**2008-1097**

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

IN RE CIPROFLOXACIN HYDROCHLORIDE ANTITRUST LITIGATION

ARKANSAS CARPENTERS HEALTH & WELFARE FUND, PAPER, A.F. OF L.-A.G.C. BUILDING TRADES WELFARE PLAN, MARK ASTON, BOARD OF TRUSTEES OF THE UNITED FOOD & COMMERCIAL WORKERS OF ARIZONA HEALTH & WELFARE FUND, ADELE BRODY, CAROLINE M. LOESCH, DONNA FRANCK, KRISTINE GADDIS, DAVID GREEN, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, JOHN H. IRONS, LOCAL 1199 NATIONAL BENEFIT FUND FOR HEALTH & HUMAN SERVICES EMPLOYEES, MARIA LOCURTO, MICHELLE CROSS, KIMBERLY MCCULLAR, ANN STUART, MECHANICAL CONTRACTORS-UA LOCAL 119 WELFARE PLAN, THERESA MEYERS, PATRICIA NELSON, MARY ANN SCOTT, FRANCES NORRIS, PAPER, ALLIED-INDUSTRIAL, CHEMICAL & ENERGY WORKERS INTERNATIONAL UNION, AFL-CIO, CLC, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, MAURICE STEWART, UNITED FOOD & COMMERCIAL WORKERS & PARTICIPATING FOOD INDUSTRY EMPLOYERS TRI-STATE HEALTH & WELFARE FUND, LINDA K. MCINTYRE, AND VISTAHEALTHPLAN, INC.,
*Plaintiffs-Appellants*,

v.

BAYER AG AND BAYER CORP.,
*Defendants-Appellees*,

and

HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC. (d/b/a Rugby Laboratories, Inc.), and WATSON PHARMACEUTICALS, INC.,
*Defendants-Appellees*,

and

BARR LABORATORIES, INC.,
*Defendant-Appellee*.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK
IN 1:00-MD-01383, SENIOR JUDGE DAVID G. TRAGER

# BRIEF OF AMICUS CURIAE FEDERAL TRADE COMMISSION,*
## IN SUPPORT OF APPELLANTS AND URGING REVERSAL

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## INTEREST OF THE AMICUS CURIAE

The Federal Trade Commission (the "Commission" or "FTC") is an independent federal agency, charged with promoting a free and competitive marketplace and protecting consumer interests. *See* 15 U.S.C. §§ 41 *et seq.* The Commission has had substantial experience with the legal and policy issues concerning the proper balance between antitrust and intellectual property laws.[1] It also has developed specific expertise regarding the operation of the "Hatch-Waxman Act"[2] in the pharmaceutical industry, and has brought several law enforcement actions targeting the very type of agreement at issue here – *i.e.*, one in which the holder of a challenged drug patent pays a would-be generic entrant to stay off the market.[3] In 2002, the Commission

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[1] *See, e.g.*, Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (October 2003) (www.ftc.gov/os/2003/10/innovationrpt.pdf); U.S. Department of Justice & Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* (April 1995) (www.usdoj.gov/atr/public/guidelines/0558.htm).

[2] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417 (codified at various sections of Titles 15, 21 and 35 of the U.S. Code).

[3] *See, e.g., In re Schering-Plough Corp.*, FTC Dkt. No. 9297, 2003 WL 22989651 (Dec. 8, 2003), *vacated & set aside, Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); *In re Bristol-Myers Squibb Co.*, FTC Dkt. No. C-4076 (April 14, 2003); *In re Hoechst Marion Roussel, Inc.*, FTC Dkt. No. 9293 (May 8, 2001).

conducted a comprehensive empirical study of generic drug entry,[4] and, since January 2004, has reviewed all drug patent settlements filed with it pursuant to the 2003 amendments to the Hatch-Waxman Act.[5] Finally, the Commission regularly reviews proposed pharmaceutical mergers for compliance with the antitrust laws, which has enabled it to gain substantial knowledge and experience regarding the operation of that particular market.[6]

In light of the importance of the issues presented to its mandated mission, and the serious risk to consumer welfare posed by anticompetitive drug patent settlement agreements, the Commission, as *amicus curiae*, files this brief pursuant to Fed. R. App. P. 29 and Circuit Rule 29, in support of appellants, urging reversal of the district court's decision. Although appellants' brief addresses a number of issues, the Commission will limit its amicus brief to the question of whether the district court

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[4] *See* Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration* (July 2002) (www.ftc.gov/os/2002/07/genericdrugstudy.pdf) (hereinafter "*FTC Generic Drug Study*").

[5] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, § 1112 (codified at 21 U.S.C. § 355(j)(5)(D)(i)(V)).

