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,

v.

BAYER AG, BAYER CORP., FORMERLY DOING BUSINESS AS MILES INC., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES, INC.

Defendants-Appellees.

On Appeal from the United States District Court
for the Eastern District of New York

BRIEF OF *AMICI CURIAE* AARP, AMERICAN MEDICAL ASSOCIATION AND PUBLIC PATENT FOUNDATION SUPPORTING APPELLANTS' PETITION FOR EN BANC REVIEW

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* 05-2863-cv has been transferred to the Federal Circuit Court of Appeals. *See* order filed 11/7/07.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 counsel for *Amici* AARP, American Medical Association, and Public Patent Foundation certifies that:

1. *Amici* are non-profit corporations that do not have any parent corporations and any publicly held corporations that own 10% or more of its stock.

May 20, 2010

s/Stacy J. Canan
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STATEMENT OF INTEREST OF *AMICI CURIAE*

Amici have a strong interest in this case since the challenged agreement here thwarted the entry of generic ciprofloxacin into the marketplace, thereby reducing access to affordable prescription drug treatments.

AARP is a nonpartisan, nonprofit membership organization for people age 50 or older, dedicated to addressing the needs and interests of older people. As the country's largest membership organization, AARP has a long history of advocating for access to affordable health care and for controlling costs without compromising quality.

The American Medical Association ("AMA") is the largest professional association of physicians, residents and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups, seated in the AMA's House of Delegates, substantially all US physicians, residents and medical students are represented in the AMA's policy making process. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health.

The Public Patent Foundation, Inc. ("PUBPAT") is a not-for-profit legal services organization that represents the public interest in the patent system, and most particularly the public interest against the harms caused by undeserved patents and unsound patent policy. PUBPAT provides the general public and

specific persons or entities otherwise deprived of access to the system governing patents with representation, advocacy and education. PUBPAT has an interest in ensuring that patent holders and their privy are not allowed to undermine otherwise sound competition law simply because they own a patent.

ARGUMENT

As long as *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2005) is controlling law in the Second Circuit, exclusion payment agreements will continue to be found per se *lawful* under Section 1 of the Sherman Act. *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 2010 U.S. App. LEXIS 8865, *33 (2d Cir. 2010).[1] However, the antitrust implications of reverse exclusionary payment settlements of patent infringement suits are of "exceptional importance" to American consumers, businesses and governments forced to pay higher prices because of these arrangements and to patients that suffer the health effects of having to go without when they are unable to afford branded medications. The full Court should reconsider *Tamoxifen* in light of the difficult questions at issue in this

[1] The United States Court of Appeals for the Second Circuit affirmed the district court judgment granting Defendants' motions for summary judgment, on the basis of the Second Circuit's opinion in *Tamoxifen*, 466 F.3d 187 (2d Cir. 2005), allowing patentees to pay alleged infringers not to contest the validity of a patent and to stay out of the market. *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 2010 U.S. App. LEXIS 8865 (2d Cir. 2010).

case and the important interests at stake by allowing exclusion payment agreements.

I. PERMITTING EXCLUSION PAYMENTS EVISCERATES THE HATCH-WAXMAN ACT'S PATENT-CHALLENGE PROVISIONS.

Prescription drug spending in the United States has skyrocketed over the last two decades from $40 billion in 1990[2] to over $300 billion in 2009.[3] In the twelve month period ending with March 2010, the price of brand name prescriptions most widely used by Medicare beneficiaries increased by 9.7 percent, the highest rate of increase observed since AARP began tracking these prices in 2002. AARP, *Rx Watchdog Report: Brand Name Drug Prices Continue to Climb Despite Low General Inflation Rate* (May 2010), *available at* http://assets.aarp.org/rgcenter/ppi/health-care/i43-watchdog.pdf. Competition from generic drugs is the most effective means of slowing the spiraling cost of pharmaceuticals. Generics typically sell for a fraction of the cost of their branded counterparts and quickly capture the majority of unit sales, thus having saved

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

[3] Press Release, IMS Health, *IMS Health Reports U.S. Prescription Sales Grew 5.1 Percent in 2009, to $300.3 Billion* (Apr. 1, 2010), *available at* http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=d690a27e9d5b7210VgnVCM100000ed152ca2RCRD&vgnextchannel=41a67900b55a5110VgnVCM10000071812ca2RCRD&vgnextfmt=default.

consumers over $734 billion in the past 10 years. AARP, *Rx Watchdog Report*, Vol. 6, Issue 4 (May 2009), *available at* http://assets.aarp.org/www.aarp.org_/cs/health/205256rxwatchdogmay09.pdf.

