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,

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 (HON. DAVID G. TRAGER, J.)

BRIEF AMICUS CURIAE OF FEDERAL TRADE COMMISSION IN SUPPORT OF REHEARING EN BANC

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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 anti-trust 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 competition and costing consumers $3.5 billion a year. Third, the practice allowed under *Tamoxifen* threatens a primary goal of the Hatch-Waxman Act: the promotion of earlier generic competition in instances where branded drugs are protected by weak or narrow patents.

1. The *Tamoxifen* majority recognized that its rule opens the door for firms to enter exclusion-payment settlements: absent antitrust constraints, it will "make obvious economic sense," 466 F.3d at 209, for the branded firm to buy off its generic rivals by paying them as much as or (as alleged here) more than they would make by entering the market.[1] As a result, owners of even "fatally weak" patents will be able

[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).

to use exclusion payments to prevent competition. *Id*. at 212. Nevertheless, the *Tamoxifen* majority adopted its rule because it believed an alternative ruling would "outlaw all, or nearly all, settlements of Hatch-Waxman infringement actions." *Id*. The majority also reasoned that such settlements would be an ineffective tool to delay competition because there would be too many generic firms to pay off. *Id*. at 211-12.

Experience shows otherwise, on both counts. First, branded and generic pharmaceutical firms can and do settle their patent litigation without exclusion payments. In fiscal year 2004, prior to the *Tamoxifen* ruling, *none* of the fourteen Hatch-Waxman settlements filed with the Commission involved an exclusion payment;[2] yet, the parties found other ways to settle.[3] Overall, of the 218 final-settlement agreements filed between FY 2004 and FY 2009, 152 (nearly 70 percent) did *not* involve such exclusion payments. *See Pay for Delay Study*,[4] at 4.

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[2] In the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress – concerned with the danger of drug patent settlements involving exclusion payments and delay, *see* S. Rep. No. 107-167, at 4 (2002) – required such settlements to be filed with the Commission and with the U.S. Department of Justice. *See* Pub. L. No. 108-173, §§ 1101-1104, 1111-1117, 117 Stat. 2461-2463 (2003).

[3] 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 FY 2004*, at 1-2 (www.ftc.gov/os/2005/01/050107-medicareactrpt.pdf).

[4] Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions: An FTC Staff Study* (January 2010) ("*Pay for Delay Study*") (www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf).

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, shortly after *Tamoxifen*, this phenomenon occurred, delaying generic entry of a drug with nearly $1 billion in annual sales. *See FTC v. Cephalon, Inc.*, No. 08-2141 (E.D. Pa. *complaint filed* Feb. 13, 2008) (alleging exclusion-payment settlements with four generic companies).

Of course, even where a branded firm pays off only a single generic challenger, significant anticompetitive effects can ensue. Paying off the first generic firm will often delay *all* entry, for years, because subsequent generic firms are often well behind in product development. During that time, the branded incumbent will profit handsomely – at the expense of consumers.

2. The "troubling dynamic" that the *Tamoxifen* majority dismissed has become a costly reality. As Commission staff recently found, exclusion-payment settlements currently protect at least $20 billion in sales of branded drugs from generic competition. *See Pay for Delay Study*, *supra* note 4, at 2. Since the *Tamoxifen* decision, the number of final patent settlements that contain both compensation to the generic firm and a restriction on its ability to market its product has increased from *three* in FY 2005 to *fourteen* in FY 2006 to *nineteen* in FY 2009. *Id*. at 1. Not

surprisingly, these settlements are most common when the generic firm is a first-filer, whose 180-day marketing exclusivity can effectively block subsequent filers' attempted entry. *Cf.* 21 U.S.C. § 355(j)(5)(B)(iv). In FY 2008, for example, 81 percent (13 of 16) of all the final settlements containing both a restriction on generic entry and compensation to the generic firm involved the generic first-filer.[5]

