Nos. 05-2851, 05-2852
05-2863

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

IN RE CIPROFLOXACIN HYDROCHLORIDE ANTITRUST LITIGATION	:	On Appeal From E.D.N.Y. Master File No. 1:00-MDL-1383

[PROPOSED] BRIEF OF AMICUS CURIAE AMERICAN ANTITRUST INSTITUTE IN SUPPORT OF PLAINTIFFS-APPELLANTS' PETITION FOR REHEARING EN BANC SEEKING REVERSAL OF DISTRICT COURT AND PANEL DECISION

Paul E. Slater
Sperling & Slater, P.C.
55 West Monroe Street
Suite 3200
Chicago, IL 60603
(312) 641-3200
Counsel for Amicus Curiae
American Antitrust Institute

November 30, 2005

CIRCUIT RULE 26.1(A) CORPORATE DISCLOSURE STATEMENT

Amicus Curiae American Antitrust Institute is a tax exempt Washington, D.C. corporation. It has no parent corporation and no publicly held corporation own 10% or more of its stock.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Legislative History

Other Authorities

STATEMENT OF IDENTITY OF AMICUS CURIAE

The American Antitrust Institute ("AAI") is an independent non-profit education, research, and advocacy organization. Its mission is to advance the role of competition, protect the interests of consumers in a competitive economy, and challenge abuses of concentrated economic power. *See* http://www.antitrustinstitute.org/about.cfm.[1] The AAI's Board of Directors has authorized the filing of this brief in the *Tamoxifen* and *Cipro* cases because it believes that the economic and legal reasoning in those cases is flawed and seriously threatens competition. If left standing, those opinions will undermine the careful statutory scheme that seeks to prevent weak or narrow patents from blocking generic entry and reducing competition. The stakes for consumers are high. The opinions will encourage and allow brand name manufacturers to pay generic competitors to keep their cheaper generic drugs off the market.

THE CASES

In *Tamoxifen*, the Panel affirmed the dismissal of an antitrust challenge to an agreement between brand name manufacturer, Zeneca, and generic manufacturer, Barr, to keep generic tamoxifen off the market. After a bench trial in which Zeneca's patent was declared invalid, Barr agreed to withdraw its challenge to the patent in return for an "exclusion payment" of $21 million to Barr and $45.4 million to Barr's raw ingredient supplier. *Id.* at 13. The Panel opinion relies on *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F.Supp.2d 514 (E.D.N.Y. 2005), *appeal pending* Nos. 05-2851, 05-2852, and 05-2863, where the district court entered summary judgment against plaintiffs on their claim that Bayer unlawfully made an exclusion payment of

---

[1] The AAI is managed by its Board of Directors. It has an Advisory Board comprised of 78 prominent law professors, economists, lawyers and business leaders, two of whom have represented companies that are plaintiffs in the *Tamoxifen* and *Cipro* cases. The author of the AAI's amicus brief has received no compensation for its preparation and has no financial interest in the outcome of these cases. The author has consulted plaintiffs' counsel about the brief.

$398 million to Barr in exchange for Barr dropping its challenge to the validity of Bayer's patent on the blockbuster drug, Cipro. AAI submits this amicus brief in support of the requests for en banc review in both the *Tamoxifen* and *Cipro* cases.

The *Tamoxifen* and *Cipro* decisions rest on three key propositions. *First*, limiting exclusion payments will severely restrict the ability of parties to settle patent litigation. *Tamoxifen,* Slip Op. at 31-32, 52-53; *Cipro*, 363 F. Supp. 2d at 533. *Second*, exclusion payments do not reduce competition because patents are presumed to be valid. *Tamoxifen*, Slip Op. at 45; *Cipro*, 363 F. Supp. 2d at 523-24. And *third*, allowing exclusion payments will not shelter weak patents because such payments will encourage additional patent challengers. *Tamoxifen,* Slip Op. at 51-52; *Cipro,* 363 F. Supp. 2d at 534-35. Each of these propositions is based on faulty economics, bad logic, and/or fundamental legal error. These mistakes threaten the competitive balance established by Congress for the pharmaceutical industry. This Court should grant the petitions for en banc review in both *Tamoxifen* and *Cipro* to correct these errors.

REASONS FOR EN BANC REVIEW

I. THE PUBLIC HAS A SIGNIFICANT INTEREST IN REMOVING UNWARRANTED BARRIERS TO GENERIC ENTRY.

The prescription drug industry is characterized by significant barriers to entry and substantial market imperfections. A new entrant must overcome: (1) substantial research and development costs; (2) the need for FDA approval; and (3) purported blocking patents. CBO, *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 14, 21 (July 1998), http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf ["*CBO Report*"]. Moreover, price competition between branded pharmaceuticals is muted because the primary decision maker for the selection of a prescription drug is not the consumer or the ultimate payer, but the physician. *See* Drug Product Selection, *Staff Report to the Federal*

Trade Commission 2-3 (January 1979).

