No. 08- 0 8 1 1 9 4 MAR 2 3 2009

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Are pharmaceutical "reverse payment" agreements — whereby the manufacturer of a brand-name drug (and patent holder) pays a generic manufacturer (and alleged patent infringer) to not launch a generic version of the brand-name drug — *per se* lawful without regard to the amount of cash paid or the strength of the underlying patent challenge?

PARTIES TO THE PROCEEDING

Petitioners, plaintiffs below, are consumers of Cipro® (ciprofloxacin hydrochloride) and third-party payor entities that purchased, paid for, and/or reimbursed for Cipro®.[1] Respondents, defendants below, are a brand-name pharmaceutical manufacturer, Bayer AG, and its United States subsidiary Bayer Corporation ("Bayer US" and, together with Bayer AG, "Bayer"); a generic pharmaceutical manufacturer, Barr Laboratories, Inc. ("Barr"); and Barr's partners relative to its efforts to market generic ciprofloxacin hydrochloride, *i.e.*, The Rugby Group, Inc. ("Rugby"); Hoechst Marion Roussel, Inc. ("HMR" but now known as Aventis Pharmaceuticals Inc.); and, Watson Pharmaceuticals Inc. ("Watson"). Collectively, all respondents are referred to herein as "Defendants."

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1. The Petitioners are: (1) Arkansas Carpenters Health and Welfare Fund; (2) A.F. of L. - A.G.C. Building Trades Welfare Plan; (3) Mark Aston; (4) Board of Trustees of the United Food & Commercial Workers of Arizona Health and Welfare Fund; (5) Adele Brody; (6) Michelle Cross; (7) Donna Franck; (8) Kristine Gaddis; (9) David Green; (10) IBEW-NECA Local 505 Health & Welfare Plan; (11) John H. Irons; (12) Local 1199 National Benefit Fund for Health and Human Services Employees; (13) Maria LoCurto; (14) Caroline M. Loesch; (15) Kimberly McCullar; (16) Linda K. McIntyre; (17) Mechanical Contractors - UA Local 119 Welfare Plan; (18) Theresa Meyers; (19) Patricia Nelson; (20) Frances Norris; (21) Paper, Allied-Industrial, Chemical and Energy Workers International Union, AFL-CIO, CLC; (22) Mary Ann Scott; (23) Sheet Metal Workers Local 441 Health & Welfare Plan; (24) Maurice Stewart; (25) Ann Stuart; (26) United Food & Commercial Workers and Participating Food Industry Employers Tri-State Health & Welfare Fund; and (27) Vista Healthplan, Inc.

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PETITION FOR WRIT OF CERTIORARI

Petitoners respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The Court of Appeals' October 15, 2008 opinion (Pet. App. 1a- 35a) is reported at 544 F.3d 1328. On December 23, 2008, the Court of Appeals denied rehearing and *en banc* rehearing in an unreported order (Pet. App. 116a). The opinion of the district court granting the Defendants' motions for summary judgment (Pet. App. 39a-115a) is reported at 360 F. Supp. 2d 514.

JURISDICTION

The judgment of the Court of Appeals was entered on October 15, 2008. A petition for rehearing was denied December 23, 2008. The jurisdiction of this Court rests on 28 U.S.C. § 1254(1).

STATUTORY PROVISION INVOLVED

Relevant portions of the Sherman Act, 15 U.S.C. §§ 1, 2; the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. N. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman Act"); and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101-1104, 1111-1118, 117 Stat. 2066, 2448-2464 (2003) ("2003 Medicare Amendments") are set out in an appendix to this petition. Pet App. 119a-141a.

STATEMENT OF THE CASE

The Court should review this case and determine the antitrust standard applicable to pharmaceutical "reverse payment" agreements that are commonly used to delay the launch of generic versions of brand-name drugs. Under such agreements, the manufacturers of branded drugs (who are patent holders) pay millions — or, as in this case, *hundreds* of millions — of dollars to generic pharmaceutical manufacturers (who are alleged patent infringers) to delay the launch of generic versions of the branded drugs. The fact that the *plaintiffs* in patent infringement litigation are paying cash to the *defendants, i.e.*, the payments are "reversed" from the usual, suggests that the parties are engaged in market allocation rather than a bona fide settlement of litigation. The Courts of Appeals that have addressed these agreements have rendered inconsistent and irreconcilable decisions on a matter of fundamental importance to public health and welfare.

In *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006), *cert. denied sub nom. Joblove v. Barr Labs., Inc.*, __ U.S. __, 127 S. Ct. 3001 (2007), the Second Circuit held that reverse payment agreements are beyond the reach of antitrust scrutiny and, for all practical purposes, *per se* legal. In reaching this conclusion, the Second Circuit relied heavily on the district court decision that has now been affirmed the Federal Circuit in this case, *see* 466 F.3d at 204-213 (citing Pet. App. 67a-91a). In contrast, the Sixth Circuit considers such agreements *per se* illegal. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003). The Eleventh Circuit applies its own test that inquires into

the validity of the underlying patent at the time of the exclusion payment before evaluating the antitrust implications of a reverse payment agreement. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003).

