No. 10-762

IN THE
Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, 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 AMICI CURIAE OF CONSUMER FEDERATION OF AMERICA, PRESCRIPTION ACCESS LITIGATION LLP, THE NATIONAL LEGISLATIVE ASSOCIATION ON PRESCRIPTION DRUG PRICES AND U.S. PIRG IN SUPPORT OF THE PETITIONER

David A. Balto
Counsel of Record
Law Offices of David A. Balto
1350 I Street, NW
Suite 850
Washington, DC 20005
(202) 577-5424
david.balto@yahoo.com

Michael A. Carrier
Professor of Law
Rutgers Law School-Camden
217 North Fifth Street
Camden, NJ 08102

Counsel for Amici Curiae

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STATEMENT OF INTEREST OF AMICI CURIAE[1]

Amici Curiae Consumer Federation of America, Prescription Access Litigation LLC, U.S. PIRG, and National Legislative Association on Prescription Drug Prices (collectively "Amici") respectfully support Petitioners' petition for certiorari because of the concerns of skyrocketing drug costs and reduced access to affordable generic drugs.

All of the amici are public interest groups and advocates for competitive health care markets. Prescription Access Litigation LLC ("PAL") is a project of Community Catalyst, Inc., a nonprofit, nonpartisan organization building consumer and community participation in the shaping of the U.S. health system. PAL is a coalition of more than 130 consumer, labor, and community organizations in 35 states, with a combined membership of over 16 million people. The Consumer Federation of America is an association of nearly 300 nonprofit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy, and education.

[1] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amici curiae or their counsel made a monetary contribution intended to fund its preparation or submission. The parties have consented to the filing of this brief and the parties have also been given at least 10 days notice of amici's intention to file.

Consumer Federation of America, www.consumerfed.org (last visited Jan. 3, 2011).

National Legislative Association on Prescription Drug Prices ("NLARx") is a national nonprofit, nonpartisan organization of state legislators who support policies to reduce prescription drug prices and expand access to affordable medicines. NLARx has promoted policies since 2000 to expand access to generic drugs and increase competition in the marketplace. U.S. PIRG, the federation of state Public Interest Research Groups ("PIRGs"), works on behalf of American consumers through public outreach to advocate for affordable health care and prescription drugs.

The Hatch-Waxman Act created incentives to challenge brand-drug patents and bring generic drugs to the marketplace sooner. Reverse-payment agreements have exactly the opposite effect. Under the agreement at issue here, Bayer paid Barr $398 million in exchange for its agreement to stay out of the market for six and a half of the remaining seven years of the ciprofloxacin ("Cipro") patent.

Few competition problems are as critical as pay-for-delay settlements such as the one involving Cipro. These agreements are currently shielding more than $20 billion of branded drugs from generic competition. Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, An FTC Staff Study*, at 2 (Jan. 3, 2010); Prepared Statement of FTC Before Subcomm. on Courts and Competition Policy of House Jud. Comm. (July 27, 2010),

at 4-5, *available at* http://www.ftc.gov/os/testimony/100727antitrustoversight.pdf.

The cost of these settlements to consumers and their health plans has been estimated at between $3.5 billion and $12 billion per year. FTC, *Pay-for-Delay;* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking To Preserve Drug Competition*, 109 COLUM. L. REV. 629, 649 (2009).

Beyond the financial costs, these agreements have severe consequences for public health. Artificially inflated drug costs lead to high out-of-pocket costs that force patients to split pills in half or to skip taking their medications. Such consumer-coping strategies expose patients to worsening symptoms, escalating medical conditions, and even death. Thomas Rice & Karen Y. Matsuoka, *The Impact of Cost-Sharing on Appropriate Utilization and Health Status: A Review of the Literature on Seniors*, 61 MED. CARE RES. & REV. 415, 420, 427-28 (2004). Just to give one example, a pastor in Ohio with narcolepsy pays $17,000 a year to insure himself and his family. But his insurance does not cover the high price of Provigil – $650-$850 per month – forcing him to reduce or skip doses on days he "won't be driving much" so he can extend his supply of the drug. Community Catalyst Blog, *Senate Fix on Pay-for-Delay Vital After Court Denies Hearing*, Sept. 9, 2010, *available at* http://blog.communitycatalyst.org/index.php/2010/09/09/senate-fix-on-pay-for-delay-vital-after-court-denies-hearing.

