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

BRIEF OF *AMICUS CURIAE* THE AMERICAN ANTITRUST INSTITUTE IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*[1]

The American Antitrust Institute ("AAI") is an independent non-profit education, research, and advocacy organization. Its mission is to advance the role of competition in the economy, protect consumers, and sustain the vitality of the antitrust laws. The Advisory Board of AAI, which serves in a consultative capacity,[2] consists of prominent antitrust lawyers, law professors, economists, and business leaders. *See http://www.antitrustinstitute.org*.

AAI's Board of Directors has authorized the filing of this brief because it believes that the Second Circuit's economic and legal reasoning is flawed and seriously threatens competition. If left standing, the opinion will undermine the careful statutory scheme that seeks to prevent weak or narrow patents from blocking the market entry of generic drugs and reducing competition. The stakes for consumers are high. The opinion will encourage and allow brand name manufacturers to pay generic competitors to keep their cheaper generic drugs off the market.

THE RELEVANT DECISIONS

Competition from generic drugs is one of the few effective means of slowing the spiraling cost of brand pharmaceuticals. Generic drugs typically sell for a fraction of the price of their brand counterparts and quickly capture the majority of unit sales, saving consumers billions of dollars on a blockbuster drug like

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[1] The written consents of all parties to the filing of this brief have been lodged with the Clerk. No counsel for a party has authored this brief in whole or in part, and no person or entity other than AAI or its counsel has made a monetary contribution to the preparation or submission of this brief.

[2] The AAI is managed by its Board of Directors. One member of the Board has recused himself from the matter. The individual views of members of the Advisory Board may differ from the positions taken by AAI. Two members of the Advisory Board have represented companies that are plaintiffs in the *Tamoxifen* case and one member has represented a defendant, but they have had no role in writing this brief.

Tamoxifen. Congress has therefore encouraged the entry of generic pharmaceuticals by, among other things, permitting generic firms to challenge the validity of pharmaceutical patents without risking infringement damages and by providing a financial bounty for successfully challenging such patents. Congress' program has been a success, with generic firms prevailing in 73% of such patent cases. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 16 (July 2002) [hereinafter "*Generic Drug Entry*"], *available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf*.

Some pharmaceutical patentees have responded to these statutorily encouraged patent challenges by paying generic firms hundreds of millions of dollars to withdraw their patent challenges and stay out of the market. As explained below, these "exclusion payment" agreements have been condemned by Congress and the Federal Trade Commission ("FTC"). In the courts, however, there has been an irreconcilable split in the circuits.

It is unlawful under the Sherman Act to pay an actual or potential competitor to stay out of the market. That rule applies regardless of the degree of certainty that the potential competitor, absent the payment, would in fact enter the market. *See, e.g.,* XII Herbert Hovenkamp, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 2030b at 213 (2d ed. 2005); *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (*en banc*). The Court of Appeals for the Sixth Circuit therefore held in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 914 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004), that an exclusion payment to a generic firm to stay out of the market pending the resolution of a patent litigation is "a plain vanilla horizontal agreement to restrain trade" and unlawful *per se*. The Court reasoned that despite a rebuttable presumption of validity, 35 U.S.C. § 282, some patents are "'paper tiger[s]' incapable of deterring the generic producer from entering the

market. . . ." *Cardizem,* 332 F.3d at 915. If the patentee "had . . . been confident of the independent durability of its patent and the validity of its infringement claim, it would not have paid $89 million to effect what the patent and infringement suit had already accomplished." *Id.* The D.C. Circuit, considering the same agreement that was at issue in *Cardizem*, likewise held that it was anticompetitive. *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 813 (D.C. Cir. 2001) (stating that an exclusion payment was "presumably in return for something that Andrx would not otherwise do, that is, delay marketing of its generic"); *see also In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 531 (D.N.J. 2004) ("It would appear obvious that this [Hatch-Waxman Act] incentive system can be distorted by cash payments made by a branded patent holder to generic manufacturers to discontinue patent validity or infringement challenges").