In the petition for certiorari that followed the *Tamoxifen* decision (No. 06-830), the United States (by the Solicitor General) agreed that "[t]he petition raises important and complex issues concerning the antitrust treatment of settlements in patent cases, particularly settlements that provide for delayed entry into the market by the alleged infringer in exchange for a 'reverse payment' from the patent holder." Brief for the United States as Amicus Curiae in *Joblove v. Barr Labs.*, No. 06-830, 2007 WL 1511527 (dated May 2007) ("US Brief in *Tamoxifen*") at 8. According to the United States, the Second Circuit "applied an insufficiently stringent standard in scrutinizing the settlement at issue here." *Id.*[2]

That same "insufficiently stringent standard" was followed by the Federal Circuit below. Pet. App. 23a-24a.[3]

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2. The United States nonetheless recommended against certiorari in *Tamoxifen* on grounds that are inapplicable to the instant petition. See pp. 15-19, *infra*.

3. The Federal Circuit applies the law of the regional circuit, in this case, the Second Circuit, to the elements of antitrust claims that are not unique to patent law. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1067-68 (Fed. Cir. 1998) (en banc in relevant part). The appeal in this case was transferred from the Second Circuit to the Federal Circuit as a (Cont'd)

The inconsistency in the approaches taken by the Courts of Appeals, as well as by antitrust enforcement authorities, continues to create enormous uncertainty, preventing clarity both in antitrust counseling and in the litigation of frequently recurring antitrust issues in the pharmaceutical field.

A. Petitioners Have Demonstrated a Horizontal Market-Allocation Agreement That Violates Federal and State Antitrust Law.

The core antitrust allegations in this litigation spring from agreements reached among several of the Defendants in a *prior* litigation. Bayer owns U.S. Patent No. 4,670,444 (the "'444 Patent"), the compound patent that claims ciprofloxacin. Barr is a competitor of Bayer's that manufactures and markets generic versions of brand-name drugs.

In 1991, Barr filed an application with the United States Food and Drug Administration ("FDA") seeking regulatory approval to sell a generic version of Cipro. In its application, Barr challenged the validity and enforceability of the '444 Patent, which prompted Bayer to sue Barr for infringement (the "*Bayer v. Barr* Patent

(Cont'd)

result of *Walker Process*-like claims unrelated to the challenged reverse payment agreements. *See* Pet. App. 36a-38a. In fact, the Second Circuit denied transfer of appeals by drug wholesalers and retailers from the same summary judgment decision at issue here, but who did not bring *Walker Process* monopolization claims. *Id.* at 37a. As of the date of this petition, those appeals remain pending in the Second Circuit [2d Cir. Nos. 05-2851 & 05-2852].

Litigation"). Were Barr to succeed in invalidating the '444 Patent, it would have made millions of dollars upon entering the ciprofloxacin market and sharply undercutting Bayer's price for Cipro. And Cipro consumers and third-party payors would benefit from the lower prices offered by Barr and other generic competitors entering the market with ciprofloxacin products. For its part, Bayer would see its lucrative Cipro monopoly, which was then yielding nearly $1 billion per year, virtually vanish.

To avoid the risk of that result, Bayer instead bought the result it wanted. On the eve of trial the parties settled the *Bayer v. Barr* Patent Litigation by entering into a series of agreements (the "Cipro Agreements"), pursuant to which Bayer, the patent holder, paid out $398 million to Barr, the alleged infringer and, directly or indirectly, to the other defendants. In exchange for these payments (referred to by the district court as "reverse payments" or "exclusion payments" (*see* Pet. App. 47a)), Barr and the other Defendants agreed not to manufacture or market any generic versions of Cipro during the life of the '444 Patent. *Id.* at 45a. Thus, Bayer was able to exclude competitors not by *enforcing* its patent, but by *ceasing* to enforce its patent and instead paying its competitors to abandon the market.

B. Defendants Co-Opted the Hatch-Waxman Act For Their Anticompetitive Purposes.

Defendants' unlawful conduct in entering into the Cipro Agreements should be considered in context. The only reason the litigation between Bayer and Barr could proceed in the first place was because specific federal legislation – the Hatch-Waxman Act – permitted, and indeed encouraged it. A company seeking to market a new prescription drug in the United States must secure approval from the FDA. 21 U.S.C. § 355(a). In 1984, Congress passed the Hatch-Waxman Act, 21 U.S.C. § 355(j), which amended the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, to establish an abbreviated process to expedite the development, approval and marketing of generic drugs. *See Andrx Pharms., Inc. v. Biovail Corp.*, 256 F.3d 799, 809 (D.C. Cir. 2001) ("Congress sought to get generic drugs into the hands of patients at reasonable prices – fast.") (citation omitted). Hatch-Waxman permits a generic drug manufacturer to file an Abbreviated New Drug Application ("ANDA") that incorporates by reference safety and efficacy data developed and previously submitted by the "pioneer" or brand-name drug manufacturer. An ANDA filer must demonstrate that its product is "bioequivalent" to the pioneer drug. 21 U.S.C. § 355(j)(2)(A)(iv).

