No. 10-762

In The
# Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUGSTORE, INC.,

*Petitioners,*

v.

BAYER AG, BAYER CORP., formerly doing business as MILES INC., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES, INC.,

*Respondents.*

**On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit**

## BRIEF OF THE STATES OF CALIFORNIA, ARIZONA, ARKANSAS, DELAWARE, FLORIDA, HAWAII, IDAHO, ILLINOIS, IOWA, MAINE, MARYLAND, MASSACHUSETTS, MINNESOTA, MISSISSIPPI, MISSOURI, MONTANA, NEBRASKA, NEVADA, NEW HAMPSHIRE, NEW MEXICO, NORTH CAROLINA, OKLAHOMA, OHIO, OREGON, SOUTH CAROLINA, TENNESSEE, TEXAS, UTAH, VERMONT, WASHINGTON, WEST VIRGINIA AND WYOMING AS AMICI CURIAE SUPPORTING PETITIONERS

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## INTEREST OF AMICI[1]

The Amici States have three interests in this matter: 1) through their chief law enforcers, the Attorneys General, the States enforce federal and state antitrust laws against anticompetitive "reverse payment" agreements of the type wrongfully immunized by *Arkansas Carpenters Health & Welfare Fund v. Bayer AG* (*In re Ciprofloxacin Hydrochloride Antitrust Litigation*), 604 F.3d 98, 106-10 (2d Cir. 2010) ("*Cipro*"); 2) as *parens patriae*, the States seek to protect their consumers and businesses from anticompetitive conduct that blocks access to lower-cost generic pharmaceuticals; and 3) as their Medicaid agencies and other governmental programs are significant third-party payors for, and direct purchasers of pharmaceuticals, the States have a duty to protect their strong proprietary interest in the availability of lower-cost generic drugs.

The States have a long history of prosecuting antitrust actions where there is collusion between pharmaceutical companies to limit or exclude generic competition.[2] However, the States have limited

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[1] All counsel of record have received ten days notice of the filing of this brief.

[2] *See, e.g.*, *FTC v. Watson Pharms., Inc.*, 611 F. Supp. 2d 1081 (C.D. Cal. 2009); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005); *Colorado v. Warner Chilcott Holdings Co. III, Ltd.*, No. 1:05-CV-2182 (CKK), 2007 WL 6215857 (S.D.N.Y. Nov. 7, 2005); *Ohio v. Bristol-Myers Squibb Co.*, No. 1:02-CV-01080 (EGS), 2003 WL 21105104 (D.D.C. May 13, 2003); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

resources that are under additional pressures from overextended budgets. When, as here, the legal standard as to reverse payment agreements is subject to widely differing interpretations and results, State antitrust enforcers need clear guidance to fulfill their role to protect their consumers and businesses from anticompetitive agreements.

## SUMMARY OF ARGUMENT

Following the Second Circuit's earlier decision in *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006) ("*Tamoxifen*"), which the *Cipro* court was duty-bound to do despite misgivings about *Tamoxifen's* soundness, *Cipro* establishes almost irrebuttable presumptions of patent validity and infringement based solely on the patent holder's untested assertions of validity and infringement. These judicially-made presumptions, subject to only minor exceptions, have no basis in law or fact, and are contrary to this Court's precedent. The presumptions, in turn, support the Second Circuit's creation of a broad immunity to the antitrust scrutiny that such collusive competitor agreements traditionally receive under this Court's rulings.

Reverse payment agreements also thwart the letter and spirit of the Drug Price Competition and Patent Term Restoration Act of 1984 ("the Hatch-Waxman Act"), 21 U.S.C. § 355(j) (2006). One of the Act's specific goals was encouraging the speedy entry

of generic competition by incentivizing litigation over and removal of weak patents that wrongly delayed generic competition.

Further, the decision below abandons common sense by attributing all the delay in generic competition to the exclusionary power of the patent. This attribution is based on the flawed assumption that the statutory privileges of a patentee include the right to collude with and pay competitors to divide up markets. Such an assumption is inconsistent with this Court's long-standing condemnation of patent licensing arrangements that go beyond the narrow monopoly rights of the patent grant, as do the reverse payment agreements, which should be treated accordingly.

