No. 03-779

IN THE
Supreme Court of the United States

ANDRX PHARMACEUTICALS, INC.,
Petitioner,
v.

THE KROGER CO., ALBERTSON'S, INC., HY-VEE, INC.,
THE STOP & SHOP SUPERMARKET CO., WALGREEN CO.,
ECKARD CORP., CVS MERIDIAN, INC.,
and RITE AID CORP., *et al.*,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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Date: December 29, 2003

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MOTION FOR LEAVE TO FILE BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

Pursuant to Rule 37.2 of the Rules of this Court, the Washington Legal Foundation (WLF) respectfully moves for leave to file the attached brief as *amicus curiae* in support of Petitioner. Petitioner has consented to the filing of this brief; its letter of consent has been lodged with the Clerk of the Court. WLF was unable to obtain the consent of Counsel for Respondents Charles Zuccarini, *et al.*, thereby necessitating the filing of this motion.

WLF is a non-profit public interest law and policy center with supporters in all 50 states. WLF regularly appears before federal and state courts to promote economic liberty, free enterprise, and a limited and accountable government. To that end, WLF has appeared in numerous federal and state courts in cases related to health care delivery. For example, WLF recently successfully challenged the constitutionality of Food and Drug Administration (FDA) restrictions on speech relating to off-label uses of FDA-approved products. *Washington Legal Found. v. Friedman,* 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dismissed,* 202 F.3d 331 (D.C.Cir. 2000). WLF also filed briefs in two cases that addressed issues virtually identical to the Question Presented in the Petition. *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.,* 344 F.3d 1294 (11th Cir. 2003); *In the Matter of Schering-Plough Corp.,* Docket No. 9297, 2003 FTC LEXIS 187 (F.T.C. Dec. 8, 2003).

WLF believes that both "innovator" and generic manufacturers play an important role in providing quality health care to the American public. If advances in health care are to continue, it is vital that innovator companies that develop new drugs and medical devices, or new methods of using those products, be afforded periods of patent protection, during which potential competitors are not permitted to market the same product. Patents provide an economic incentive for new product development by ensuring that pharmaceutical companies that gamble the substantial sums necessary for research and development of new therapies will be able to realize a return on their investment when their research and development expenditures bear fruit. On the other hand, once an appropriate period of patent exclusivity has expired, consumers are well served by government policies that encourage other companies to

market generic versions of the new drug, thereby ensuring the competition necessary to produce lower prices.

Competition between innovator and generic producers inevitably will lead to disagreements regarding precisely how long the legally-mandated exclusivity period for an innovator company's products should last. Those disagreements often will result in litigation, which usually is extremely time-consuming and expensive and diverts the attention of pharmaceutical executives away from finding ways to provide the public with innovative, low-cost pharmaceutical products. Accordingly, WLF believes that the law should provide strong incentives for parties to pharmaceutical patent litigation to settle their disagreements as quickly as possible.

WLF is concerned that the decision below provides precisely the wrong incentives. The Sixth Circuit appears to view litigation as just another forum within which innovator and generic companies can carry out their competition, and that litigation is to be encouraged as a means of ensuring that every potentially invalid patent is challenged in court. WLF is filing this brief because it strongly disagrees with that view. WLF believes that the settlement of litigation in most instances is pro-competitive. WLF also believes that the Sixth Circuit's position, by calling into question the legality of virtually all patent settlements, will actually discourage meritorious challenges by generic companies who are reluctant to undertake an expensive battle of indeterminate duration and outcome knowing that pre-trial settlement may not be an option.

WLF seeks to file this brief solely because of its interest in promoting the efficient settlement of patent disputes, including but not limited to, settlements between innovator and generic drug companies in the pharmaceutical industry. It has no direct interest, financial or otherwise, in the

outcome of this case. Nor does it take a position on the merits of the underlying antitrust dispute.

For the foregoing reasons, the Washington Legal Foundation respectfully requests that it be allowed to participate in this case by filing the attached brief.

Respectfully submitted,

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December 29, 2003

QUESTION PRESENTED

Whether an interim settlement of patent infringement litigation, in which the alleged infringer, for consideration, agrees to keep its product off the market until the claim of infringement is resolved, constitutes a *per se* violation of the Sherman Antitrust Act, irrespective of the validity of the claim of infringement or the reasonableness of the interim settlement.