Many countries have addressed these market imperfections with price controls. Congress has chosen instead to rely on competition from generic drugs, enacting a statutory framework that removes regulatory hurdles *and encourages patent challenges*. *CBO Report*, at 34-35. Under the Hatch-Waxman Act, generic manufacturers have prevailed in challenges to brand name patents in 73% of cases litigated to a conclusion. *Generic Drug Entry Prior to Patent Expiration,* at viii (2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf. ["*Generic Study*"]. As a result, generic drugs now account for 53% of the prescriptions (at only 12% of the dollar volume cost). Generic Pharmaceutical Association, "Generic Pharmaceutical Facts at a Glance," http://www.gphaonline.org/aboutgenerics/factsabout.html. The savings to consumers amount to tens of billions of dollars. *CBO Report*, at 12.

When it learned of the use of exclusion payments, Congress again refrained from enacting direct regulatory controls and instead sought vigilant antitrust scrutiny of such pay-offs. *See* Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (requiring that exclusion payment agreements be filed with the FTC and DOJ). Congress enacted this reporting legislation specifically to facilitate FTC enforcement actions against these agreements. *See, e.g.,* 148 CONG. REC. S7348 (July 25, 2002) (Sen. Hatch: "The FTC is doing the right thing in taking enforcement actions against those who enter into anti-competitive agreements that violate our Nation's antitrust laws"); 148 CONG. REC. S7460 (July 29, 2002) (Sen. Hatch: "We ought to pay attention to the experts at the FTC and elsewhere"); 146 CONG. REC. S7908-01 (July 27, 2000) (Sen. Leahy: congratulating the FTC for "instantly lower[ing] the boom on the companies").

If allowed to stand, the *Tamoxifen* and *Cipro* decisions will effectively insulate exclusion

payments from public or private antitrust scrutiny. Such abdication would undermine Congress' decision to rely on antitrust laws as an alternative to direct regulatory controls on pharmaceuticals. *See* T. Muris, *Principles For A Successful Competition Agency*, 72 U. Chi. L. Rev. 165, 169 (2005) ("Antitrust law is, in effect, a form of regulation that competes with other regulatory structures and . . . makes direct regulation unnecessary"); S. Salop, *Preserving Monopoly: Economic Analysis, Legal Standards, and Microsoft*, 7 GEO. MASON L. REV. 617, 671 (1999) (courts should not abdicate their responsibility to apply antitrust law unless they can explain why direct regulation is a better remedy). However one ultimately decides the antitrust issue, Congress should be told that antitrust regulation is not a viable option only if that is the conclusion of the full Court.

II. THE DECISIONS' FLAWED ASSUMPTIONS SERIOUSLY THREATEN COMPETITION.

There are serious questions as to each of the three analytical pillars of *Tamoxifen* and *Cipro*. Review by the full Court is necessary to ensure that the conclusions reached are supported by sound economics and law.

A. Limiting Exclusion Payments Will Not Discourage Patent Settlements.

Economic analysis and real life experience refute the key factual assumption of both *Tamoxifen* and *Cipro* that the settlement of a patent litigation would be unduly hampered if exclusion payments are held unlawful. *See Tamoxifen,* Slip Op. at 31-32, 52-53; *Cipro,* 363 F. Supp. 2d at 533. Neither decision cites any support for this critical assertion of fact, and the published economic literature demonstrates the contrary.

Economic analyses have demonstrated that essentially all Hatch-Waxman cases can be

settled without any exclusion payments.[2] *See* K. Leffler & C. Leffler, *Settling the Controversy Over Patent Settlements,* 21 RESEARCH IN LAW & ECON. 477, 485 (2004); K. Leffler & C. Leffler, *Efficiency Trade-Offs in Patent Litigation Settlements,* 39 U.S.F.L. REV. 33, 42 (2004). Rather, the cases can be readily settled through the time-honored -- and *procompetitive* -- alternative of licensed generic entry. 21 RESEARCH IN LAW & ECON. at 482.

These economic predictions are borne out by real world experience. In the 7 years between 1992 and 1999, there were 14 final settlements between brand and first filing generic manufacturers, 9 of which involved exclusion payments. *Generic Study,* at 31-32, 34. A follow up report after the FTC began prosecuting exclusion payment cases found 14 settlement agreements between brand and first filing generic manufacturers in the year between 2003 and 2004, *none* of which involved an exclusion payment. *See* http://www.ftc.gov/opa/2005/01/drugsettlements.htm. Contrary to the unwarranted *Tamoxifen/Cipro* prediction, patent settlements actually increased once the use of exclusion payments was questioned and suspended.