As detailed in the Petition for a Writ of Certiorari ("Pet. Cert."), the approach of the Second Circuit diverges significantly from that of the Sixth and Eleventh Circuits. The Attorneys General need guidance as to the legality of reverse payment agreements that clearly eliminate generic competition and impact our States' budgets and citizens. We respectfully urge the Court to grant the Petition for a Writ of Certiorari.

## REASONS FOR GRANTING CERTIORARI

### I. A SURGE IN REVERSE PAYMENT AGREEMENTS IS THREATENING THE EXISTENCE OF GENERIC COMPETITION AND THE AVAILABILITY OF AFFORDABLE DRUGS TO THE STATES AND THEIR CITIZENS.

Maintaining open competition in pharmaceutical markets is critical to the States' ability to provide drugs to their consumers at a reasonable cost, and to control escalating drug costs that threaten to swamp already-strained State budgets. In 2008, State and local governments nationwide spent some $14.5 billion for drug prescriptions, while health-care spending consumed some 24% of state revenues.[3] Nationally, drug prescriptions in 2008 cost some $234 billion, more than five times the $40.3 billion spent in 1990.[4]

Brand name drugs, many of which have patent protection, account for most of the increase in the nation's burgeoning drug costs. Generic drugs, on the other hand, typically cost less than a third of the price of branded drugs, and are one of the primary

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[3] Centers for Medicare and Medicaid Services, U.S. Dep't of HHS, *National Health Expenditures, by Source of Funds and Type of Expenditure: Calendar Years 2003-2008* ("*HHS Study*"), Table 4, http://www.cms.gov/NationalHealthExpendData/downloads/tables.pdf; California Health Care Foundation, *Health Care Almanac, Health Care Costs 101* (2010), at 11, http://www.chcf.org/~/media/Files/PDF/H/PDF%20HealthCareCosts10.pdf.

[4] *HHS Study*, *supra* note 3, at Table 2.

factors responsible for slowing the rate of increase in drug costs.[5]

Yet robust generic competition is being seriously undermined by the surge of reverse payment agreements that force States and consumers to pay monopolistic prices for branded drugs. In the instant case, Bayer enjoyed a billion dollars annually in Cipro sales. Competition from Barr[6] and other generic companies would have quickly and drastically reduced Bayer's revenues, while at the same time saving consumers hundreds of millions of dollars. By paying the generics $398 million, Bayer estimated it was able to preserve more than $1.6 billion in monopoly profits. Pet. Cert. 7. At the same time, the generics also profited handsomely from their financial pact with Bayer, making more than double what they would have made had they invalidated the Bayer patent and launched generic competition to Cipro. *Id*. at 7-8.

The aggregate financial burden of these collusive reverse payment agreements on consumers is

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[5] Kaiser Family Foundation, *Prescription Drug Trends* (2010), at 1-3, http://www.kff.org/rxdrugs/upload/3057-08.pdf; Center for Drug Evaluation and Research, U.S. FDA, *Generic Competition and Drug Prices*, http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm.

[6] One of this case's defendants, Barr Labs, is the most frequent generic participant in reverse payment agreements, and, together with its parent, Teva, has entered into some twenty such agreements. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 656 (2009).

staggering. Studies by the Federal Trade Commission ("FTC") and prominent academics gauge the impact to be between $3.5 billion and $14 billion annually.[7]

The surge in reverse payment agreements is largely the result of the decision in *Tamoxifen*, widely viewed as sanctioning and encouraging these agreements.[8] Before that decision, patent litigation rarely settled with payments being made by the patent holders to the alleged infringers.[9] Moreover, the reverse payments made under *Tamoxifen's* protective umbrella secure generic companies' agreements to delay marketing lower-cost drugs beyond what they would agree to do in the absence of the monetary payments.[10] A recent FTC study estimates that these payments delay entry of competition for nearly 17 months relative to patent settlements lacking reverse payments.[11]

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[7] FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions,* at 2 (Jan. 2010) ("FTC Recent Study"), http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf; Hemphill, *supra* note 6, at 650.