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

INTERESTS OF *AMICUS CURIAE*

The interests of *amicus curiae* Washington Legal Foundation (WLF) are set forth in the motion accompanying this brief.[1]

STATEMENT OF THE CASE

WLF hereby incorporates by reference the Statement of the Case contained in the Petition for a Writ of Certiorari.

In brief, this case is an antitrust challenge to a patent settlement agreement entered into between Petitioner Andrx Pharmaceuticals, Inc. and Hoescht Marion Roussel, Inc. (HMR). In 1996, HMR sued Andrx in federal district court in Florida, alleging that Andrx's plans to market a generic version of Cardizem CD (a drug initially developed by HMR) infringed various patents held by HMR.[2] The filing of the suit meant that FDA could approve Andrx's ANDA no

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief.

[2] In 1995, Andrx had submitted an Abbreviated New Drug Application (ANDA) to the Food and Drug Administration (FDA), seeking permission from FDA to market a generic version of Cardizem CD. Under federal law, the mere filing of an ANDA (regardless whether any infringing product is ever manufactured, sold, or used) is deemed an act of infringement sufficient to trigger a patent holder's right to file a patent infringement suit. *See* Federal Food Drug and Cosmetic Act (FDCA) § 505(j), 21 U.S.C. § 355(j); *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

earlier than July 1998 -- 30 months after Andrx notified HMR of its intent to market a generic version of Cardizem CD. *See* 21 U.S.C. § 355(j)(5)(B)(iii). There is no dispute that the suit was vigorously contested by both sides.

FDA issued its final approval of Andrx's ANDA on July 9, 1998. Pursuant to the terms of the September 1997 Andrx/HMR interim settlement agreement (the "Stipulation"), Andrx began marketing its generic version of Cardizem CD in June 1999. That date was 11 months after Andrx received FDA approval of its ANDA, but many years before expiration of the patents that HMR alleged were being infringed by Andrx.

The Stipulation provided that Andrx would not begin marketing its product for so long as the patent infringement litigation was still pending and so long as no other generic versions of Cardizem CD were being marketed, regardless whether FDA approved its ANDA. Pet. App. 99a. In return, HMR agreed to pay Andrx $10 million per quarter year until the litigation was resolved. *Id.* at 100a-102a. If Andrx ultimately prevailed in the litigation, the Stipulation provided that HMR would pay Andrx $100 million for each year that the litigation lasted after the ANDA was approved (less credit for amounts previously paid). *Id.* If HMR prevailed, the Stipulation provided that Andrx could obtain a license from HMR to market its product.[3] Andrx and HMR entered into a final settlement of the patent litigation on June 9, 1999. HMR paid Andrx an additional $50.7 million at the

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[3] The Stipulation also required HMR to provide Andrx with certain information that would assist Andrx's marketing efforts, and prohibited HMR from seeking preliminary injunctive relief. *See id.* at 9a & n.6.

time of the final settlement, bringing to just under $90 million its total payments to Andrx.

The Andrx/HMR patent settlement agreement gave rise to a number of antitrust lawsuits filed by Respondents, drug purchasers who alleged that they were injured by the settlement. Those suits were eventually consolidated by the Judicial Panel on Multidistrict Litigation for pretrial proceedings in U.S. District Court for the Eastern District of Michigan. Respondents alleged that the Stipulation constituted an unreasonable restraint of trade, in violation of § 1 of the Sherman Act, 15 U.S.C. § 1, and various state antitrust laws. The district court thereafter granted Respondents' motion for partial summary judgment, ruling that the Stipulation was a horizontal restraint of trade that constituted a *per se* violation of antitrust law. Pet. App. 34a-82a.