Recognizing the clear consumer benefit that accompanies generic drug competition, Congress sought to speed up generic entry by enacting the Hatch-Waxman Act,[4] which "institutionalize[d] and provide[d] incentive for a system of attacks on presumptively valid patents" by generic manufacturers. *Innovation and Patent Law Reform: Hearings on H.R. 3285, H.R. 3286 and H.R. 3605 Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice of the H. Comm. on the Judiciary*, 38th Cong. 2d Sess., Part 1, at 444 (1984).

In creating the incentive to challenge patents, Congress was not seeking simply to line the pockets of the generic drug manufacturers. Hatch-Waxman challenges were supposed to be vehicles for earlier entry of generic drugs into the marketplace, thus giving consumers earlier access to lower-priced prescription drug alternatives. H. Rep. No. 98-857, pt. 1, at 1 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647 (the purpose of the Hatch-Waxman Act "is to make available more low cost generic drugs by establishing a generic drug approval procedure"). Indeed, generics make up nearly 70 percent of drugs prescribed today, whereas

[4] The Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355).

generics constituted only 12 percent[5] of prescription drugs dispensed prior to the passage of the Hatch-Waxman Act. *See* AARP, *Rx Watchdog Report*, Vol. 6, Issue 4 at 4.

The rise of exclusion payment agreements, however, has had a drastic effect on generic drug entry prior to patent expiration. Brand-name firms have used exclusion agreements to delay entry of generics on average by 17 months and to terminate patent challenges that would otherwise generate *billions* of dollars in consumer savings. Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 4 (Jan. 2010), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

Under the exclusion payment agreement here, for example, Bayer paid its generic competitors $398 million in exchange for the generics' agreement to stay out of the market for 6 1/2 years of the remaining 7-year life of the Cipro patent. In other words, Defendants' agreement ensured that consumers would have to wait another 6 1/2 years to buy lower-priced generic ciprofloxacin.

Economists at the Federal Trade Commission (FTC) estimate that, if nothing changes, exclusion payment settlements will cost consumers $35 billion over the next 10 years. *Id.* at 2; *see also* C. Scott Hemphill, *An Aggregate Approach to*

[5] Food and Drug Administration, *Protecting America's Health Through Human Drugs: Greater Access to Generic Drugs* (Jan. 2006), *available at* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143545.htm.

Antitrust: Using New Data and Rulemaking to Preserve Drug Competition, 109 Colum. L. Rev. 629, 650 (2009) (estimating that exclusion payments have already cost consumers over $12 billion).

If *Tamoxifen* remains controlling law, allowing settlements between brand-name and generic firms through exclusion payment agreements, the patent-challenge provisions of the Hatch-Waxman Act would be eviscerated, and American consumers would be left to pay the price.

II. INCREASED USE OF EXCLUSION PAYMENTS PREVENTS COMPETITION AND HARMS CONSUMERS.

At the end of 2008, brands were attempting to block generic entry on products with roughly $90 billion in pharmaceutical sales. FTC, *Pay-for-Delay*, at 9. Delaying the entry of affordable generic drugs not only prevents competition, but the lack of low cost treatment options reverberates throughout the entire health care system. The price of a brand drug can be prohibitive for uninsured patients who do not have help covering the cost of their prescription drugs. Even for those patients who are insured but who are on fixed or limited incomes, having a generic option is often the difference between having access to a health care treatment and not having any treatment option at all. When a generic pharmaceutical's entry into the market is delayed, it limits treatment access to vulnerable patient populations and prolongs the difficultly that physicians have in prescribing affordable treatment options. Further, when patients do not obtain necessary treatment

because no financially feasible options are available, conditions left untreated will worsen and result in a higher cost of care over time.[6]

Allowing exclusion payments that "grant monopoly privileges to the holders of invalid patents," *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100-101 (1993), results in lost consumer health and welfare greatly disproportionate to the relatively modest costs of patent litigation. *See* Herbert Hovenkamp, et al., *Balancing Ease & Accuracy In Assessing Pharmaceutical Exclusion Payments*, 88 Minn. L. Rev. 712, 717 (2004).

CONCLUSION

Consumers have been and will continue to be harmed by exclusion payment settlements blocking generic competition. *Amici* respectfully submit that this Court should acknowledge the "exceptional importance" of the antitrust implications of reverse exclusionary payment settlements of patent infringement suits. Appellants' petition for rehearing by the Court of Appeals en banc should be granted.

[6] American Medical Association, Statement for the Record to the Subcomm. on Commerce, Trade, and Consumer Protection for the H. Comm. on Energy and Commerce, *Impact of "Pay-for-Delay" Settlements On Patient Access to Affordable Generics and Overall Health Care System Costs* (April 13, 2009).

Respectfully submitted,

May 20, 2010

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing brief *amici curiae* was filed *electronically* in PDF in accordance with the CM/ECF instructions and mailed this 20th day of May 2010 by Federal Express overnight delivery to Clerk of U.S. Court of Appeals for the Second Circuit and copies were sent *electronically* and mailed by first class mail to counsel listed:

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