Amici have a long history of advocating for access to affordable health care and for controlling costs without compromising quality. Because prescription drug spending has skyrocketed over the last decade and a half and national health expenditures on prescription drugs have quadrupled, Amici have a strong interest in the challenged settlement here, which thwarted the entry of generic ciprofloxacin into the marketplace, thereby reducing access to affordable prescription drug treatments. If the reasoning of the decision below is allowed to stand, millions of consumers will be harmed by being denied access to more affordable prescription drugs. This Court should grant Petitioners' petition for certiorari and reverse the Second Circuit's decision.

SUMMARY OF ARGUMENT

The Hatch-Waxman Act presents Congress's nuanced views on the intersection of patent and antitrust law in the pharmaceutical industry. This legislation includes multiple provisions to foster generic competition and brand-drug innovation. But a central tenet of the Act – promoting challenges to invalid patents to lower price for consumers – has been eviscerated by settlement agreements like the one at issue here. Bayer's payment of $398 million to Barr renders ineffective the central role played by generics in challenging invalid patents.

The decision by the court below, based on the precedent in *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006), repeated many of the errors on which courts in the Federal and Eleventh Circuits have relied. Four arguments, slavishly followed by the courts, have introduced the gravest mistakes: (1) settlements are beneficial, (2) patents are presumed valid, (3) reverse payments fall within the scope of the patent, and (4) reverse-payment settlements are a natural by-product of the Act. Strict adherence to these arguments flies in the face of the Hatch-Waxman Act and unnecessarily increases price and jeopardizes patients' health.

ARGUMENT

This Court should grant certiorari for three primary reasons:

(1) To resuscitate the text and legislative history of the Hatch-Waxman Act;

(2) To ensure the viability of *Trinko* in the pharmaceutical regulatory regime;

(3) To reverse the erroneous holdings of *Cipro* and other courts.

I. This Court Should Grant Certiorari To Resuscitate the Text and Legislative History of the Hatch-Waxman Act.

This Court should grant certiorari to rescue the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the Hatch-Waxman Act. Through this legislation, Congress enacted a complex regulatory regime to solve urgent problems. The marketplace in the early 1980s suffered from sparse generic entry and stifled brand-drug firm innovation.

Fostering Generic Competition. First, Congress promoted generic competition. Generic drugs have the same active ingredients and performance as brand drugs. At the time of the Hatch-Waxman Act, however, generic firms needed to undertake lengthy, expensive trials to demonstrate safety and effectiveness. FDA approval took years, and because the required tests constituted infringement, generics could not even begin the process during the patent term. At the time Congress enacted Hatch-Waxman, there was no generic on the market for 150 brand-name drugs whose patents had already expired. H.R. Rep. No. 98-857, pt. 1, at 17 (1984).

The Act's drafters lamented the "practical extension" of the patentee's "monopoly position" beyond expiration. H.R. Rep. No. 98-857, pt. 2, at 4 (1984). They sought to "make available more low-cost generic drugs." H.R. Rep. No. 98-857, pt. 1, at 14. Generic competition would save the federal and state

governments many millions of dollars each year. And given that older Americans used nearly 25 percent of prescription drugs, competition would "do more to contain the cost of elderly care than perhaps anything else this Congress has passed." H.R. Rep. No. 98-857, pt. 1, at 17; 130 Cong. Rec. 24427 (Sept. 6, 1984).

The first tool created to accelerate generic entry was the Abbreviated New Drug Application ("ANDA") process that allowed generic firms to rely on the brand drug's safety and effectiveness studies and avoid the expensive and lengthy new-drug-application process. 21 U.S.C. § 355(j)(2)(A), § 355(j)(8)(B).

