No. 08-1194

IN THE
Supreme Court of the United States

ARKANSAS CARPENTERS HEALTH AND WELFARE FUND, PAPER, A.F. OF L., *ET AL.*,

Petitioners,

v.

BAYER AG AND BAYER CORP., *ET AL.*,

Respondents.

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

BRIEF AMICI CURIAE OF 54 INTELLECTUAL PROPERTY LAW, ANTITRUST LAW, ECONOMICS, AND BUSINESS PROFESSORS, THE AMERICAN ANTITRUST INSTITUTE, THE PUBLIC PATENT FOUNDATION, AND THE AARP IN SUPPORT OF THE PETITIONER

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QUESTION PRESENTED

Whether an agreement by a patent owner to pay a potential competitor not to enter the market is illegal *per se*, as the Sixth Circuit has held, is legal *per se*, as the Second and Federal Circuits have held, or should be judged under the antitrust rule of reason, as the Eleventh Circuit has held.

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INTEREST OF THE AMICI CURIAE

The Academic Amici are professors who have collectively written extensively on innovation, intellectual property, competition and antitrust. We come from a variety of fields, including intellectual property law, antitrust law, economics, and business schools. The American Antitrust Institute (AAI) is an independent non-profit education, research and advocacy organization whose mission is to advance the role of competition in the economy, protect consumers, and sustain the vitality of the antitrust laws. The Public Patent Foundation at Benjamin N. Cardozo School of Law ("PUBPAT") is a not-for-profit legal services organization that represents the public interest in the patent system, and most particularly the public interest against the harms caused by undeserved patents and unsound patent policy. AARP is a nonpartisan, nonprofit membership organization of 40 million persons, age 50 or older, dedicated to addressing the needs and interests of older Americans. As the country's largest membership organization, AARP has a long history of advocating for access to affordable health care and for controlling costs without compromising quality. To that end, AARP works at the state and national levels for laws and policies that will bring more generic competition to the marketplace.

Amici have no stake in the outcome of this case.[1]

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[1] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. (Cont'd)

(A list of signatories is in Appendix A). Our sole interest in this case is that patent and antitrust law develop in a way that serves the public interest and public health by promoting both innovation and competition.

REASONS FOR GRANTING THE PETITION

I. The Second/Federal Circuit Rule Is Unprecedented and Conflicts With the Approaches of the Sixth Circuit, the Eleventh Circuit, and the Federal Trade Commission

The Federal Circuit's opinion in this case contains fundamental errors of economic reasoning and would shield many anti-competitive agreements from the reach of antitrust law, causing great harm to competition, to U.S. consumers, and (by unjustifiably raising the costs of needed medicines) to public health. According to the opinion, an agreement between a patent holder and an alleged infringer to settle their patent litigation cannot violate the antitrust laws so long as the patent litigation was not a sham or otherwise baseless and the settlement agreement does not impose restrictions on the alleged infringer that extend beyond the scope of the patent. *In re Ciprofloxacin Hydrochloride Antitrust Litigation,* 544 F.3d 1323 (Fed. Cir. 2008). Such

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No person other than *amici curiae* or their counsel made a monetary contribution intended to fund its preparation or submission. The parties have consented to the filing of this brief and such consents are being lodged herewith. The parties have also been given at least 10 days notice of amici's intention to file.

settlements are immune from antitrust scrutiny even if, as here, the patent holder makes a substantial payment to the alleged infringer in exchange for the latter's promise not to sell the patented product independently during the patent's lifetime, and even if the patent in question is "fatally weak." *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212 (2d Cir. 2006). In so holding, the Second and Federal Circuits have adopted a rule of near per se *legality* for a naked market division scheme, a horizontal agreement that seems anticompetitive on its face.

This rule, moreover, is based on the mistaken premise that (absent fraudulent procurement) a patent grants full immunity from antitrust scrutiny for any and all anticompetitive effects "within the exclusionary power of the patent." 544 F.3d at 1336 (citing *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 175-77 (1965)); *but cf. Illinois Tool Works, Inc. v. Independent Ink, Inc.*, 547 U.S. 28, 39 (2006) (544 F.3d 1323 ("defendant's patents did not . . . afford the defendant any immunity from the antitrust laws") (citing *International Salt Co. v. U.S.*, 332 U.S. 392, 395-95 (1947)). This Court recently rejected the Federal Circuit's similar efforts to limit the application of the exhaustion doctrine as to conduct (post-sale restrictions) within the scope of the patent right. *See Quanta Computer, Inc. v. LG Electronics, Inc.*, 128 S.Ct. 2109, 2117-22 (2008) (applying exhaustion to method claims for products that substantially embody the method, notwithstanding the patent holder's efforts to contractually restrict uses within the scope of the grant). And even if the Federal Circuit's understanding of the scope of antitrust immunity attaching to an

