05-2851-cv(L)

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

BRIEF AMICUS CURIAE OF THE UNITED STATES IN SUPPORT OF REHEARING IN BANC

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

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INTEREST OF THE UNITED STATES

The Department of Justice is responsible for enforcing the federal antitrust laws and has a strong interest in the correct application of those laws. At the Court's invitation, the United States filed a brief at the panel stage of this case addressing the question whether settlements of pharmaceutical patent infringement litigation involving "reverse payments" from the patentee to the alleged infringer violate the federal antitrust laws.

STATEMENT

Plaintiffs-appellants allege that an agreement settling patent infringement litigation in the context of the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585, violated section 1 of the Sherman Act, 15 U.S.C. 1, because it provided for a would-be generic competitor to abandon its claim that a drug manufacturer's patent was invalid and delay its entry into the market, in return for a substantial monetary payment. The panel, per curiam, affirmed the district court's grant of summary judgment for defendants, explaining that the settlement agreement was not unlawful under the standard adopted in *Joblove v. Barr Labs. Inc. (In re Tamoxifen Citrate Antitrust Litig.*), 466 F.3d 187 (2d Cir. 2006) ("*Tamoxifen*"), and that it was "bound by *Tamoxifen* 'absent a change in law by higher authority or by way of an in banc proceeding.'" Slip op. at 16 (citation omitted).

Although it was bound by *Tamoxifen*, the panel offered "several reasons why this case might be appropriate for reexamination by our full Court." *Id.* at 16-19. In particular, it noted, among other things, that "there is evidence that the practice of entering into reverse exclusionary payment settlements has increased" since the *Tamoxifen* decision, and that the United States believes that the *Tamoxifen* standard is incorrect. Moreover, the panel said, the *Tamoxifen* panel relied on a mistaken understanding that the Hatch-Waxman Act would allow subsequent generic challengers to claim the statutory exclusivity period when it concluded that it would be difficult for the owner of a weak patent to buy off all likely challengers.[1] Finally, the panel observed that, unlike *Tamoxifen*, this case would allow the Court to consider the issue in the context of a fully developed record. Accordingly, the panel expressly "invite[d] plaintiffs-appellants to petition for rehearing in banc," *id.* at 19.

[1]Two defendants have sought to "correct" the statement regarding the *Tamoxifen* opinion on this point, reading that opinion not to suggest that "ANDA-IV filers" other than the first one are sometimes eligible for the statutory exclusivity period, but only that the question was unresolved at times relevant to Tamoxifen. Bayer AG and Bayer Corp.'s Motion to Correct Per Curiam Opinion at 5, 8. But the motion concedes that "[t]oday, the right to 180 days of market exclusivity is only available to the 'first applicant' to file an ANDA IV." *Id.* at 5.

ARGUMENT

The Court Should Grant Rehearing In Banc To Reconsider The *Tamoxifen* Standard.

The United States strongly agrees with the panel that this case should be considered by the full Court. As the panel made clear, its holding was dictated by the legal standard set forth in *Tamoxifen*. That standard has encouraged "pay for delay" settlements in the pharmaceutical industry, thereby protecting undeserved patent monopolies and depriving consumers of potentially enormous savings from the generic competition Congress sought to encourage in enacting the Hatch-Waxman Act. By shielding most private reverse payment settlement agreements from antitrust liability, the *Tamoxifen* standard improperly undermines the balance Congress struck in the Patent Act between the public interest in encouraging innovation and the public interest in competition. We urge the Court to grant the petition for rehearing in banc and reconsider the *Tamoxifen* standard.

1. Reverse payments settlements can delay generic competition in pharmaceutical markets significantly beyond the date it would otherwise occur. Indeed, settlement "agreements with compensation [from the branded drug firm to the generic] on average prohibit generic entry for nearly 17 months longer than agreements without payments." Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions, An FTC Staff Study* 2 (January

2010) (based on settlements in FY2004-FY2009) ("FTC Staff Study"), *available at* http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf.

A standard shielding most reverse payment settlements from antitrust scrutiny encourages their proliferation. As the panel noted:

> [p]rior to [the] *Tamoxifen* decision, there were fourteen settlements of Hatch-Waxman lawsuits, none of which involved reverse payments to a generic manufacturer. [Citation omitted.] After *Tamoxifen*, however, plaintiffs represent that twenty of twenty-seven Hatch-Waxman settlements have involved reverse payments.