An ANDA filer must make one of four certifications in its ANDA, two of which matter here, *i.e.*, the "Paragraph III Certification," which states that the patent for the pioneer drug listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") will

expire on a particular date and the ANDA filer does not seek FDA approval of its ANDA before that date, and the "Paragraph IV Certification," which states that the patent listed in the Orange Book is invalid or will not be infringed by the sale of the generic company's product. 21 U.S.C. § 355(j)(2)(A)(vii).

An ANDA applicant making a Paragraph IV Certification (an "ANDA(IV) filer") must notify the patent owner (the "ANDA Notification"). 21 U.S.C. § 355(j)(2)(B). Thereafter, the patent holder may initiate a patent infringement suit against the ANDA(IV) filer; if an infringement action is initiated within 45 days, the FDA is forbidden from granting final approval to the ANDA until: (1) the patent expires; (2) the expiration of 30 months from the ANDA Notification (the "30-Month Stay"); or (3) a final judicial determination of invalidity or non-infringement. 21 U.S.C. § 355(j)(5)(B)(iii).

To encourage patent challenges, the first ANDA(IV) filer is eligible for a 180-day period as the exclusive producer of the generic formulation of the pioneer drug. 21 U.S.C. § 355(j)(5)(B)(iv). The exclusivity period will not begin to run until triggered by either: the commercial marketing of the generic drug by the first ANDA(IV) filer; or a decision of a court finding the pioneer drug's patent to be invalid, unenforceable or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv); *see also* 21 C.F.R. § 314.107. Until the 180-day exclusivity period has been triggered and run its course, the FDA is prevented from approving any other ANDA. 21 U.S.C. § 355(j)(5)(B)(iv)(I).

As Barr was the first ANDA(IV) filer, Bayer also bought Barr's cooperation in manipulating the exclusivity period for their joint benefit and to the detriment of other generic competitors. The Cipro Agreements required Barr to withdraw its Paragraph IV Certification and replace it with a Paragraph III Certification. However, Barr retained the option to refile a Paragraph IV Certification in the event a competitor successfully challenged the '444 Patent. This worked as a disincentive for other competitors because it removed the financial incentive of the exclusivity period and introduced the prospect of additional delay before market entry. *See, e.g.*, C. Scott Hemphill, *Paying for Delay*, 81 N.Y.U. L. Rev. 1553, 1586 (Nov. 2006) ("Generic firms other than the 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.").

In entering the Cipro Agreements, Defendants turned Hatch-Waxman – the "Drug Price Competition" statute – on its head, delaying generic entry into the ciprofloxacin market and ensuring that consumers and their prescription drug benefit providers would pay *more than ever* for Cipro. With its monopoly intact, Bayer raised the price of Cipro to fund its exorbitant exit payments to Barr and the other defendants. Indeed, to call the Cipro Agreements a "settlement" ignores economic reality; Barr and its litigation partners made more from the exit payments than they would have made

had they invalidated the '444 Patent and entered the market with a competing generic product.[4]

C. The Course of the Proceedings and the Disposition in The District Court.

In 2000 and 2001, antitrust actions challenging the Cipro Agreements were filed in state and federal courts. Pursuant to 28 U.S.C. § 1407, the Judicial Panel on Multidistrict Litigation centralized all cases in the United States District Court for the Eastern District of New York, before the Hon. David G. Trager. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, MDL No. 1383, 2001 WL 253240 (J.P.M.L. Jan. 10, 2001).

On October 1, 2001, the district court remanded nine cases to various state courts, and retained jurisdiction over two cases that satisfied the requirements for diversity jurisdiction. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F. Supp. 2d 740 (E.D.N.Y. 2001). On December 18, 2001, Petitioners filed an amended consolidated class action complaint that asserted claims for injunctive and declaratory relief for violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and for damages under state law.[5]

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4. For example, Petitioners' economic expert opined that $398 million was more than twice the but-for profits that Barr could have reasonably expected to earn. *See* Fed. Cir. Appendix A-3426-28.

5. It is well recognized that conduct that violates Sections 1 and 2 of the Sherman Act also will violate most corresponding state antitrust statutes. *United States v. Microsoft Corp.*, (Cont'd)

On May 20, 2003, the district court, *inter alia*, granted Watson's motion to dismiss all claims against it for failure to state a claim. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188 (E.D.N.Y. 2003).

On March 31, 2005, the district court granted Bayer's partial summary judgment motion and Barr's, Rugby's and HMR's joint summary judgment motion, dismissing Counts I through IV of the Complaint, and granted Bayer's motion to dismiss Count V of the Complaint. Pet. App. 39a-115a.

Final judgment was entered on April 8, 2005, and after being granted an extension of time within which to file an appeal, Petitioners timely filed a Notice of Appeal to the Second Circuit on June 6, 2005.