[8] *FTC Recent Study*, *supra* note 7, at 1; Jon Leibowitz, Commissioner, FTC, *Exclusion Payments to Settle Pharmaceutical Patent Cases*: *They're B-a-a-a-ck!*, at 7-8 (Apr. 26, 2006), http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf.

[9] Hemphill, *supra* note 6, at 638, 657.

[10] *FTC Recent Study*, *supra* note 7, at 2, 4; Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. Econ., 391, 394 (2003); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1749-63 (2003).

[11] *FTC Recent Study, supra* note 7, at 2, 4.

## II. *TAMOXIFEN* AND *CIPRO* ESTABLISH ALMOST CONCLUSIVE PRESUMPTIONS OF VALIDITY AND INFRINGEMENT NOT SUPPORTED BY STATUTE, FACT OR JUDICIAL PRECEDENT.

It is fundamental that agreements between rivals not to compete and to allocate markets between themselves are *per se* illegal antitrust violations. *See, e.g.*, *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990); *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984) ("Certain agreements, such as horizontal price fixing and market allocation, are thought so inherently anticompetitive that each is illegal *per se* without inquiry into the harm it has actually caused."). Reverse payment agreements are a species of horizontal market allocation agreements, under which competing drug companies collude and allocate 100% of the market to the branded company. *See, e.g.*, *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) ("There is simply no escaping the conclusion that the Agreement . . . was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade."); *Tamoxifen*, 466 F.3d at 211 (recognizing the "troubling dynamic" of reverse settlements that "inevitably protect patent monopolies that are, perhaps, undeserved"). The pernicious impact on our consumers of allowing competitor collusion is self-evident. *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004)

(calling competitor collusion "the supreme evil of antitrust").

Where the generic's agreement not to compete is secured solely by the enforcement of a patent found to be valid and infringed, the competitive exclusion is within the exclusionary power of the patent, and is unobjectionable. This is because a valid patent possesses the legal power to preclude competition from an infringing generic. 35 U.S.C. § 154(a)(1); *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969) ("[P]atentee has the exclusive right to manufacture, use, and sell his invention."). Correspondingly, a patent that is invalid, unenforceable or not infringed has no exclusionary power, and thus cannot justify any exclusionary agreement between competitors. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 495 (1974) ("Congress in the patent laws decided that where no patent existed, free competition should prevail"); *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1292 (Fed. Cir. 2008) (If plaintiff's "generic drug does not infringe [defendant's] patent, then it has a right to enter the generic drug market").

It is undisputed that patents are critical to encourage and protect the massive investments required for the development and launch of new innovative drugs. *In re Bilski*, 545 F.3d 943, 1005-06 (Fed. Cir. 2008) (*en banc*) ("the pharmaceutical industry relies on patent protection in order to recoup the large sums it invests to develop life-saving and life-enhancing drugs"); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d

1368, 1383 (Fed. Cir. 2006) ("the patent system provides incentive to the innovative drug companies to continue costly development efforts").

But while valid patents are undoubtedly critical to pharmaceutical innovation, patents that are not valid or that are asserted against non-infringers can impede innovation and choke off competition from lower-priced drugs. Hence this Court has recognized that 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." *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892); *see also Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100-01 (1993) (explaining the "importance to the public at large of resolving questions of patent validity").

Congress recognized that questionable patents were being used to thwart generic competition, and enacted the Hatch-Waxman Act to incentivize generic manufacturers to challenge the weak patents that thwarted generic competition. *Cipro*, 604 F.3d at 108 (Hatch-Waxman Act sought to provide an incentive for generic manufacturers to challenge presumptively valid patents, which challenges, if successful, would result in the entry of generic drugs into the market and potentially significant savings to consumers). The Hatch-Waxman Act, like our antitrust and patent laws, seeks to foster innovation and competition by recognizing and supporting valid innovative patents while, at the same time, eliminating those invalid or non-infringed patents that wrongly impede competition and innovation.