In the wake of the decisions in *Cardizem* and *Andrx*, a unanimous FTC similarly concluded that exclusion payments in the pharmaceutical industry are presumptively anticompetitive. *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651 (F.T.C. Dec. 8, 2003). That decision, however, was vacated by the Court of Appeals for the Eleventh Circuit. *Schering Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006). That Court placed heavy reliance on the rebuttable presumption of patent validity. *Id.* at 1066. The generic firm's principal argument in the underlying patent litigation, however, was non-infringement. The Eleventh Circuit responded by asserting that there is also a presumption that the accused product infringes the patent in question. *Id.* ("By virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they proved . . . that their products . . . did not infringe Schering's patent"). Thus, patentees can lawfully make exclusion payments to potential generic entrants regardless of whether the underlying patent litigation "turns on validity . . . as opposed to infringement." *Id*. at 1075; *see also Valley*

Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1304 (11th Cir. 2003) ("A patent grants its owner the lawful right to exclude others"), *cert. denied*, 543 U.S. 934 (2004).

The decision at issue here takes the Eleventh Circuit analysis even further. The Second Circuit holds that exclusion payments are *per se lawful* unless the plaintiff proves that the underlying patent was procured by fraud or that the infringement action is a sham. Pet. App. at 42a, 51a-52a. Mere invalidity or non-infringement of the patent is insufficient to allow the exclusion payment to be challenged under the antitrust laws. The Second Circuit's analysis is founded on the rebuttable presumption of validity and on the judicial policy in favor of settling disputes. *Id.* at 48a-49a. Accordingly, although many patents are "fatally weak," *id.* at 51a, "the fact that the patent holder is paying to protect its patent monopoly, without more, [does not] establish[ ] a Sherman Act violation." *Id.* at 36a; *see also In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 536 n.21 (E.D.N.Y. 2005) ("[P]atent law imposes no such restriction against cash payments by a patent holder, and, accordingly, antitrust law does not impose such a restriction.").

The proper antitrust treatment of exclusion payments in patent settlements has also been the subject of extensive and conflicting scholarly analysis.[3] As explained below, the AAI believes it is time for this Court to resolve the issue.

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[3] For analyses suggesting that exclusion payments are anticompetitive, see Jeremy Bulow, *The Gaming of Pharmaceutical Patents,* INNOVATION POLICY AND THE ECONOMY, VOLUME 4 145, 159-73 (Adam B. Jaffe et al. eds. 2004); Joseph F. Brodley & Maureen A. O'Rourke, *Preliminary Views: Patent Settlement Agreements*, Antitrust, Summer 2002, at 53; C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement As A Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553 (2006); Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. Rev. 11 (2004); Herbert Hovenkamp et al., *Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712 (2004); Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719 (2003)*;* Cristofer

(Cont'd)

BACKGROUND

The manner in which this issue is resolved will have enormous consequences for consumers. Patent challenges under the Hatch-Waxman Act have resulted in significant economic gains for consumers. *Generic Drug Entry*, *supra*, at 9. These gains occur when a generic firm wins a patent litigation and enters the market. In one case, the brand manufacturer refused to make an exclusion payment because it believed such a payment would violate the antitrust laws. *See* Bethany McLean,

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(Cont'd)
Leffler & Keith Leffler, *Settling the Controversy Over Patent Settlements: Payments by the Patent Holder Should Be Per Se Illegal*, 21 Res. In L. & Econ. 475 (2004); Keith Leffler & Cristofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements: Analysis Gone Astray?*, 39 U.S.F. L. Rev. 33 (2004); Suzanne Michel, *The Right Balance of Competition Policy & Intellectual Property Law*, 46 IDEA - The Intell. Prop. L. Rev. 867 (2006); Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements: A Commentary on Hovenkamp, Janis and Lemley,* 87 Minn. L. Rev. 1767 (2003); Joel Schrag, *The Value of a Second Bite at the Apple: The Effect of Patent Dispute Settlements on Entry and Consumer Welfare* (Working Paper No. 281) 3-4 (2006); Carl Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, Antitrust, Summer 2003, at 70; Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391 (2003).

For analyses suggesting that exclusion payments are not unlawful, see Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 Antitrust L.J. 1069 (2004); Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis and Lemley*, 87 Minn. L. Rev. 1789 (2003); Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Settlements*, 88 Minn. L. Rev. 698 (2004); Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 Fla. L. Rev. 747 (2002); Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives*, Antitrust, Spring 2003, at 68; Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033 (2004); Robert D. Willig & John P. Bigelow, *Antitrust Policy Towards Agreements That Settle Patent Litigation*, 49 Antitrust Bull. 655 (2004).

