No. 05-273

IN THE
Supreme Court of the United States

FEDERAL TRADE COMMISSION,
Petitioner,
v.

SCHERING-PLOUGH CORP., *et al.*,
Respondents.

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

BRIEF OF STATES AS AMICI CURIAE IN SUPPORT OF FEDERAL TRADE COMMISSION

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CONSTITUTIONS, STATUTES, LAWS, AND REGULATIONS:

INTEREST OF THE AMICI CURIAE

The amici states listed on the front cover ("the States"), by their attorneys general, file this brief as friends of the Court on behalf of Petitioner, the Federal Trade Commission ("FTC"). The attorneys general, as the chief law enforcement or legal officials for their respective states, enforce both federal and state antitrust laws and, thus, have a considerable interest in the issues that this case raises before the Court. Specifically, the States have a profound interest in ensuring that the federal antitrust laws are interpreted in harmony with sound antitrust policy and relevant judicial precedent.

In their capacities as *parens patriae*, the States, through their attorneys general, are empowered to protect the consumers in their states from violations of the federal antitrust laws. *See* 15 U.S.C. § 15c. State attorneys general also seek to ensure that consumers have affordable access to the medications that they need.[1] The attorneys general enforce the antitrust laws to ensure that consumers are not denied access to vital health care needs because of artificially high prices resulting from illegal conduct on the part of drug companies.

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[1] In January 2005, Attorney General of Vermont William H. Sorrell, President of the National Association of Attorneys General convened a symposium as part of his Presidential Initiative on Pharmaceutical Pricing. The symposium gathered pharmaceutical experts from government, industry and the private sector to study the benefits as well as the escalating costs of prescription drugs and to seek solutions to the difficulties faced by consumers and government agencies alike in budgeting to cover their rapidly increasing pharmaceutical expenses. In June 2005, Attorney General Sorrell issued his 2005 NAAG Presidential Initiative Report: *Addressing the Cost and Benefits of Prescription Drugs,* available at http://www.naag.org/naag/pdf/20050708-PR-AddressingTheCostAndBenefitsOf PrescriptionDrugs.pdf.

The attorneys general also represent government entities, state agencies and political subdivisions that pay or reimburse for prescription drugs with public funds. The States are struggling to finance state employee drug benefit plans, the prescription drug needs of state hospitals and prisons, injured workers insurance funds and Medicaid and other state pharmaceutical assistance programs.[2] The States spend billions of taxpayers' dollars on pharmaceutical products every year. The State of Maryland, for example, which comprises only about 1.8 percent of the nation's population, spent approximately $710 million in 2004-2005 on prescription drugs for the State's Medicaid and pharmacy assistance program beneficiaries alone.[3]

In these two capacities, as *parens patriae* representatives of consumers and as counsel acting on behalf of the states' proprietary interests, the attorneys general have prosecuted or are pursuing antitrust cases and investigations against pharmaceutical companies that, like the *Schering* matter before the Court, involved reverse payment settlements of patent infringement suits between brand name and generic drug companies.[4] Additionally, the Commonwealth of Pennsylvania currently has an antitrust action pending against Respondents Schering-Plough Corp. and Upsher-Smith Laboratories, Inc.

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[2] NAAG Presidential Initiative Report at p. 93.

[3] Derived from Maryland State Pharmacy Expenditures for Fiscal Year 2005, Maryland Pharmacy Program, Department of Health & Mental Hygiene, unpublished materials on file with the State.

[4] *See, e.g.*, *In re Cardizem CD Antitrust Litigation*, MDL No. 1278 (E.D. Mich. 2003); *In re Terazosin Hydrochloride Antitrust Litigation*, MDL No. 1317 (S.D. Fla. 2005); *In re Buspirone Antitrust Litigation*, MDL No. 1413 (S.D.N.Y. 2002); *Ohio v. Bristol-Myers Squibb Co.*, Civ. No. 02-1080 (D.D.C. 2003).

alleging the same illegal conduct that is the subject of the FTC's petition.[5] Finally, many states have ongoing non-public antitrust investigations involving several pharmaceutical companies, possible abuses of patent protection and potentially illegal agreements between competitors to deter generic entry. Antitrust prosecutions, settled on behalf of consumers and government purchasers, have resulted in strong injunctive relief and monetary recoveries of hundreds of millions of dollars in overcharges to public and private purchasers of prescription drugs.