The Sixth Circuit granted interlocutory appeal and subsequently affirmed. *Id.* 1a-33a. The appeals court said that the Stipulation was an agreement among competitors to allocate markets/limit production and that such horizontal output limitations "'are ordinarily condemned as a matter of law under an "illegal *per se*" approach because the probability that these practices are anticompetitive is so high.'" *Id.* at 17a (quoting *National Collegiate Athletic Ass'n v. Board of Regents*, 468 U.S. 85, 100 (1984)). The court rejected arguments that a *per se* approach was inappropriate in the context of drug patent litigation settlements; the court said that the *per se* approach should apply to all horizontal market allocation agreements, regardless of the industry and regardless that the agreement arose in the context of a patent settlement. *Id.* at 19a. The appeals court deemed

"irrelevant" Andrx's contention that the Stipulation lacked anticompetitive effects and had procompetitive benefits:

> To reiterate, the virtue/vice of the *per se* rule is that it allows courts to presume that certain behaviors as a class are anticompetitive without expending judicial resources to evaluate the actual anticompetitive effects or procompetitive justifications in a particular case.

Id. at 20a.

REASONS FOR GRANTING THE PETITION

This case raises health care, patent, and antitrust issues of exceptional importance. By characterizing the Andrx/HMR patent litigation settlement agreement as a "market allocation agreement" subject to *per se* antitrust treatment, the Sixth Circuit has significantly degraded the value of intellectual property rights. The appeals court's ruling surely will make it far more difficult for drug patent holders to reach amicable settlements of disputes with potential infringers. Moreover, the ruling is likely to have ramifications far beyond drug patents; the appeals courts' reasoning includes any patent settlement where an alleged infringer agrees to cease infringing.

Patent protection for innovative drug products promotes further innovation by ensuring that pharmaceutical companies that gamble the substantial sums necessary for research and development of new therapies will be able to realize a return on their investments when their research and development expenditures bear fruit. By undermining the value of that protection, the appeals court is undermining long-term health care in this country by reducing the financial incentives

necessary to ensure that new, life-saving medical products continue to be developed.

As the Petition well demonstrates, the appeals court decision conflicts with decisions from numerous other federal courts, including the U.S. Court of Appeals for the Eleventh Circuit. The extent of that conflict increased just days after the Petition was filed, when a unanimous Federal Trade Commission issued an adjudicative decision rejecting the Sixth Circuit's *per se* approach. The FTC stated, "The current trend of authority seems to be moving in another direction," away from the Sixth Circuit's approach. *In the Matter of Schering-Plough Corp.*, No. 9297, 2003 FTC LEXIS 187 at *34-*35 (FTC Dec. 8, 2003). The FTC criticized the Sixth Circuit for failing to "take[] adequate account of Supreme Court decisions that mandate a more nuanced approach." *Id.* at *35 n.26.

WLF writes separately in order to emphasize just how far out of step the Sixth Circuit is with modern antitrust jurisprudence. This Court has condemned business practices as *per se* antitrust violations only in those instances in which courts consistently have found nearly identical practices in prior cases to have anticompetitive effects. Yet, the Sixth Circuit condemned the Andrx/HMR interim settlement as *per se* illegal without citing a single prior decision that determined similar patent litigation settlements to have anti-competitive effects. The Sixth Circuit deemed "irrelevant" Andrx's arguments that its settlement agreement and similar settlement agreements were procompetitive, indicating that *any* agreement by a potential patent infringer not to compete with the patent holder is *per se* illegal. Indeed, although the Sixth Circuit noted that Andrx received cash from HMR pursuant to the Stipulation, the court gave no indication that

its ruling was limited to cases involving cash payments. Review is warranted to correct this major departure from established antitrust law which, if left uncorrected, will have significant negative impact both on intellectual property rights and on the delivery of health care.

I. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW IS FAR OUT OF STEP WITH THIS COURT'S RECENT DECISIONS ON *PER SE* ANTITRUST ANALYSIS

This Court has made clear that *per se* treatment should be applied with great caution and only in the few cases where sufficient experience has shown that the conduct "always or almost always tend[s] to restrict competition and decrease output." *Northwest Wholesale Stationers, Inc. v. Pacific Stationery & Printing Co.*, 472 U.S. 284, 289-90 (1985) (quoting *Broadcast Music, Inc. v. Columbia Broadcasting Sys.*, 441 U.S. 1, 19-20 (1979)). Indeed, only four years ago the Court warned that "the plausibility of competing claims about the effects of the [conduct at issue] rules out the indulgently abbreviated review." *California Dental Ass'n v. FTC*, 526 U.S. 756, 778 (1999).