A Bitter Pill, Fortune, Aug. 13, 2001, at 5. The patent was subsequently found invalid and the early market entry of the generic drug saved consumers an estimated $2.5 billion.[4]

Consumers also gain when patent litigation is settled in the traditional manner — with the patentee granting a license and the alleged infringer entering the market. Licensed generic entry under the Hatch-Waxman Act results in substantial consumer benefit because the generic firm can obtain market share only by selling at a significant discount to the brand price. The generic firm's incentive therefore is to negotiate for as early an entry date and as low a royalty rate as is possible in light of the merits of the patent litigation. Thus, the outcome for consumers under the license will mirror the expected (*i.e.,* risk-adjusted) outcome under litigation. In essence, licensed entry liquidates and delivers to consumers their expected gains from the patent litigation. Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391, 397-99 (2003).

In contrast, an exclusion payment settlement divides the expected consumer surplus between the brand manufacturer and the generic challenger and delivers none of it to consumers.[5] *See* Herbert Hovenkamp, *Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712, 712 n.4 (2004) [hereinafter "*Balancing Ease and Accuracy*"] ("[A]n exclusion payment aligns the generic's incentives with the patentee's; they are dividing up a monopoly to which the patentee may not have been entitled"). Instead of earning profits by competing in the market, the generic firm

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[4] *See* Comment of the Generic Pharmaceutical Association in Support of Citizen Petition Docket No. 2004P-0075/CP1, at 3 (filed May 21, 2004), *available at http://www.fda.gov/ohrms/dockets/dailys/04/June04/060404/04p-0075-c00003-vol1.pdf*.

[5] Some exclusion payment settlements, including the one at issue in this case, allow entry strictly limited in time or at a very high royalty rate. Because the legal and economic issues are the same, we will for ease of reference refer to a settlement agreement that includes any exclusion payment as if it resulted in *no* generic entry.

receives a gain from the litigation, plus a share of the consumers' expected gains, in exchange for not competing. Consumers get *nothing* from the litigation. They continue to pay the higher price to the only market participant. Their expected benefit is divided between the brand manufacturer and the generic firm.

Exclusion payment settlements thus prevent consumers from obtaining expected gains from the patent litigation. The generic firm neither wins the litigation and enters the market nor uses the threat of winning to obtain a license. Instead, an exclusion payment simply divides the expected consumer benefit (*i.e.*, lower prices) between the two manufacturers.

The FTC therefore announced in March 2000 that it would aggressively prosecute exclusion payment settlement agreements. *Abbott Labs. and Geneva Pharms.,* File No. 981-0395 (Statement of FTC Chairman Robert Pitofsky and Commissioners Sheila F. Anthony, Mozelle W. Thompson, Orson Swindle and Thomas B. Leary) (Mar. 16, 2000), *available at http://www.ftc.gov/os/2000/03/ho9eschtandrxcommstmt.htm*. In response, brand manufacturers stopped entering into such agreements. From 2000 to 2004, brand manufacturers either negotiated settlements that included early generic entry via license or continued to litigate their cases. *See Prepared Statement of the Federal Trade Commission*, at 13 (Jan. 17, 2007) *available at http://www.ftc.gov/speeches/leibowitz/071701oralstatement.pdf*. [hereinafter "*FTC Prepared Statement*"]. Subsequent to the Second Circuit's decision in this case, however, the manufacturers have begun again to use exclusion payment agreements to terminate challenges to their patents. In fiscal 2006 (the Second Circuit decision issued in November 2005), nine of the eleven Hatch-Waxman settlement agreements with generic firms included exclusion payments. *See FTC Prepared Statement, supra*, at 17. A reasonable estimate of the economic impact of just one of those settlements — for the drug Provigil — is that it will cost consumers as much as

$850 million.[6] Collectively these nine settlements will cost consumers billions of dollars in higher drug prices.

In addition to transferring billions of dollars from consumers to pharmaceutical manufacturers, these exclusion payment agreements also cause substantial "deadweight loss," *i.e.,* sales not made because prices are too high. In the pharmaceutical industry, these losses have palpable, human consequences — patients who choose not to have their prescriptions filled, or who skip their medications or split their pills in half. *See, e.g.,* Thomas Rice & Karen Matsuoka, *The Impact of Cost-Sharing On Appropriate Utilization and Health Status: A Review of the Literature On Seniors*, 61 Med. Care Research & Rev. 415, 427-28 (2004). Mortality, self-reported pain, worsening medical conditions, and other adverse health effects all result from patients' decisions "not [to] comply with physicians' medication recommendations because of high costs." *Id.* at 427-28.