Yet despite the supreme importance of determining the true validity and scope of an asserted patent to the proper application of antitrust law and the Hatch-Waxman Act, the Second Circuit decisions have adopted a curious "bury-your-head-in-the-sand" approach to the patent's real exclusionary power. The decisions require that courts turn a blind eye to the subject, rejecting all evidence of the exclusionary scope of the patent, except in three limited instances: 1) where the infringement claims that are settled are sham and objectively baseless; 2) where the patent was obtained by fraud; or 3) where the settlement agreement imposes restrictions beyond the facial scope of the asserted patent. *Tamoxifen*, 466 F.3d at 208 ("so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly"); *id*. at 213 ("Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent."); *Cipro*, 604 F.3d at 106 ("[W]e are bound to review the *Cipro* court's ruling under the standard adopted in *Tamoxifen*.").

Thus, the Second Circuit's acceptance, without inquiry, of the "facial" asserted scope of the patent, creates what amounts to irrebuttable or conclusive presumptions of patent validity and infringement that enable anticompetitive conduct in the name of

the patent. In establishing this analytical framework, the Second Circuit expressly recognized that it would "inevitably protect patent monopolies that are, perhaps, undeserved" and that protect "weak patents." *Tamoxifen*, 466 F.3d at 211-12.

Such presumptions are not only rejected by other Circuits,[12] but have no basis in statute, fact or judicial precedent. This Court has consistently prohibited judicial creation of presumptions not based on express Congressional mandate. *See, e.g.*, *Iannelli v. United States*, 420 U.S. 770, 790-91 (1975) ("there simply is no basis for relying on a presumption to reach a result so plainly at odds with congressional intent"); *Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 41-42 (2006) (eliminating market power presumption in light of Congressional action). In the area of antitrust, this Court has also consistently counseled against maintenance of presumptions not based upon economic analysis and actual marketplace realities. *See*, *e.g.*, *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 229 (1993) (antitrust analysis is based on market facts); *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S.

[12] See cases discussed at length in Pet. Cert. 13-23. *See also Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003) (court reviewed the strength of the patent at the time of the settlement agreement); *In re Cardizem*, 332 F.3d at 900 ("The Agreement whereby HMR paid Andrx $40 million per year not to enter the United States market for Cardizem . . . is *per se* illegal under the Sherman Act and under the corresponding state antitrust laws.").

451, 466-67 (1992) ("Legal presumptions that rest on formalistic distinctions rather than actual market realities are generally disfavored in antitrust law."); *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 59 (1977) (antitrust cases "must be based upon demonstrable economic effect rather than . . . formalistic line drawing").

*Cipro's* presumptions about patent validity and infringement subvert controlling Supreme Court precedent in a number of ways. First, there is no statutory support for the presumptions created in this case. The oft-cited statutory presumption of patent validity, 35 U.S.C. § 282, which seemingly underpins the Second Circuit's decision to make this leap (*Tamoxifen*, 466 F.3d at 209 n.22), is unavailing. The presumption of patent validity is simply a procedural device for allocating the burden of proof to an infringer, and "has no separate evidentiary value." *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983). Not only is this presumption rebuttable, but also it only applies with a full adjudication, and, thus, for example, provides no evidence that could be weighed for determining if an injunction should issue to exclude competition. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007); *New Eng. Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878, 882 (Fed. Cir. 1992) (existence of issued patent is not evidence which can be "weighed" in determining likelihood of success for determining if injunction should issue).

Likewise, the presumption of infringement created by the *Tamoxifen/Cipro* decisions below has no statutory predicate, and also offends long-standing precedent assigning the burden of proving infringement of the asserted claims on the patentee. *See, e.g.*, *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 374 (1996); *Under Sea Indus., Inc. v. Dacor Corp.*, 833 F.2d 1551, 1557 (Fed. Cir. 1987) (stating that burden is always on the patentee to show infringement). Judicial creation of a new presumption of infringement by the Second Circuit decisions is unsupported and unsupportable in case and statutory law.