[6] *See, e.g., In re Actavis Group*, FTC Dkt. No. C-4190 (May 18, 2007) (www.ftc.gov/os/caselist/0710063/070522do0710063.pdf); *In re Hospira, Inc. and Mayne Pharma Ltd.*, FTC Dkt. No. C-4182 (Mar. 21, 2007) (www.ftc.gov/os/-caselist/0710002/070323do0710002.pdf); *In re Johnson & Johnson and Pfizer Inc.*, FTC Dkt. No. C-4180 (Jan. 16, 2007) (www.ftc.gov/os/caselist/0610220/-0610220c4180decisionorder_publicversion.pdf).

erred in holding that patent law immunizes the challenged settlement agreement from antitrust scrutiny on the ground that its exclusionary terms are within the nominal scope of the asserted patent.

## STATEMENT OF THE CASE

This case raises an issue – the legality of exclusion payments in pharmaceutical patent settlements – that greatly affects American consumers' ability to continue receiving the benefits of generic drugs. In the Hatch-Waxman Act, Congress sought to speed the market entry of low-cost generic drugs by encouraging challenges to pharmaceutical patent claims that impermissibly stand in the way of entry. The Act has been remarkably successful; generic challengers have prevailed in most cases in which courts have ruled on arguments that drug patents were either invalid or not infringed by the challengers, and, as a result, American consumers have saved billions of dollars.

The present case involves a stratagem that a number of pharmaceutical companies have used to frustrate Congress's resolve to eliminate unwarranted patent obstacles to generic entry, namely, entering into agreements that allow them to block generic competition and share the profits derived from maintaining supracompetitive drug prices. Because the branded drug manufacturer's enhanced profits from the delayed generic entry typically far exceed the generic competitor's anticipated profits

from entry, the parties to such an agreement can share a windfall – at the expense of consumers. Below, the district court immunized from the antitrust laws a patent holder's agreement to pay nearly $400 million to eliminate the generic competitor's market entry for the entire term of the patent because, it reasoned, regardless of the strength or weakness of the patentee's infringement claims, any competition forgone was within the *nominal* scope of the patent. The ruling is not compelled by the patent laws, however, and it conflicts with fundamental antitrust principles. Moreover, because such agreements are profitable to both the brand and generic firms, the ruling below, if left standing, would likely lead to less frequent generic entry prior to patent expiration, thus undermining an important statute designed to promote the health and economic well-being of American consumers.

### A. The Hatch-Waxman Regime

In the Hatch-Waxman Act, Congress struck a balance that would "make available more low cost generic drugs," while fully protecting legitimate patent claims and incentives to develop new drugs. H.R. Rep. No. 98-857(I), at 14 (1984). The Act allows for accelerated approval of a drug by the Food and Drug Administration ("FDA") through an Abbreviated New Drug Application ("ANDA"), upon a showing that the new (generic) drug is "bioequivalent" to an already approved one. 21 U.S.C. § 355(j). It also encourages the development of generic drugs by

declaring various research and development activities non-infringing. 35 U.S.C. § 271(e)(1); *see Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005). To encourage branded companies to develop new drugs, on the other hand, the Act allows for patent terms to be extended to account for the FDA approval process. 35 U.S.C. § 155.

The Act contains an elaborate incentive structure to accelerate the marketing of generic drugs. It requires that the branded drug company submit to the FDA a list of all the patents that the company claims cover its drug (to become part of the FDA's "Orange Book"). 21 U.S.C. § 355(b)(1); *see Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1338 (Fed. Cir. 2003). A generic firm submitting an ANDA must make a certification regarding the coverage of any listed patent over its proposed product. Most pertinent here, a "Paragraph IV certification" states that the patent is either invalid or not infringed. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Congress encouraged the early commencement of patent litigation in this context – and linked it to the regulatory process – by defining the filing of an ANDA with a Paragraph IV certification as a "new (and somewhat artificial) act of infringement" that permits the patentee to bring suit before the generic applicant markets its product, thus enabling the generic competitor to test the asserted patents without risking the infringement damages attendant to actual market entry. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990); 35 U.S.C. § 271(e)(2). *See also Teva Pharm. Indus. Ltd. v.*

*Crawford*, 410 F.3d 51, 54 (D.C. Cir. 2005). The Act also provides that the first generic filing a "Paragraph IV-ANDA" obtains 180 days of marketing exclusivity for its product. 21 U.S.C. § 355(j)(5)(B)(iv). No parallel economic incentive is provided for ANDA filings that do not challenge the branded drug's patent. *See* James T. O'Reilly, *Prescription Pricing & Monopoly Extension: Elderly Drug Users Lose the Shell Game of Post-Patent Exclusivity*, 29 N. Ky. L. Rev. 413, 414 (2002) (Congress recognized the possible barriers that pharmaceutical patents pose to the marketing of generic counterparts and provided the 180-day generic exclusivity period as "a reward for challenging monopolists' abuse of weak patents").

Congress also created in the Act an economic incentive for the patent holder to promptly commence a lawsuit to adjudicate the patent challenge. Upon receipt of notice from a Paragraph IV-ANDA filer, the patent holder receives an automatic 30-month FDA stay, precluding generic entry, *if* it sues the generic for infringement within 45 days. 21 U.S.C. § 355(j)(5)(B)(iii). If litigation is not commenced within 45 days, however, the FDA approval process may proceed, and the generic competitor can market its product upon fulfilling the regulatory requirements. *Id.*[7]

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[7] The patent holder's election not to sue, therefore, returns the parties to the patent litigation dynamic customary outside the Hatch-Waxman context: the generic, having received regulatory clearance, can enter the market at any time – with the attendant risk of damages in the event its product is later found to infringe the asserted patent.