On November 11, 2007, the Second Circuit granted Defendants' motion to transfer Petitioners' appeal (2d Cir. No. 05-2863) to the Federal Circuit. Pet. App. 36a-38a. In that same order, the Second Circuit denied

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(Cont'd)

87 F. Supp. 2d 30, 54 n. 7 (D.D.C. 2000) ("The facts proving that Microsoft unlawfully maintained its monopoly power in violation of § 2 of the Sherman Act are sufficient to meet analogous elements of causes of action arising under the laws of each plaintiff state.") (footnote citing eighteen state statutes omitted), *affirmed in part rev'd in part on other grounds by*, 253 F.2d 34 (D.C. Cir. 2001). In fact, many state antitrust statutes expressly adopt federal antitrust precedents as controlling guidance. *E.g.*, Ariz. Rev. Stat. § 44-1412; D.C. Code Ann. § 28-4515; Iowa Code § 553.2; N.M. Stat. Ann. § 57-1-15; S.D. Codified Laws § 37-1-22; W. Va. Code Ann. § 47-18-16.

Defendants' motion to transfer related appeals filed by drug wholesalers and retailers (2d Cir. Nos. 05-2851 & 05-2852). Those appeals remain pending in the Second Circuit, resulting in the extraordinary circumstance of two distinct appeals, to different Circuits, from the same summary judgment order.

D. The Disposition by the Federal Circuit.

On October 15, 2008, a panel of the Federal Circuit affirmed judgment in favor of Defendants. Pet. App. 1a-35a. Following the Second Circuit decision in *Tamoxifen* (which followed the district court opinion that was affirmed by the Federal Circuit below), the panel agreed that "any adverse anti-competitive effects within the scope of the '444 patent could not be redressed by antitrust law." Pet. App. 3a.

> 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.

Pet. App. 23a-24a (citing *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 175-77 (1965)).

REASONS FOR GRANTING THE PETITION

Review by this Court is necessary to reconcile conflicting standards adopted by the Courts of Appeals relative to a matter of vital importance to all Americans, *i.e.*, the escalating cost of prescription drugs. The disagreements among the circuits, on an issue of such basic importance, will continue to cause uncertainty, litigation and delays in generic entry, resulting in billions of dollars in overpayments for pharmaceuticals or, sadly, some consumers' inability to purchase needed medications.

Brand-name drugs, many of which claim patent protection, account for most of the increase in drug costs. Generic drugs — chemically and pharmacologically identical but lacking a brand-name — are much less costly, on average about half the price of comparable brand-name drugs. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration; An FTC Study* 9 (2002), *available at* www.ftc.gov/os/2002/07/genericdrugstudy.pdf. When generic versions of popular brand-name drugs are launched, the generics quickly capture the bulk of the market, saving consumers billions of dollars. *See* Federal Trade Commission, *Prepared Statement of the Federal Trade Commission before the Special Committee on Aging of the United States Senate on Barriers to Generic Entry*, July 20, 2006 ("FTC July 2006

Statement")[6], p. 6 ("As a result of price competition, as well as the policies of public and private health plans and state laws that encourage the use of generic drugs, generic sellers typically capture anywhere from 44 to 80 percent of branded sales within the first full year after launch of the lower-priced generic product.") (footnote omitted); *Sanofi-Syntholabo v. Apotex Inc.*, No. 02-2255, 2006 WL 2516486, at *25 (S.D.N.Y. Aug. 31, 2006) (generic version of popular brand-name drug Plavix captured 78.4% of sales within three weeks).

A delay in the launch of a generic version of a widely prescribed drug forces consumers to pay millions of dollars *a day* in monopoly rents. Thus, brand-name manufacturers have become adept at abusing the Hatch-Waxman regime to block, frustrate and delay generic entry. When all else fails, brand companies often pay cash to forestall competition. *See* pp. 25-26, *infra*. In the end, consumers must pay higher prices for branded drugs for longer periods as a result of a patent challenge originally launched under the provisions of the Hatch-Waxman Act.

> These settlements, which appear to be unique to the pharmaceutical industry, occur when a branded company shares a portion of its future profits with a potential generic entrant in exchange for the generic's agreement not to market is product. Although both the brand company and the generic company are better off financially, these settlements

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6. *Available at:* http://www.ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySenate07202006.pdf.

> restrict competition at the expense of consumers, whose access to lower-priced generic drugs may be deferred for years.

FTC July 2006 Statement, p. 5-6.

Under the standard set forth in the decision below and *Tamoxifen*, antitrust scrutiny of pharmaceutical reverse payment agreements will be limited to: (1) whether infringement claims based on the patent at issue constitute a "sham" or fraud; and (2) whether the agreement is limited to the facial scope of the patent. *See* Pet. App. 23a-24a; *Tamoxifen*, 466 F.3d at 208-09. Review under the Sixth and Eleventh Circuit standards require markedly different approaches. *See In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) (reverse payment agreements *per se* illegal); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294 (11th Cir. 2003) (rule of reason inquiry into the strength of the patent at the time of the reverse payment); pp. 20-22, *infra*.

