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

PETITION FOR REHEARING EN BANC OF APPELLANTS LOUISIANA WHOLESALE DRUG CO., INC., ARTHUR'S DRUG STORE, INC., CVS PHARMACY, INC. AND RITE AID CORPORATION (PUBLIC-REDACTED VERSION)

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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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Plaintiffs[1] request rehearing en banc because this case "involves a question of exceptional importance." Fed. R. App. P. 35(a)(2). Although finding itself bound by a prior decision, the panel here unanimously recognized "the 'exceptional importance' of the antitrust implications of reverse exclusionary payment settlements of patent infringement suits" and took the extraordinary step of "invit[ing] plaintiffs-appellants to petition for rehearing en banc." Op. at 2.

The Federal Trade Commission estimates that these anticompetitive "exclusion payments" in the pharmaceutical industry cost consumers more than $3.5 billion annually.[2] The industry's use of exclusion payments grew exponentially after this Court rendered the 2-1 decision by which the panel here felt bound, *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2005).

Manufacturers of brand pharmaceuticals make exclusion payments to generic manufacturers that are preparing to enter the market and have formally certified that the patent on the drug is invalid or not infringed. In exchange for the

[1] Plaintiffs are CVS Pharmacy, Inc. and Rite Aid Corporation, individually; and Louisiana Wholesale Drug Co. and Arthur's Drug Store, Inc., individually and on behalf of a proposed class of direct purchasers of Cipro. Defendants are brand manufacturers Bayer Corporation and Bayer AG ("Bayer"), and generic manufacturers Barr Laboratories, Hoechst Marion Roussel and Rugby Group ("Generic Defendants").

[2] Federal Trade Commission, *Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions*, at 2 (Jan. 2010). Another study has put the annual consumer losses at more than $12 billion. Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 650-51 (2009).

cash exclusion payments, the generic agrees to confess validity and infringement of the patent and stay out of the market.

Tamoxifen held that unless the patent was obtained by fraud or the brand's claim of patent infringement is so weak as to be a sham, the brand may lawfully pay the generic to confess judgment on the patent and delay entry until the patent expires. 466 F.3d at 213. This is a hollow antitrust standard because patent fraud and sham patent litigation are unlawful as *unilateral* conduct under Section 2 of the Sherman Act regardless of whether there is an exclusion payment.[3] The *Tamoxifen* standard gives no antitrust significance -- under Section 1 of the Sherman Act -- to a payment from one competitor to another to stop trying to enter the market.

The *Tamoxifen* majority itself recognized "the troubling [competitive] dynamic that is at work in these cases," and acknowledged that its standard will allow patentees to buy exclusion of generic competitors based on "fatally weak patents." *Tamoxifen*, 466 F.3d at 212. The majority believed, however, that an exclusion payment to the first generic challenger would not cause consumer harm because: (1) subsequent generic challengers would be eligible under the Hatch-

[3] *See Walker Process Equip. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965); *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993).

Waxman Act[4] for a 180-day-exclusivity incentive (*see infra* at 8) and will therefore immediately pick up the patent challenge, 466 F.3d at 214; (2) brand manufacturers could not afford to pay off all subsequent challengers, *id*. at 212; and (3) in any event, exclusion payments are necessary if pharmaceutical cases are to settle at all, *id*.

The *Tamoxifen* majority's belief that subsequent generic challengers would ameliorate the anticompetitive effects of exclusion payments was founded on an error -- subsequent generic challengers are *not* eligible for the 180-day exclusivity under the Hatch-Waxman Act. And contrary to the key factual assumptions made in *Tamoxifen* -- which was decided without a record on a motion to dismiss the complaint -- brand manufacturers can and do pay off subsequent generic challengers. The record here also shows that patent cases can be settled without exclusion payments, using other, lawful means.

The full Court should use the detailed record here to reexamine a 2-1 decision that permits massive consumer harm based on mistaken assumptions.

BACKGROUND

The Hatch-Waxman Act promotes entry of low-cost drugs by streamlining pharmaceutical patent litigation and providing a financial incentive for generic manufacturers to overcome patents and enter the market. 21 U.S.C.

[4] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (1999).

§355(j)(5)(B)(iv). In fact, many pharmaceutical patents are not valid or infringed, and generics have won 73% of Hatch-Waxman patent cases litigated to conclusion. A-3506. When a generic wins a patent case and enters the market, the brand's former monopoly profits are now split three ways: (1) the brand continues to make some sales; (2) the generic makes many sales; and (3) consumers who buy the generic reap enormous savings -- often billions of dollars.

The Economic Harm of Exclusion Payments. In the 1990s, however, brand manufacturers started settling Hatch-Waxman cases by making exclusion payments to the generics. By settling the patent case with a payment in exchange for stopping entry efforts, the brand and generic act jointly to preserve the monopoly, eliminate the savings that consumers would have received, and split the preserved monopoly profits between themselves.[5] Plaintiffs here, and plaintiffs and antitrust enforcement agencies in other cases,[6] assert that these exclusion payment settlements are classic violations of Section 1 of the Sherman Act in

[5] A-5863; *see also* Jon Leibowitz, Comm'r, FTC, Prepared Statement to the S. Judiciary Comm., *Anticompetitive Patent Settlements in the Pharmaceutical Industry*, at 11-12 (Jan. 17, 2007) ["FTC Prepared Statement"].