Slip op. at 17.[2]

The resulting delay in competitive entry threatens substantial harm to consumers, because prices for generic drugs ordinarily are significantly lower than prices for the bioequivalent branded drug. *See* Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical* Industry (July 1998), *available at* http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf. According to one estimate, "the annual savings to purchasers of drugs that would result from eliminating 'reverse-payment' settlements would be approximately $3.5 billion," FTC Staff Study 8, with, presumably, lesser savings from restricting but not eliminating such settlements. Another study estimated that, across the drugs involved in 21 settlements with monetary compensation to the

[2]*See also* FTC Staff Study 4 (finding no such agreements in FY2004 and 3 in FY2005, but after court decisions upholding some of them in 2005, finding 14 in FY 2006, 14 in FY 2007, 16 in FY 2008, and 19 in FY2009).

generic, "a one-year delay in generic entry represents, under conservative assumptions, a transfer from consumers to producers of about $14 billion." C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition,* 109 Colum. L. Rev. 629, 650 (2009). Accordingly, the practical effect of the *Tamoxifen* standard is to impose enormous costs on consumers of pharmaceuticals.

2. The *Tamoxifen* antitrust standard legitimizes virtually all pharmaceutical patent settlements with a payment for a generic firm's agreement not to compete by selling a product within the scope of the branded firm's patent. *Tamoxifen*, 466 F.3d at 213.[3] This sweeping antitrust immunity for private agreements not to compete in exchange for compensation is without justification in competition or innovation policy.

The Patent Act authorizes a patentee to enforce its statutory right to exclude by filing an action for infringement. 35 U.S.C. 281. Thus, there is ordinarily no risk of antitrust liability for filing such an action, even though its purpose may be to eliminate competition. *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 176-77 (1965). The Patent Act, however, forces the patentee seeking

[3]The only exceptions are for patents procured by fraud and patent suits that are objectively baseless. *Tamoxifen*, 466 F.3d at 213. Nor does the *Tamoxifen* standard shield agreements extending to products outside the scope of the patent. *Id.*

to enforce its patent through litigation to accept the risk that the patent will be found invalid, unenforceable, or not infringed. 35 U.S.C. 282. If the patent is adjudged invalid, the patentee loses the right to exclude any generic challenger. *See Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313 (1971). These risks reflect the balance Congress struck in the Patent Act between (1) encouraging innovation through enforcement of legitimate patent rights, and (2) protecting consumers' interests in a competitive marketplace through invalidation of undeserved patents. *Cf. Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892) ("It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.")

The risk that patent infringement litigation may lead to invalidation of a pharmaceutical patent is substantial. *See* Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* 20 (July 2002), *available at* www.ftc.gov/os/2002/07/genericdrugstudy.pdf. Patentees – and particularly patentees who know their patents are vulnerable – thus have a strong incentive to avoid the statutorily imposed risk of patent invalidation by settling infringement claims prior to judgment. But a settlement is a private contract, and like other private contracts, it is subject to the antitrust laws.

Neither public policy favoring settlements nor the rebuttable statutory

presumption of patent validity justifies treating a private agreement not to compete in exchange for compensation as the equivalent of a litigated judgment in favor of the patentee. The presumption of patent validity is simply a procedural device that assigns burdens, *Stratoflex, Inc. v. Aeroquip Corp.,* 713 F.2d 1530, 1534 (Fed. Cir. 1983), in litigation challenging the validity of an issued patent, *In re Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985). There is no basis for treating that presumption as virtually conclusive and allowing it to serve as a substantive basis to limit the application of the Sherman Act.

As the United States explained in more detail in its invited brief before the panel, most patent settlements are efficiency enhancing and lawful under the antitrust laws. In the absence of a payment from the patentee to the would-be generic entrant or an agreement extending beyond the scope of the patent, a settlement generally reflects the parties' expectations as to the likely outcome of the litigation and their desire to avoid unnecessary litigation costs. Thus, settlements of patent infringement litigation are properly evaluated under antitrust's rule of reason, which takes account of potential justifications as well as anticompetitive effects. But the anticompetitive potential of a private agreement in which monetary compensation is exchanged for an agreement not to challenge a patent and to delay entry into the market is apparent. A rule shielding virtually all such agreements from antitrust scrutiny – even in the absence of any explanation for the payment

other than a desire to purchase more protection from competition than the patentee could reasonably expect to achieve through litigation or settlement – promotes neither competition nor innovation.

CONCLUSION

The Court should grant rehearing in banc.

Respectfully submitted.

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Certificate of Compliance with Fed. R. App. P. 32(a)

1. This brief complies with the type-volume limitation of Fed. R. App. P. 29(d) and 35(b)(2) because it fewer than seven and a half pages, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in 14-point Times New Roman, a proportionally-spaced TrueType font, using WordPerfect Version x4.

Proposed: May 19, 2010
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David Seidman

Certificate of Service

I hereby certify that on June 3, 2010 I caused two copies of the foregoing Brief Amicus Curiae of the United States in Support of Rehearing In Banc to be served by Federal Express, and one copy of the PDF version of the same to be served via e-mail, on the following:

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