Second, Congress resuscitated the experimental use defense. The Act exempted from infringement the manufacture, use, or sale of a patented invention for uses "reasonably related to the development and submission of information" under a federal law regulating the manufacture, use, or sale of drugs. 35 U.S.C. § 271(e)(1).

Third, Congress increased competition by (as discussed more fully below) creating a 180-day period of marketing exclusivity, reserved for the first generic to certify that the brand firm's patent was invalid or not infringed.

Encouraging Brand Drug Innovation. In addition to promoting generic competition, Hatch-Waxman included several mechanisms to increase incentives for brand-firm innovation.

First, Congress increased the effective patent life by extending the patent term, with the extension currently amounting to half the time the drug is in clinical trials plus the period spent awaiting FDA approval after trials. 35 U.S.C. § 156(c). Second, Congress granted an automatic 30-month stay of FDA approval to patent holders who sue Paragraph IV generic filers within 45 days. This period provides an additional exclusionary right benefiting brand firms who – even without obtaining a preliminary injunction or demonstrating entitlement to one – will not face generic competition for a substantial period of time. 21 U.S.C. § 355(j)(5)(B)(iii). Finally, Congress provided for periods of market exclusivity not based on patents, such as the four-year exclusivity period for a drug with a new active ingredient. 21 U.S.C. § 355(j)(5)(F)(ii).

The Act's drafters emphasized the equilibrium between competition and innovation. Representative Henry Waxman underscored the "fundamental balance of the bill." 130 Cong. Rec. 24425 (Sept. 6, 1984). The Energy and Commerce Committee Report explained that allowing early generic challenges "fairly balanced" the exclusionary rights of patent owners with the "rights of third parties" to contest validity and market products not covered by the patent. H.R. Rep. No. 98-857, pt. 1, at 28. And the House Judiciary Committee noted that it "has merely done what the Congress has traditionally done in the area of intellectual property law: balance the need to stimulate

innovation against the goal of furthering the public interest." H.R. Rep. No. 98-857, pt. 2, at 30.

Central Role of 180-Day Exclusivity. A central element of this equilibrium was the 180-day period of marketing exclusivity. This period was reserved for the first generic firm to successfully challenge a patent and introduce competition before the end of the patent term.

When the FDA approves a new drug application ("NDA"), it lists the drug and any relevant patents in a publication known as the Orange Book. Before entering the market, a generic applicant must provide one of four certifications for each patent listed in the Orange Book relating to the relevant NDA.

The first three certifications – no patent on the drug, an expired patent, and a promise to wait until the patent expires – do not result in periods of exclusivity. Only the "Paragraph IV" certification, by which the generic claims that the patent is invalid or not infringed, leads to exclusivity. 21 U.S.C. § 355(j)(2)(A)(vii). Given the drafters' goals to encourage entry against invalid patents before the end of the patent term, exclusivity limited to Paragraph IV makes sense.

In contrast to this straightforward purpose, settlements like the one at issue in this case have twisted the 180-day period beyond recognition. This period has morphed into a regulatory barrier to entry that allows brand drug firms to block all challenges to its patents, however weak or narrow, simply by

settling with the first-filing Paragraph IV generic. Outside this drug context, patent settlements typically involve a challenger paying a patentee to *enter* the market. Here, in contrast, brand drugs pay generics *not* to enter the market.

Drafters' disapproval of reverse-payment settlements. In the years since the passage of the Hatch-Waxman Act, the primary drafters of the legislation have expressed their disapproval of reverse-payment settlements. Representative Waxman explained that such agreements "turn[ ] the . . . legislation on [its] head." Motion of Representative Henry A. Waxman as Amicus Curiae Supporting Petitioner at *v, *FTC v. Schering-Plough Corp.*, 548 U.S. 919 (2006), 2005 WL 2462026. Waxman emphasized that the purpose of the legislation was to promote generic competition, not to allow generics "to exact a portion of a brand-name manufacturer's monopoly profits in return for withholding entry into the market." *Id.*

Senator Hatch similarly found such agreements "appalling." And his assessment mirrored that of Waxman in making clear that "[w]e did not wish to encourage situations where payments were made to generic firms not to sell generic drugs and not to allow multi-source generic competition." 148 Cong. Rec. S7566 (July 30, 2002).