unquestionably *valid* patent were correct, the patent grant itself provides only a presumption of validity. The Federal Circuit rule has effectively converted that rebuttable (and oft-rebutted) presumption into an irrebuttable one. And it has done so in the face of evidence – a $398.1 million payment to the defendant to drop its validity challenge – that suggests there was good reason for the parties to think at the time they settled the case that this particular patent was invalid.[2]

The Federal Circuit's rule is far outside the mainstream of judicial and academic analysis of settlements that involve such payments and promises ("exclusionary settlements"). The Sixth Circuit considers such agreements per se *illegal*, *see In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), the Federal Trade Commission considers them presumptively anticompetitive, *see In re Schering Plough Corp.*, No. 9297 (F.T.C. Dec. 18, 2003), *rev'd*, 402 F.3d 1056 (11th Cir. 2005), while the Eleventh Circuit applies its own modified version of the rule of reason that inquires into the underlying validity of the patent before characterizing the conduct, *see Valley Drug Co. v. Geneva Pharmaceuticals, Inc.,* 344 F.3d 1294 (11th Cir. 2003). No other circuit has applied the *Tamoxifen-Cipro* approach.

Similarly, although academic commentators are divided on the treatment to be accorded such

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[2] In evaluating the anticompetitive effect of a settlement, the relevant question is what the parties believed about the validity of the patent at the time they entered into the settlement.

settlements, they uniformly agree they should not be considered per se *legal*. Some, including some of the undersigned, have written that settlements involving a large payment from the patent holder to the challenger should be presumptively anti-competitive.[3] Others have argued for applying the rule of reason[4] or for per se illegality.[5] Other courts and commentators note that the

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[3] *See, e.g.*, 1 *Herbert Hovenkamp et al., IP and Antitrust* §7.4e2, at 7-38 to 39 (2009 Supp.); Robin Cooper Feldman, *The Role of Science in Law* 167 (Oxford 2009); Jeremy Bulow, "The Gaming of Pharmaceutical Patents," in 4 *Innovation Policy and the Economy*, (Adam B. Jaffe et al. eds. 2004); Michael A. Carrier, "Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality," 108 Mich. L. Rev. __ (forthcoming 2009), *available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1354826*; Joseph Farrell & Carl Shapiro, "How Strong Are Weak Patents?" 98 *Am. Econ. Rev.* (2008); Scott A. Hemphill, "Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem," 81 *NYU L. Rev.* 1553 (2006); Herbert Hovenkamp et al., "Anticompetitive Settlement of Intellectual Property Disputes," 87 *Minn. L. Rev.* 1719 (2003); Mark A. Lemley & Carl Shapiro, "Probabilistic Patents," 19 *J. Econ. Perspectives* 75 (2005); Carl Shapiro, "Antitrust Limits to Patent Settlements," 34 *Rand J. Econ.* 391 (2003); American Antitrust Institute, The Next Antitrust Agenda 337 (Albert A. Foer ed., 2008), available at *http://www.antitrustinstitute.org/archives/transitionreport.ashx*.

[4] 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).

[5] Maureen A. O'Rourke & Joseph F. Brodley, "An Incentives Approach to Patent Settlements," 87 *Minn. L. Rev.* 1767, 1781-82 (2003).

antitrust analysis is more complex for settlements that generate offsetting benefits to consumers, e.g., those involving negotiated entry dates or patent licenses.[6] But none take the position adopted by the Federal Circuit in this case – that "the court need not consider the validity of the patent in the antitrust analysis" of whether that patent could have excluded a generic competitor from the market, but can instead conclusively presume that validity. *Ciprofloxacin*, 544 F.3d at 1336.