SUMMARY OF ARGUMENT

There is an irreconcilable conflict between the Sixth and Eleventh Circuits as to the appropriate antitrust analysis of patent settlements that involve reverse payments, i.e., payments from the patentee to the alleged infringer. This split in legal precedent creates confusion regarding the scope of patent rights and frustrates the consistent enforcement of federal and state antitrust laws. Furthermore, the Eleventh Circuit's decision is analytically unsound and ill-advised because it ignores the statutory balance between intellectual property rights and competition, resulting in harm to consumer and state purchasers of prescription drugs. Finally, the Eleventh Circuit's decision disserves the public interest in two ways. First, the decision nullifies any benefit that would otherwise flow to the public as a result of the settlement of legal disputes. Second, it discourages enforcement of the antitrust laws by requiring litigation of the underlying patent dispute, even before analyzing the anticompetitive effects of the reverse payment settlement. Its test examines (1) the scope of the exclusionary

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[5] *See Pennsylvania v. Schering-Plough Corp.*, Civ. No. 01-328-E (filed Oct. 4, 2001 W.D. Pa.) *transferred to In re K-Dur 20 Antitrust Litigation*, MDL No. 1419 (D.N.J.2001).

potential of the patent; (2) the extent to which the agreements at issue exceed that scope; and (3) the resulting anticompetitive effects. The Eleventh Circuit, thus, articulates a test that is inconsistent with well-settled antitrust principles and precedent; its analysis improperly shifts burdens of proof, thereby making it unduly onerous for antitrust enforcers to mount effective challenges to anticompetitive patent settlement agreements.

ARGUMENT

I. THE ELEVENTH CIRCUIT'S DECISION DIRECTLY CONFLICTS WITH THE SIXTH CIRCUIT'S DECISION ON AN ISSUE OF NATIONAL CONSEQUENCE.

The Eleventh Circuit's holding that reverse payments are, in effect, per se legal directly conflicts with the Sixth Circuit's decision which held that patent infringement disputes settled by reverse payments are per se illegal. This Court's resolution of the conflict is needed not only to provide consistency in the courts, but also to provide guidance to the pharmaceutical industry, state and federal antitrust enforcement agencies and all public and private purchasers of prescription drugs.

Both proponents and opponents of per se antitrust analysis of reverse payment settlements have acknowledged the conflict between the Circuits and have sought the Court's review. On October 12, 2004, the Court denied two pertinent petitions for certiorari. In *In re Cardizem CD Antitrust Litigation*,[6] the Sixth Circuit held that an agreement among parties to a patent infringement suit, whereby the patent owner paid the alleged

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[6] *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharms., Inc. v. Kroger Co.*, 125 S.Ct. 307 (2004).

infringer to stay out of the United States market for Cardizem CD and its generic equivalents, constitutes a horizontal market allocation agreement and, therefore, is per se illegal under the Sherman Act.[7] The petitioner, pharmaceutical manufacturer Andrx Pharmaceuticals, Inc., in appealing the Sixth Circuit's finding that reverse payment settlements are per se illegal, argued that the Sixth and Eleventh Circuits reached opposite conclusions on the same issue in indistinguishable cases.[8]

On the same day, the Court denied the petition for certiorari in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*[9] The *Valley Drug* case, decided by the Eleventh Circuit, held that settlement agreements, whereby the patent owner paid the alleged infringers not to enter the United States market for Hytrin, its generic equivalent and other generic terazosin hydrochloride products, are not per se illegal under the Sherman Act.[10] That petition for a writ of certiorari was filed by Louisiana Wholesale Drug Company, Inc. and Valley Drug Company, who were not the parties to the patent infringement settlement, but rather were purchasers allegedly injured by the anticompetitive agreement entered into by the two pharmaceutical companies, Geneva Pharmaceuticals, Inc. and Abbott Laboratories. Unlike the petitioner seeking certiorari in the *Andrx* case, the petitioners in *Valley Drug* argued that the court of appeals erred in failing to apply the per se rule to

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[7] 332 F.3d at 908-09.