Moreover, the presumptions are contrary to the facts and the actual reality that many asserted patents are either invalid or not infringed. Studies of fully-litigated pharmaceutical patents found that the generics prevailed in establishing that the asserted patents were either invalid or not infringed in 70% of the cases, according to one study, and in 73% of the cases, according to another study. Paul Janicke & LiLan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Q.J. 1, 20 (2006); FTC, *Generic Drug Entry Prior to Patent Expiration* 1, 20 (July 2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf. The results are consistent with other studies finding that patents of all kinds challenged in litigation were held invalid in some 46% to 58% of the cases. Alden Abbott and Suzanne Michel, *The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation*, 46 IDEA 1, 11-12, n.41 and n.42 (2005).

The statistics likely reflect the reality of the patent examination process, in which examiners work on an *ex parte* basis (unlike examiners in virtually all other countries), struggle under severe budget constraints, have a backload of more than 700,000 applications, use rules skewed to favor the issuance of patents, have work quotas, and are typically allotted only 19 hours to review and finally dispose of each patent application, no matter how long or complex they might be. U.S. GAO, *Intellectual Property*: *USPTO Has Made Progress in Hiring Examiners, but Challenges to Retention Remain* at 5-6, 16, 25, 28 (Jun. 2005), http://www.gao.gov/new.items/d05720.pdf; Mark A. Lemley, *Rationale Ignorance, at the Patent Office*, 95 Nw. U. L. Rev. 1495, 1499 (2001). The time constraints on patent examiners prompted one prominent patent scholar's ironic observation that "the average American will spend more time watching television this week than the federal government likely spent reviewing any of the patents that made television possible." Mark A. Lemley, et al., *What to Do About Bad Patents?*, 28 Regulation 10, 10 (Winter 2005-2006).

Allowing courts to conclusively presume that patents are valid and infringed renders most, if not all, reverse payment agreements *per se* legal. The States, the Federal Trade Commission, the Department of Justice, the American Antitrust Institute and 86 professors of law or economics all agree that the decisions below in *Tamoxifen/Cipro* set a standard that is too lax, shields harmful competitor collusion,

and must be modified to permit some examination of the true confines of the patent. *In re Ciprofloxacin* (2d Cir. 2010) (Nos. 05-2851-cv(L), 05-2852-cv(CON), 05-2863-cv(CON)), Amicus Curiae Briefs supporting *en banc* review by the Second Circuit, by the 34 Attorneys General (May 20, 2010), by the United States (May 19, 2010), by the FTC (May 20, 2010), by the American Antitrust Institute (May 20, 2010) and by 86 Intellectual Property Law, Antitrust Law, Economics, and Business Professors, *et al.* (May 20, 2010).

## III. REVERSE PAYMENTS THWART CONGRESSIONAL INTENT BEHIND AND THE PROVISIONS OF THE HATCH-WAXMAN ACT PROMOTING EARLIER GENERIC ENTRY.

Realization of the great savings and benefits of generic competition both to government programs and consumers inspired Congress' enactment of the Hatch-Waxman Act in 1984. H.R. Rep. No. 98-857(I) at 14, 17 (1984), reprinted in 1984 U.S.C.C.A.N. 2647. Through this Act, Congress established a regulatory structure designed to place lower-cost generic drugs in the hands of consumers at reasonable prices and to do so "fast." *Andrx Pharms., Inc. v. Biovail Corp.*, 256 F.3d 799, 809 (D.C. Cir. 2001).[13] A significant part of

[13] In exchange, branded drug makers received an extended patent term and the ability to trigger an automatic 30-month stay of generic competition, a power unique among patent holders. 35 U.S.C. § 156; 21 U.S.C. § 355(j)(5)(B)(iii).

the regulatory scheme recognizes that weak and dubious patents could be used to thwart generic competition, so the Act included various market incentives for generic drug makers to promptly challenge these patents. Thus, the Hatch-Waxman Act encourages a patent holder to commence patent litigation prior to the generic firm bringing its drug to market,[14] and reduces a generic entrant's potential loss in mounting the patent challenge.[15] Most importantly, the generic company is provided with a powerful financial incentive – in the form of a 180-day marketing exclusivity – to challenge weak pharmaceutical patents. 21 U.S.C. § 355(j)(5)(B)(iv) (2006).