The undersigned amici differ in their views on precisely what standard should be applied to judge the legality of exclusionary settlements. We need not resolve those differences in this case because we all agree that exclusionary settlements of patent lawsuits can sometimes violate the antitrust laws. The court took the unprecedented step of concluding that exclusionary settlements can never be illegal *as a matter of law* unless the underlying lawsuit was a sham. As a result, unless the opinion is reversed case law in the Second Circuit – and perhaps in the country as a whole[7] – will never

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[6] *Schering Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (finding that a cross-license agreement did not violate the antitrust laws); 1 *Hovenkamp et al., supra* note 2, at §7.4e3 (discussing delayed entry settlements).

[7] The Federal Circuit decision, while it follows the Second Circuit decision in *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212 (2d Cir. 2006), does not specify whether it did so because the Federal Circuit applies regional circuit antitrust law in most cases or because it applied its own law but agreed with the Second Circuit rule. *See Nobelpharma AB v. Implant*

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develop to distinguish pro- and anti-competitive settlements. Worse, without review by this Court businesses will lack guidance on the legality of their conduct because fundamental conflicts between the approaches of the different circuits will persist.

II. Exclusion Payments Are Generally Anti-Competitive

A. The Settling Parties Have an Incentive to Preserve Monopoly Profits in Ways That Harm Consumers, Competition, and Public Health.

A monopolist and any uniquely strong or early-arriving potential entrant have a strong incentive to enter into an exclusionary settlement. The settlement preserves the monopoly and thus keeps prices and profits high. Recognizing this, antitrust law has long condemned horizontal market division schemes as illegal per se. *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46 (1990). In the Hatch-Waxman setting, where the first drug manufacturer to file a successful Abbreviated New Drug Application (ANDA) to produce a generic version of a patent pharmaceutical is entitled to a period of statutory exclusivity, the patent owner's incentive to

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Innovations, Inc., 141 F.3d 1059, 1067 (Fed. Cir. 1998) (Federal Circuit applies regional circuit antitrust law except where the antitrust issue is intimately bound up with patent policy). If the Federal Circuit decision is interpreted to apply its own law, that law will bind antitrust plaintiffs throughout the country, but only in cases that arise under the patent laws.

settle with that first generic entrant is particularly great. And because the Food and Drug Administration regulates entry into the pharmaceutical market, if a generic ANDA filer agrees to leave the market it may be years before another challenger can legally arise.

The fact that the *parties* to the settlement can maximize their profits through a horizontal market division agreement does not mean that such a settlement is in the *public* interest. The extra profit the parties share comes from somewhere. In the case of an exclusionary settlement under the Hatch-Waxman Act, it comes from the pockets of consumers: users of medicines who would be able to purchase lower cost medications if the generic manufacturer's legal arguments were successful. Absent the settlement, the patent litigation might reveal that the patent was invalid or not infringed, leading to more competition and lower prices. With an exclusion payment, the pharmaceutical patentee buys assurance that its patent will not be invalidated—something the patent law alone does not give and that the Hatch Waxman Act did not contemplate. It uses some of this extra monopoly profit, obtained by avoiding what might have been a successful legal challenge, to pay off the potential competitor.

Such a settlement denies consumers the benefits of enhanced competition that Congress intended to result if the patent were found invalid or not infringed. Those benefits are not merely a windfall from abrogation of a legitimate patent. On the contrary, they result from the right to invalidate patents the government should never have issued. This Court has repeatedly emphasized the importance of encouraging challenges to weak patents.

See, e.g., United States v. Glaxo Group, Ltd., 410 U.S. 52, 57 (1973); *Blonder-Tongue Labs. v. Univ. of Illinois Found.*, 402 U.S. 313 (1971); *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969); *see also Aronson v. Quick Point Pencil Co.,* 440 U.S. 257, 264 (1979). Discovering the truth about the patent's validity or scope is integral to the operation of a patent system fundamentally bound up with the public interest. The interests of consumers are given no weight at all in the court's calculus. Nor is the public interest in testing weak patents given any weight at all.[8]

Under the Federal Circuit's opinion, a patent owner and potential entrant are permitted to enter into an exclusionary settlement that denies these benefits to consumers *regardless* of contemporaneous evidence about the likelihood that the patent will be found invalid or not infringed. In particular, the Federal Circuit ignored evidence in the form of a large exclusionary payment from the patent holder to the potential rival, surely an indication that the patent holder considered its patent to be weak. Indeed, that payment was so large ($398.1 million) that it dwarfed the profits the generic manufacturer would expect to receive from successful entry. *See* Fed. Cir. Appendix A-3426-28 (proferred evidence that the settlement was more than twice the profits Barr would reasonably have expected to earn from entry). Put another way, even if it was *absolutely certain that the patent was invalid*, the patent owner could have paid Barr $398.1 million not to invalidate the patent, and Barr would have been better off taking the