In addition to the inconsistent positions of the Courts of Appeals, the FTC has advanced a "rule of reason" inquiry that does not require direct analysis of the patent merits at all, at least in government enforcement proceedings, but instead focuses on the existence and amount of the reverse payment and other circumstantial factors. *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651 (FTC Dec. 8, 2003), *rev'd, Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (rejecting the FTC's approach), *cert. denied*, 548 U.S. 919 (2006). The United States (through the Solicitor General), has stated that

"[i]n determining whether the exclusionary effect of a settlement involving a reverse payment renders the settlement unreasonable and anticompetitive, a court at a minimum should take into account the relative likelihood of success of the parties' claims viewed ex ante." US Brief in *Tamoxifen* at 12; *accord* Brief for the United States as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273 (dated May 2006) at 11.

The Court should accept review of this case to resolve the stark inconsistency in circuit and other authority.[7]

This case also provides an appropriate context in which to consider the question presented. In *Tamoxifen*, the Solicitor General opined that "[a]lthough the court of appeals applied an erroneous standard for scrutinizing patent infringement settlements that include reverse payments, this case is not an attractive vehicle for the Court's consideration of the difficult and context-sensitive questions involved in assessing the legality of such settlements." US Brief in *Tamoxifen* at 16-17. For at least four reasons, a different conclusion is appropriate in this case.

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7. The Court 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. *See, e.g.*, C. Scott Hemphill, *Paying for Delay*, 81 N.Y.U. L. Rev. 1553 (Nov. 2006). There, Professor Hemphill maintains that the FTC, the Eleventh Circuit and the Second Circuit incorrectly analyze these cases in terms of whether the patent or antitrust laws should be accorded primacy, because: (1) the Hatch-Waxman Act established a regulatory regime that trumps the patent law in that particular context; and (2) the issue is how the antitrust laws should be applied under that regulatory regime (not under the patent laws).

First, the Solicitor General rested his conclusion largely on an assertion that the factual setting in *Tamoxifen* was "atypical and unlikely to recur" because "[t]he fact that the settlement at issue in this case occurred after a judgment of invalidity highlights the court of appeals' error in refusing to assess the validity of the patent, and might play a substantial role in the Court's analysis of the merits." *Id.* at 19. By contrast, in this case there was no such finding of patent invalidity prior to the settlement, and no such finding was vacated in connection with the settlement. Thus, this central aspect of the Solicitor General's arguments against a grant of certiorari in *Tamoxifen* is completely inapplicable in this case.

Second, the Solicitor General opined in *Tamoxifen* that the federal injunctive claims appeared to be moot – despite the established rule that an injunction can properly enjoin a repeated antitrust offender from engaging in similar unlawful practices even after the challenged conduct has ceased as to the specific matters at issue in a case[8] — based on the hypothesis that the

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8. *See, Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 133 (1969)("[W]hen one has been found to have committed acts in violation of the law he may be restrained from committing other related unlawful acts."); *United States v. W.T. Grant Co.*, 345 U.S. 629, 632-33 (1953)("The defendant is free to return to his old ways. This, together with a public interest in having the legality of the practices settled, militates against a mootness conclusion."); *Friends of Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 189 (2000)("It is well settled that a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power

(Cont'd)

issue might be considered in a later case, in the event of further unlawful behavior by the repeatedly wrongdoing defendant, because *other* patents held by that defendant might not expire before the plaintiffs "could obtain relief." US Brief in *Tamoxifen* at 17. However, respondent Barr Laboratories, Inc. was a defendants both in this case and in *Tamoxifen*. That the patent in this case expired prior to the petition for certiorari here, just as occurred in *Tamoxifen*, tends to confirm that patents at issue in these cases will often expire prior to an opportunity for review by this Court, thereby causing the issue of unlawfulness of the conduct to "evade review" if the injunctive claims are regarded as moot merely because the particular patent in question expires before a petition for certiorari is considered.

Third, an examination of the Federal Circuit's decision gives no indication whatsoever that it believed

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(Cont'd)

to determine the legality of the practice" unless it is "absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur."). Respondent Barr Labs., Inc. is the foremost example of a reverse payment recidivist, having been party to a large number of reverse payment agreements. *See* C. Scott Hemphill, *Drug Patent Settlements Between Rivals, A Survey*, at 3 (Mar. 12, 2007) attached to Testimony of C. Scott Hemphill before the House Committee on Energy and Commerce, Hearing on H.R. 1902, May 2, 2007, available at: *http://energycommerce.house.gov/cmte_mtgs/110-ctcp-hrg.050207.Hemphill-testimony.pdf*. ("Of the seventeen innovators and eighteen generic firms that are party to the settlements, a few appear repeatedly. Generic firm Barr Laboratories, for example, reached settlement with respect to eight different drugs.").

its decision stemmed from anything specific in the state laws under which the damage claims are asserted. Indeed, the Federal Circuit's decision, just like that of the District Court, analyzes the reverse payment claims in this case entirely as though they were asserted *under federal law* rather than state law. *See* Pet. App. 33a ("[W]e affirm the district court's grant of summary judgment on Counts I-IV, holding that the Agreements *were not violative of Section 1 of the Sherman Act . . . .*") (emphasis added). Counts I-IV of the complaint include all of the reverse payment claims, including claims for injunctive relief under federal law (Count I) and state law (Count III). Just as in *Michigan v. Long*, 463 U.S. 1032, 1040-41 (1983), it is clear at a minimum that the Court of Appeals' "interpretation of state law has been influenced by an accompanying interpretation of federal law." *Three Affiliated Tribes of Fort Berthold Reservation v. World Engineering, P.C.*, 467 U.S. 138, 152 (1984). It is clearly appropriate for this Court to grant certiorari to correct misapprehensions, such as those unambiguously expressed in the Federal Circuit's opinion, as to what type of conduct is unlawful under the Sherman Act.