Congress also amended the Hatch-Waxman Act in 2003 to require that reverse payment settlements be reviewed by two federal enforcement agencies, the Federal Trade Commission and Department of Justice. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. § 355(j)(5)(D)(i)(V); 148 Cong. Rec. S7348 (Jul. 25,

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[14] The Hatch-Waxman Act deems the mere filing of a generic drug maker's Paragraph IV certification with the U.S. Food and Drug Administration ("FDA") a technical act of infringement. 35 U.S.C. § 271(e)(2)(A). To encourage patent holders to promptly file a patent infringement suit, the Hatch-Waxman Act provides a 30-month automatic stay of FDA approval to those firms that file a patent infringement action within 45 days of a Paragraph IV filing. 21 U.S.C. § 355(j)(5)(B)(iii).

[15] Under the Hatch-Waxman Act, the generic does not face damages or the loss of its investments necessary to launch a drug where it has not actually competed in the market with a generic drug. *See Tamoxifen*, 466 F.3d at 206-07.

2002) (statement of Sen. Hatch, co-author of the Hatch-Waxman Act.) ("The FTC is doing the right thing in taking enforcement actions against those who enter into anti-competitive agreements that violate our Nation's antitrust laws."). This amendment reflected Congress's view of these settlements as "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs that are intended to keep lower cost drugs off the market." S. Rep. No. 107-167, at 4 (2002). Congressman Henry Waxman, one of the principal authors of the Hatch-Waxman Act, noted that the statute was amended to "re-emphasize" the Act's "original intent of enhancing competition, not collusion, between generic and name-brand drug manufacturers." Brief for Rep. Henry A. Waxman as *Amicus Curiae* Supporting Petitioner, *FTC v. Schering-Plough Corp.*, No. 05-273, 2005 WL 2462026, at *10 (Sept. 30, 2005).

Thus, Congress, via the Hatch-Waxman Act, mandated prompt generic competition and swift patent challenges, and subjected reverse payment agreements to federal enforcers for review. Unfortunately, the *Tamoxifen/Cipro* standard adopted by the Second Circuit after the 2003 amendments renders most reverse payment agreements *per se* legal, making any antitrust review under the Act nearly meaningless except in extreme cases. This Court has cautioned that judicial decisions that render statutory provisions superfluous are disfavored. *Circuit City Stores, Inc. v. Adams*, 532 U.S. 105, 113 (2001) ("Our cases express a deep reluctance to interpret a statutory provision so as to render superfluous other provisions

in the same enactment"); *Conn. Nat. Bank v. Germain*, 503 U.S. 249, 253 (1992) ("courts should disfavor interpretations of statutes that render language superfluous").

Overturning *Tamoxifen* and *Cipro,* and permitting broader antitrust scrutiny of reverse payments would reinforce Congressional intent underlying the Hatch-Waxman Act. Doing so also would not undermine the courts' general policy of promoting settlement. Without reverse payments, patent litigants can settle, as they did in the pre-*Tamoxifen* years, with licensed entry, in which the license terms are based on the strength of the patent rather than sharing of monopoly profits. Reverse payments are not necessary to settle patent cases, and the payments "serve no obvious redeeming social purpose." *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 625 F.3d 779, 780 (2d Cir. 2010) (J. Pooler, dissenting). State antitrust enforcers have a keen interest in ensuring that generic exclusion results from the strength of the patent rather than rivals' common interest in eliminating competition and sharing the spoils at the consumers' expense.

## IV. IN *CIPRO*, COMPETITION WAS EXCLUDED BY USE OF MONEY AND COMPETITOR COLLUSION, NOT THE POWER OF THE PATENT.

By their nature, reverse payments call into question precisely what the party is purchasing in exchange for the monetary payment. The court in

evaluating a reverse payment settlement must determine whether the source of the competitive exclusion is within or outside of the scope of the patent grant, because, as this Court has consistently maintained, there is no antitrust exemption for restrictions that are not plainly and fairly within the patent monopoly. *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942) (patentee cannot extend grant by contract or agreement); *United States v. New Wrinkle, Inc.*, 342 U.S. 371, 378 (1952); *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948) ("It is equally well settled that the possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly."). As the Sixth Circuit explained in *In re Cardizem*, 332 F.3d at 908 (footnote omitted), it is "one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market."