II. This Court Should Grant Certiorari To Ensure the Consistent Application of *Trinko*.

In *Verizon Communications v. Law Offices of Curtis V. Trinko*, 540 U.S. 398 (2004), this Court articulated a powerful framework governing the intersection of antitrust and regulation. Applied to this case, the structure underscores the importance of ensuring that the antitrust analysis fits the regulatory structure of the Hatch-Waxman Act.

Application of *Trinko* to Hatch-Waxman Regulatory Regime. As this Court explained in *Trinko*, "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue." *Id.* at 411. Courts must take "careful account" of "the pervasive federal and state regulation characteristic of the industry." *Id.* And the analysis must "recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies." *Id.*

In *Trinko*, this Court found that the Telecommunications Act of 1996 "deter[red] and remed[ied] anticompetitive harm" by requiring incumbent local exchange carriers ("ILECs"), which had state-provided monopolies in the provision of local phone service, to share their networks with competitors. *Id.* at 412.

Consistent with this approach, this Court in *Credit Suisse Securities v. Billing* concluded that the securities law regime "implicitly preclud[ed]" the

application of the antitrust laws. 551 U.S. 264, 267 (2007). Practices by which underwriting firms forced securities buyers to purchase shares, pay high commissions, and purchase less desirable securities fell "squarely within the heartland of securities regulations" that the Securities and Exchange Commission ("SEC") could, and did, supervise. *Id.* at 285.

Just as the telecommunications and securities regimes presented comprehensive frameworks, the Hatch-Waxman Act offers an exhaustive scheme that prescribed Congress's desired balance between competition and innovation in the drug industry. The drafters used patent term extensions, market exclusivity, and 30-month stays to foster innovation. And they revived the experimental use defense and created a streamlined approval process and marketing-exclusivity period to promote generic competition. Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 69 (2009). Congress' careful balance of innovation and competition in the drug industry is particularly valuable in freeing courts from the thorny task of reconciling the patent and antitrust laws.

Reverse-Payment Settlements Gutting Regime's Effectiveness. Reverse-payment settlements have blown a hole in Hatch-Waxman's effectiveness. In determining the appropriate role for antitrust enforcement, it is not just the presence of the regulatory regime that matters, but also its effectiveness. *Id.* at 70-71. For if antitrust is forced to stand down

due to an ineffective regime, there would be a significant danger of false negatives that are addressed by neither antitrust nor regulation.

The importance of a regulatory regime's effectiveness is evident in this Court's rulings. In *Trinko*, the Court explained that phone companies that provided local service were required to "be on good behavior" and not to discriminate in providing access to certain facilities before they could enter the long-distance market. 540 U.S. at 412. In addition, firms that did not satisfy these conditions were subject to financial penalties, daily or weekly reporting requirements, and the suspension or revocation of long-distance approval. *Id.* at 412-14. In *Credit Suisse*, the Court noted the SEC's active enforcement, pointing as one example to its detailed definitions of "what underwriters may and may not do and say during their road shows" and bringing actions against underwriters who violated the regulations. 551 U.S. at 277.

In contrast, in the Hatch-Waxman setting, generic firms have recently been ineffective in promoting competition through the central mechanism of patent challenges. The Act's drafters encouraged challenges to invalid patents, seeking to obtain earlier market entry and lower prices for consumers. Carrier, 108 MICH. L. REV. at 71.

Although generic entry has burgeoned in the quarter-century since Congress enacted the law, generics are increasingly not serving their designated

function. *Id.*; C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1615 (2006); Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F.L. REV. 11, 19 (2004). They are agreeing not to challenge patents and not to enter markets in exchange for payment. Many settlements even provide more money than the generic could have received by proving invalidity and noninfringement and entering the market.