Finally, there are federal injunctive and damage claims in the companion case presently pending in the Second Circuit [2d Cir. Nos. 05-2851 & 05-2852], and both appeals stem originally from the same district court opinion. To facilitate comprehensive review of the entire decision of the district court on reverse payment issues, it would be most appropriate to defer ruling on this petition for certiorari until a petition is filed by the parties in the parallel portion of the case that is on appeal in the Second Circuit, and to consider both petitions for

certiorari together. There were no such parallel "direct purchaser" claims under federal antitrust law in the *Tamoxifen* case. The Solicitor General's brief in *Tamoxifen* sheds no light on what the recommendation of the Solicitor General would have been, with regard to the petition for certiorari in *Tamoxifen*, if comparable parallel federal damage claims had been present in that case.

I. The Standard Adopted By Decisions Below and *Tamoxifen* Conflicts with Standards Articulated by Other Circuits, the Federal Trade Commission and Scholarly Commentators.

Under the majority opinion in *Tamoxifen*, an agreement between a patent holder and an alleged infringer to settle Hatch-Waxman patent litigation cannot violate the antitrust laws unless the patent litigation was a fraud, sham or otherwise baseless, or the settlement agreement imposes restrictions on the alleged infringer that extend beyond the scope of the challenged patent. *Tamoxifen*, 466 F.3d at 208-09. The Federal Circuit agrees that "[t]he essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent." Pet. App. 24a. Pharmaceutical reverse payment agreements are therefore beyond the reach of antitrust scrutiny, even if, as here, the patent holder makes enormous payments to the alleged infringer in exchange for the latter's promise to abandon the patent challenge and its efforts to launch a generic product.

The *Tamoxifen* majority recognized that such *per se* legality shields questionable settlements involving

"fatally weak" patents, but concluded that the policy favoring settlement is so strong that it trumps antitrust concerns. *Tamoxifen*, 466 F.3d at 211 ("So long as the law encourages settlement, weak patent cases will likely be settled even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved."). As the Solicitor General has recognized, however, the general preference for settlements must be tempered when settlements have important adverse consequences on third-parties. *See* US Brief in *Tamoxifen* at 9 ("Although public policy wisely encourages settlements of legal disputes, it does not follow that all settlements are consistent with the antitrust laws.") (citation and quotation marks omitted).

The Sixth and Eleventh circuits have reached different conclusions. In *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), the Sixth Circuit upheld the trial court's summary judgment ruling that a reverse payment agreement was *per se* illegal, *i.e.*, *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 683 (E.D. Mich. 2000). "There is simply no escaping the conclusion that the Agreement, all of its other conditions and provisions notwithstanding, was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade." 332 F.3d at 908. The substantial reverse payment made by the patent holder to the patent challenger was the driving force in the Sixth Circuit's reasoning. "It is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors *by paying the only potential*

competitor $40 million per year to stay out of the market." *Id.* (emphasis added). The Sixth Circuit's decision is irreconcilable with the decisions below, which render issues such as the size of any reverse payment made to the patent challenger legally irrelevant. Indeed, the Federal Circuit has expressly disagreed with the Sixth Circuit's approach. Pet. App. 21a ("To the extent that the Sixth Circuit may have found a per se antitrust violation based solely on the reverse payment, we respectfully disagree.").

Valley Drug Co. v. Geneva Pharm., Inc., 344 F.3d 1294 (11th Cir. 2003) reversed a trial court ruling that a reverse payment agreement was *per se* illegal. The Eleventh Circuit held that because the "exclusionary power" of the patent needed to be considered, a rule of *per se* liability would be inappropriate "when no court had declared [the brand manufacturer's] patent invalid or unenforceable at the time of the Agreements." *Id.* at 1306 & n.18. Thus, the Eleventh Circuit has also expressly disagreed with the Sixth Circuit.[9] *Valley Drug*

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9. *See Valley Drug*, 344 F.3d at 311 n.26 ("To the extent that the Sixth Circuit [in *Cardizem CD*] 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.") (emphasis added); *accord Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065 (11th Cir. 2005), *cert. denied*, 126 S.Ct. 2929 (2006). *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 (Cont'd)

held that a fair analysis of the "exclusionary power" of the patent should include such factors as "what lost profits [the brand-name manufacturer] expected from generic competition or what profits [the generics] expected to gain from entry." 344 F.3d at 1310. This inquiry is necessary because "the size of the payments might be evidence supporting a claim that the patentee knew that the patent was procured by fraud, or knew that the patent was invalid, or that there was no objective basis to believe the patent was valid." *Id.* at 1310 n.22. These elements of the *Valley Drug* opinion are irreconcilable with the decisions below and *Tamoxifen*.[10]

Hatch-Waxman Act reverse payment agreements have also been a "hot button" issue in antitrust scholarship for years. Academic literature is largely divided between "rule of reason" proponents, on the one hand, and *per se* illegality proponents on the other. Until *Tamoxifen*, no one had argued for *per se* legality, as the

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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.").