In ascertaining the source of the exclusion, as discussed above, antitrust law requires the courts to look at the reality of the practice, clearly mandating use of fact-based analysis, rather than formalistic line-drawing. *See, e.g.*, *Illinois Tool Works*, 547 U.S. at 42-43; *Continental T.V.*, 433 U.S. at 59 (antitrust cases "must be based upon demonstrable economic effect"). This Court has also repeatedly counseled the importance of using "common sense" in drawing the

boundaries of the patent grant. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 401 (2007).

It is through these prisms that the Court must address the $64,000 question, or, in this case, the $398 million question: what was the quid pro quo for the $398 million payment? Absent some explanation – and none was forthcoming here – common sense indicates that the payment secured a delay of competition not obtainable through the exclusionary power of the patent. Had the patent been strong, Bayer would not have had to pay such a huge sum to block the generics. The *Tamoxifen/Cipro* assumption that Bayer had an ironclad right to exclude the generic competitors fails to make sense of the most important economic fact in the case – the fact that Bayer made enormous payments to the generics.

The record in this case, including the settlement negotiations, confirms what common sense counsels. Bayer offered the generics two options: a small payment with only six months of generic delay, and the alternative, which the generics accepted, of a $398 million payment for six years of generic delay. Pet. Cert. 7-8. Secondly, the $398 million that Bayer paid to the generics is more than twice what the generics would have made if they had defeated the Bayer patent and competed. *Id*.

Thus, it is evident that the generics did not settle because they viewed the Bayer patent to be strong and valid. To the contrary, it is clear that they abandoned their efforts to enter the market for several

years because they were paid hundreds of millions to do so. *See Andrx Pharms.*, 256 F.3d at 813 (finding that the patentee's $10 million dollar quarterly payments to generic competitors were in return for something that the generics "would not otherwise do, that is, delay marketing of its generic"). Likewise, the exclusionary power of the Bayer patent was not viewed as sufficient to induce the generics to quit the market, so Bayer paid for the market exclusion that the patent could not provide. Thus, Barr was not exercising the power of its patent, but rather the power of $398 million to suppress competition through combination with its competitors.

## V. PATENT RIGHTS DO NOT INCLUDE THE RIGHT TO PAY COMPETITORS NOT TO COMPETE OR TO COLLUDE WITH COMPETITORS.

The Second Circuit in *Tamoxifen/Cipro* incorrectly reasons that a valid patent not only includes the right to exclude through enforcement of the patent, but also to exclude through payments to rivals not to compete. *Tamoxifen*, 466 F.3d at 208-09 (by paying the generic, the brand is merely "protect[ing] that to which it is presumably entitled"). No cases from this Court support such an expansive view of the patent monopoly. To the contrary, this Court has consistently rejected patentee's efforts to expand the "narrow monopoly" of patents by engrafting ingenious "private perquisites" onto them. *Line Material*, 333 U.S. at 316-17.

The patent monopoly consists of the patentee's exclusive right to make, use and vend the invention, and it "affords no immunity for a monopoly not fairly or plainly within the grant." *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942); *United States v. Univis Lens Co., Inc.*, 316 U.S. 241, 250 (1942). Since "patents are privileges restrictive of a free economy," this Court has long required that patent rights be "strictly construed" so as "not to derogate from the general law beyond the necessary requirements of the patent statute." *Masonite*, 316 U.S. at 280. Patent rights must also be interpreted in light of the "primary purpose of our patent laws [which] is not the creation of private fortunes for the owners of patents but is to promote the progress of science and the useful arts" as directed by the Constitution under which the patent statutes are enacted. *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 626 (2008) (quotation omitted).

