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, Mar

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INTEREST OF THE AMICUS CURIAE

The Federal Trade Commission is an independent federal agency, charged with enforcing the antitrust laws, promoting the efficient functioning of the marketplace, and protecting consumer welfare. 15 U.S.C. §§ 41 et seq. It exercises primary responsibility for federal antitrust enforcement in the pharmaceutical industry. Over the past decade, the Commission has been particularly concerned with pharmaceutical patent settlements involving "exclusion payments" – payments to delay entry of a lower-cost generic drug – and has challenged agreements it believes violate the antitrust laws. It has also extensively studied settlements in patent cases arising under the Hatch-Waxman Act and has examined every such settlement since 2004. As discussed below, this empirical evidence provides strong support for the Court to grant rehearing en banc to reconsider the ruling in In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006), which bound the panel here.

ARGUMENT

Though sparingly granted, rehearing en banc is warranted for issues of "exceptional importance." Fed. R. App. P. 35(a)(2). As the panel correctly observed, Op. 2, this case presents just such an issue. Under Tamoxifen, the law of this Circuit effectively shields a pernicious practice, which imposes enormous costs on American consumers of pharmaceutical drugs, from robust antitrust scrutiny. Neither the Patent Act nor the public policy in favor of settlements justifies immunizing from antitrust

scrutiny agreements that compensate generic firms for delaying competition. There are three additional and compelling reasons for rehearing en banc, on which we focus here. First, although the Tamoxifen majority recognized the incentives for drug companies to use exclusion payments to protect the weakest patents, it dismissed this "troubling dynamic" based on mistaken assumptions about the pharmaceutical industry. Second, five years of empirical evidence confirms that this troubling dynamic has created a costly reality. Exclusion-payment settlements have become more common, delaying

[1] This is due primarily to the pricing policies of generic firms, which generally offer their products at significant discounts, reaching "80 percent or more" compared to their branded counterparts. *See* How Pay-for-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs (FTC Prepared Stmt. Before House Subcomm. on Commerce, Trade, and Consumer Protection), at 13 (Mar. 31, 2009) (www.ftc.gov/os/2009/03/P859910payfordelay.pdf).

In the Medicare Prescri

Also contrary to the Tamoxifen majority's assumption, branded firms can (and do) pay off multiple generic firms. When multiple generic firms are poised to enter, expected competition among them will substantially reduce their prospective profits, and each will find it advantageous to agree not to enter, even for a modest exclusion payment. Indeed, the Commission has charged that, shor

[5] 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 FY2008, at 2 (www.ftc.gov/os/2010/01/100113-mpdim2003rpt.pdf).

[6] See also Paying off Generics to Prevert Competition with Brand Name Drugs: Should it Be Prohibited?: Hearing Before Senate Judiciary Comm., 110th Cong. 164, 166 (2007) (Stmt. of Michael Wroblewski, Consumers Union) (savings in 2006 alone from generic competition to Zocor, Pravachol, Zoloft, Wellbutrin, and Flonase estimated at $6.6 billion).

Compare Tamoxifen with In re Cardizem CD Antit

Apotex, Inc. v. Thompson

Congress's decision to reward generic filers challenging patents and to require that pharmaceutical patent settlements be filed with the federal antitrust agencies expresses a clear policy preference that pharmaceutical companies not be allowed to protect weak and narrow patents by buying off challengers. But the Tamoxifen ruling allows such an outcome, and economic realities make such deals irresistible as long as they are condoned. This Court should act now to revitalize the congressional policies undermined by Tamoxifen.

CONCLUSION

The Court should grant rehearing en banc.

Respectfully submitted,

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BUREAU OF COMPETITION

MAY 20, 2010

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