10. The Eleventh Circuit revisited these issues in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), but made clear that it continues to adhere to *Valley Drug*. *Id.* at 1065 ("We are bound by our decision in *Valley Drug*."). The *Schering* opinion also states that although the mere existence of a reverse payment is insufficient to establish unlawfulness, "[t]his alone underscores *the need to evaluate the strength of the patent*." *Id.* (emphasis added).

dissent there points out. *Tamoxifen*, 466 F.3d at 227-28 (Pooler, J., dissenting).[11] One of the foremost antitrust commentators has expressed the frank view that the district court's reasoning below (in *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005)) just "doesn't work under Hatch-Waxman." Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *IP and Antitrust*, § 7.4 at 7-37 (2007 Supp.); *see also* Hemphill, 81 N.Y.U. L. Rev. at 1582-85 (addressing the *Tamoxifen* court's misunderstanding of the exclusivity period incentive).

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11. Some 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. *See* C. Scott Hemphill, *Paying for Delay*, 81 N.Y.U. L. Rev. 1553 (Nov. 2006); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *IP and Antitrust*, § 7.4e2 at 7-36 to 41 (2009 Supp.); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719 (June 2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391 (2003); Jeremy Bulow, *The Gaming of Pharmaceutical Patents, in 4 Innovation Policy and the Economy*, (Adam B. Jaffe et al. eds. 2004); Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, 19 J. Econ. Perspectives 75 (2005); Joseph Farrell & Carl Shapiro, *How Strong Are Weak Patents?* Competition Policy Center Working Paper 05-054 (2005), *available at* http://repositories.cblib.org/iber/cpc/CPC05-54/. Others have argued for application of the rule of reason, Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla. L. Rev. 747, 779-96 (2002); Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 Antitrust Bull. 491, 534-38 (2002), or for per se illegality. Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements*, 87 Minn. L. Rev. 1767, 1781-82 (2003).

II. Recent Decisions have Undermined FTC Enforcement Efforts that had virtually Eliminated Pharmaceutical Exclusion Payments

Recent decisions, including the decisions below, have encouraged pharmaceutical companies to collude rather than compete and have undermined FTC enforcement of competition law. Prior to the *Schering* and *Tamoxifen* decisions, FTC enforcement actions[12] and private antitrust litigation[13] had virtually eliminated reverse payment settlements in Hatch-Waxman patent litigation. Section 1112 of the 2003 Medicare Amendments, signed by President Bush on December 8, 2003, requires the submission of pharmaceutical agreements to the FTC and Department of Justice. Congress passed this law to "re-emphasize the Hatch-Waxman Act's original intent of enhancing competition, not collusion, between generic and name-brand manufacturers." Brief for Henry A. Waxman as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273, 2005 WL 2462026 (dated Sept. 30, 2005) at 10.

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12. *See, e.g., In the matter of Hoechst Marion Roussel, Inc., et al.*, No. 9293 Decision and Order (FTC May 8, 2001) (regarding Cardizem CD), *available at* http://www.ftc.gov/os/2001/05/hoechstdo.htm; *In the matter of Abbott Laboratories, et al.*, No. C-3945, Decision and Order (FTC May 22, 2000) (regarding Hytrin), *available at* http://www.ftc.gov/os/2000/05/c3945.do.htm. Most recently, the FTC and the State of California have challenged a pay-for-delay agreement in *FTC v. Watson Pharm., Inc.*, CV No. 09-00598 (C.D. Cal.) (complaint filed Jan. 29, 2009).

13. *See, e.g. In re Cardizem CD Antitrust Litig.*, 218 F.R.D. 508 (E.D. Mich. 2003), *aff'd in part and dismissed on other grounds*, 391 F.3d 812 (6th Cir. 2004).

For fiscal year 2004, none of the fourteen reported agreements between brand and generic manufacturers contained a payment from the brand to the generic accompanied by deferred generic entry.[14] *http://www.ftc.gov/oos/2005/1/050107medicareactrpt.pdf)* In other words, the parties to Hatch-Waxman patent litigation found ways to settle that did not require paying-off the generic manufacturer. For fiscal 2005, there were sixteen settlements and three included payments to the generic companies to defer market entry.[15] The Eleventh Circuit decision in *Schering*, issued midway through the fiscal year, had revived the practice.

The FTC reports for fiscal years 2006 and 2007 found dramatic increases in exclusion payments.[16] For

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14. 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 FY 2004: A Report by The Bureau of Competition* (Jan. 7, 2005), *available at* http://www.ftc.gov/opa/2005/01/drugsettlement.htm.