Experience has borne out the correctness of Congress's premises – *i.e.*, that many patents, when challenged, will not stand in the way of generic entry, and that successful challenges can yield billions of dollars in savings to consumers. The Commission studied all patent litigations initiated between 1992 and 2000 between branded drug manufacturers and Paragraph IV generic challengers, and found that in the cases resulting in a court decision, the generics prevailed in cases involving 73 percent of the challenged drug products. *FTC Generic Drug Study, supra* note 4, at 19-20. Successful challenges to "blockbuster" drugs Prozac, Zantac, Taxol, and Plantinol alone are estimated to have saved consumers more than $9 billion.[8] These savings result from the pricing policies of generic firms, which generally price their products at a substantial discount from their branded counterparts. *See* Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* ("*CBO Study*"), at xiii (1998).

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[8] *Generic Pharmaceuticals: Marketplace Access and Consumer Issues: Hearing Before Senate Commerce Comm.*, 107th Cong. 56, 61 (2002) (Statement of Kathleen D. Jaeger, Pres. & CEO, Generic Pharma. Ass'n). For a recent estimate on savings from generic drugs, see *Paying off Generics to Prevent Competition with Brand Name Drugs: Should it Be Prohibited?: Hearing Before Senate Judiciary Comm.*, 110th Cong. 164, 166 (2007) (Statement of Michael Wroblewski, Project Director, Consumers Union) (consumer savings in 2006 alone from generic competition to Zocor, Pravachol, Zoloft, Wellbutrin, and Flonase are estimated at $6.6 billion).

## B. Pharmaceutical Patent Settlements and Congressional Response

As reflected in the instant case, the parties to a pharmaceutical patent litigation can use settlement agreements to avoid competition. There is no indication, however, that Congress meant to pre-empt the application of settled antitrust principles to anticompetitive agreements. Indeed, prompted by concern over the anticompetitive effects of agreements such as the one at issue here, Congress amended the Hatch-Waxman Act as part of the 2003 Medicare Amendments, *supra* note 5. Those amendments sought in part to stamp out the "abuse of the Hatch-Waxman law" resulting from "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). In the words of Rep. Waxman, "[t]he law has been turned on its head. * * * We were trying to encourage more generics and through different business arrangements, the reverse has happened." Cheryl Gay Stolberg *et al.*, *Keeping Down the Competition: How Companies Stall Generics and Keep Themselves Healthy*, The New York Times, July 23, 2000, at A11 (quoting Rep. Waxman). Similarly, Senator Hatch characterized such agreements as "appalling." 148 Cong. Rec. S7566 (daily ed. July 30, 2002). Among the various corrective measures to address such abuses, the amendments require branded drug companies and generic applicants who enter into patent litigation

settlements to file those settlement agreements with the Commission and the Department of Justice for antitrust review. Pub. L. No. 108-173, §§ 1111-1118.

Congress's repeated attention to this area of the law is amply warranted. Pharmaceutical patent settlements affect a major sector of the national economy, with scores of billions of dollars at risk to consumers each year.[9] Indeed, of the ten top-selling brand-name drugs in the U.S. in 2006,[10] at least six (Nexium, Prevacid, Singulair, Effexor XR, Plavix, and Lexapro) – with sales of over $16 billion in 2006 alone – currently are the subject of patent litigation against generics seeking market entry under the Hatch-Waxman regime.[11] The potentially enormous consumer

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[9] Consumers and health plans spend nearly two hundred billion dollars annually on prescription drugs. The Henry J. Kaiser Family Foundation, *Prescription Drug Trends* (www.kff.org/rxdrugs/upload/3057-05.pdf), at 1 (June 2006); *see also* Centers for Medicare & Medicaid Services, *National Health Expenditures Accounts: 2006 Highlights* (www.cms.hhs.gov/NationalHealthExpendData/downloads/highlights.pdf), at 1 (prescription drug spending rose 8.5% in 2006 and 5.8% in 2005).

[10] *See* Drug Topics, *Top 200 Brand-Name Drugs by Retail Dollars in 2006* (www.drugtopics.com/drugtopics/data/articlestandard/drugtopics/072007/405100/article.pdf).

[11] *See, e.g.*, Sanofi-Aventis, *2007 Half-Year Financial Report* (http://-en.sanofi-aventis.com/Images/070802_FinReport_S1-2007_EN_tcm24-18706.pdf), at 21; Wyeth, *2006 Financial Report* (http://library.corporate-ir.net/library/-78/781/78193/items/235812/FR2006LORES.pdf), at 33-34; Posting of Aaron F. Barkoff, *Hatch-Waxman Tracker* (www.orangebookblog.com/2007/11/hatch-waxman-tr.html) (Nov. 14, 2007). *See also* Federal Trade Commission, *Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution, Prepared Statement Before Senate Judiciary Committee* (Jan. 17, 2007) (www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_senate.pdf), at 17.

savings from generic competition are at great risk, however, because of the increasing prevalence of problematic settlements – a trend that is plainly reflected in the pharmaceutical patent settlements filed with the antitrust agencies pursuant to the 2003 congressional mandate.