The reason for this caution is clear. When the *per se* rule is applied to an agreement, a claimant need not prove: that a relevant market exists; that the accused parties have market power; that the accused parties' purpose is anticompetitive; or that the agreement has actual anticompetitive effects. Equally important, particularly in the context of these agreements, the defendant may not offer any explanation of the rationale for entering into the challenged agreement. The agreement is *presumed* to be illegal with limited inquiry into the exact type of harm caused. *Northwest Wholesale Stationers*, 472 U.S. at 289. Because

the *per se* rule categorically condemns business arrangements, courts have explained that "a presumption exists that the circumstances of a case will be looked at in light of the rule of reason standard and will not be deemed per se unreasonable." *All Care Nursing Serv., Inc. v. High Tech Staffing Servs., Inc.*, 135 F.3d 740, 746 (11th Cir. 1998).[4]

The *per se* rule should thus only be invoked when its application would generate a low risk of error – *i.e.*, to circumstances in which the courts have consistently found unambiguously anticompetitive conduct after applying the rule of reason to nearly identical conduct in prior cases:

> The object is to see whether the experience of the market has been so clear, or necessarily will be, that a confident conclusion about the principal tendency of a restriction will follow from a quick (or at least quicker) look, in place of a more sedulous one. And of course what we see may vary over time, if rule-of-reason analyses in case after case reach identical conclusions.

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[4] Indeed, in recent years, the Court has specifically disapproved the application of *per se* rules in cases involving activity that in an earlier era might have been analyzed as *per se* unlawful. *See*, *e.g.*, *Broadcast Music*, 441 U.S. at 24 (blanket license agreement with price fixing effects not *per se* unlawful); *NCAA v. Board of Regents*, 468 U.S. 85, 103 (1984) (*per se* rule not applied to plan for televising college football games that included horizontal price fixing and output restrictions); *Northwest Wholesale Stationers*, 472 U.S. at 294 (appeals court's application of *per se* rule to concerted refusal to deal held inappropriate). Moreover, the Court has even reversed its own precedent in rejecting application of the rule to conduct previously considered to be *per se* unlawful. *See State Oil v. Kahn*, 522 U.S. 3, 7 (1997) (reversing Court's previous application of the *per se* rule to agreements to fix maximum resale prices).

California Dental, 526 U.S. at 780-81; *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 458 (1986) (refusing to force alleged conduct "into the 'boycott' pigeonhole" to resolve claim under *per se* rule).

The Sixth Circuit's application of the *per se* rule to the Andrx/HMR Stipulation is inconsistent with this well established "practice makes perfect" approach. It took this Court more than half a century of experience with group boycotts before the Court was willing to apply the *per se* rule to that type of conduct.[5] And since then, the Court has, on at least two occasions, further refined and narrowed its application of the *per se* rule in that context. *See Indiana Federation of Dentists*, 476 U.S. at 458-49; *Northwest Wholesale Stationers,* 472 U.S. at 294.

The Court's experiment with condemning vertical territorial restraints as *per se* illegal is similarly instructive of its caution. *Compare White Motor Co. v. United States*, 372 U.S. 253, 261-63 (1963) (reversing district court finding that vertical non-price restraints were illegal *per se* because "[w]e need to know more than we do about the actual impact of [vertical restraints] on competition to decide whether they … should be classified as per se violations of the Sherman Act") *with United States v. Arnold, Schwinn & Co.*, 388 U.S. 365, 379 (1967) (applying *per se* treatment, noting that territorial "restraints are so obviously destructive of competition that their mere existence is enough") *and Continental T.V., Inc.*

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[5] Arguably, the first significant boycott case heard by the Court was *W.W. Montague & Co. v. Lowry*, 193 U.S. 38 (1904). The Court did not formally declare group boycotts *per se* illegal under the Sherman Act until its decision in *Klor's, Inc. v. Broadway-Hale Stores, Inc.*, 359 U.S. 207 (1959).

v. GTE Sylvania Inc., 433 U.S. 36, 48-50, 58-59 (1977) (describing *Schwinn* as "formalistic line drawing" and emphasizing that "[p]er se rules of illegality are appropriate only when they relate to conduct that is manifestly anticompetitive").

