Litig.*, 317 F.3d 134, 151 (2d Cir. 2005) ("Most immunities are affirmative defenses."). Although the presence of a federal patent defense does not make a case "arise under" federal law for purposes of original jurisdiction, *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800, 809 (1988),

the same federal interests advanced by a grant of certiorari to address federal law claims are equally advanced by certiorari to address a federal law defense to a state-law claim. Thus, even when a state court rejects a claim of federal preemption, such a decision is reviewable by the Court notwithstanding that the assertedly preempted claim is a state-law claim. *Franchise Tax Board v. Construction Laborers Vacation Trust*, 463 U.S. 1, 12 n. 12 (1983) (citing *Fidelity Federal Sav. & Loan Ass'n v. De la Cuesta*, 458 U.S. 141 (1982)).

c. Even if the injunctive claim and federal patent defense were absent, the legality of reverse payment settlements would still be squarely raised by Petitioners' claims for damages under state antitrust statutes. Differences between federal and state antitrust statutes generally relate only to jurisdiction (state violations need not impact interstate commerce) and injured parties who may assert claims for damages.[4] On the other hand, it is well recognized that *conduct* that violates Sections 1 and 2 of the Sherman Act also will violate most corresponding state statutes. *See* Pet. 9-10 n.5; *Cardizem*, 332 F.3d at 900. It is not surprising, therefore, that the court of appeals' analysis focused exclusively on whether the Sherman Act was violated. Pet. App. 13a-14a. As "the adequacy and independence of any possible state law ground is not clear from the face of the opinion," this Court should "accept as the

4. While indirect purchasers lack standing to bring suit for damages under Section 4 of the Clayton Act, 15 U.S.C. § 15, *see Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), this Court has expressly left it to the states to determine if state laws should permit indirect purchasers to bring antitrust damage suits. *See California v. ARC America Corp.*, 490 U.S. 93, 102-03 (1989).

most reasonable explanation" that the Court of Appeals "decided the case the way it did because it believed that federal law required it to do so." *Michigan v. Long*, 463 U.S. 1032, 1040-41 (1983). It is clearly appropriate for this Court to grant certiorari to correct such misapprehensions as to what conduct is unlawful under the Sherman Act.

d. Finally, the fact that appeals from the *same* district court opinion at issue here remain pending in the Second Circuit, Pet. 18-19, does not detract from petitioners' federal claim for injunctive relief. Petitioners bring the Court's attention to those related appeals solely because they may be material to the Court's consideration of this petition. On April 6, 2009, the Second Circuit invited the executive branch to address the question of

> whether settlement of patent infringement lawsuits violate the federal antitrust laws when a potential generic drug manufacturer withdraws its challenge to the patent's validity, which if successful would allow it to market a generic version of a drug, and the brand name patent holder, in return, offers the generic manufacturer substantial payments.

[2d Cir. No. 05-2851, doc. entry 4/6/09.] Assistant Attorney General Christine A. Varney has responded to the Second Circuit that an amicus brief on behalf of the United States can be expected by July 6, 2009. [2d Cir. No. 05-2851, doc. entry 5/7/09.] We respectfully submit that an invitation to the Solicitor General to express her views in this matter would be similarly appropriate.

3. Respondents also maintain that review is not warranted because, in their view, the Federal Circuit ruling is correct. Bayer Br. 26-37; Generic Def. Br. 6-11. This view is not shared by, among others, the FTC, the office of the Solicitor General (based on its brief in *Tamoxifen*[5]) and 54 Intellectual Property Law, Antitrust Law, Economics, and Business Professors, the American Antitrust Institute, the Public Patent Foundation, and the AARP, all of whom joined in the Brief Amici Curiae submitted by Professor Lemley.

The Federal Circuit incorrectly ruled that even untested patent rights trump any antitrust inquiry "in the absence of fraud or sham litigation." Pet. App. 26a. In reaching this conclusion the Federal Circuit (like respondents, *see* Bayer Br. 27-28; Generic Def. Br. 7-8) emphasized that "a patent is presumed to be valid, 35 U.S.C. § 282, and patent law bestows the patent holder with 'the right to exclude others from profiting by the patented invention.'" *Id.* at 26a-27a. For consumers who must ultimately foot the bill, however, the Federal Circuit's ruling has effectively rendered the presumption of validity *irrebuttable*. *Cf. In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 534 n. 23 (D.N.J. 2004) (observing in an analogous "pay for delay" case that the presumptions of validity and non-infringment "are rebuttable.").

Respondents ignore the vital public interest in patent challenges, which are the only means of ensuring that consumers are not burdened by unwarranted patent-based monopolies. *See, e.g., Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100-101 (1993); *United States v. Glaxo Group, Ltd.*, 410 U.S. 52, 57 (1973); *Blonder-Tongue Labs.*

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5. Brief for the United States as Amicus Curiae in *Joblove v. Barr Labs.*, No. 06-830, 2007 WL 1511527 (dated May 2007) at 8.

v. Univ. of Illinois Found., 402 U.S. 313, 343-45 (1971). With respect to pharmaceutical patents, Congress underscored this overriding public interest by providing a 180-day exclusivity bounty in order to *encourage* generic manufacturers to challenge brand patents. *See* U.S.C. § 355(j)(5)(B)(iv); *Pharmachemie B.V. v. Barr Labs., Inc.*, 276 F.3d 627, 629 (D.C. Cir. 2002). The Hatch-Waxman Act regime has resulted in pre-patent expiration generic entry on a number of blockbuster drugs, saving consumers billions of dollars. Of the ten best-selling drugs from 2000, for example, at least four — Paxil, Prilosec, Prozac and Zocor — have faced generic competition prior to patent expiration. *See* C. Scott Hemphill, *Paying for Delay*, 81 N.Y.U. L. Rev. 1553, 1567 n.57 (Nov. 2006). By granting pharmaceutical patentees automatic exclusion limited to 30 months during the pendency of Hatch-Waxman litigation between brand and generic manufacturers, 21 U.S.C. § 355(j)(5)(B)(iii), Congress confirmed that patent law otherwise does not provide automatic exclusion.