In 2000 and 2001, the Commission initiated enforcement actions involving similar collusive settlements, most of which resulted in consent orders.[12] Following those actions, indications were that drug makers had refrained from entering into settlements with substantial exclusion payments – and litigants had successfully reached settlements in other ways. In the first year following Congress's filing requirement, the Commission reported that *fourteen* agreements resolving patent infringement actions by brand-name manufacturers against a generic rival were filed, but *none* involved an exclusion payment.[13] In contrast, during the following reporting year (during which the Eleventh Circuit handed down its decision in *Schering, supra* note 3), there were *eleven* final settlements of brand-generic patent litigation, of which *three* (27%) included both compensation to the generic and a

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[12] *See, e.g., In re Abbott Labs.*, FTC Dkt. No. C-3945 (May 22, 2000); *In re Geneva Pharm., Inc.*, FTC Dkt. No. C-3946 (May 22, 2000); *In re Hoechst Marion Roussel, Inc.*, FTC Dkt. No. 9293 (May 8, 2001).

[13] Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004* (www.ftc.gov/os/2005/01/050107medicareactrpt.pdf), at 1-2.

restriction on its ability to market its product.[14] Finally, in the most recently released Report, the number of brand-generic patent litigation settlements more than doubled, to 28 agreements, of which *fourteen* (50%) included both compensation to the generic and a restriction on its ability to enter the market.[15]

### C. The Present Litigation

The case at bar illustrates the kind of "abuse of the Hatch-Waxman law" that prompted congressional intervention in 2003. S. Rep. No. 107-167, at 4. It involves agreements between Bayer AG and its U.S. subsidiary Bayer Corporation (collectively, "Bayer") – manufacturer of the wide-spectrum antibiotic drug ciprofloxacin hydrochloride ("Cipro") and assignee of U.S. Patent No. 4,670,444 ("the '444 patent") which claims the active ingredient in Cipro – and generic manufacturers Barr Laboratories, Inc. ("Barr"), The Rugby Group, Inc., Hoechst Marion Roussel, Inc., and Watson Pharmaceuticals, Inc. *District Court Slip Opinion* ("Op.") 1, 4. Under the terms of those agreements (executed in January 1997), Bayer paid the

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[14] Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2005* (www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf), at 3-4.

[15] Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2006* (www.ftc.gov/reports/mmact/MMAreport2006.pdf), at 2.

generic companies approximately $398 million in exchange for their agreements not to manufacture any form of Cipro and for Barr's agreement to convert its ANDA for a generic form of Cipro from a paragraph IV application (challenging the validity of the '444 patent) to a paragraph III application (permitting Barr to market its generic drug only upon expiration of the '444 patent, in December 2003). *Id.* at 6-8. Bayer and Barr also agreed to a consent judgment terminating their patent infringement litigation stemming from Barr's ANDA filing, which had been scheduled for trial a few weeks thereafter. *Id.* The antitrust challenges at issue here were filed by direct and indirect purchasers of Cipro, and were dismissed by the court below on defendants' motions for summary judgment. *Id.* at 1-2.

The district court began its analysis by reiterating its earlier ruling (*see* 261 F. Supp. 2d 188) that the exclusionary terms of Bayer's agreement with Barr must be analyzed under the rule of reason, because their exclusionary effect was "within the scope of the '444 patent." Op. 10. The court found that Bayer's "obvious ability to control prices," along with evidence that it "charged high prices" for Cipro, sufficed to "conclude both that the relevant market is for ciprofloxacin and that Bayer had market power within that market." *Id.* at 17-18. The court then turned to what it defined as the "ultimate question" of "whether any adverse effects on competition stemming from the Agreements were outside the exclusionary zone of the '444 patent." *Id.* at 18. It rejected plaintiffs' argument – based on the Commis-

sion's own reasoning in *Schering, supra* note 3 –[16] that the reasonableness of the challenged agreement should be determined by comparing the competition that occurred under the agreement with the competition that was likely to occur without it. Op. 36-37. Instead, the court held that "it would be inappropriate to engage in an after-the-fact analysis of the patent's likely validity. Nor is it appropriate to discount the exclusionary power of the patent by any probability that the patent would have been found invalid." *Id.* at 57. Thus, the court concluded, "any conduct within the scope of the patent is exempt from antitrust scrutiny." *Id.* at 19.