The cost to consumers of these agreements is enormous. In its recent study of these agreements, Commission staff found that settlements containing exclusion payments delay generic entry, on average, by nearly 17 months, compared to settlements with no such payments. *See Pay for Delay Study, supra* note 4, at 9. Furthermore, Commission staff found that, even if the practice becomes no more prevalent than it is now, these settlements already cost consumers an estimated $3.5 billion annually, by conservative estimates. *Id*. at 2.[6]

If the *Tamoxifen* rule were to become settled law nationwide, moreover, the costs are likely to be even higher. In light of the current uncertainty of the legal

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[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 Prevent 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).

standard,[7] firms are showing restraint. *See supra*, text accompanying note 4. If these agreements were clearly beyond antitrust scrutiny, however, there would almost certainly be more of them (as they are profitable to both sides), causing further delay in generic entry, beyond current levels, and dramatically increasing the cost to consumers.

3. Finally, the *Tamoxifen* rule threatens to eviscerate one of the primary goals of the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). In that Act, Congress struck a balance that would "make available more low cost generic drugs," while fully protecting legitimate patent claims. H.R. Rep. No. 98-857(I), at 14 (1984).[8] The Act includes a range of regulatory mechanisms and economic incentives to accelerate the marketing of generic drugs. It spurs early commencement and resolution of the patent challenge in this context, by declaring the filing of a "Paragraph IV-ANDA"[9] an act of infringement, 35 U.S.C. § 271(e)(2); *Eli Lilly & Co.*

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[7] *Compare Tamoxifen with In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) (holding such agreements can be *per se* unlawful).

[8] The Act fast-tracks FDA drug approval via an Abbreviated New Drug Application (ANDA), upon a showing that the new (generic) drug is "bioequivalent" to an already approved one. 21 U.S.C. § 355(j). It promotes generic drug development by declaring certain research and development activities non-infringing, 35 U.S.C. § 271(e)(1); *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005), but maintains the incentives to develop new drugs by extending patent terms to account for the FDA approval process. 35 U.S.C. § 155.

[9] The Act requires drug firms to submit to the FDA a list of all the patents that the firm claims cover its drug (the FDA's "Orange Book"). 21 U.S.C. § 355(b)(1); *see*

v. Medtronic, Inc., 496 U.S. 661, 676 (1990), and by granting the patent holder an automatic 30-month stay on FDA approval of generic entry if – but only if – it sues the generic firm for infringement within 45 days, 21 U.S.C. § 355(j)(5)(B)(iii). It also grants the first generic firm to file a Paragraph IV-ANDA a 180-day marketing exclusivity for its product, 21 U.S.C. § 355(j)(5)(B)(iv), providing an extra incentive for challenges to pharmaceutical patents.[10]

Congress reinforced its statutory policy to encourage such challenges in its 2003 amendments to the Hatch-Waxman Act. *See* 117 Stat. 2066, 2448-2464 (2003). Those amendments sought to stamp out the "abuse of the Hatch-Waxman law" resulting from "pacts between big pharmaceutical firms and makers of generic versions of brand name drugs, that are intended to keep lower-cost drugs off the market." S. Rep. No. 107-167, at 4 (2002).[11]

Apotex, Inc. v. Thompson, 347 F.3d 1335, 1338 (Fed. Cir. 2003). A generic firm filing an ANDA must make a certification regarding the coverage of any listed patent over its proposed product. Most pertinent here, a "Paragraph IV certification" states that the claimed patent is invalid or is not infringed. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

[10] *See* James T. O'Reilly, *Prescription Pricing & Monopoly Extension: Elderly Drug Users Lose the Shell Game of Post-Patent Exclusivity*, 29 N. KY. L. REV. 413, 414 (2002) (Congress provided the 180-day exclusivity period as "a reward for challenging monopolists' abuse of weak patents").

[11] Among their corrective measures, the amendments required the reporting of drug patent settlements, to facilitate review by the antitrust enforcement agencies. *See supra*, note 2. Surely Congress would not have imposed such a requirement if it believed that those agreements raised antitrust concerns only in the rare circumstances recognized by the *Tamoxifen* rule.

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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