[8] *See* Petition for a Writ of Certiorari, *Andrx Pharms.*, 2003 WL 22867750 at *2,*8-*12.

[9] 344 F.3d 1294 (11th Cir. 2003), *cert. denied* ,125 S. Ct. 308 (2004).

[10] *Id.* at 1309-10.

reverse payment settlements of patent disputes.[11] Nevertheless, petitioners in *Valley Drug* also acknowledged the split between the Sixth and Eleventh Circuits in indistinguishable cases addressing the same issue.[12] Thus, both sides of the debate, those favoring per se treatment and those opposing it, have acknowledged the conflict between the Circuits and have requested the Court's guidance in resolving it.

This case involves a third antitrust challenge to agreements between parties in a patent infringement suit where the patent owner paid the alleged infringers not to enter the U.S. market for a branded drug, here K-Dur 20, and its generic equivalents. Given the Eleventh Circuit's decision in *Valley Drug*, it came as no surprise that Schering-Plough and Upsher-Smith Laboratories, Inc. chose that forum in which to file their appeal of the FTC's ruling against them. Indeed, the Eleventh Circuit went beyond its holding in *Valley Drug* and ruled that reverse or exclusion payments from the patent owner to the alleged infringer are not only *not per se illegal*, but further are fully within the potential exclusionary power of the challenged patent and therefore, in effect, *per se lawful*.[13] More troubling

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[11] *See* Petition for a Writ of Certiorari, *Valley Drug*, 2004 WL 322428 at *19-*24.

[12] *Id.*

[13] See *Schering-Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056 at 1075-76 (11th Cir. 2005). In its petition, the FTC does not contend (and the States do not here assert) that the Eleventh Circuit erred in failing to apply the per se rule to the K-Dur 20 agreements. Instead, the States highlight the Circuit conflict in order to stress the urgency of the need for the Court's review of patent settlement agreements that raise antitrust implications, especially those that involve reverse payments and even more critically, those that purport to resolve the patent infringement dispute within the

still, the court of appeals held that before any anticompetitive effect of the settlement could be measured, the antitrust plaintiff must first litigate the merits of the underlying patent dispute.

Before the Eleventh Circuit's *Schering* opinion, some questioned whether the Circuits were truly split as to the appropriate antitrust analysis of reverse payments settlements.[14] Today, however, no doubt exists that the issue is ripe for the Court's review.[15] The Sixth Circuit and the Eleventh Circuit cannot both be correct. In fact, at least in the context of an agreement that resolves the patent dispute within the patent's potential term and scope, some would argue that neither analysis adequately balances the competing interests represented at the intersection of intellectual property law and antitrust principles, further indicating the need for the Court's review. The States request that the Court grant the FTC's petition and resolve this irreconcilable conflict between the Circuits.

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potential term and scope of the challenged patent.

[14] *See, e.g.*, Brief for the United States as Amicus Curiae, *Andrx Pharms. v. Kroger Co.*, 125 S. Ct. 307 (2004), 2004 WL 1562075 at *11-*16.

[15] Even counsel for Respondent Schering-Plough Corp. acknowledged the conflict between the Sixth and Eleventh Circuits (months before the Eleventh Circuit's *Schering* decision), characterizing the range in the two courts' treatments of reverse payment settlements as "from per se condemnation to virtual per se legality." *See* Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1039 (2004).

II. THE ELEVENTH CIRCUIT'S DECISION SUBVERTS THE PURPOSE AND EFFECT OF THE HATCH-WAXMAN ACT AND INJURES CONSUMERS AND GOVERNMENT PURCHASERS.