The court acknowledged that the logical outcome of a rule that allows the buying off of patent challenges would be that "the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity." Op. 45. But even an undesirable outcome such as that was of no serious concern to the court because it assumed without analysis that "the economics simply would not justify" the patent holder's paying off all challengers. *Id.* at 46. Thus, the court effectively decided that Bayer's assertion of infringement,

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[16] An in-depth review of the legal and policy issues in that case – which mirror those presented here – can be found in the Commission's *Certiorari* Petition, Reply and Supplemental Briefs before the Supreme Court, *available at* <www.ftc.gov/os/adjpro/d9297/index.shtm>.

without more, immunized from antitrust scrutiny its agreement to pay a potential competitor to stay off the market.[17]

## ARGUMENT

The district court erred in holding that the patent laws immunize from antitrust scrutiny any agreement by a patent holder (even one with market power) to pay a potential rival to abandon competition and stay off the market so long as the exclusionary terms of their agreement are within the nominal scope of the patent. Based on an apparent belief that patent law effectively creates an antitrust immunity for such agreements *regardless* of the weakness of the patent, the court disregarded well established antitrust principles in the intellectual property arena and misconstrued the policies and incentives of the Hatch-Waxman Act. As a result, it adopted an erroneous and sweeping rule that gives patentees free rein to "buy off" potential competitors, even though Congress, while protecting legitimate patent rights, has twice specifically sought to promote patent challenges to facilitate non-infringing generic entry.

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[17] The court also dismissed indirect plaintiffs' state law claims – based on Bayer's alleged fraud in procuring, and sham litigation in enforcing, the '444 patent – on the ground that "those claims are preempted by federal patent law." Op. 66.

## I. THE DISTRICT COURT ERRED IN HOLDING THAT PATENT SETTLEMENT AGREEMENTS CONTAINING EXCLUSION PAYMENTS ARE IMMUNE FROM ANTITRUST SCRUTINY

Although it purported to apply the rule of reason to the challenged agreement, the district court's holding that it is "inappropriate" to engage in any antitrust analysis beyond a perfunctory comparison between the four corners of the agreement and the nominal scope of the asserted patent in fact immunizes all such agreements from any antitrust scrutiny. *See* Op. 19 ("any conduct within the scope of the patent is exempt from antitrust scrutiny"). Such a rule contravenes not only well established antitrust principles, but indeed the clear intent of Congress in amending Hatch-Waxman to do the exact opposite, namely, subject such agreements to rigorous antitrust scrutiny.

As the district court recognized in an earlier ruling in this case, unless excused by the lawful exercise of patent rights, market division agreements between competitors (such as when one pays another to stay out of the market) have long been condemned as violations of the antitrust laws. *See* 261 F. Supp. 2d at 235-36 (citing, *inter alia*, *United States v. Addyston Pipe & Steel Co.*, 85 F. 271, 293-94 (6th Cir. 1898), *aff'd*, 175 U.S. 211 (1899); *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 608 (1972); *Palmer v. BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990) (*per curiam*)). The presence of a patent does not, of course, alter this basic principle.

*See, e.g., United States v. Masonite Corp.*, 316 U.S. 265 (1942); *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436 (1940). The overarching principle in those precedents is clear: that "[t]he owner of a patent cannot extend his statutory grant by contract or agreement," *Masonite*, 316 U.S. at 277; *see also Ethyl*, 309 U.S. at 455-56; *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948), even if the agreement takes the form of a litigation settlement. *See United States v. Singer Mfg. Co.*, 374 U.S. 174, 197-200 (1963) (White, J., concurring) (competitors' collusive termination of a patent interference proceeding to help broaden the patent's scope runs afoul of the Sherman Act).

The agreement between Bayer and Barr extends the latter's market exclusion beyond the patent grant because Bayer obtained Barr's absence from the market not through its patent but through its substantial payment. Until a patentee obtains a court judgment, the patent's power to exclude competitors is tempered by the probability that the patentee will fail. If, for instance, the parties settle by agreeing to a patent license, the stronger the patentee's validity and infringement arguments, the more advantageous the terms it can negotiate.[18] The accused infringer will accept

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[18] *See, e.g.,* Michael J. Meurer, *The Settlement of Patent Litigation*, 20 RAND J. Econ. 77, 77-79 (1989) (discussing that a patentee will often settle a dispute by licensing the patent in exchange for royalty payments to avoid the threat of having its patent invalidated; the terms of the license depend, in part, on the probability of the patentee's prevailing in litigation).

a degree of limitation on its ability to compete in proportion to its views of the probable, but uncertain, outcome of the patent litigation. That degree of limitation, which will typically be manifested by the size of a royalty payment from the accused infringer to the patentee, reflects the exclusionary power of the patent at the time of the settlement. Not all settlements involve royalty payments, however, so the accused infringer may accept some other type of limitation on its ability to compete, such as delayed market entry. In that case, the entry date agreed to by the parties will reflect their views of the probable outcome of the patent litigation and demonstrate the exclusionary power of the patent. Thus, when a patentee asserts its patent and threatens a lawsuit with the goal of excluding a competitor from the market, the patentee can hope that the strength of its patent will either convince the accused infringer to accede or convince a court to issue an injunction. *See Zenith Radio Corp.* v. *Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969) ("The heart of [a patentee's] legal monopoly is *the right to invoke the State's power* to prevent others from utilizing his discovery without his consent") (emphasis added).