The 180-day bounty, in particular, has been twisted from an incentive for the generic to challenge patents to a barrier to entry preventing challenge. By settling with the first challenger, the brand firm can significantly delay other generics' entrance into the market. *See* Herbert Hovenkamp, et al., IP AND ANTITRUST, § 15.3 at 15-45 (2d ed. 2010). Later generics would be less motivated to pursue a challenge since they would be further behind in the approval process, would not be entitled to the market exclusivity period, and would receive a return dependent on the outcome of the first filer's suit. Hemphill, *Paying for Delay*, at 1586. Such hurdles loom large given the costs of developing generic drugs, receiving FDA approval, and pursuing costly patent litigation.

In short, the Hatch-Waxman Act's carefully balanced regulatory regime is not working as intended to promote competition.

Significant Antitrust Harm of Agreements. The settling parties' usurpation of the Hatch-Waxman

regime ensures that antitrust is essential in remedying anticompetitive behavior. Antitrust's responsibility is bolstered by the severe anticompetitive dangers threatened by reverse-payment settlements. As FTC Chairman Jon Leibowitz has recently explained, "[a]greements to eliminate potential competition and share the resulting profits are at the core of what the antitrust laws proscribe." As a result, the Commission "believes strongly that these pay-for-delay settlements are prohibited under the antitrust laws." Prepared Statement of FTC Before Subcomm. on Antitrust, Competition Policy, and Consumer Rights of Sen. Jud. Comm. (June 9, 2010), at 4.

Of all the types of business activity, agreements by which competitors divide markets threaten the most dangerous anticompetitive effects. Market division restricts *all* competition between the parties on *all* grounds. Even price fixing allows the parties to compete on factors other than price.

This Court has explained that "[o]ne of the classic examples of a *per se* violation . . . is an agreement between competitors at the same level of the market structure to allocate territories in order to minimize competition." *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 608 (1972). Courts have consistently found territorial allocations among competitors to be per se illegal. In *Palmer v. BRG of Georgia*, 498 U.S. 46, 49-50 (1990), for example, this Court applied per se illegality to an agreement by which competitors divided markets, agreeing not to compete in the other's territory.

Settlement agreements by which brands pay generics not to enter the market threaten dangers similar to territorial market allocation. But instead of allocating geographic space, they allocate time, with the brand blocking all competition for a period of time. *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

Uniquely Concerning Aspects of Reverse Payments. The question of market division depends on the patent's validity and infringement. These determinations are difficult to conduct in antitrust litigation. But conspicuous red flags appear in the form of substantial payments to generics not warranted by the strength of the patent. Carrier, 108 MICH. L. REV. at 73.

Assisting in the raising of the flags are the aligned incentives of the settling parties. By delaying generic entry, the brand firm increases its monopoly profits. It then uses some of these profits to pay the generic. *See, e.g.,* Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND. J. ECON. 391, 394 (2003); Herbert Hovenkamp, et al., *Anticompetitive Settlements of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1759 (2003). Sharing monopoly profits is more profitable for the brand and generic firms than competing for duopoly (and, as additional generics enter, even smaller) profits.

By contrast, other types of settlements do not align the parties' incentives as directly and can lead to more competition. One example is a traditional licensing agreement by which an alleged infringer

pays a patentee to enter the market. Such an agreement offers different incentives, with the patentee seeking higher royalties and the infringer desiring lower payments. Carrier, 108 MICH. L. REV. at 74.

In the Hatch-Waxman context, an agreement concerning the generic entry date, without any cash payment, should reflect the odds of the parties' success in patent litigation. A brand is likely to gain additional exclusivity by supplementing the parties' entry-date agreement with a payment to the generic. The *quid pro quo* for the payment would appear to be the generic's agreement to stay off the market beyond the expected entry date.

III. The Court Below, Like Courts in the Federal and Eleventh Circuits, Relied on Erroneous Arguments in Creating a Rule of Near-Per Se Legality.