In the past five years, there has been an explosion of academic commentary addressing the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), also known as the Hatch-Waxman Amendments to the Federal Food, Drug & Cosmetic Act ("Hatch-Waxman"), and the antitrust implications of patent infringement settlements involving reverse payments.[16] Federal

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[16] *See, e.g.*, Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Applications*, 54 Fla. L. Rev. 747, 752 (2002); Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719 (2003); Herbert Hovenkamp, Mark D. Janis & Mark A. Lemley, *Balancing Ease and Accuracy in Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712 (2004); James Langenfeld & Wenqing Li, *Intellectual Property and Agreements to Settle Patent Disputes: The Case of Settlement Agreements with Payments from Branded to Generic Drug Manufacturers*, 70 Antitrust L.J. 777 (2003); Jonathan M. Lave, *Responding to Patent Litigation Settlements: Does the FTC Have It Right Yet?*, 64 U. Pitt. L. Rev. 201 (2002); Marcy Lobanoff, Comment, *Anti-Competitive Agreements Cloaked as "Settlements" Thwart the Purpose of the Hatch-Waxman Act,* 50 Emory L.J. 1331, 1353 (2001); Kevin D. McDonald, *Patent Settlements and Payments that Flow the "Wrong" Way: The Early History of a Bad Idea,* 15 Antitrust Health Care Chron. (ABA Section of Antitrust Law Newsletter) 2, 12-13 (2002); Kevin D. McDonald, *Hatch-Waxman Settlements and Antitrust: On "Probabilistic" Patent Rights and False Positives,* Antitrust, Spring 2003, at 68; Maureen A. O'Rourke & Joseph F. Brodley, *An Incentives Approach to Patent Settlements: A Commentary on Hovenkamp, Janis & Lemley*, 87 Minn. L. Rev. 1767 (2003); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34

courts have struggled with these complex, yet critical issues, resulting in confusing and inconsistent rules of law. While opinions diverge widely on what the law should be with regard to reverse payments, amidst the lively debate, there is serious doubt that the Eleventh Circuit's approach in *Valley Drug* and *Schering* is compatible with the provisions of the Hatch-Waxman Act that promote generic competition.[17]

By enacting Hatch-Waxman, Congress intended not only to preserve valid and enforceable patent rights, but, at the same time, to expedite the availability of generic alternatives to brand name prescription drugs. Hatch-Waxman encourages generic entry by (1) permitting the generic drug applicant to rely on the safety and efficacy studies performed by the brand name drug pioneer in obtaining FDA approval; and (2) encouraging generics to challenge weak or dubious patents as invalid or not infringed by awarding the first successful challenger 180 days of marketing exclusivity. 21 U.S.C. § 355 (j)(5)(B)(iv)(1984), *amended by* 117 Stat. 2066, Pub.L. 108-173 § 1102 (2003). In the House Report recommending adoption of the Act, the House Committee on Energy and Commerce noted the cost savings to federal and state governments as the result of additional generic entry. After noting that the availability of a generic alternative for one drug had saved the Department of Defense $1.2 million, the Committee said, "Federal and state governments will be denied comparable savings on drugs approved after 1962 because of the lack of an approval procedure [for new generic drugs]." H.R. Rep. 98-857 (I), at 17,

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RAND J. Econ. 391 (2003).

[17] *See*, *e.g.*, 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).

1984 U.S.C.C.A.N. 2647, 2650.

In contrast to the goals set forth in Hatch-Waxman, the Eleventh Circuit's decision not only fails to encourage generic entry, it affirmatively supports collusive resolutions of patent infringement challenges. Specifically, the Eleventh Circuit decision allows Hatch-Waxman to be manipulated to shield payments from one competitor to another in exchange for the second competitor's forbearance in entering the market. If the Eleventh Circuit were correct, generic entry following a patent challenge would be rare. In virtually all cases, the patent owner can afford to pay the generic challenger more to drop its challenge and exit the market than the generic could make marketing its product. In other words, if the patent owner's potential loss exceeds the generic challenger's potential gain, it will be in both parties' mutual best interest to settle the case by dividing up monopoly profits. While it is a win-win situation for the pharmaceutical companies, the big losers are the victims of antitrust violations: the end-payor purchasers of prescription drugs, primarily consumers, government agencies and healthcare benefit plans.