B. The Decisions Erroneously Rely on a Legal Presumption Rather Than Market Realities.

An important characteristic of antitrust law over the last 30 years has been the use of economic analysis, rather than formalistic line-drawing, to decide cases. *See, e.g., Continental T.V., Inc. v. GTE Sylvania,* 433 U.S. 36 (1977) (antitrust cases "must be based upon demonstrable economic effect rather than . . . formalistic line drawing"). There is no dispute that such economic analysis shows that exclusion payments are anticompetitive. A patentee would

[2] The few hypothetical cases that cannot settle without an exclusion payment occur under extreme assumptions by the parties about their chances of prevailing and are unlikely to occur in the real world. 39 U.S.F.L. REV. at 43.

not make nor a challenger require a payment unless the payment reduced competition to a level below that which each party expected under litigation. *See, e.g.,* C. Shapiro, *Antitrust Limits to Patent Settlements,* 34 RAND J. OF ECON. 391 (Summer 2003); H. Hovenkamp, *Anticompetitive Settlement of Intellectual Property Disputes,* 87 MINN. L. REV. 1719, 1759 (2003); *In re Schering Plough*, No. 9297, at 26 (Dec. 8, 2003), *vacated*, 402 F.3d 1056 (11th Cir. 2005), *petition for cert. filed*, 74 U.S.L.W. 3130 (Aug. 29, 2005).

Rather than apply economic analysis, however, *Tamoxifen* and *Cipro* offer a "formalist line drawing" premised on a patent's rebuttable presumption of validity. *Tamoxifen*, Slip Op. at 45; *Cipro*, 363 F. Supp. 2d at 535. According to the decisions, that *presumption* allows patentees to pay competitors not to challenge patents or enter the market. Even if antitrust analysis could be based on formalistic rather than economic grounds, these decisions are wrong even on their own terms. At the time of settlement, the patent in *Tamoxifen* had been declared invalid by the district court and thus was clearly not entitled to a presumption of validity on appeal or otherwise. *Shelcore, Inc. v. Durham Indus., Inc.*, 745 F.2d 621, 624-25 (Fed. Cir. 1984).[3]

Patent law provides no ironclad guarantee of exclusion even before a district court finding of invalidity. Congress provided for judicial review of PTO determinations of validity, and the rebuttable presumption of validity "is a procedural device, not substantive law." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983). It merely assigns burdens to litigants in patent trials and cannot "acquire an independent evidentiary role in any [other] proceeding." *In re Berwyn E. Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985). Moreover,

---

[3] Moreover, research shows that courts have *never* granted or continued an injunction prohibiting allegedly infringing entry after a district court has found the patent invalid, and district court findings of invalidity are entitled to collateral estoppel effect pending appeal. *See, e.g., Abbott Laboratories v. Mylan Pharmaceuticals, Inc.*, 37 F. Supp.2d 1076, 1078 & n.5 (N.D.
(continued...)

Congress did not provide for automatic stays or injunctions in patent litigation; provided in the Hatch-Waxman Act for only a 30-month stay; and expressly encouraged generics to challenge brand patents. There is no evidence that Congress intended to allow patentees to *purchase* even greater protection from competition and market entry.

Antitrust analysis should not be returned to outdated formalism without the imprimatur of the full Court. And even if formalism is to displace economic analysis, the full Court should consider whether that formalist analysis should be founded on one small part of the patent system -- the rebuttable presumption of validity -- rather than on *all relevant aspects* of that system.

C. Theoretical Long Run Competition Does Not Ameliorate the Anticompetitive Effect of Exclusion Payments.

Tamoxifen and *Cipro* assume away any anticompetitive effects of the exclusion payments by asserting that a payment to one challenger would only encourage the entry of other challengers. *Tamoxifen,* Slip Op. at 51-52; *Cipro,* 363 F. Supp. 2d at 534-35. That unsupported assumption ignores the entry barriers that prevent immediate entry by others after the first challenger is bought off. Most prominently, subsequent challengers must wait out the *automatic* Hatch-Waxman 30-month stay. 21 U.S.C. § 355 (j)(5)(B)(iii). Even the most ardent supporters of the Chicago-School "market efficiency" economic model take such regulatory barriers to entry into account. *See* R. Bork, THE ANTITRUST PARADOX, at 347-64 (Free Press 1993) .