15. 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 2005: A Report by the Bureau of Competition* (April 24, 2006), *available at*: http://www.ftc.gov/opa/2006/04/drugsettlements.shtm.

16. *See* 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* (Jan. 17, 2007) ("FY 2006

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FY 2006, fourteen of the twenty-eight final settlements (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. *See* FY 2006 Report at 4 ("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."). For FY 2007, fourteen of the thirty-three final settlements (42%) included such provisions. FY 2007 Report at 3. "The vast majority of these agreements involved first filer generic companies (79%)." *Id.* at 2.

There can be no doubt that the *Schering* and *Tamoxifen* decisions 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[17] ("If the *Schering* and *Tamoxifen* decisions are not reversed — that is, if branded firms are empowered by

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Report"), *available at*: http://www.ftc.gov/opa/2007/01/drugsettlements.htm; 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 2007: A Report by the Bureau of Competition* (May 2008) ("FY 2007 Report"), *available at*: http://www.ftc.gov/opa/2008/05/drug.shtm.

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

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.") & 13-14 ("[J]ust before *Schering* and *Tamoxifen*, there were no [reverse] payments; just after them, this appears to be the new way to do business."). Those decisions, followed by the Federal Circuit in this case, fostered a new era for reverse payment agreements that keep lower-priced generic drugs *out* of consumers' hands, contrary to the express purposes of the Hatch-Waxman Act. Judge Pooler's dissent in *Tamoxifen* — which characterized the majority's "tacit assumption that the settling parties will not act to injure the consumer or competition" as "panglossian" (466 F.3d at 228 n. 5) — has proved prophetic.

The FTC continues to challenge reverse payments, but it has conspicuously avoided bringing such cases in district courts within the Second and Eleventh Circuits and its own administrative proceedings (wherein an aggrieved defendant can choose the Court of Appeals). *See, e.g.*, *Federal Trade Commission v. Cephalon, Inc.*, No. 08-cv-2141-RBS (E.D. Pa.) (concerning reverse payment agreement delaying generic versions of Provigil); Federal Trade *Commission v. Watson Pharmaceuticals, Inc.*, No. 09-cv-598 (C.D. Cal.) (concerning reverse payment agreement delaying generic versions of AngroGel).

III. This Case Presents a Straightforward Pay-for Delay Agreement Without Materially Unique Fact Issues.

This case is a particularly attractive vehicle for addressing conflicting circuit court standards because it involves an unambiguous pay-for-delay deal that was entered before increased scrutiny from the FTC caused pharmaceutical companies to conceal exclusion payments in increasingly complex arrangements. As recently explained in testimony before Congress, reverse payment settlements have occurred in two distinct waves.[18] The first wave began in 1993 and ended in 2000, after the FTC made clear its opposition to pay-for-delay settlements. The second wave began in 2005, in "direct response to the failure of federal courts [in *Schering-Plough* and *Tamoxifen*] to recognize and resolve the pay-for-delay issue." Hemphill Testimony at 8. "That failure is likely to be compounded, moreover, by an evolution in the means by which innovators now pay for delay." *Id.*

> In the earliest settlements, such as tamoxifen, BuSpar, Zantac and ***Cipro*** settlements, payment *was a relatively straightforward*

18. Testimony of C. Scott Hemphill, Associate Professor, Columbia Law School, House Committee on Energy and Commerce, Subcommittee on Commerce, Trade and Consumer Protection, Hearing on H.R. 1902, Protecting Consumer Access to Generic Drugs Act of 2007 (May 2, 2007) ("Hemphill Testimony") at 7; *available at:* http://energycommerce.house.gov/cmte_mtgs/110-ctcp-hrg.050207.Hemphill-testimony.pdf.

> *affair*. In exchange for the generic firm's delayed entry, the brand-name firm paid cash. Modern settlements also entail payment for delay, *but the parties avoid a straight conveyance of cash*, preferring instead to employ a variety of alternative forms of payment.

Id. at 8-9 (emphasis added).

More recent agreements often rely upon complicated side deals as "means to smuggle compensation to the generic firm." *Id.* at 9; *see, e.g.*, Brief for the United States as Amicus Curiae in *FTC v. Schering-Plough Corp.*, No. 05-273, 2006 WL 1358441 (dated May 2006) at 12-13 (recommending denial of certiorari because, *inter alia*, "[t]he court of appeals determined that Schering's $60 million payment to Upsher was not compensation for delayed market entry by Upsher, but was instead an independent and bona fide royalty payment by Schering to license Upsher's product.") (citation to record omitted). Indeed, in *Schering* the Solicitor General pointed to eventual review of the *Ciprofloxacin* litigation as grounds to deny plenary review there. *See id.* at 16.

Accordingly, the facts of this case and the rulings below will allow the Court to address the antitrust implications of a straightforward, pay-for-delay agreement. Absent guidance by this Court, the conflicting circuit court standards leave everyone — the pharmaceutical industry, antitrust regulators, and the purchasers and consumers of pharmaceuticals (*i.e.*, those who ultimately must pay the bill) — in a quandary.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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