When Congress amended the Hatch-Waxman Act in 2003, it cited as one reason for legislative reform that the unusual configuration of interests and incentives created by the statutory scheme had the unintended consequence of enticing brand and generic drug companies to enter into potentially anticompetitive settlement agreements.[18] Among the corrective provisions

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[18] *See* 148 Cong. Rec. 7565-01, S7566 (2002) (Statement of Senator Orrin Hatch, Senate Floor Debates on the Greater Access to Pharmaceuticals Act, S. 812) ("As a coauthor of the Drug Price Competition and Patent Term Restoration Act, I can tell you that I find these type of reverse payment collusive arrangements appalling.... We did not wish to encourage situations where

enacted to curtail anticompetitive abuses is the requirement that brand and generic drug companies entering into patent litigation settlements submit those settlements to federal antitrust enforcers for review.[19] These reviews of patent settlements by antitrust agencies are likely to be of marginal effectiveness in ensuring compliance with the antitrust laws if government challenges of those agreements are held to the incorrect and overly burdensome standards set forth by the Eleventh Circuit.

The benefits that Congress intended to bestow upon purchasers of prescription drugs in this country through Hatch-Waxman are needed now more than ever before. Innovations in pharmacological research, which deserve appropriate marketing protection by proper interpretation of the patent laws, have led to an increased ability to treat many medical ailments pharmaceutically.

Every year, this country spends more than $100 billion on prescription drugs and those expenditures are rising rapidly.[20]

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payments were made to generic firms not to sell generic drugs and not to allow multi-source generic competition.... However the K-Dur case ultimately is decided, I commend [the FTC for continuing its] policy of zealously reviewing these types of reverse payment cases to determine whether such agreements run afoul of the antitrust laws").

[19] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 117 Stat. 2066 §§ 1111-1118.

[20] Spending in the U.S. increased an average annual rate of 14.5% from 1997-2002. *See* Congressional Budget Office, *Would Prescription Drug Importation Reduce U.S. Drug Spending?* (April 29, 2004). According to the Centers for Medicare and Medicaid Services, pharmaceutical expenditures rose 14.9% in 2002 and 10.7% in 2003. Center for Medicare & Medicaid Services,

For example, in 2002, nationwide expenditures for prescription drugs totaled over $160 billion.[21] However, not only is the country buying more drugs, pharmaceutical prices continue to rise as well. During the decade from 1993-2003, retail prescription drug prices increased an average of 7.4 percent per year, nearly three times the average yearly inflation rate of 2.5 percent during the same time period.[22] Moreover, the prices for drugs claiming patent protection continue to rise at an alarming rate relative to the increase in price for generic substitutions. The cost of brand name prescription drugs has been rising steadily at twice the rate of inflation, while the cost of generics is increasing at the rate of less than 1 percent.[23]

The FDA has estimated that consumers and state agencies can save at least 50 percent on their pharmaceutical needs by

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Highlights-National Health Expenditures, 2003 at 1 (January 11, 2005) ("CMS, *Highlights*"). In the twenty years since Hatch-Waxman was enacted, while healthcare spending has increased dramatically overall, expenditures for prescription drugs have remained the fastest growing component. *See* The Henry J. Kaiser Family Foundation, *Prescription Drug Trends* at 1 (Oct. 2004); Stephen Heffler et al., *Health Spending Projections Through 2013*, Health Affairs Web Exclusive, Feb. 11, 2004.

[21] *See Prescription Drug Trends* at 1 (Oct. 2004)

[22] *Id.*; CMS, *Highlights*.

