

05-2851-cv(L)

05-2852-cv(CON), 05-2863-cv(CON)*

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,

SOL LUBIN, ANN STUART, LINDA K. MCINTYRE,

PLAINTIFFS,

-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

***Brief Of 34 State Attorneys General As Amici Curiae In Support Of Petition For
Rehearing En Banc Filed By Appellants Louisiana Wholesale Drug Co., Inc.,
CVS Pharmacy, Inc., Rite Aid Corporation, and Arthur's Drug Store, Inc.***

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INTEREST OF AMICI

The Attorneys General of Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Iowa, Kentucky, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Missouri, Montana, Nevada, New Hampshire, New Mexico, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, West Virginia, and Wyoming are the chief law enforcement or legal officials of their respective states. The Attorneys General have a long history of enforcing state and federal antitrust laws, and protecting consumers and state entities from actions that unlawfully thwart competition. The Attorneys General have a strong interest in this case because the agreement entered into by Bayer AG and its subsidiary, Bayer Corporation (collectively “Bayer”) and Barr Laboratories, Inc. (“Barr”) allegedly delayed the entry of generic ciprofloxacin for six and a half years, reducing both consumers’ and state entities’ access to lower cost antibiotics.

The Attorneys General are uniquely situated to provide the Court with guidance regarding the analytical framework for evaluating reverse payment agreements. As *parens patriae* representatives of consumers and as representatives of the states’ proprietary interests, the Attorneys General have prosecuted several antitrust cases against pharmaceutical companies involving reverse payment

settlements of patent infringement suits.¹ As a result, the Attorneys General have insight into the policy concerns implicated by such agreements, including the detrimental effect these agreements have on consumers and state entities.

Access to affordable prescription medication is particularly important to the states and their consumers during these difficult economic times. Government entities pay approximately 33% of the \$234 billion spent on drugs in the United States per year.² Competition from generic drug manufacturers is critical to the affordability of drugs – competition decreases the price of prescription drugs by 20% to 80% or more.³ However, reverse payment agreements are expressly designed to delay and prevent competition in pharmaceutical markets. The interest of the Attorneys General in this case is that antitrust law be interpreted consistent

¹See, e.g., *Florida v. Abbott Labs.*, No. 01-4006 (S.D. Fla. 2005) (*In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005)) (“Hytrin”); *Ohio v. Bristol-Myers Squibb Co.*, No. 02-cv-01080, 2003 WL 21105104 (D.D.C. 2003); *New York v. Aventis S.A.*, No. 01-cv-71835 (E.D. Mich. 2001) (*In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003)); *Alabama v. Bristol-Myers Squibb Co.*, No. 01-cv-11401 (S.D.N.Y. 2002) (*In re Buspirone Antitrust Litig.*, 185 F. Supp. 2d 340 (S.D.N.Y. 2002)).

²Kaiser Family Foundation, *Prescription Drug Trends 1* (2008), available at http://www.kff.org/rxdrugs/upload/3057_07.pdf.

³Food and Drug Administration, Center for Drug Evaluation and Research, *Generic Competition and Drug Prices* (2010), available at <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm129385.htm>; David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 Rev. Econ. & Stat. 37, 38 (2005).

with the spirit of the Hatch-Waxman Act,⁴ and in a manner that serves the public interest and promotes competition.

I. Background

On April 29, 2010, a panel of this Court entered an order affirming summary judgment for the defendants in *Arkansas Carpenters Health & Welfare Fund v. Bayer AG (In re Ciprofloxacin Hydrochloride Antitrust Litigation)* (“*Cipro*”),⁵ stating that it was bound by its earlier decision in *Joblove v. Barr Laboratories, Inc. (In re Tamoxifen Citrate Antitrust Litigation)* (“*Tamoxifen*”),⁶ and therefore the plaintiffs’ claims in *Cipro* could not survive. The *Cipro* Court recognized, however, that there are compelling reasons to revisit *Tamoxifen* and invited Appellants to petition for rehearing en banc.⁷

II. Argument

Federal Rule of Appellate Procedure 35(a) allows a rehearing en banc when the proceeding involves a question of exceptional importance.⁸ This is such a case. The *Cipro* Court itself recognized that exclusionary reverse payment agreements involve difficult and important antitrust issues and that the number of these

⁴Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”), 35 U.S.C. § 271(e)(1) (2000).

⁵Nos. 05-2851-cv(L), 05-2852-cv(CON), 2010 WL 1710683 (2d Cir. Apr. 29, 2010).

⁶466 F.3d 187 (2d Cir. 2006).

⁷*Cipro*, 2010 WL 1710683, at *7-8.

⁸FED. R. APP. P. 35(a).

agreements is increasing.⁹ The frequency and divergent treatment of these agreements make the issues in this case of exceptional importance.

The *Tamoxifen* decision has been the subject of widespread criticism. As the *Cipro* Court acknowledged, the principal drafter of the Hatch-Waxman Act, Senator Hatch, denounced reverse payment agreements as “appalling.”¹⁰ The Federal Trade Commission and the U.S. Department of Justice, as well as a large contingent of state Attorneys General¹¹, legal scholars, and economic scholars have strongly criticized the *Tamoxifen* decision.¹² Additionally, Congress has recognized that reverse payment agreements are problematic, although a recent attempt to pass legislation banning reverse payment agreements failed. Regardless of Congress’ failed legislation, this Court should shape the antitrust rules in a manner that protects consumers. *See State Oil Co. v. Khan*, 522 U.S. 3, 20 (1997) (“Congress expected the courts to give shape to the [Sherman Act’s] broad mandate by drawing on common-law tradition” (quotation omitted)).

There is good reason for the criticism of *Tamoxifen*. As reported by the Federal Trade Commission, the *Tamoxifen* decision has demonstrably escalated the

⁹*Cipro*, 2010 WL 1710683, at *8.

