05-2851-cv (L), 05-2852-cv(CON)

IN THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

ARKANSAS CARPENTERS HEALTH AND WELFARE FUND, MARIA LOCURTO, PAPER, ALLIED-INDUS, UNITED FOOD AND COMMERCIAL WORKERS UNION-EMPLOYER, LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, INC.,

Plaintiffs-Appellants,

-against-

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

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK IN CONSOLIDATED CASE NO., 00-MD-1383, JUDGE DAVID G. TRAGER.

BRIEF FOR CONSUMERS UNION, CONSUMER FEDERATION OF AMERICA, U.S. PIRG AND NATIONAL LEGISLATIVE ASSOCIATION ON PRESCRIPTION DRUG PRICES AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLANTS' PETITION FOR REHEARING *EN BANC*

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May 20, 2010

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 28(a)(1) and 47.4(a), counsel for *Amici Curiae* Consumers Union, U.S. PIRG and the National Legislative Association on Prescription Drug Prices certifies the following:

1. The full name of every party or amicus represented by us is:

   Consumers Union of United States, Inc.
   Consumer Federation of America
   U.S. PIRG
   National Legislative Association on Prescription Drug Prices

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by us is:

   None.

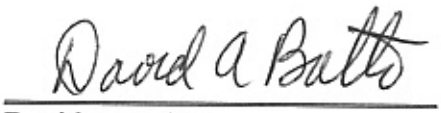
3. All parent corporations and any publicly held companies that own 10% or more of the stock of any party represented by us are:

   None.

4. The names of all law firms and the partners or associates that appeared for the parties now represented by us in the trial court or expected to appear in this court are:

   None

Dated: May 20, 2010



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I. INTRODUCTION[1]

Amici Curiae Consumers Union, Consumer Federation of America, U.S. PIRG and National Legislative Association for Prescription Drug Prices ("NLARx") (collectively "Amici") respectfully support Plaintiffs-Appellants' petition for panel rehearing en banc because of the concerns of escalating drug costs and the potential limitation on access to affordable generic drugs.

Plaintiffs-Appellants seek review of the panel's decision that the pay-for-delay settlement agreement between Defendants-Appellees was not anticompetitive, notwithstanding "the 'exceptional importance' of the antitrust implications of reverse exclusionary payment settlements of patent infringement suits." Op. at 2.

The Hatch-Waxman Act enacted incentives to challenge brand drug patents and bring generic drugs to the marketplace sooner. Exclusion payment agreements have exactly the opposite effect. Under the exclusion payment agreement at issue, Bayer paid its generic competitors $398 million in exchange for their agreement to

[1] Pursuant to Second Circuit Rule 29.1, no party's counsel authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting this brief; and no person other than amici, their members or their counsel contributed money that was intended to fund preparing or submitting this brief. All parties have consented to this filing.

stay out of the market for six and a half of the remaining seven years of the Cipro patent.[2]

The Federal Trade Commission estimates that these anticompetitive "exclusion payments" in the pharmaceutical industry cost consumers more than $3.5 billion annually.[3] If *Tamoxifen*'s incorrect reasoning allows these exclusion payment settlements to continue, consumers will be harmed by being denied the benefit of quicker access to more affordable prescription drugs. This Court should grant Plaintiffs-Appellants' petition for panel rehearing en banc under Fed. R. App. P. 35 and reverse the original panel's ruling.

II. STATEMENT OF INTEREST OF *AMICI CURIAE*

All of the amici are public interest groups and advocates for competitive health care markets. Consumers Union of United States, Inc., publisher of *Consumer Reports*®, is a non-profit membership organization chartered in 1936 to provide consumers with information and counsel about goods, services, health, and personal finance. Consumers Union's publications and services have a combined paid circulation of approximately 8.3 million, and regularly carry articles on

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[2] This is one of many facts that distinguishes the *Cipro* case from cases like *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2005). Unlike the agreement here, the agreement in *Tamoxifen* permitted Barr to enter for nine of the remaining ten years of the patent term. *Id.* at 194, 215. In contrast, the agreement here foreclosed entry for all but six months of the remaining seven-year patent term.

[3] Federal Trade Commission, *Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions*, at 2 (Jan. 2010).

Consumer Union's product testing and on health, product safety, and marketplace economics. Consumers Union's income is solely derived from the sale of *Consumer Reports*®, its other publications and services, fees, and noncommercial contributions and grants. Consumers Union's publications and services carry no outside advertising. Consumer Federation of America is a non-profit association of over 280 consumer groups, with a combined membership of more than 50 million people. CFA was founded in 1968 to advance consumers' interest through advocacy and education. NLARx is a nonprofit, nonpartisan organization of state legislators across the country. 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.

These leading consumer organizations have a long history of advocating for access to affordable health care and for controlling costs without compromising quality. Since 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.

III. LEGAL REASONS FOR EN BANC REVIEW

Although bound by *Tamoxifen*, the panel below explained the significant problems with *Tamoxifen*. The four reasons it highlighted (along with two others) provide compelling justifications for en banc review.