But Bayer did neither. By paying Barr to settle the patent litigation, Bayer avoided judicial scrutiny of its asserted right to exclude Barr from the market. And with nearly $400 million in naked exclusion payments to Barr – which allegedly amounted to more than Barr could have made from even a successful entry, *see* Brief for Appellants, at 7 – it is hardly in doubt that the *quid* of Barr's agreement to forgo

market entry flowed not from Barr's view of the exclusionary power of Bayer's patent, but from the *quo* of the exclusion payments. *See Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 813 (D.C. Cir. 2001) ("[patent holder's] ten million dollar quarterly payments were presumably in return for something that [generic competitor] would not otherwise do, that is, delay marketing of its generic"). Indeed, even if Bayer had *not* had any patent protection for Cipro, its willingness to pay its potential rival more than what that rival could expect to earn by competing would almost certainly have yielded the exact same outcome: the rival's exit from the market. Thus, Barr here did not accede to the patent, but instead agreed to refrain from marketing its accused product for the life of the patent only when paid handsomely to do so. The exclusionary power of the patent at the time of settlement was insufficient to obtain that marketing restriction, so Bayer purchased the exclusion that its patent could not provide. Because its agreement with Barr does not represent Bayer's exercise of a patentee's right to exclude, the patent does not immunize the agreement from antitrust scrutiny. *See Masonite*, 316 U.S. at 277 ("A patent affords no immunity for a monopoly not fairly or plainly within the grant").

That Bayer's patent survived *subsequent* validity challenges does not cure the district court's analytical error of failing to recognize that the agreement included a payment to eliminate potential competition that could not be immunized by patent

law. The reasonableness of an agreement under the antitrust laws must be judged, of course, as of the time that the parties entered into it. *See Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1306-07 (11th Cir. 2003) (subsequent invalidation of patent does not alone render the challenged agreement anticompetitive). The district court took account of this principle when it concluded that it would be "inappropriate for an antitrust court * * * to conduct an after-the-fact inquiry into the validity of the underlying patent," Op. 35, but then ignored it when it ruled out any "discount [to] the exclusionary power of the patent by any probability that the patent would have been found invalid." *Id.* at 57. In doing so, the court failed to take account of the uncertainty at the time of the settlement surrounding Bayer's ability to exclude Barr from the market through the legitimate exercise of its patent rights.

## II. PAYING A POTENTIAL COMPETITOR NOT TO COMPETE IS A WELL ESTABLISHED ANTITRUST VIOLATION

The district court's approach – of equating the exclusionary power of a patent, and the breadth of the antitrust immunity conferred by it, with the nominal scope of the patent claims – ignores the most salient factor that gives rise to patent litigation and settlements: the existence of *uncertainty* regarding whether a patent is valid (as

was the focus here) or infringed by the competing products.[19] Having filed its ANDA, Barr clearly stood as a potential competitor to Bayer, and their settlement agreement, which eliminated the prospect of this competition in exchange for cash, harmed consumers by depriving them of the potential benefits of such competition.

It is well established that antitrust law condemns restraints on potential, as well as actual, competition. In *Palmer*, for example, two companies that had competed in providing bar review courses within Georgia agreed to stop competing; instead, one company became the exclusive distributor for the other in Georgia and agreed not to compete outside of Georgia. The court of appeals held that the agreement of one party (BRG) not to enter into the bar review business outside of the state of Georgia could not be condemned as a market allocation agreement, because "BRG had never done business outside the state of Georgia, [and] nothing in the record suggested that it ever intended to do so * * * ." 874 F.2d 1417, 1424 (11th Cir. 1989). The Supreme Court rejected that reasoning, holding that "[s]uch agreements

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[19] Available empirical data reinforce the importance of taking such uncertainties into account in any practical assessment of the "exclusionary potential" of a patent claim. A study examining nearly all written, final validity decisions by the district courts and this Court from 1989 through 1996 found that 46 percent of patents challenged in litigation were invalidated. John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205-206 (1998). As discussed above, the percentage of vulnerable patent claims appears to be even greater in the Hatch-Waxman context, in which branded companies have often aggressively made multiple patent claims for drugs facing generic challenge. *See FTC Generic Drug Study, supra* note 4, at 19-20.

are anticompetitive regardless of whether the parties split a market within which both do business * * * ." 498 U.S. at 49-50. "[T]he anti-trust laws are as much violated by the prevention of competition as by its destruction." *United States v. Griffith*, 334 U.S. 100, 107 (1948) (citation omitted); *see also United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) ("it would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will"). As one leading commentator has put it, citing *Palmer*, "the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." XII Herbert Hovenkamp, *Antitrust Law*, ¶ 2030b, at 213 (2d ed. 2005).