The Sixth Circuit's application of the *per se* rule flies in the face of the experience of those courts that have actually assessed the competitive impact of patent litigation settlements. Before the appeals court's ruling, courts universally applied a rule of reason analytical framework to evaluate the legality of patent litigation settlements.[6] The only exception to this approach was where the agreements were found to mask an industry-wide price-fixing conspiracy.[7]

In rejecting the Sixth Circuit's approach, the Eleventh Circuit identified numerous potentially procompetitive effects of patent litigation settlement agreements, even agreements that involve cash payments from the patent holder to the alleged infringing party. For example, the Eleventh Circuit stated that *per se* antitrust analysis of patent litigation

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[6] *See, e.g., Standard Oil Co. (Indiana) v. United States,* 283 U.S. 163 (1931); *Hartford-Empire Co. v. United States,* 323 U.S. 386, 400, *clarified,* 324 U.S. 570 (1945); *Clorox Co. v. Sterling Winthrop, Inc.,* 117 F.3d 50 (2d Cir. 1997) (applying rule of reason in trademark case even though the settlement resembled a market allocation agreement).

[7] *See Noll v. O.M. Scott & Sons Co.,* 467 F.2d 295, 301 (6th Cir. 1972); *United States v. New Wrinkle,* 342 U.S. 371, 374 (1952); *see also Duplan Corp. v. Deering Milliken, Inc.,* 540 F.2d 1215, 1220 (4th Cir. 1976) ("it is only when settlement agreements are entered into in bad faith and are utilized as part of a scheme to restrain or monopolize trade that antitrust violations may occur").

settlement agreements is inappropriate *even when the patent is later ruled invalid* because:

> Patent litigation is too complex and the results too uncertain for the parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent. This uncertainty, coupled with the treble damages penalty, would tend to discourage settlement of any validity challenges except those that the patentee is certain to win at trial and the infringer is certain to lose. By restricting settlement options, which would effectively increase the cost of patent enforcement, the proposed rule would impair the incentives for disclosure and innovation.

Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 344 F.3d 1294, 1308 (11th Cir. 2003).

Although it noted that HMR paid cash to Andrx in connection with the interim settlement, the Sixth Circuit did not limit its application of the *per se* rule to patent litigation settlements involving cash payments.[8] Under the Sixth

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[8] The appeals court's decision appears to have been based in part on a misunderstanding of the hurdles a generic drug manufacturer must clear before bringing a product to market. A generic drug manufacturer may not market its product unless two conditions are met: (1) it has received marketing authority from FDA in the form of an approved ANDA; and (2) marketing will not violate a product monopoly granted by the federal government to another manufacturer, in the form of a patent. The Sixth Circuit apparently believed that only an approved ANDA was necessary. *See* Pet. App. 17a-18a (for "the

(continued...)

Circuit's inflexible rule, *any* generic drug company that agrees not to market a product after receiving FDA approval of its ANDA violates § 1 of the Sherman Act. Moreover, there is no principled basis for limiting the Sixth Circuit's ruling to cases involving cash payments. As Judge Richard Posner has pointed out, in a decision criticizing the Sixth Circuit's *per se* approach:

> [*A*]*ny* settlement agreement can be characterized as involving "compensation" to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden "reverse payment," we shall have no more patent settlements.

Asahi Glass Co. v. Pentech Pharmaceuticals, Inc., ___ F. Supp. 2d ___, 2003 U.S. Dist. LEXIS 19370, at *21 (N.D. Ill. Oct. 29, 2003).

In sum, the Sixth Circuit's condemnation of patent litigation settlement agreements as *per se* antitrust violations not only conflicts directly with numerous other federal court decision but is far out of step with this Court's case law. Review is warranted to address those conflicts.

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[8](…continued)
price of $10 million per quarter" Andrx agreed to stay out of the market "even after it had obtained FDA approval"); *id.* at 2a (same). FDA does not, of course, pretend to grant generic drug companies authority to market products in violation of existing patents.