[23] A survey of wholesale prices conducted by AARP and published in August 2005, showed that a 12-month average increase for 195 brand name drugs was 6.6% or more than double the 3.1% rise in the Consumer Price Index that monitors general inflation rates. *See* David Gross, et al., *Trends in Older Americans-First Quarter 2005 Update*, *AARP Public Policy Institute* (July 2005), available at http://www.assets.aarp.org/ rgcenter/health/dd122_ drugprices.pdf.

purchasing generic products.[24] Generic drugs acquire, on average, 44 percent of sales from bioequivalent brand name drugs during the first year after generic entry.[25] Timely availability of these products is key; each day that generics are illegally kept out of the market represents millions of dollars in unwarranted overcharges for consumers and government payors. In 1994 alone, consumers saved between $8-10 billion by purchasing generic versions of brand name drugs.[26]

The prompt availability of generic alternatives is increasingly important as more and more states enact laws and promulgate regulations mandating generic substitution, pharmaceutical formularies and preferred drug lists,[27] and institute supplemental pharmaceutical assistance programs to provide affordable access to prescription drugs for their citizens.[28] At the federal level, expedited access to generic drugs

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[24] *See* U.S. Food and Drug Administration, *Savings from Generic Drugs Purchased at Retail Pharmacies* (May 3, 2004).

[25] *See* Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, xii (July 1998) ("CBO 1998").

[26] *See* CBO 1998 at ix.

[27] The enforcement of state laws designed to promote the utilization of generic drugs is further frustrated by the Eleventh Circuit's decision. *See e.g.*, National Conference of State Legislatures, 2005 Prescription Drug State Legislation Mid-Year Edition: August 15, 2005, available at http://www.ncsl.org/programs/health/drugdisc05.htm (NCSL 2005 Prescription Drug State Legislation")

[28] As of May 2005, at least 39 states have established or authorized some type of program to provide pharmaceutical coverage or assistance, primarily to the low-income elderly or to persons with disabilities who do not qualify for Medicaid. *See* NAAG Presidential Initiative Report at p. 93; NCSL 2005 Prescription Drug State

takes on an even greater fiscal urgency as the country finalizes plans to provide Medicare beneficiaries with drug benefits in January 2006 under the Part D program.[29] If generic drugs are not made available in the manner intended by Hatch-Waxman, these already costly government programs may quickly become cost-prohibitive.

The need for the Court's guidance is crucial and the FTC's petition comes at a critical time. Many expensive brand name drugs--at least 60 percent of the fifty top-selling brands--are currently facing patent challenges from generic competitors as contemplated and, indeed, encouraged by Hatch-Waxman.[30] The Eleventh Circuit's decision, however, frustrates the statute's

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Legislation.

[29] *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

[30] For example, eighteen of the thirty top-selling brand name prescription drugs are subject to patent challenges by generic competitors. Manufacturers of Lipitor, Effexor-XR, Plavix, Celebrex, Neurontin, Protonix, Norvasc, Zyprexa, OxyContin, Fosamax Risperdal, Zoloft, Zocor, Pravachol, Actos, Aciphex, Levaquin and Lovenox have all received abbreviated new drug application paragraph IV certifications from generic drug competitors challenging the validity and/or enforceability of the brand name drugs' patent protection. *See, e.g.,* NDC Health Corporation, The Top 200 Prescriptions for 2004 by U.S. Sales (Mar. 2005) available at http://www.ndchealth.com/press_center/uspharamaindustrydata.asp; FDA Center for Drug and Evaluation and Research, Paragraph IV Patent Certifications as of August 15, 2005, U.S. Food & Drug Administration, (created Feb. 16, 2005, updated August 15, 2005) available at http://www.fda.gov/cder/ogd/ppiv.htm

intent by articulating a test that not only discourages generic entry, but also promotes unwarranted extension of patent rights and the division of monopoly profits by pharmaceutical companies, at the expense of American consumers. The Court's analysis is needed to ensure that the provisions of Hatch-Waxman, both those that promote innovation by protecting patent rights, as well as those that accelerate generic competition, are not circumvented by errors in judicial interpretation.