For instance, the uncertainty of market entry flowing from an entry barrier such as regulatory clearance cannot justify a monopolist's paying its rival to stay off the market. Had Bayer paid the nearly $400 million to a potential generic to forgo market entry where the only impediment to entry was uncertainty about the generic's ability to obtain FDA approval for its product, there would be no question that such an agreement would be anticompetitive. *See Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d at 806-809 (uncertainty of FDA approval does not preclude antitrust claim). There is no reason why uncertainty regarding patent litigation should be treated differently where the certain exclusion of a potential rival is obtained through a cash payment and not through the strength of the patent assertion. Thus, the

settlement agreement here violates the antitrust law, and the district court should be reversed.

## III. THE DISTRICT COURT MISCONSTRUED THE POLICIES AND INCENTIVES OF THE HATCH-WAXMAN ACT AND MISCONCEIVED THE PRACTICAL IMPLICATIONS OF ITS RULING

The effect of generic entry on pharmaceutical markets is profound. Although the ownership of a patent does not automatically confer market power on the patentee,[20] empirical research shows that the impact of entry of generic substitutes on the sales of certain brand-name drugs is both rapid and dramatic.[21] In these circumstances a brand-name manufacturer such as Bayer that can forestall generic entry frequently does have market power.[22] Within the first full year after launch of

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[20] *Illinois Tool Works, Inc. v. Independent Ink, Inc.*, 547 U.S. 28 (2006); *see Guidelines for the Licensing of Intellectual Property, supra* note 1, § 2.2.

[21] *See, e.g.*, Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act*, 35 J.L. & Econ. 331 (1992); Richard E. Caves, *et al.*, *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, Brookings Papers on Economic Activity, Microeconomics (1991).

[22] *See In re Brand Name Prescription Drugs Antitrust Litig.*, 186 F.3d 781, 787 (7th Cir. 1999) (Posner, J.); *cf.* Op. 15-18 (finding that Bayer had predicted the loss of substantial sales of Cipro to Barr, and concluding that Bayer had market power in the Cipro market).

a generic product, branded drugs lose an average of 44% of their sales to the new, significantly lower-priced generic entrant.[23]

The district court accorded no weight, however, to this consumer benefit that Congress sought to confer via Hatch-Waxman. To the contrary, the court drew exactly the wrong conclusion from Bayer's exchange of $400 million in naked payments for Barr's forgoing competition for the entirety of Bayer's patent term: that "there might not be any date that represents a reasonable litigation compromise for early (pre-patent expiration) entry for the generic challenger." Op. 48-49. But even aside from the fallacy of this justification in most cases as a matter of economics,[24] experience has shown that when parties to patent litigation believed (correctly) that exclusion payments were unlawful, they were still able to settle their disputes in other, legitimate ways. *See, supra*, at 10. Congress, as evident by its 2003 amendments, justifiably viewed patent settlements involving exclusion payments

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[23] *See CBO Study*, *supra*, at xiii. State drug-substitution laws and the policies of private health payors contribute significantly to this dramatic impact. Virtually all States encourage generic competition through laws that allow pharmacists to dispense a generic drug when presented with a prescription for its branded counterpart, unless the physician directs otherwise. Similarly, many health plans, including Medicaid and other public assistance programs, capitalize on those substitution laws by encouraging or even mandating the use of generic versions of drugs whenever possible. *See, e.g.*, Conn. Gen. Stat. Ann. § 17b-274 (mandating the dispensing of generic substitutes to recipients of public assistance).

[24] *See* Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 Rand J. Econ. 391, 407-08 (2003).

with suspicion, and thus mandated that they be reviewed by the antitrust authorities. The immunity from antitrust challenge granted to such settlements by the ruling below flies in the face of this congressional judgment, however, by rendering any such governmental review pointless. Viewed in the proper statutory context, therefore, exclusion payments may well be mutually advantageous to the drug firms, "due to the disparity between the brand-name manufacturer's and generic challenger's expected profits," Op. 48, but that hardly justifies their use as an artifice to subvert Congress's intended policies. *See* Herbert Hovenkamp *et al.*, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1758 (2003) (it does not follow "that because it is rational for the patentee to agree to an exclusion payment, that [the] payment cannot be anticompetitive. Far from it"); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement As a Regulatory Design Problem*, 81 N.Y.U.L.R. 1553, 1577-78 (2006) (rejecting justification that exclusion payments are "natural by-product" of Hatch-Waxman).

Finally, none of the district court's purported practical justifications for its sweeping rule withstands scrutiny.[25] First, the court's notion that a rule that accounts

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[25] The court's use of the term "scope of the patent" does nothing to distract from the sweeping nature of its rule. Its ultimate holding precludes any patent claim analysis as part of the antitrust case, and calls for using only the nominal scope of the patent claims (and in cases involving only a validity challenge, such as here, for using only the date of the patent term expiration) to conduct its competitive effects comparison. *See* Op. 19-35, 57-58.

for the uncertainty of litigation would somehow undermine patent law's presumption of validity is mistaken. *See* Op. 41. In fact, the court's refusal to consider the allegations of invalidity converts the law's rebuttable presumption into an effectively conclusive one. Moreover, application of the district court's rule requiring only a perfunctory comparison between the four corners of the challenged agreement and the nominal, asserted scope of the patent claims grants broad antitrust immunity to patentees who have not carried their burden of proving infringement. See, *e.g.*, *Kegel Co., Inc. v. AMF Bowling, Inc.*, 127 F.3d 1420, 1425 (Fed. Cir. 1997) (the patentee bears the burden of proving infringement). Such a result would effectively, and improperly, establish a presumption of infringement in this context.