If exclusion payments are lawful, the economic evidence is that they will become the norm — every pharmaceutical patent case that *can* be settled *will* be settled with an exclusion payment rather than generic entry. Cristofer Leffler & Keith Leffler, *Settling the Controversy over Patent Settlements*, 21 Res. in L. & Econ. 475, 486 (2004) [hereinafter "*Settling the Controversy*"]. If the patent litigants are permitted to split the expected consumer gain from market entry and lower prices, the economic incentive is for them to do just that. *Id.* Perhaps this can be squared with the purpose of the Hatch-Waxman Act to encourage generic firms to challenge weak patents. But there are substantial arguments that it cannot, and the negative impact on American consumers should not occur without this Court's review.

This case also is important to the proper functioning of government. As explained below, the Hatch-Waxman Act's co-

[6] Provigil has annual sales of $500 million. We assume a 50 percent chance that the generic firm would have prevailed in the patent litigation, a generic penetration rate of 85 percent, a generic price 80 percent less than the brand price, and five years of damages.

authors decried the use of exclusion payments to undermine the statutory scheme and applauded the FTC's enforcement efforts. In 2002, Congress heard testimony from pharmaceutical manufacturers that exclusion payments violate the antitrust laws. Congress, therefore, enacted legislation that merely required pharmaceutical patent settlements to be reported to the FTC, which could then take appropriate enforcement action. The Eleventh and Second Circuits, however, have now concluded that the payments are not unlawful. Contradicting both Congress and the FTC, the Department of Justice ("DOJ") declined to support the FTC's effort to have the Eleventh Circuit's *Schering-Plough* decision reviewed by this Court. In short, federal policy on this issue, as articulated by Congress, the courts, and the two primary antitrust law enforcement agencies, is a shambles. This Court should grant review and resolve the controversy.

The disagreement among the three branches of government is amplified by a stark split between the Circuit courts. The Second Circuit's decision in this case has brought the divide between the Circuits to its limit. The Second Circuit now holds exclusion payments to be (with limited exceptions) *per se lawful* while the Sixth Circuit holds them to be *per se unlawful*. The Court should grant review in order to resolve this split and decide whether the procompetitive justifications offered by the Second and Eleventh Circuits have merit.

Review is also warranted by the Second Circuit's unfaithfulness to this Court's precedents recognizing the strong public interest in judicial testing of patent validity. *See, e.g., Cardinal Chem. Co. v. Morton Int'l, Inc.,* 508 U.S. 83, 100-101 (1993); *Blonder-Tongue Labs., Inc. v. University of Illinois Found.,* 402 U.S. 313, 344 (1971); *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969). That policy is reinforced here by the Congressional policy, set forth in the Hatch-Waxman Act, to encourage generic firms to judicially test pharmaceutical patents. 21 U.S.C. § 355(j)(5)(B)(iv). The Second Circuit nevertheless held that this policy is trumped by the judicial policy in favor of settling disputes. Pet. App. at 48a-49a. This Court's precedents

and the intent of the Hatch-Waxman Act establish a strong public policy in favor of the judicial testing of patents, which seems necessarily to be at odds with the Second Circuit's announced policy in favor of *avoiding* such tests.

DISCUSSION

I. THE COURT SHOULD GRANT REVIEW IN ORDER TO RESOLVE THE DIVISION BETWEEN THE THREE BRANCHES OF GOVERNMENT.

This Court should grant review to end the disharmony among the three branches of government as to the appropriate antitrust treatment of exclusion payments. And consideration of the historic timeline shows a pressing need for the Court to act now.

In careful fashion, the Hatch-Waxman Act allows generic firms to challenge weak pharmaceutical patents. Congress streamlined FDA approval of generic drugs, 21 U.S.C. § 355(j)(2)(A)(iv); provided that generic firms can challenge pharmaceutical patents without risking infringement damage liability, *id.* § 271(e)(i); and created a financial incentive for generic firms to overcome weak patents, *id.* § 355(j)(5)(B)(iv). These provisions are part of the balance reached by Congress in the Hatch-Waxman Act, which also granted to brand manufacturers patent term extensions, *id.* § 156; non-patent exclusivities, *id.* § 355(c)(3)(D)(ii) & (iii); and an automatic 30-month stay during the patent litigation, *id.* § 355(j)(5)(B)(iii).