¹⁰*Id.*

¹¹Brief of States as *Amici Curiae* in Support of FTC, *FTC v. Schering-Plough Corp.*, 548 U.S 919 (2006) (No. 05-273), 2005 WL 2454839.

¹²Brief *Amici Curiae* of 28 Professors of Law, Business, and Economics in Support of Appellants at 2, *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008) (No. 08-1097), 2008 WL 644392.

use of reverse payment settlement agreements between brand and generic pharmaceutical companies.¹³ One recent study quantified the cost of reverse payment agreements to be some \$12 billion per year in excessive drug costs paid by consumers and state governments.¹⁴ The resulting inflated and monopolistic pharmaceutical prices only aggravate the financial distress of our citizens and state budgets. The *Tamoxifen* Court's endorsement of reverse payment agreements to thwart generic competition requires further review to avoid continued undue financial hardship on both consumers and the states.

En banc review is appropriate when a court has doubts as to whether the issues have been resolved correctly in another case. *See Cafeteria & Rest. Workers Union, Local 473 v. McElroy*, 284 F.2d 173, 189 (D.C. Cir. 1960) (perpetuating errors does not make for sound judicial administration). Here, the *Cipro* Court has expressed concern that the *Tamoxifen* Court relied on a clear misunderstanding of the terms of the Hatch-Waxman Act.¹⁵

¹³Federal Trade Commission, *Generic Drug Entry: Prior to Patent Expiration* (July 2002) 31-32, available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

¹⁴Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 651-53 (2009).

¹⁵*Cipro*, 2010 WL 1710683 at *8.

The *Tamoxifen* Court also relied on an unfounded assumption that a patentee could not realistically pay off all potential generic competitors,¹⁶ although this occurred with the pharmaceutical product Provigil. Provigil's manufacturer, Cephalon, settled with each of the four potential generic entrants. In exchange for payments, each generic manufacturer allegedly agreed not to compete. *King Drug Co. v. Cephalon*, No. 6-cv-1797, 2010 WL 1221793, at *4 (E.D. Pa. Mar. 29, 2010). To date, a generic version of Provigil is still not available on the market.

The *Cipro* Court also expressed concern that it could not address important policy arguments because it was bound by the *Tamoxifen* decision.¹⁷ The *Tamoxifen* Court dismissed the plaintiffs' complaint before any discovery occurred; it therefore lacked a full evidentiary record on which to evaluate the important implications of exclusionary reverse payment agreements.

The *Cipro* case is also of exceptional importance because the United States Supreme Court has refused to review the split between the Sixth and the Eleventh Circuits. In 2001, the Attorneys General of twenty-nine states brought an antitrust action against a brand pharmaceutical manufacturer, Hoechst Marion Roussel, for its reverse payment agreement with a generic pharmaceutical company, Andrx Pharmaceutical.¹⁸ In *Cardizem*, the Sixth Circuit found that the agreement was a

¹⁶*Tamoxifen*, 466 F.3d at 212.

¹⁷*Cipro*, 2010 WL 1710683 at *8.

¹⁸*In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2004).

“naked horizontal restraint of trade that is *per se* illegal because it is presumed to have the effect of reducing competition . . . to the detriment of consumers.”¹⁹

The State of Florida and others also challenged a reverse payment agreement in *In re Terazosin Hydrochloride Antitrust Litigation*, 352 F. Supp. 2d 1279 (S.D. Fla. 2005) (“*Hytrin*”). In *Hytrin*, the district court found that the reverse payment agreement was *per se* illegal.²⁰ On appeal, however, the Eleventh Circuit reversed and found that reverse payment agreements are not *per se* illegal if they do not extend beyond the protection of the patent. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F. 3d 1294, 1312 (11th Cir. 2003). Given the uncertainty within this area of the law, granting a rehearing en banc in *Cipro* will yield more effective judicial administration. *See Eisen v. Carlisle & Jacquelin*, 479 F.2d 1005, 1020-21 (2d Cir. 1973), *vacated on other grounds*, 417 U.S. 156 (1974).

Finally, a rehearing en banc in this case is appropriate because the principal question is important to the development of the law. *See Lanza v Drexel & Co.*, 479 F.2d 1277, 1279 (2d Cir. 1973). Both the *Hytrin* and *Cardizem* cases were decided after extensive litigation, unlike the *Tamoxifen* case. Because the Attorneys General have developed a thorough understanding of the antitrust issues involved in reverse payment agreements, they are in a unique position to provide guidance regarding the standard that should apply to these agreements.

¹⁹*Id.* at 911.

²⁰*Hytrin*, 352 F. Supp. 2d at 1286.

III. Conclusion

The Attorneys General have had substantial experience analyzing and enforcing the antitrust laws regarding reverse payment agreements. The use of reverse payment agreements subverts the purpose and spirit of the Hatch-Waxman Act to the detriment of consumers and state entities. This Court should grant the Petition for Rehearing En Banc of Appellants Louisiana Wholesale Drug Co., Inc., Arthur's Drug Store, Inc., CVS Pharmacy, Inc., and Rite Aid Corporation because en banc review will provide more effective judicial administration and resolve uncertainty on an issue of exceptional importance.

Dated: May 20, 2010

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CERTIFICATE OF SERVICE

I, Sarah E.B. London, certify that on May 20, 2010, I caused copies of *Brief Of 34 State Attorneys General As Amici Curiae In Support Of Petition For Rehearing En Banc Filed By Appellants Louisiana Wholesale Drug Co., Inc., CVS Pharmacy, Inc., Rite Aid Corporation, and Arthur's Drug Store, Inc.* to be served on the persons listed below by electronic and U.S. mail at the addresses indicated.

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