Courts applying patent law have not read into the rebuttable presumption of validity the ironclad right of exclusion. *See IP and Antitrust* § 7.4e2 at p. 7-41 ("[A] patent is not a right to exclude but rather a right to try to exclude.") (footnote omitted). Instead, the rebuttable presumption "is a procedural device, not substantive law." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983); *see also D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1147 n.2 (Fed. Cir. 1983). It merely assigns burdens to litigants in patent trials and cannot "acquire an independent evidentiary role in any [other] proceeding." *In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985).

Prior to an adjudication on the merits — for example, at the preliminary injunction stage — "the *patentee* carries

the burden of showing likelihood of success on the merits with respect to the patent's validity." *Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991) (emphasis in original); *see also Reebok Int'l Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1555-56 (Fed. Cir. 1994). In pharmaceutical as well as other patent cases, courts applying patent law frequently deny preliminary injunctions on the ground that, until a judicial finding of validity and infringement, the alleged infringer has a "right to compete." *See, e.g., Illinois Tool Works, Inc. v. Grip-Pak, Inc.*, 906 F.2d 679, 684 (Fed. Cir. 1990). The rebuttable presumption should not immunize the conduct of a patentee who shuns formal processes for enforcing its patent via litigation and simply pays his rivals not to enter.[6]

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6. Bayer's success in subsequent litigation involving the ciprofloxacin patent, Bayer Br. 25, does not diminish petitioners' claims arising out of the pay-for-delay agreement with Barr. *See Durango Assocs., Inc. v. Reflange, Inc.*, 843 F.2d 1349, 1356 n.4 (Fed. Cir. 1988) ("A patent should not be declared 'valid' by a court because other challengers may be able to prove invalidity using different evidence.") (citation omitted). As the first generic company to challenge the ciprofloxacin patent, Barr was the only company in a position to make significant profits from breaking the ciprofloxacin monopoly. *See* Hemphill, 81 N.Y.U.L. Rev. at 1586. Because the return on other generic manufacturers' patent challenges also "depends on the outcome of the first filer's suit (and possible settlement)," other generic manufacturers had "a strategic motivation to slow down until that uncertainty [was] reduced." *Id.* Accordingly, other generic companies did not challenge the ciprofloxacin patent until after Barr abandoned its challenge. And even then, so little time remained in the patent life that record evidence shows the challengers were compelled to narrow the bases of their challenge to the patent to omit the inequitable conduct issues that were Barr's primary challenge to

(Cont'd)

The Court should accept review of this case and reject the conclusion that the mere existence of patent rights renders pharmaceutical exclusion payment agreements — regardless of amounts paid — *per se* legal and immune from all antitrust scrutiny. As Professors Hovenkamp, Janis and Lemley have stated, pharmaceutical patentees who agree to exclusion payments seek more than enforcement of patent rights: They seek "a guaranteed insulation from competition, without the risk that the patent is held invalid." *IP and Antitrust*, § 7.4e2, at p. 7-41 (2007 Supp.). "IP policy does not offer such a guarantee, and does not immunize from antitrust scrutiny those who seek it by entering into agreements that exclude potential competitors." *Id.* The Federal Circuit's excessively deferential holding that pharmaceutical reverse payments are immunized from antitrust scrutiny so long as the competition excluded is within the facial scope of a patent should be rejected, and a more reasonable and restrictive legal standard, more consistent with forthcoming guidance to be provided to the Second Circuit by the United States government, should be adopted.

(Cont'd)

the patent, because those issues would have been too time-consuming to litigate. Fed. Cir. App. A-4891-02. Moreover, Bayer's argument that the PTO itself "confirmed the validity of" the patent on reexamination is also unfounded, since Barr's primary challenge to the patent was based on inequitable conduct, and Sections 2014, 2217 and 2258 of the Manual of Patent Examining Procedure ("MPEP") make clear that questions of inequitable conduct are not considered by the PTO on reexamination.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

PATRICK E. CAFFERTY
CAFFERTY FAUCHER LLP
101 North Main Street
Suite 450
Ann Arbor, MI 48104
(734) 769-2144

BERNARD PERSKY
CHRISTOPHER J. MCDONALD
LABATON SUCHAROW
& RUDOFF LLP
100 Park Avenue
12th floor
New York, NY 10017-5563
(212) 907-0700

JOSEPH SAVERI
ERIC FASTIFF
LIEFF, CABRASER, HEIMANN
& BERNSTEIN, LLP
780 Third Avenue
48th Floor
New York, NY 10017
(212) 355-9500

MARC H. EDELSON
HOFFMAN & EDELSON
47 West Court Street
Doylestown, PA 18901-4223
(215) 230-8043

J. DOUGLAS RICHARDS*
COHEN MILSTEIN SELLERS
& TOLL PLLC
150 East 52nd Street
Thirtieth Floor
New York, NY 10022
(212) 838-7797

ROBERT S. SCHACHTER
JOSEPH LIPOFSKY
DANIEL DRACHLER
ZWERLING, SCHACHTER
& ZWERLING, LLP
41 Madison Avenue
32nd Floor
New York, NY 10017
(212) 223-3900

DAVID KALOW
SCOTT LOCKE
KALOW & SPRINGUT LLP
488 Madison Avenue
19th Floor
New York, NY 10022
(212) 813-1600

* *Counsel of Record*

Counsel for Petitioners