III. THE PUBLIC INTEREST IS DISSERVED BECAUSE THE ELEVENTH CIRCUIT'S DECISION DISCOURAGES ANTITRUST SCRUTINY OF PATENT SETTLEMENT AGREEMENTS.

Antitrust enforcers, patent infringement litigants and the courts agree that "public policy wisely encourages settlements" of legal disputes. *McDermott Inc., v. AmClyde*, 511 U.S. 202, 215 (1994). Patent litigation, particularly in areas involving complex technical issues like those involved in the pharmaceutical industry, is extremely expensive for the parties and burdensome for the courts. When a legal dispute is pursued through trial, the expenses of litigation are passed on to the public in the form of increased prices of products and services provided by both parties. In the ideal case, settlement avoids these costs and allows the parties in pharmaceutical patent disputes to focus on ways of inventing, producing and marketing new medications, for the benefit of the public.

However, not all settlements are actually in the public interest. If the patent settlement results in an unlawful extension of monopoly rights, the public interest requires challenging that

settlement under the antitrust laws. In reviewing the FTC's antitrust challenge of the patent infringement settlements at issue in this case, the Eleventh Circuit devised a three-part test that mandates an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects. *Schering-Plough v. Federal Trade Commission*, 402 F.3d 1056, 1066 (11th Cir. 2005). This test not only vitiates the purported benefit to the public from the patent settlement (i.e., avoidance of lengthy and expensive trial and concomitant increase in the price of pharmaceutical products), but also deters enforcement of the antitrust laws to the further detriment of the public good. In order to prove an antitrust challenge, an antitrust prosecutor or plaintiff must first prove the invalidity and/or noninfringement of the underlying patent. The Eleventh Circuit's decision disserves both the public interest favoring settlement of legal disputes and the public interest in ensuring compliance with the antitrust laws.

Although the Eleventh Circuit does not expressly advocate a *post hoc* analysis of patent validity and/or infringement, that is precisely what its three-part approach requires. The Eleventh Circuit has erroneously extended the statutory presumption of *validity* of the patent[31] to an unprecedented and unwarranted presumption of *infringement* of that patent. The Eleventh Circuit's decision reassigns the burdens of proof (1) from the generic challenger to the government to show that the patent is invalid; and (2) from the patent owner to the government to

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[31] 35 U.S.C. §282.

show that the patent is not infringed,[32] before any settlement of the patent challenge may be scrutinized under the antitrust laws.[33] According to the Eleventh Circuit, if antitrust enforcers do not rebut those presumptions by showing invalidity of the patent and/or that the patent litigation was a sham, then the scope of the exclusionary potential of the patent is deemed to be that of the patent, had it been judicially determined valid and infringed. *Id.* at 1068. In other words, if the patent is presumed valid and infringed, and the antitrust enforcer fails to prove otherwise, then the exclusionary potential is the full term and scope of the patent, and a division of monopoly profits between the patent owner and the generic challenger is deemed justified as within those parameters. *Id.* at 1074-76. The illogic of this circular reasoning is manifest in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005), where the district court, relying in large part on the Eleventh Circuit's analysis, expressly concluded that reverse payments are legal, and also tacitly concluded that the weaker the patent

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[32] The Eleventh Circuit erroneously stated that "Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the '743 patent was invalid or that their products... did not infringe Schering's patent." *See* 402 F.3d at 1066-67. The correct burden of proof in a patent dispute is upon the *patentee* to show by a preponderance of the evidence that a competitor's product infringes his patent. *See, e.g., Kegel Co., Inc. v. AMF Bowling, Inc.,* 127 F.3d 1420, 1425 (Fed. Cir. 1997).