In 1999, the FTC began three investigations against manufacturers that had used exclusion payments to terminate patent challenges. The first two resulted in consent orders,[7] and the third resulted in the unanimous FTC decision in *Schering-Plough*. *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651 (F.T.C. Dec. 8, 2003). In the meantime, the

[7] *See Abbott Laboratories*, No. C-3945 (May 22, 2000) (Consent Order), *available at* http://www.ftc.gov/os/2000/03/abbott.do.htm; *Hoechst Marion Roussel, Inc.*, No. 9293 (May 8, 2001) (Consent Order), *available at* http://www.ftc.gov/os/2001/05/hoechstdo.htm.

Sixth Circuit had rendered its decision in *Cardizem* holding such payments to be per se unlawful. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

Congress closely monitored the exclusion payments controversy and held hearings on the issue. It was clear from the hearings that exclusion payments were widely condemned, including by the co-authors of the Hatch-Waxman Act. *See, e.g.,* 148 Cong. Rec. S7566 (daily ed. July 20, 2002) (remarks of Sen. Hatch) ("As coauthor of the [Hatch-Waxman Act], I can tell you that I find these types of reverse payments collusive arrangements appalling"); 146 Cong. Rec. E1538-02 (daily ed. Sept. 20, 2000) (remarks of Rep. Waxman).

In determining what action to take, Congress heard testimony from the brand manufacturers' trade association, the Pharmaceutical Research Manufacturers Association ("PhRMA"). A PhRMA representative testified that merely requiring exclusion payment agreements to be reported to the FTC was sufficient *because those payments violate the Sherman Act*:

> *Senator Dorgan*: Dr. Glover, you've heard the testimony of the chairman of the Federal Trade Commission, and I have a list of a wide range of issues here of companies that have been involved in attempting to delay or prohibit or in other ways impede the opportunity for a generic to come to the market. Are you saying that there isn't a problem here, or the problem is a small problem? . . . Is there, with respect to the behavior of some companies, according to the FTC, is there a problem in some magnitude here? And if so, what is that? Or is it your position, "This thing's working just fine. There's no problem."?
>
> *Dr. Glover*: [I]f you . . . take the facts as presented by the [FTC] as being accurate, these are circumstances [*i.e.,* the facts of *In re Cardizem CD Antitrust Litig.*, *Valley Drug Co. v. Geneva Pharm., Inc.*, and *Schering-Plough Corp.*

> *v. FTC*] where it is not going to solve the problem to change the Hatch-Waxman Act, because those cases outline facts . . . that would have been violations of the antitrust laws and/or the patent laws whether the Hatch-Waxman Act existed or not.[8]

Congress accepted PhRMA's testimony and enacted legislation that merely required exclusion agreements to be reported to the FTC.[9] The clear intent was that the FTC would prosecute and stop exclusion payments settlements. *See, e.g.,* 148 Cong. Rec. S7348 (daily ed. July 25, 2002) (remarks of Sen. Hatch) ("The FTC is doing the right thing in taking enforcement actions against those who enter into anti-competitive agreements that violate our Nation's antitrust laws"). Despite this legislative history, The Eleventh Circuit reversed the FTC's *Schering* decision. The Second Circuit similarly ruled here.

The disagreement among the governmental branches became complete when the DOJ not only declined to support the FTC's *certiorari petition* in *Schering*, but filed a separate brief disagreeing with the FTC on the merits and suggesting that the Court deny the FTC's petition.[10] While expressly disagreeing with the FTC, the DOJ's brief simply ignored Congress. The DOJ brief omitted any mention of the Hatch-Waxman Act's streamlined procedures for patent challenges, the Act's financial encouragement of such challenges, the condemnation of exclusion payments by the co-authors of the

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[8] Generic Pharmaceuticals: Marketplace Access and Consumer Issues: Hearing No. 107-1081 Before S. Comm. on Commerce, Science, and Transportation, 107th Cong. at 71 (2002) (testimony of Dr. Greg Glover).

[9] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, at 2071.

[10] *See* Brief of the United States as Amicus Curiae in *Federal Trade Commission v. Schering-Plough Corp., et al.*, No. 05-273 (submitted May 2006), *available at www.usdoj.gov/atr/cases/f216300/216358.htm*.

Act, PhRMA's testimony that such agreements are unlawful, and the enactment of the settlement-reporting legislation consistent with that testimony.

Despite PhRMA's testimony to Congress, its members have been emboldened by the inter-branch disagreement and by the Eleventh and Second Circuit's decisions. Nine of eleven "first filer" settlement agreements reported by PhRMA's members to the FTC subsequent to the Second Circuit's decision include exclusion payments.