The court below, like previous courts in the Second, Federal, and Eleventh Circuits, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006), *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), relied on general arguments that are inapt in the setting of the Hatch-Waxman Act.[2] These courts have taken upon

[2] The Sixth Circuit, in contrast, concluded that a reverse-payment settlement was "a horizontal agreement to eliminate competition . . . a classic example of a *per se* illegal restraint of

(Continued on following page)

themselves the Herculean task of reconciling competition and innovation. They have done this even though the legislature's preferred equilibrium appears before them on the silver platter of the Hatch-Waxman Act.

The *Tamoxifen* standard, on which the court below relied, established a much-too-permissive standard of near-per se legality. It held that "absent an extension of the monopoly beyond the patent's scope . . . and absent fraud . . . the question is whether the underlying infringement lawsuit was 'objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.'" 466 F.3d at 213. The requirement that there be sham or fraud inappropriately borrows a concept from the different setting of First Amendment petitioning (which deserves a higher bar than private agreements among rivals not to compete). The high bar warranted by the important policies fostered by petitioning is not appropriate for private, collusive arrangements among horizontal competitors not to compete.

Four arguments have introduced the gravest errors in the Second Circuit and elsewhere: (1) settlements are beneficial, (2) patents are presumed valid, (3) reverse payments fall within the scope of

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trade." *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908 (6th Cir. 2003).

the patent, and (4) reverse-payment settlements are a natural by-product of the Act.

"**Settlements are Beneficial" Fallacy.** First, courts have voiced a general policy in favor of settlement. They have recognized that settlements conserve resources, provide certainty that encourages investment, and result in licenses increasing competition. Carrier, 108 MICH. L. REV. at 60. For these reasons, the *Tamoxifen* court explained that "'courts are bound to encourage' . . . settlement[s]." 466 F.3d at 202.

But reverse-payment agreements are not typical settlements. They are agreements that dispose of the validity and infringement challenges central to the Hatch-Waxman scheme. Any general preference in the law for settlement was significantly weakened by the Act's specific framework. Carrier, 108 MICH. L. REV. at 60. A 180-day period of exclusivity for the first ANDA to challenge a patent only makes sense in the context of encouraging patent challenges. Moreover, the purpose of the exclusivity period, to ensure that a generic competitor could not "free ride" on a rival's litigation efforts before the first filer recovered litigation costs, is not promoted if the litigation never produces a judgment benefiting other generics. Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 423 (1999).

In addition, the 180-day bounty itself demonstrates the unique nature of these agreements.

General patent settlements do not prevent other competitors from challenging the patent. In these cases, even if the settling defendant agrees not to challenge the patent, many others often wait in the wings to do so. In contrast, the Hatch-Waxman bounty creates a regulatory barrier to entry that can significantly delay other patent challenges. *Id.* In short, general policies favoring settlements should give way to an industry-specific resolution that encourages patent challenges.

Finally, prohibiting exclusion payments does not undermine the general policy in favor of settlement. The patent litigants can settle via other means, such as traditional early-entry licenses. As discussed below, litigants can and do settle Hatch-Waxman cases without exclusion payments, with those payments "serv[ing] no obvious redeeming social purpose." *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 625 F.3d 779 (2d Cir. 2010) (Pooler, J., dissenting from denial of rehearing en banc). Indeed, economists have shown that exclusion payments are not needed to achieve efficient settlements. *See* Cristofer Leffler & Keith Leffler, *Settling the Controversy Over Patent Settlements*, 21 RES. L. ECON. 475, 484-85 (2004); Keith Leffler & Cristofer Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements,* 39 U.S.F.L. REV. 33, 42 (2004).

"Patents are Presumptively Valid" Fallacy. Second, courts have upheld settlement agreements based on Section 282 of the Patent Act, which states that patents "shall be presumed valid." Courts have

relied on this presumption to determine the validity that is so crucial to deciding the appropriate antitrust treatment. The *Tamoxifen* court, for example, found that the presumption of validity allows parties to settle "weak patent cases" even though "such settlements will inevitably protect patent monopolies that are, perhaps, undeserved." 466 F.3d at 211. For five separate reasons, however, the Patent Act's presumption of validity is entitled to far less weight than courts have accorded it.