First, this Court should establish a standard that restricts anticompetitive settlements and is consistent with the Hatch-Waxman Act in promoting generic competition.[4] At the time of passage, there was no generic on the market for 150 brand name drugs whose patent had already expired.[5] The Act's drafters sought to ensure the provision of "low-cost, generic drugs for millions of Americans."[6]

At the same time, the Act fostered innovation through patent term extensions, non-patent market exclusivity for new chemical entities and clinical investigations, and an automatic 30-month stay for brand firms.[7] This equilibrium between competition and innovation was at the core of the statute.[8] Exclusion

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[4] For a detailed summary of the Act's goals, see Michael A. Carrier, *Unsettling Drug Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 41-47 (2009).

[5] H.R. REP. NO. 98-857, pt. 1, at 17 (1984).

[6] Id., pt. 2, at 4, *reprinted in* 1984 U.S.C.C.A.N. 2686, 2688; 130 CONG. REC. 24427 (Sept. 6, 1984) (statement of Rep. Waxman).

[7] For elaboration and citations, see Carrier, at 43-45.

[8] *See* 130 CONG. REC. 24425 (Sept. 6, 1984) (statement of Rep. Waxman highlighting the "fundamental balance of the bill"); H.R. REP. NO. 98-857, pt. 1, at 28 (Energy and Commerce Committee Report explaining 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).

payment settlements, on the contrary, have upset the Act's careful balance. For while the Act *encouraged* patent challenges, such settlements allow brand companies to pay generic companies to *prevent* patent challenges.

Second, nothing demonstrates the distorted state of affairs more than the 180-day period of marketing exclusivity which the Act reserved for the first generic company challenging the patent and seeking to introduce competition before the end of the patent term (through the filing of an Abbreviated New Drug Application (ANDA) with a paragraph IV certification).[9] By providing incentives for the first filer, the Act inadvertently created a regulatory barrier to entry because the brand company need only buy off one party. Moreover, these agreements are not typical patent settlements. In most settlements, a challenger pays the patentee to *enter* the market. But here, the patentee can comfortably rely on the exclusivity period to pay a generic challenger to *not* enter the market.

Third, as the Department of Justice explained in its brief to this court, patentees normally can choose between litigation (with the risk of the patent being invalidated) and private settlements "that avoid the risk of patent invalidation but provide no antitrust immunity."[10] The problem with *Tamoxifen* is that the court "inappropriately permits patent holders to contract their way out of the statutorily

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[9] 21 U.S.C. § 355(j)(5)(B)(iv).

[10] Brief for the United States in Response to the Court's Invitation, *Arkansas Carpenters Health and Welfare Fund v. Bayer*, 05-2851-cv(L), at 14-15 (2d Cir., July 6, 2009), *available at* http://www.justice.gov/atr/cases/f247700/247708.pdf.

imposed risk that patent litigation could lead to invalidation of the patent while claiming antitrust immunity for that private contract."[11] Such conduct, of course, "deprives consumers of significant benefits from price competition."[12]

Fourth, 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. Many settlements included such payments between 1992 and 1999 (before Federal Trade Commission scrutiny) and after 2005 (after being blessed in *Schering-Plough* and *Tamoxifen*).[13, 14] In contrast, in the period of most aggressive scrutiny, from 2000 to 2004, *not one* of 20 reported agreements involved a brand paying a generic to delay entering the market.[15] Parties settled their disputes, but in ways less restrictive of competition, such as through licenses allowing early generic entry.

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[11] *Id.*

[12] *Id.* at 16-17.

[13] *Schering-Plough Corp. v. FTC*, 402 F. 3d 1056 (11th Cir. 2005).

[14] *See* Carrier, at 74-75 (noting that reverse payments appeared in 8 of the 14 final settlements between brands and generic first-filers from 1992 to 1999, and 31 of 72 agreements from 2005 to 2007) (sources omitted).

[15] Federal Trade Commission Bureau of Competition, *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*, at 4 (Apr. 2006), http://www.ftc.gov/os/2006/04/fy2005drugsettlementsrpt.pdf.

Fifth, *Tamoxifen* establishes a far too permissive standard of near per se legality.[16] 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). And the rule that settlement restrictions on non-infringing or unrelated products are anticompetitive does not suggest that agreements on products covered by potentially-invalid patents are automatically legal.

Sixth, the *Tamoxifen* court relied on other assertions that ignore the Hatch-Waxman Act and bolster anticompetitive behavior:

- "[C]ourts are bound to encourage the settlement of litigation"[17]—even though the Act expressly replaced this general preference with its specific provision for patent challenges.

- Limits on settlements "would heighten the uncertainty surrounding patents and might delay innovation"[18]—even though generic competition forces brands to pursue new products and the Act's innovation provisions expressly did not include settlements.[19]

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[16] *Tamoxifen*, 466 F.3d at 213 ("[A]bsent 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.'").

[17] *Id.* at 202 (internal quotation omitted).

[18] *Id.* at 203.

[19] Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, (Oct. 2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

- Reverse payments "are particularly to be expected" under the Hatch-Waxman Act[20]—even though this demonstrates the sharing of monopoly profits, not the validity of the behavior.

IV. CONCLUSION

This court's en banc review is essential to put a judicial finger in the dike of cascading anticompetitive settlements that put the price of prescription drugs out of reach for millions of consumers.

Respectfully submitted,

May 20, 2010

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[20] *Tamoxifen*, 466 F.3d at 206.

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