As this timeline shows, the current case involves a split between the Circuits and between the two agencies principally responsible for enforcing the antitrust laws. The result is that Congress has been whipsawed. The pharmaceutical manufacturers avoided Congressional action by admitting that exclusion payments are unlawful and then successfully defended those payments in court. The inter-branch disagreement has been widely noted in both the popular and professional press.[11] The fact is that "The conflicting positions presented by the FTC and the DOJ as well as the courts, have left companies and their counsel without clear guidance."[12] This Court should resolve the issue and provide needed clarity.

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[11] *See, e.g.*, Ronald W. Davis, *Reverse Payment Patent Settlements: A View into the Abyss, and a Modest Proposal*, Antitrust, Fall 2006, at 26 (noting that conflict between DOJ and FTC "is without precedent in antitrust history"); John T. Delacourt & Lee Istrail, *Schering-Plough at the Supreme Court: Justices Decline to Resolve the FTC-DOJ Dispute Regarding Reverse Payments*, theantitrustsource (October 2006), *available at* www.antitrustresource.com; Stephen Labaton, *When It Comes to Antitrust, Washington is Antibust*, Int'l Herald Trib., May 6, 2006.

[12] Strafford CLE Teleconferences, *Reverse Payment Settlements: Restraint of Trade or Legitimate Contract? Unraveling the FTC, DOJ and Federal Court Conflict* (to be held March 8, 2007), *available at* http://www.straffordpub.com/products/reversepayment/ProgramOutline.pdf.

II. THE COURT SHOULD GRANT REVIEW IN ORDER TO RESOLVE A WIDENING SPLIT BETWEEN THE CIRCUITS.

The disagreement among the governmental branches is magnified by an irreconcilable split within the Circuits. Fundamentally, this split is over how to determine the level of competition that would likely occur absent an exclusion payment.

Whether an agreement is anticompetitive is determined by comparing the amount of competition that occurs under the agreement to the amount of competition that would likely occur absent the agreement. *See Board of Trade of City of Chicago v. United States*, 246 U.S. 231, 238 (1918). In an exclusion payment case, it is known how much competition occurs under the agreement, so the issue in dispute is how much competition would likely occur in the absence of the agreement. The Sixth and D.C. Circuits, along with the FTC, assert that the proper baseline measurement is the amount of competition that the patent litigants themselves expected to occur as a result of the litigation, *i.e.,* their own views — as objectively manifested by their conduct — of the likely outcome of the litigation. *See In re Cardizem*, 332 F.3d at 915; *Andrx*, 256 F.3d at 809; *In re Schering-Plough*, 2003 WL 22989651. These authorities rely on strong economic evidence — the fact that the generic firm demanded the exclusion payment and that the brand manufacturer was willing to pay it — to show that the settlement reduced competition below the level expected by the parties. *In re Cardizem*, 332 F.3d at 915;[13] *Andrx*, 256 F.3d at 809; *In re Schering-Plough*, 2003 WL 22989651. This is consistent with the baseline measurement adopted by this Court in

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[13] As the Sixth Circuit put it, if the "independent durability of [the brand manufacturer's] patent and the validity of its infringement claim" had been sufficient on their own to exclude generic competition, then the patentee "would not have paid $89 million to effect what the patent and infringement suit had already accomplished." *In re Cardizem*, 332 F.3d at 915.

examining patent settlement agreements. *See Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931) (settlement by way of cross-licenses was lawful because it presumably reflected "a division of royalties according to the value attributed by the parties to their respective patent claims"); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 265 (1979) (exclusionary power of patent application "depends on how likely the parties consider it to be that a valid patent will issue").

Key to these decisions is a realistic view of the exclusionary power of patents. A particular patent might be strong or it might be "a 'paper tiger' incapable of deterring the generic producer from entering the market." *In re Cardizem*, 332 F.3d at 915. The "right to exclude" conferred by a patent is not absolute and thus does not create an "impenetrable legal impediment" to competition. *Id.* at 914. Exclusion payments unlawfully "bolster the patent's effectiveness in inhibiting competitors," by transforming a limited, qualified right to exclude into a paid-for "guarantee[ ]" against competition. *In re Cardizem*, 332 F.3d at 908-907; s*ee also Andrx*, 256 F.3d at 813; *In re Schering-Plough*, 2003 WL 22989651, at *17.