[33] This analysis assumes that the Eleventh Circuit would even permit the antitrust enforcer to rebut the twin presumptions of validity and infringement; *Valley Drug* can be also read to exclude any *post hoc* determinations except in cases of fraud or sham litigation. See *Valley Drug*, 344 F.3d at 1309.

owner believes his patent to be, the more he is willing to pay a competitor not to challenge it. *Id.* at 534.

If the patent infringement dispute must be litigated as a prerequisite to any attempt to define the parameters of the patent's authority to exclude, then any efficiencies realized as a result of the patent settlement would inure, if at all, only to the parties to the settlement.[34] Moreover, if the antitrust plaintiff must first prove invalidity and/or noninfringement, many unlawfully anticompetitive settlements will go unchallenged.

The appropriate analysis of an antitrust challenge of a patent infringement settlement, therefore, assesses the strength of the patent in the context of the infringement settlement itself. This is true regardless of whether the settlement includes a reverse payment and regardless of whether reverse payments are deemed per se illegal. Underlying this analysis is the question whether, given the terms of the settlement, it is more likely than not that the patent would have been found (1) invalid and/or unenforceable; or (2) valid and enforceable, but not infringed. In such an analysis, the presence of a reverse payment is but one indicator of the strength or weakness of the patent at issue. Thus, if a patent settlement includes a substantial payment to the generic challenger, "absent proof of other offsetting consideration, it is logical to conclude that the quid pro quo for

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[34] Ironically, the Eleventh Circuit relied upon the public policy preference for settlement of legal disputes, citing the benefits of cost savings to the parties and to the public when it articulated its antitrust test. The Eleventh Circuit's test requires litigation of the patent dispute in any event, resulting in cost savings to no one. 402 F.3d at 1072-73, 1075.

the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise."[35] Further, a patent settlement that resolves a dispute with money rather than with time[36] would indicate a relatively weak patent claim and the more substantial the payment, the weaker the patentee's case is likely to be.[37]

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[35] *See* FTC Petition for a Writ of Certiorari at p.18. ("FTC Pet.")

[36] As the FTC noted in its Petition, patent settlements permitting earlier generic entry instead of payment to the generic challenger are beneficial or at least neutral to purchasers of prescription drugs. *See* FTC Pet. at p.18. The States do not advocate that patent settlements are improper unless they benefit the public, but rather that the Eleventh Circuit's ruling erroneously approves settlements that directly thwart the public interest.

[37] Judicial tests based upon probability are well-established in many areas of the law, including intellectual property and antitrust. For example, preliminary injunctions, frequently applicable to patent infringement disputes, require a showing of probable success on the merits. *See, e.g., Amazon.com, Inc. v. BarnesandNoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). Clayton Act merger challenges also rely on probability, i.e., the challenger carries a burden of proving a reasonable probability that the transaction would substantially lessen competition. *See, e.g.*, 15 U.S.C. §18; *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962). Proof of negligence takes into account the gravity of the harm, discounted by its improbability, and balances that against the burden of adequate precaution. *See*, e.g., *Red Star Towing & Transportation Co. v. Woodburn*, 18 F. 2d 77 (2d Cir. 1927). In environmental cases, remedial orders essentially weigh the probability and severity of imminent and substantial endangerment within the meaning of 42 U.S.C. §§ 6973, 9606 against the costs of fixing the problem. *See*, *e.g., United States v. Seymour Recycling Corp.*, 554 F.Supp 1334, 1337-38 (D. Ind. 1982).

The Eleventh Circuit failed to provide a reasoned analysis that would permit antitrust scrutiny of patent settlements, short of trial on the merits of the underlying patent dispute. Such analysis misconstrues and misallocates the appropriate burdens of proof. Moreover, in so doing, it countermands any societal benefit inherent in the policy favoring settlement of legal disputes in the first instance and discourages fair and efficient enforcement of the antitrust laws. Both results run counter to the public interest and disrupt the appropriate balance struck by Congress between enforcement of intellectual property rights and enforcement of the antitrust laws.

CONCLUSION

For the reasons stated, the Federal Trade Commission's petition for a writ of certiorari should be granted.

Respectfully submitted,

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