A patentee may vindicate its exclusive rights either through litigation or by entering license agreements. However, if the patentee does the latter, the fact that it has the right to refuse a license agreement does not mean that it can attach any conditions on the license that are not within the strict limits of the patent monopoly. *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 666 (1944) (fact that the patentee has the power to refuse a license does not enable it to enlarge the monopoly of the patent by the expedient of attaching conditions to its use); *Masonite*, 316 U.S. at 279 (while the patentee has the power to refuse a

license, he "does not have the lesser power to license on his own conditions" as there are "strict limitations" on the patentee's power).

Accordingly, this Court has consistently applied the Sherman Act to prohibit patent license agreements that extend beyond the strict exclusionary scope of the patent. For example, the Court has condemned, as outside of the exclusionary power of the patent monopoly, patent license agreements that fix the price of patented goods. *See Masonite*, 316 U.S. at 279 (agreements fixing prices for sale of patented product "secure protection from competition which the patent law unaided by restrictive agreements does not afford"); *Bauer & Cie v. O'Donnell*, 229 U.S. 1, 17 (1913) (patent grant does not include privilege to "keep up prices and prevent competition by notices restricting the price"); *Boston Store of Chicago v. Amer. Graphophone Co.*, 246 U.S. 8, 25 (1918) (resale price condition "not within the monopoly conferred by the patent law").

Patent pools that impose price limitations are also beyond the exclusionary scope of patents. *See, e.g.*, *Line Material*, 333 U.S. at 311 (no case construes patent statute to permit patentees by cross licenses to fix prices on their respective products); *Std. Sanitary Mfg. Co. v. United States*, 226 U.S. 20, 48 (1912) (price limitations in pooled patent licenses "transcend what was necessary to protect the use of the patent"). Nor may patentees control the price or use of a patented product after its sale. *See, e.g.*, *Quanta Computer*, 553 U.S. at 626 (the patent right is exhausted

by the sale); *Univis Lens*, 316 U.S. at 251 (patentee fixing resale prices derives no support from the patent); *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 516 (1917) (notice restricting use of machine to showing certain unpatented films is invalid because enforcement would "create a monopoly . . . wholly outside of the patent in suit and of the patent law as we have interpreted it").

The restrictions in these clearly unlawful patent license agreements suppressed competition with respect to price or use. The exclusion resulting from reverse-payment agreements is more pervasive and pernicious; it eliminates not only price competition between the competitors, but all other forms of competition between the parties. *Blue Cross & Blue Shield United of Wisc. v. Marshfield Clinic*, 65 F.3d 1406, 1415 (7th Cir. 1995) ("It would be a strange interpretation of antitrust law that forbade competitors to agree on what price to charge, thus eliminating price competition among them, but allowed them to divide markets, thus eliminating all competition among them.").

There are no cases from this Court that gives patent holders the right to exclude competition by colluding with its competitors. Such a rule would not advance the progress of science and would seriously injure the public whose interest is foremost under the patent system. Nor is there any evidence that Congress intended to provide such a right to patent holders.

A patentee that pays its competitor to abandon efforts to enter the market gets "not a benefit inherent in the right of exclusion but a benefit which flows from suppression of competition by combination with his competitors." *Line Materials*, 333 U.S. at 319. "That is more than an 'exclusive right' to an invention; it's an 'exclusive right' to form a combination with competitors." *Id*. This Court has never recognized such a right.

This Court's rulings on the rights of a patentee in litigation are similarly instructive. This Court distinguishes the patent right itself from the availability of remedies for violations of that right. Thus, in *eBay v. MercExchange, LLC*, 547 U.S. 388, 392-93 (2006), the Court found that the statutory patent rights, even of a patentee with a final adjudication of infringement, do not include the automatic right to permanently enjoin or exclude the infringing competitor. That right requires satisfaction of the traditional requirements for equitable relief and obtaining an injunction from the court. This conclusion is inconsistent with the rule of law advanced in *Cipro* that essentially allows all patentees to exclude competition by the simple expedient of paying for the exclusion.

## CONCLUSION

The Attorneys General respectfully urge the Court to grant the Petition for a Writ of Certiorari in this matter.

Dated: January 7, 2011

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