[8] Indeed, the Second Circuit decision followed in *Cipro* even ignored the fact that at the time of settlement the patent in question had been held invalid in the district court.

money and allowing the patent to remain in force than invalidating the patent. The presence of such a payment may or may not be conclusive evidence that the patent was invalid, but it is certainly evidence that could have led a jury to find that at the time they entered into the settlement, the parties believed the patent was likely invalid.[9]

B. The Federal Circuit Wrongly Assumes That Every Patent Holder Has an Absolute Right to Prevent Competition

The Federal Circuit acknowledged that the agreement in this case "may have some adverse effects on competition," and may even bar future challenges to the underlying patent. *Cipro*, 544 F.3d at 1333-34. But it concludes that those competitive effects cannot be addressed by antitrust law so long as the settlement does not "restrict competition beyond the exclusionary zone of the patent." *Id.* at 1336. And in the absence of evidence of inequitable conduct or sham litigation, the court concluded, it "need not consider the validity of the patent in the antitrust analysis." *Id.*

By claiming to focus on the "exclusionary zone" of the patent, but ignoring the question of whether the patent was valid in the first place, the Federal Circuit falls back on the *assumption* that the patent holder, by

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[9] The district court did consider the amount in proportion to the revenue the *patentee* was making, Appx. at 79a, but that is only part of the story. The share of the patentee's revenue establishes an upper bound on the likelihood of validity, but not a lower bound. *See* 1 *H. Hovenkamp et al., IP and Antitrust* § 7.4e3, at p. 7-47 n. 102 (2008 Supplement).

virtue of the patent grant, has an absolute right to enter into a settlement that excludes competitors from the market, simply because of the presumption of validity afforded to patents. But that assumption is false. A patent does not confer a certain legal right. *In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985). Rather, it reflects an initial judgment by the Patent and Trademark Office that the invention is patentable. That judgment is made after only a cursory scrutiny. When a patent is asserted in litigation, accused infringers are entitled to demonstrate that the patent should not have issued. As this Court put it in *Lear, Inc. v. Adkins,* 395 U.S. 653 (1969):

> A patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office. Moreover, the legal conclusion is predicated on factors as to which reasonable men can differ widely. Yet the Patent Office is often obliged to reach its decision in an ex parte proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity. Consequently, it does not seem to us to be unfair to require a patentee to defend the Patent Office's judgment when his licensee places the question in issue . . .

Id. at 670. Virtually every accused infringer asserts invalidity, and nearly half of all litigated patents are ultimately found invalid.[10] The number is even higher in

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[10] John R. Allison & Mark A. Lemley, "Empirical Evidence on the Validity of Litigated Patents," 28 *Am. Intell. Prop. L.*

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pharmaceutical cases—an FTC study of all pharmaceutical patent litigation between 1992 and 2000 found that the patent owner lost in 73% of the cases. *http://ftc.gov/os/2006/07/P052103BarrierstoGenericEntryTestimonySenate07202006.pdf* (page 10).

Further, in cases such as this one, the fact that the patent owner must pay the accused infringer a large sum of money to stay out of the market and not to challenge the patent is strong evidence that the parties to the litigation—those with the most knowledge of the facts—see the patent as likely to be held invalid or not infringed. The patent holder in such situations rationally understands that to protect the value of a monopoly to which it was never in fact and in law entitled, it must share some of the ill-gotten revenue with those who would otherwise invalidate it. The defendants, in turn, have every incentive to settle in exchange for a share of the monopoly profits rather than to litigate. Because the generic competitor can charge only a competitive price, it is possible for a settlement to provide a share of the monopoly price profits that convey to the generic competitor even greater profits than would be achieved by a successful lawsuit. Indeed, that appears to be precisely what happened here. *See* Fed. Cir. Appendix A-3426-28.

Where, as here, the case arises on summary judgment, the courts must draw all reasonable

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Ass'n. Q.J. 185 (1998) (studying all patent validity litigation over an 8-year period and finding that 46% of all patents litigated to judgment were held invalid).

inferences in favor of the plaintiffs. If there is evidence from which the patent might have been proven invalid, the settlement can certainly be anticompetitive and thus should be subject to antitrust review.