First, even if a patent is presumed to be valid, the burden of proof is always on the patentee, not the infringer, to prove infringement. *E.g.*, *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665 (Fed. Cir. 2008). In fact, courts' focus on validity has led to an insufficient recognition of the issue of infringement.

Second, the presumption is only procedural in nature. Patentees cannot, for example, rely on the presumption as substantive evidence in preliminary-injunction proceedings. *New Eng. Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878, 882 (Fed. Cir. 1992).

Third, the presumption should be entitled to the *least* amount of deference where the parties enter agreements that prevent validity from even being challenged. Carrier, 108 MICH. L. REV. at 64. As this Court has recognized, patent litigation plays an important role in testing weak patents and ensuring that the public does not suffer the adverse effects of invalid ones. *MedImmune, Inc. v. Genentech, Inc.*, 549

U.S. 118 (2007); *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969).

Fourth, the Hatch-Waxman Act's text and legislative history demonstrate the importance of invalidity challenges. Congress's 180-day bounty to the first generic to challenge a patent's invalidity was crucial to the regime. Settlements preventing patent challenges thus are a particularly inappropriate setting for the presumption. Carrier, 108 MICH. L. REV. at 64.

Fifth, empirical studies have consistently shown that a significant percentage of granted patents are invalid. Surveys have found that:

• courts invalidated 46% of patents between 1989 and 1996, John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205 (1998);

• the alleged infringer prevailed in 42% of the patent cases that reached trial between 1983 and 1999, Kimberly A. Moore, *Judges, Juries, and Patent Cases*, 99 MICH. L. REV. 365, 385 (2000); and

• in patent cases between 2000 and 2004, courts found 43% of patents invalid and 75% not infringed, Patstats.org, Univ. of Houston Law Ctr. Decisions for 2000-2004, Issue Codes 1-16, 23, 24, *available at* http://www.patstats.org/2000-04.htm.

In the context of generic challenges in particular, the rate of invalidity is even higher. In a study of Paragraph IV challenges between 1992 and 2000, the FTC found that the generic prevailed in 73% of the

cases. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* at 16 (2002). This invalidity rate is particularly concerning, and the potential anticompetitive effects especially staggering, given the importance of the drugs that have been the subject of lawsuits. Carrier, 108 MICH. L. REV. at 65.

"Scope of Patent" Fallacy. The third argument to which courts have deferred involves the patent's scope. Courts have upheld reverse payments as a type of activity falling within the temporal scope of the patent. The court below asked whether entry-delaying settlements fell "within the scope" of the patentee's rights or whether they were "illegal market-sharing agreements." *Arkansas Carpenters*, 604 F.3d at 104. And the *Tamoxifen* court found that the settlement did not "unlawfully extend the reach" of the patent. 466 F.3d at 213; *see also Ciprofloxacin*, 544 F.3d at 1336 ("The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent.").

The concept of temporal scope, however, cannot do all the work courts require of it. The overriding question in these cases (besides infringement) is whether the patent is valid. If it is, then an agreement allowing entry before the end of the patent term is within the scope. But if the patent is not valid, it does not have any scope. For that reason, judicial inquiries into the temporal scope of the patent assume validity and thus frustrate antitrust analysis. In assuming the very validity it seeks to prove,

therefore, temporal scope is not an appropriate inquiry. Carrier, 108 MICH. L. REV. at 66.

"Natural By-Product" Fallacy. The fourth argument that some courts have accepted centers on the "natural" status of reverse payments under the Act. The *Tamoxifen* court noted that reverse payments were "particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them." 466 F.3d at 206; *see also Schering*, 402 F.3d at 1074 ("Reverse payments are a natural by-product of the Hatch-Waxman process"); *Ciprofloxacin*, 544 F.3d at 1333 n.11 ("sizable" reverse payments are a "not unexpected" occurrence under Hatch-Waxman).