II. REVIEW IS WARRANTED BECAUSE THE DECISION BELOW WILL DISCOURAGE LEGITIMATE SETTLEMENTS OF PATENT DISPUTES

Review is also warranted because the Sixth Circuit's decision, if left uncorrected, will have significant negative effects on intellectual property rights and on the development of new, life-saving therapies by the pharmaceutical industry.

In particular, largely for the reasons noted above, application of the *per se* rule in this case will have significant harmful consequences by discouraging patent settlements. The public policy favoring settlements is so well established that one author has deemed it a "truism." Stephen Bundy, *The Policy in Favor of Settlement in an Adversary System*, 44 HASTINGS L.J. 1, 48 (1992); *see, e.g.*, *Marek v. Chesny*, 473 U.S. 1, 10 (1985) ("settlements rather than litigation will serve the interests of plaintiffs as well as defendants"); *Williams v. First Nat'l Bank*, 216 U.S. 582, 592 (1910) ("compromises of disputed claims are favored by the courts").

These considerations are magnified in the patent context:

> Settlement is of particular value in patent litigation, the nature of which is often inordinately complex and time consuming. Settlement agreements should therefore be upheld wherever equitable and policy considerations so permit. By such agreements are the burdens of trial spared to the parties, to other litigants waiting their turn before over-burdened courts, and to the citizens whose taxes support the latter. An amicable compromise

> provides the more speedy and reasonable remedy for the dispute.

Aro Corp. v. Allied Witan Co., 532 F.2d 1368, 1372 (6th Cir. 1976) (citing *D.H. Overmeyer Co. v. Loflin*, 440 F.2d 1213 (5th Cir. 1971)). Indeed, studies show that patent litigation tends to be extraordinarily complex and expensive.[9] In addition, patent cases pose significant risks for both an intellectual property owner and an alleged infringer. An alleged infringer faces the potential of enormous damages awards,[10] while an intellectual property owner faces the

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[9] John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 187-88 (1998) ("patent litigation tends to be exceptionally costly, with legal expenses often exceeding one million dollars per party"); Steven C. Carlson, *Patent Pools and the Antitrust Dilemma*, 16 Yale J. on Reg. 359, 380 (1999) ("Roughly $1 billion dollars is spent annually in the United States on patent litigation"); Tom Arnold, *Suggested Form of Contract to Arbitrate a Patent or Other Commercial Dispute*, 2 Tex. Intell. Prop. L.J. 205, 208 (Spring, 1994) (asserting that it takes "an average of more than six years for patent cases to make their way through the trial and appeal process").

[10] *See*, *e.g.*, Carlson, *supra* note 9, at 380 ("[P]atent cases have produced some of the largest damages awards in history."); *Jury Finds Infringement of Plane Device Patent*, Nat'l L.J., Feb. 4, 2002, at C13 (verdict of nearly $47 million); John F. Manser, *Connolly Bove Lands $65 Million Verdict in IP Case: Trio Wins Fight Over Corn Gene in N.C. Trial*, Del. L. Wkly., Apr. 27, 1999, at 1 ($15 million in damages and $50 million in punitive damages); Kathleen Hollingsworth, *Federal Circuit: $72 Million in Damages in Hip Replacement Case Affirmed*, West's Legal News, Oct. 4, 1996, at 1996 WL 561184 ($72 million verdict).

possibility of its patents being found invalid or unenforceable.[11]

Contrary to the strong public policy favoring settlements, the Sixth Circuit's ruling discourages the orderly resolution of patent disputes. As suggested by FTC Commissioner Thomas B. Leary, application of *per se* treatment will "cast a cloud over all patent settlements"[12] so that patent owners and accused infringers will hesitate before entering into an agreement to resolve a patent dispute in fear that a court will deem their agreement to be *per se* unlawful. Much of this hesitation would flow naturally from the practical implications of the *per se* rule. Categorizing conduct as *per se* unlawful inevitably provides greater incentives for antitrust challenges. At least some of those challenges likely will be directed at conduct that, if analyzed under the rule of reason, would ultimately be found pro-competitive. In today's technology-based society,[13] where

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[11] *See*, *e.g.*, *Bet-the-Company Suit Leaves Chip-Maker Afloat*, Nat'l L.J., Feb. 4, 2002, at C29 (ethernet patent found invalid); *Shell Oil Prevails in Suit by Union Carbide*, Nat'l L.J., Jan. 21, 2002, at C7 (patents covering process of making ethylene oxides found invalid); *Genentech Defeats Huge Claim Over Cancer Drugs*, Jan. 21, 2002, at C7 (method and cell line patent claims found invalid); Margaret C. Fisk, *Company Loses $271 Million Claim Over Wireless Patents*, Del. L. Wkly., Jan. 8, 2002, at 4 (patents for infrastructure equipment used in cellular phone systems found invalid).