The cases here provide excellent examples. In *Cipro*, the first challenger received its exclusion payment on the eve of trial in January 1997. Subsequent challengers did not get even

---

(continued...)

Ill. 1999), *aff'd,* WL 9701 86 (Fed. Cir. Oct. 4, 1999).

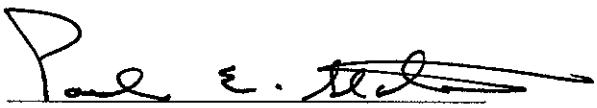
to the summary judgment stage until February 2001 -- more than 4 years later. *Cipro*, 363 F. Supp.2d at 518; *Bayer AG v. Schein Pharm., Inc.* 129 F. Supp.2d 705 (D.N.J. 2001). In *Tamoxifen*, the first challenger received its exclusion payment in March 1993, while awaiting a Federal Circuit ruling. The subsequent challengers did not obtain a Federal Circuit ruling until April 1997 -- more than four years later. *Tamoxifen*, Slip Op. at 13; *Zeneca Ltd. v. Novopharm Ltd.*, 111 F.3d 144 (Fed. Cir. 1997). The entry barriers ignored in *Tamoxifen* and *Cipro* may keep subsequent challengers at bay for years while hundreds of millions of dollars in overcharges may be inflicted on pharmaceutical consumers in only a matter of months.

CONCLUSION

The AAI respectfully urges the Court to grant the petitions of the *Tamoxifen* and *Cipro* plaintiffs for en banc review. Both decisions seriously threaten competition and the proper role of the antitrust laws.

Dated: November 30, 2005

Respectfully submitted,



Paul E. Slater
Sperling & Slater, P.C.
55 West Monroe Street
Suite 3200
Chicago, IL 60603
(312) 641-3200

Counsel for Amicus Curiae
American Antitrust Institute

LOCAL RULE 32(E) CERTIFICATION

I, Paul E. Slater, certify that, in accordance with Local Rule 32 (a)(1)(E), the PDF version of this brief has been scanned for viruses and no virus has been detected.

Paul E. Slater

CERTIFICATE OF SERVICE

I, Paul E. Slater, certify that on this 30th day of November, 2005, I caused the foregoing Amicus Brief of the American Antitrust Institute to be submitted in PDF form as an e-mail attachment to briefs@ca2.uscourts.gov and served on each of the following in hardcopy and PDF form via email and U.S. Mail:

Heather S. Woodson
STINSON MORRISON HECHER LLP
9 Corporate Woods, Suite 450
9200 Indian Creek Parkway, Suite 450
Overland Park, KS 66210
913-344-6716 (tel.)

David E. Everson
STINSON MORRISON HECHER LLP
Suite 2800, 1201 Walnut Building
Kansas City, MO 64106
816-691-3127 (tel.)

Counsel for Appellees Hoechst Marion Roussel, Inc., The Rugby Group, Inc. and Watson Pharmaceuticals, Inc

Karen N. Walker
Edwin U
KIRKLAND & ELLIS
655 Fifteenth Street, N.W.
Washington, DC 20005
202-879-5096 (tel.)

Counsel for Appellee Barr Laboratories, Inc.

Monica L. Rebuck
HANGLEY ARONCHICK SEGAL & PUDLIN
30 North Third Street, Suite 700
Harrisburg, PA 17101-1713
Telephone: (717) 364-1030

Counsel for Appellants CVS Meridian Inc. and Rite Aid Corp.

Fred H. Bartlit
Peter Bensinger
BARTLIT BECK HERMAN PALENCHAR & SCOTT LLP
54 West Hubbard Street, Suite 300
Chicago, IL 60610
312-494-4444 (tel.)

Phillip A. Proger
Larry D. Rosenberg
JONES DAY
51 Louisiana Avenue, N.W.
Washington, DC 20001
202-879-4668 (tel.)

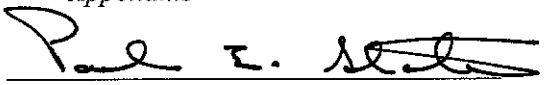
Counsel for Appellees Bayer Corporation and Bayer A.G.

Bernard Persky
Barbara J. Hart
LABATON SUCHAROW & RUDOFF LLP
100 Park Avenue
New York, NY 10017-5563
212-907-0700 (tel.)

Co-Lead Counsel for Indirect Purchaser Class Plaintiffs-Appellants

Bruce E. Gerstein
Barry S. Taus
GARWIN GERSTEIN & FISHER, LLP
1501 Broadway, Suite 1416
New York, NY 10036
212-398-0055 (tel.)

Co-Lead Counsel for Direct Purchaser Class Plaintiffs-Appellants



Paul E. Slater