Courts are correct that reverse payments have accompanied settlement agreements under the Act. But that is a far cry from a conclusion that such a development is beneficial. In fact, it may reflect no more than the parties' preference for sharing monopoly profits. To consider the point more broadly, we would not justify collusion in an industry based on rivals' effortlessly engaging in it. Similarly, the legality of reverse-payment settlements in no way depends on their frequency. Carrier, 108 MICH. L. REV. at 66-67.

Finally, as an empirical matter, reverse payments are not needed to settle disputes between brands and generics. Such payments disappear when challenged and reappear when the antitrust coast is clear. Between 1992 and 1999, 8 of the 14 final settlements

between brands and generic first-filers involved reverse payments. Federal Trade Commission, *Agreements Filed with FTC under Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005*, at 4.

In 2000, the FTC announced that it would challenge such settlements. Abbott Labs and Geneva Pharms., File No. 981-0395 (Mar. 16, 2000). In the succeeding four years, between 2000 and 2004, *not one* of 20 reported agreements involved a brand paying a generic to delay entering the market. Federal Trade Commission, *Agreements Filed with FTC under Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2006*, at 4. During this period, parties continued settling their disputes, but in ways less restrictive of competition, such as through licenses allowing early generic entry.

In 2005, after the *Schering* and *Tamoxifen* courts took a lenient view of these agreements, the reverse-payment floodgates opened. Between 2005 and 2007, 31 of 72 final settlements between brand and generic firms included such payments. *Id.*; Federal Trade Commission, *Agreements Filed with FTC under Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2007*, at 3. Equally concerning, in recent years, roughly 70 to 80 percent of settlements between brand firms and first generic filers have involved reverse payments. *Id.* at 5; FY 2006 Agreements, at 6.

In short, the court below, relying on *Tamoxifen*, together with courts in the Eleventh and Federal Circuits, relied on inappropriate arguments in upholding reverse-payment settlements. These arguments fly in the face of the Hatch-Waxman Act, and, when accepted by courts, stifle the very generic competition at the heart of the Act.

IV. This Case Presents an Ideal Vehicle for the Court To Address Vital Competitive Questions.

This case presents an ideal vehicle to remedy the anticompetitive harms presented by reverse-payment settlements. Like the earlier cases, it involves a simple, and undisputed, payment from the brand to the generic to delay entering the market.

The latest round of settlements, and the ones that would confront this Court in future cases, are more complicated. They involve agreements that the parties claim entail "independent" side deals. Brand firms have paid generics for intellectual property licenses, the supply of raw materials or finished products, and product promotion. And they have paid milestones, up-front payments, and development fees for unrelated products. FY 2007 Agreements, at 2; FY 2006 Agreements, at 4-5.

This case cleanly presents the important antitrust issues for review, allowing the Court to sidestep the potentially nettlesome question of whether the payment is for delay at all.

In 2003, a representative of the brand firms' trade association, the Pharmaceutical Research Manufacturers Association ("PhRMA"), explained to Congress that wholesale changes to the Hatch-Waxman Act were not needed. Why? Because reverse-payment cases such as *Cardizem* and *Schering-Plough* "outline facts that would have been violations of the antitrust laws and/or the patent laws whether the Hatch-Waxman Act existed or not." Generic Pharmaceuticals: Hearing No. 107-1081 Before Subcomm. on Commerce, Science, and Transportation, 107th Cong. at 71 (2002). If PhRMA itself could admit the serious antitrust concerns with these agreements, there should be no question that the rule of near-per se legality is inappropriate.

CONCLUSION

This Court should grant certiorari to reverse the court below, to give effect to the Hatch-Waxman Act, and to save consumers billions of dollars from anti-competitive settlements.

Respectfully submitted,

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DAVID A. BALTO
Counsel of Record
LAW OFFICES OF
DAVID A. BALTO
1350 I Street, NW
Suite 850
Washington, DC 20005
(202) 577-5424
david.balto@yahoo.com

MICHAEL A. CARRIER
Professor of Law
RUTGERS LAW SCHOOL-CAMDEN
217 North Fifth Street
Camden, NJ 08102

Counsel for Amici Curiae