The Federal Circuit does not merely protect established rights of patent holders. Rather, by letting patent owners buy immunity from competition even with "fatally weak" patents, the Federal Circuit has greatly expanded the patent holders' rights, turning a rebuttable (and often-rebutted) presumption into an irrebuttable one. A presumption of validity does not entitle a patentee to evade the test of patent litigation, any more than a criminal defendant's presumption of innocence entitles him to avoid trial. Allowing holders of weak patents thus to boost their profits is a poor way to encourage innovation, because by definition a weak patent often reflects no true innovation. And allowing them to do so by buying insulation from the very challenge that would invalidate the weak patent is perverse. This Court has recognized "the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain." *Lear*, 395 U.S. at 670. That interest would be ill-served by allowing patentees to avoid any scrutiny of the validity or scope of application of their patents simply by agreeing to split their unwarranted profits with those who would challenge their right to those profits.

C. Permitting Exclusion Payments Is Not Necessary To Encourage Settlements in the Public Interest

The Federal Circuit recognized that its rule shields troubling settlements from the antitrust laws, but concludes that the policy favoring settlement is so strong that it must extend even to what the Second Circuit has acknowledged are "fatally weak" patents, "even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved." *Tamoxifen Citrate*, 466 F.3d at 211.

We agree that there is a general policy in favor of settlement. We strongly disagree, however, with the Federal Circuit's view that patent settlements must *always* be encouraged. That view confuses a general policy in favor of settlements that are in the public interest with an endorsement of a particular kind of settlement despite evidence that it is not in the public interest because of its anticompetitive effects. The general preference for settlement over litigation must be tempered when settlements have important adverse effects on third parties; in the language of economics, there is no good reason to encourage settlements that impose significant negative externalities. Patent litigation serves the crucial role of testing weak patents and protecting the public from monopolies based on invalid patents. The social benefit of invalidating weak patents is well established in a line of this Court's cases. *See, e.g., United States v. Glaxo Group, Ltd.*, 410 U.S. 52, 57 (1973); *Blonder-Tongue Labs. v. Univ. of Illinois Found.*, 402 U.S. 313 (1971); *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969); *see also Aronson v. Quick Point Pencil*

Co., 440 U.S. 257, 264 (1979) (referring to the "desirability of encouraging licensees to challenge the validity of patents").[11] That benefit is particularly important in the context of the Hatch-Waxman Act, which exhibits a Congressional desire to encourage generic drug manufacturers to challenge pharmaceutical patents.

A successful patent challenge provides valuable (and in the case of medicines necessary) benefits to third parties, including anyone who seeks to practice the patented technology and consumers via enhanced competition.[12] The Federal Circuit's rule dramatically undermines the important role of patent litigation in protecting the public from undeserved monopolies based on patents that may well prove to be invalid.

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[11] Indeed, in its most recent opinion on the issue, this Court went so far as to hold that even a party that has already resolved a dispute by agreeing to take a license to a patent could nonetheless challenge the validity of that patent. In *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), the parties had entered into a license agreement that provided that the licensee would continue to pay royalties unless the patent was held invalid in court. When the licensee sued for a declaratory judgment that the patent was invalid, this Court entertained the suit notwithstanding the fact that the licensee faced no risk of being sued for patent infringement.

[12] *See, e.g.*, Joseph Farrell & Robert Merges, "Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help," 19 *Berkeley Tech L.J.* 943 (2004); Joseph Scott Miller, "Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents," 19 *Berkeley Tech. L.J.* 667 (2004).

Reversing the Federal Circuit's rule insulating cartels involving weak patents from scrutiny would by no means subject every patent settlement to an antitrust challenge. As noted above, some (including some of the undersigned) have suggested that a large exclusionary payment could be a suitable red flag, providing a limiting principle on such challenges; experience over time might suggest other approaches, but no such evolution can occur if the Federal Circuit's holding stands, particularly if it is understood as adopting a uniform rule for all patent cases. The public interests involved warrant judicial evaluation of the facts of particular cases, and (if the Federal Circuit holding is reversed) the courts can develop additional rules to provide guidance and to limit the burdens on the courts.