In sharp contrast, the Eleventh and Second Circuits take a decidedly different approach to determining the competitive baseline. Relying on the statutory rebuttable presumption of patent validity and a (previously unknown) presumption of infringement, these courts assert that a patent is presumed to be valid and infringed and therefore that *no competition* was likely to occur as a result of the litigation. Pet. App. at 57a-58a; *Schering-Plough*, 402 F.3d at 1066-67. To the extent that a patent settlement allows *any* competition before the expiration of the patent, the settlement is deemed to *increase* competition as compared to the baseline of zero competition. Pet. App. at 57a-58a; *Schering-Plough*, 402 F.2d at 1067-68. The split between the Sixth and the Second Circuits is made especially sharp by the former's conclusion that exclusion payments are per se *unlawful* and the latter's conclusion that (absent sham litigation or fraud on the PTO) they are per se *lawful*.

This dichotomy invites scrutiny not only of the procompetitive justifications offered for exclusion payments, but also of the practical consequences of adopting one position or the other. If exclusion payments are permitted, *all* patent cases that can be settled will be settled with exclusion payments rather than licensed entry. *Settling the Controversy*, *supra*, at 486. If exclusion payments are not permitted, generic firms will prevail in a substantial number of cases — 73% to date — or will use that leverage to obtain licensed entry.

A Circuit split over the wisdom of permitting patentees to terminate patent challenges by purchasing the non-entry of a potential competitor clearly warrants this Court's review. *See eBay, Inc. v. MercExchange, LLC*, 126 S. Ct. 1837, 1842 (2006) (Kennedy, J., concurring) (courts must take account of the infirmities in our patent system and the "suspect validity of some . . . patents"); *see also* Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* 8 (Oct. 2003) (noting that "the PTO is underfunded, and PTO patent examiners all too often do not have sufficient time to evaluate patent applications fully"), *available at http://www.ftc.gov/os/2003/10/ innovationrpt summary.pdf*.

III. THE COURT OF APPEALS' DECISION SIGNIFICANTLY CONFLICTS WITH THIS COURT'S PRECEDENTS.

The fact that patents are often found to be invalid or not infringed has prompted this Court to hold, for more than fifty years, that the public has an overriding interest in the judicial testing of patents. The Second Circuit avoids this precedent by juxtaposing a contrary policy in favor of settlement and speculating that other, subsequently filed challenges might adequately test the patent's validity. Pet. App. at 29a-32a, 51a, 55a-58a. The Second Circuit's unfaithfulness to precedent on this issue also warrants this Court's review.

As the Court has explained, "The heart of [a patentee's] legal monopoly is *the right to invoke the State's power* to prevent

others from utilizing his discovery without his consent." *Zenith Radio Corp. v. Hazeltine Research, Inc.,* 395 U.S. 100, 135 (1969) (emphasis added). In order to succeed in invoking the State's power, the patentee must defend the validity of the patent and prove infringement in court. Congress made the presumption of validity rebuttable, rather than absolute, and there is a paramount public interest in 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) (Court has "emphasized the importance to the public at large of resolving questions of patent validity"); *accord*, *Blonder-Tongue Labs., Inc. v. University of Illinois Found.,* 402 U.S. 313, 344 (1971); and *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969).

With respect to pharmaceutical patents, Congress underscored this overriding public interest by providing a 180-day exclusivity bounty in order to encourage generic entry through patent litigation. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Significantly, Congress did *not* create a bounty in the form of a tax break or a cash reward for merely *filing* a patent challenge — the bounty is the right to *earn profits in the marketplace by making low-priced sales*. Taking a share of the monopoly rents in exchange for ceasing efforts to enter the market is facially contrary to that Congressional intent.

The Second Circuit nevertheless relies on the general policy in favor of settlement. Pet. App. at 50a-51a. The Court asserts, without citation or analysis, that prohibiting exclusion payments will prevent "all, or nearly all, settlements of Hatch-Waxman infringement actions." Pet. App. at 50a. This unsupported factual contention is demonstrably incorrect. History establishes that prohibiting exclusion payments will merely channel settlements into lawful forms. For more than 100 years, patentees and challengers have settled cases without resorting to exclusion payments – which are an entirely recent phenomenon. *See* Herbert Hovenkamp, et al., IP And Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law

§ 7.4e2, at 7-36 (Supp. 2007) ("Exclusion payments were not common in patent infringement litigation prior to the passage of the Hatch-Waxman amendments."). Historically, settlements simply took a different form — licensed entry. *Balancing Ease and Accuracy*, *supra*, at 716. Indeed, during the five-year period when pharmaceutical manufacturers were wary of exclusion payments (*i.e.*, after the original FTC consent orders and before the Eleventh Circuit's *Schering* decision) the drug manufacturers settled patent cases at the same rate as before. *See FTC Prepared Statement, supra,* at 13.