[12] Thomas B. Leary, *Antitrust Issues in the Settlement of Pharmaceutical Patent Disputes* at 9 (Nov. 3, 2000), *available at* www.ftc.gov/speeches/leary/learypharma.htm.

[13] There are approximately two million patents in force. *See* U.S. Patent & Trademark Office, *U.S. Patent Statistics, Calendar Years 1963-2000* (2001). The U.S. Patent & Trademark Office ("PTO") (continued...)

prompt, consensual conflict resolution is critical to continued innovation, any increased fear of settlement of patent disputes will have devastating consequences.

Nor can the Sixth Circuit's decision be ignored as an aberration that will have little impact elsewhere. Most pharmaceutical companies, including Andrx, sell their products nationwide. Any nationwide company that does business within the Sixth Circuit can be sued there and thus can be made subject to its rule. Unless the decision below is reversed, parties involved in drug patent litigation will be far more reluctant to enter into settlements, regardless where in the nation the drug patent litigation is pending.

The settlement-discouraging effects of the Sixth Circuit's approach are particularly disturbing because the antitrust laws are intended to encourage competition, yet the discouragement of patent litigation settlements is, in many instances, so clearly anticompetitive. As Judge Posner recognized, "A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive." *Asahi Glass*, 2003 U.S. Dist. LEXIS at *21.

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[13](…continued)
received nearly 300,000 patent applications in 2000, an increase of more than 12 percent over the previous year. *See* U.S. Patent & Trademark Office, *A New Organization for a New Millennium: Performance and Accountability Report (Fiscal Year 2000)*, *available at* www.uspto.gov/web/offices/com/annual/2000. The PTO also issued a "record number" of patents in 2000. U.S. Patent & Trademark Office, *Patenting Trends Calendar Year 2000*, *available at* www.uspto.gov/web/offices/ac/ido/oeip/taf/pat_tr00.htm.

Moreover, a settlement that delays a generic company's entry into the market must be deemed procompetitive if, in the absence of a settlement, the patentee would likely have prevailed in the litigation and thereby obtained an injunction against any generic competition until long after the entry date permitted by the settlement. *Id.* Indeed, as the Petition notes, experience has shown that most generic companies are reluctant to market their product even after obtaining FDA approval of their ANDAs, for so long patent infringement litigation is still pending. The reason for that reluctance is not difficult to fathom. The advent of generic competition following expiration of a pharmaceutical patent generally leads to a sharp drop in a drug's price, and a corresponding drop in the innovator drug company's profits. If the generic competitor is found to have infringed an unexpired patent, its liability for repayment of all those lost profits would dwarf any profits it would have derived from selling the drug at a reduced price. Thus, because the threat of ruinous damage awards generally prevents the entry of generic competitors for so long as patent litigation continues, settlements (even ones providing for a delay of a generic company's market entry) are often procompetitive. Conversely, the Sixth Circuit's *per se* approach is anticompetitive because it discourages settlements.

Equally disturbing is the effect that the Sixth Circuit's *per se* approach is likely to have on innovation within the pharmaceutical industry. Any rule that decreases a patent holder's flexibility in negotiating with potential infringers renders the patent less valuable. Pharmaceutical companies are less likely to maintain their multi-billion-dollar commitment to research and development of new products if they are afforded a decreased level of protection for the intellectual property that arises from those activities. The dramatic reduction in intellectual property rights threatened

by the Sixth Circuit's decision is an issue of significant public concern. The Court should grant review to determine whether Congress really intended the antitrust laws to undermine the patent system in such a dramatic manner.

CONCLUSION

The Washington Legal Foundation respectfully requests that the Court grant the petition for a writ of certiorari.

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