Second, the court incorrectly reasoned that "[i]f [a patentee] had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit." Op. 50-51 (quoting *Valley Drug*, 344 F.3d at 1309). As discussed above, whether a patentee can exclude a competitor by virtue of having a patent depends on its ability to either win in litigation or convince the competitor of the strength of its patent such that the competitor agrees to enter only with a license. But the patentee can also fail in those tasks. Buying off that possibility of failure (with the resulting competitor's *certain* exclusion from the market) does indeed mean that "competition was limited more" by use of an exclusion payment than by reliance on the patent alone. That Bayer

*might have* won its patent litigation had it not paid Barr to settle does not alter the fact that Bayer obtained its market exclusivity through a cash payment and not through the strength of its patent, in violation of the antitrust laws' prohibition on buying off potential albeit uncertain competition.

Similarly, the court's warning that a different rule would chill patent settlements, and could even expose garden-variety licensing agreements to the risk of antitrust challenges is unwarranted. *See* Op. 33, 42. As discussed above, in the period after the Commission's initial enforcement efforts signaled to the industry that patent settlements with exclusion payments will be subjected to close antitrust scrutiny, litigants continued to settle their disputes, in other ways. *See, supra*, notes 12-13 and accompanying text.

More importantly, the court's reasoning ignores a central feature of the Hatch-Waxman Act. It is axiomatic that "public policy wisely encourages settlements." *McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994). The ruling below erroneously imputes to this judicial policy such force, however, that it precludes the condemnation of patent settlements even when they entrench monopolies created by patents having "the most questionable validity." Op. 45. The court found "no support for the view that Hatch-Waxman intended to thwart settlements," *id.* at 39, but ignored the ample evidence (*see, supra*, at 4-6) showing that Congress – while preserving legitimate patent rights – has specifically sought to *encourage* litigation

challenging pharmaceutical patent claims, in order to facilitate the market entry of low-cost generic drugs. The rule adopted below not only allows pharmaceutical firms to avoid judicial resolution of such challenges altogether by sharing the monopoly profits at the expense of consumers, but also trivializes Congress's 2003 mandate to subject these very agreements to review by the antitrust authorities. *See, supra*, at 8-9.[26]

Lastly, the court's Panglossian dismissal of the ability of a pharmaceutical patent holder to buy off subsequent challengers, *see* Op. 45-46, not only betrays a misapprehension of the economics of the pharmaceutical industry, but has been shown to be mistaken. Of course, paying off the first generic company ready to enter will often delay entry for years, during which time the branded (and generic) firms will profit handsomely, at the expense of consumers. The court failed even to address this consumer harm. And even if subsequent generics are ready to enter, the anticipated profits of each will remain substantially lower than the branded firm's, and also lower than the first generic's (having no exclusivity period from which to benefit). Each will find it advantageous, therefore, to agree not to enter, even for a

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[26] *See also* Brief of Amicus Curiae Federal Trade Commission In Support of Plaintiffs-Appellants' Petition For Panel Rehearing and Rehearing En Banc, *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2nd Cir. 2006) (No. 03-7641), *cert. denied sub nom. Joblove v. Barr Labs., Inc.*, ___ U.S. ___, 127 S. Ct. 3001 (2007), *available at* (www.ftc.gov/os/2005/12/051202amicustamoxifen.pdf).

modest payment. *See, e.g.*, Class Action Complaint, *In re Modafinil Antitrust Litig.*, No. 06-1797 (E.D. Pa. *complaint filed* Apr. 27, 2006), at ¶¶ 43-49, 82-100 (allegations of branded drug manufacturer making exclusion payments to multiple generic rivals). The court's ruling would permit such forestalling of competition regardless of the patent's weakness. Consequently, the challenges to drug patents that Congress sought to encourage in Hatch-Waxman may well result in a wealth transfer to would-be generic entrants, but no benefit to consumers.

## CONCLUSION

The Court should reverse the district court's ruling.

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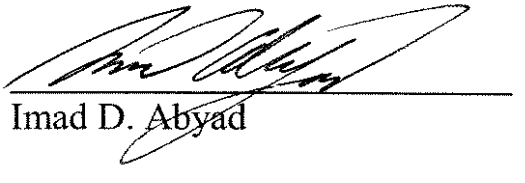

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## CERTIFICATE OF COMPLIANCE

I certify that this brief complies with Fed. R. App. P. 32(a)(7)(B)(i) with respect to word type-volume. It contains 6,759 words, excluding those portions exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Circuit Rule 32(b).

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