This view is consistent with the economic literature, which demonstrates that exclusion payments are necessary to achieve an efficient settlement in less than one-half of one percent of the possible cases. *Settling the Controversy*, *supra*, at 483-86. And those rare instances occur only when the litigants have diametrically opposed views as to the strength of the patent — a circumstance that rarely occurs. *Id.* at 485-86. This analysis is unchallenged in the volumes of economic literature on this subject.

Even if exclusion payments were necessary to settle a substantial number of patent cases, proper antitrust analysis would weigh the increased costs of litigation (if any) that results from prohibiting exclusion payments against the lost consumer welfare that results from allowing such payments. The Second Circuit made no such weighing. In pharmaceutical patent cases, however, any saved litigation costs would be utterly swamped by the lost consumer welfare. *See Balancing Ease and Accuracy*, *supra*, at 717; *see also Blonder-Tongue*, 402 U.S. at 349 (given the public interest in testing patent validity, "any reduction in litigation in this context is by comparison an incidental matter").

The Second Circuit also erroneously suggests that upholding exclusion payments does not offend the policy in favor of testing patent validity because a payment made to the first generic challenger will simply entice other generic firms to challenge the patent. Pet. App. at 55a-58a. The Court's

premise is that the prospect of obtaining the 180-day exclusivity period will motivate subsequent generic firms to challenge the patent's validity. Pet. App. at 55a (subsequent challengers will be "spurred by the additional incentive . . . of potentially securing the 180-day exclusivity"). The premise is simply incorrect. It is crystal clear that *only* the first challenger can be awarded the 180-day exclusivity. 21 U.S.C. § 355(j)(5)(B)(IV). Because subsequent challengers are not eligible for the 180-day exclusivity, a significant free-rider problem — the very problem that caused Congress to enact the 180-day bounty in the first place — blunts their incentive to aggressively attack the patent.[14]

The Second Circuit also ignores the significant entry barriers faced by subsequent challengers. These barriers include the substantial cost of developing a generic drug, the cost and time to prepare and file an ANDA, the cost and time to gain FDA tentative approval, and the Hatch-Waxman Act's automatic 30-month stay. *See Geneva Pharm. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 496 (2d Cir. 2004) ("We find evidence of particularly high barriers to entry resulting . . . from the regulatory requirements to sell generics"); *See* Herbert Hovenkamp, et al., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 7.4e2, at 7-37 (Supp. 2007) ("The regulatory scheme for pharmaceutical patents means that by settling with an ANDA filer, a patent owner can delay entry by any other generic for three years or more").

The effects of the free-rider problem and the regulatory barriers were evident in the *Tamoxifen* case itself. The first generic challenger in *Tamoxifen* received its exclusion payment

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[14] Generic firms have diminished incentive to initiate costly, time-consuming challenges to the validity of patents because (absent the 180-day exclusivity) a finding of invalidity benefits not only the successful litigant, but every other potential generic manufacturer as well. *See Blonder-Tongue*, 402 U.S. at 350; Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 Berkeley Tech. L.J. 667, 725 (2004) ("[T]he free rider problem . . . undercuts [the incentive to file] definitive patent challenges").

in March 1993. The subsequent generic challengers did not obtain a Federal Circuit ruling until April 1997 — more than four years later. Pet. App. at 10a; *Zeneca Ltd. v. Novopharm Ltd.,* 111 F.3d 144 (Fed. Cir. 1997). The effects of these barriers were also evident in *Cipro*. The first challenger there received its exclusion payment in January 1997. The subsequent challengers did not get their case to even the summary judgment stage until February 2001 — more than four yeas later. *Cipro*, 363 F. Supp. 2d at 518; *Bayer AG v. Schein Pharm., Inc.*, 129 F. Supp. 2d 705 (D.N.J. 2001).

The strong public policy in favor of testing patent validity is not served by decisions that defer such testing for years. *See Cardinal Chem. Co.*, 508 U.S. at 102 (public policy forbids practices that "prolong[ ] the life of invalid patents"). This is most evident with respect to pharmaceutical patents, which can cause consumers to incur hundreds of millions of dollars *per month* in unwarranted costs. The Second Circuit's decision so far departs from this Court's precedents concerning the public interest in testing patent validity that review is warranted.

CONCLUSION

For the reasons stated above, the Court should grant the petition for review.

Respectfully submitted,

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