Nor is immunizing exclusion payments necessary to encourage the many settlements that are in the public interest. Both generally and in the pharmaceutical context, patent owners and generic firms can and do settle patent cases without exclusion payments, by agreeing to let the generic company enter in exchange for a license fee, by agreeing to delay entry without a payment, or in other ways that do not involve paying the generic company to forego competition. Indeed, the Federal Trade Commission, to which pharmaceutical patent settlements must now be reported, found 14 agreements settling patent litigation during 2003 and 2004, with none involving an exclusion payment. *See http://www.ftc.gov/opa/2005/01/drugsettlement.htm*. The fact that pharmaceutical companies can and do settle

litigation without exclusion payments shows that there is no need to allow anticompetitive settlements in order to get the social benefits that most settlements provide.[13]

III. This Case Presents a Question of Extraordinary Importance, and Is an Appropriate Vehicle For Addressing That Question

This Court has long recognized that decisions on the validity of patents implicate important public interests. *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.,* 324 U.S. 806, 816 (1945) ("A patent by its very nature is affected with a public interest."); *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172, 177 (1965); *Pope Manufacturing Co. v. Gormully*, 144 U.S. 224, 234 (1892) ("It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly."). Nowhere is that more true than in the area of pharmaceuticals. Consumers pay literally tens of billions of dollars more for patented drugs than they would for the same drugs if unpatented. Numerous studies have shown that higher drug prices result in consumers having to forego needed medicines. One study found that among people 65 and older, "a one-

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[13] Unfortunately, as a result of the *Tamoxifen* and *Cipro* decisions, pharmaceutical companies have once again begun including reverse payments in their settlements. *See http://www.ftc.gov/os/2008/05/mmaact.pdf* (report on FY 2007).

dollar increase in the out-of-pocket per tablet cost resulted in the purchase of 114 fewer tablets per year."[14]

Where those patents are validly granted, the monopoly price arguably reflects a needed incentive to innovation. But where a patent owner insulates a "fatally weak" patent from judicial scrutiny by entering into an anticompetitive agreement to avoid invalidation, it is the public that bears the cost of an *improperly* obtained monopoly on needed medicines. Anticompetitive settlements of this sort are all too common, and violate the legislative purpose behind the Hatch-Waxman Act, which was in part to encourage generic manufacturers to challenge weak patents. Just ten existing pay-for-delay settlements involve drugs that cost consumers and the government on the order of $17 billion per year, by one estimate. C. Scott Hemphill, "An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition," 109 *Colum. L. Rev.* __ (forthcoming May 2009), *available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1356530.* And the American Medical Association has identified pay-for-delay settlements as a significant driver of higher drug costs. Statement of the American Medical Association before the

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[14] Jan Blustein, *Drug Coverage and Drug Purchases by Medicare Beneficiaries with Hypertension*, 19 Health Aff. 219, 228 (2000); *see also* Kaiser Family Foundation et al., *National Survey on Prescription Drugs* 4 (Sept. 2000) (reporting that 9% of U.S. citizens 65 and older have had to cut down on food or other basic necessities to pay for prescription drugs), *available at* http://www.pbs.org/newshour/health/prescriptions/summary andchartpack.pdf.

Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce, United States House of Representatives, April 13, 2009.

Further, this case is an appropriate vehicle for resolving the important questions presented here. The settlement in this case is a straightforward payment to Barr to stay out of the market, in contrast to other cases in which the payments are commingled with other business relationships. The conflict among the Circuits is now clear. And pharmaceutical companies have taken the Federal Circuit's decision as a green light to enter into settlements like this. Those anticompetitive agreements will continue to proliferate unless and until the courts recognize the potential for anticompetitive harm and apply the antitrust laws accordingly. And in light of the ruling in this case, only Supreme Court review can make that happen.

CONCLUSION

We urge the Court to grant certiorari and to reverse the decision of the Federal Circuit Court of Appeals.

Respectfully submitted,

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APPENDIX A

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Visiting Professor, Yale Law School

Appendix A

Professor Rudolph J.R. Peritz
New York Law School

Professor Daniel B. Ravicher
Lecturer in Law
Benjamin N. Cardozo Law School

Professor Michael Risch
West Virginia University School of Law

Professor Catherine Sandoval
Santa Clara University Law School

Professor Joshua D. Sarnoff
Washington College of Law
American University

Professor Kurt M. Saunders
College of Economics and Business
California State University-Northridge

Professor Ted Sichelman
University of San Diego School of Law (beginning August 2009)

Professor Katherine Strandburg
DePaul College of Law
NYU School of Law (beginning July 2009)

Professor Spencer Weber Waller
Loyola University Chicago School of Law