[6] Judicial treatment of exclusion payments ranges from finding them *per se* unlawful, to ruling that the court in the antitrust case must re-litigate the patent issues, to finding them nearly *per se* lawful (this Court's position, discussed *infra*). The various decisions are discussed in detail in Plaintiffs-Appellants' Petition for Hearing En Banc, filed on November 30, 2005**.**

which an incumbent shares the monopoly profits with a potential competitor in exchange for an agreement to stop trying to enter the market.

Plaintiffs do *not* allege that it is unlawful for litigants to settle Hatch-Waxman cases. For more than a century, patentees and alleged infringers have routinely settled patent cases by lawful means through licensed entry.[7] The patentee gauges the strength of the patent (the likelihood that the court will find it valid and infringed), and offers to give a license to the alleged infringer for, say, 5 of the 10 years of the remaining patent term. The alleged infringer also gauges the strength of the patent and may accept the 5-year license.

These ordinary settlements do not violate the Sherman Act because judicial testing of patent validity is not an end in itself, but a means of eliminating unwarranted patent monopolies.[8] Consumers get the same benefit from litigation of the patent case to conclusion -- the outcome of which is based on the patent's strength -- and from a settlement via a license that permits generic entry for a period of time determined by the litigants' assessments of the patent's strength.[9]

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[7] *See* Hovenkamp, et al., IP AND ANTITRUST, §7.4 at 7-36 (2009 Supp.).

[8] *See, e.g., Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 343 (1971) (judicial testing of patents ensures public does not suffer from unwarranted patent-based monopolies); *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969) (same).

[9] Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1758 (2003) (A-3617); Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. Econ. 391, 397-99 (Summer 2003) (A-3920-22).

Exclusion payment settlements are entirely different. In a customary settlement, the generic makes money only by entering the market and selling a low-cost product to consumers; consequently, the generic will agree to a license that keeps it out of the market only to the extent dictated by the patent's strength, and not a day longer. In stark contrast, in an exclusion payment settlement, the generic makes money by agreeing not to sell the product; consequently, the generic will agree to stop trying to enter the market regardless of the patent's strength or weakness. The brand's agreement to share the monopoly profits with the generic turns an adversary into an ally. For example, here the Generic Defendants agreed to stay out of the market for 6.5 of the remaining 7 years of the patent, in exchange for a payment that represented between 97% and 200% of the amount they would have made by winning the patent case and entering the market. A-5835; A-3427-38.

The Unlawfulness of the Agreement Here. These anticompetitive features make exclusion payments contrary to antitrust law, patent law, and the Hatch-Waxman Act. Section 1 of the Sherman Act prohibits an incumbent from paying a potential competitor not to enter, including when it is uncertain (as it is in patent litigation) whether he could have successfully entered. *See, e.g., United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc); XII Hovenkamp, ANTITRUST LAW ¶ 2030b at 213 (2d ed. 2005). Patent law provides no immunity

for this conduct. A patentee might have[10] a right to exclude competitors *if* a court finds the patent valid and infringed, but has no right to pay to avoid a judicial determination *whether* the patent is valid and infringed.[11] And exclusion payments are an obvious affront to the Hatch-Waxman Act because Congress encouraged patent challenges not in order to allow brands and generics to share monopoly profits, but to bring low-cost drugs to consumers.[12]

The agreement here well illustrates why exclusion payments are anticompetitive. In the patent case, the Generic Defendants had defeated Bayer's summary judgment motions. There was a "substantial question" as to validity, R

REDACTED

A-996; REDACTED . On the eve of trial, Bayer agreed to pay the Generic Defendants more than $398 million to confess judgment and stay out of the market for all but 6 months of the remaining 7-year patent term. *See* A-2880; A-2898;

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[10] Even after a final judgment of validity and infringement, a patentee can obtain exclusion of a competitor from the market only by satisfying the traditional requirements for injunctive relief. *See eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392-93 (2006).

[11] *See, e.g., Blonder-Tongue*, 402 U.S. at 344 (patent law "encourage[s] authoritative testing of patent validity").

[12] *Protecting Consumer Access to Generic Drugs Act of 2007, Hearing No. 110-39 Before H. Comm. On Energy and Commerce*, 110th Cong. at 7 (May 2, 2007) ["Protecting Consumer Access"] (statement of Rep. Waxman) ("We established an abbreviated regulated pathway to encourage generics to enter the market as soon as possible, not to authorize the companies to use that regulatory pathway as a means for sharing the brands' monopoly profits.").

A-613. The agreement gave Bayer the option to either make the payments or grant the Generic Defendants a traditional license that permitted generic entry 6 years before patent expiry. A-2873-75. The facts thus make crystal clear that exclusion payments buy the absence of generic entry -- and huge consumer savings -- that otherwise would have occurred.

ARGUMENT

A. *Tamoxifen's* Legal Error Misshaped Its Standard.

The *Tamoxifen* majority assumed that exclusion payments would cause no harm because subsequent generic challenges would be "spurred by the additional incentive (at the time) of potentially securing the 180-day exclusivity period." 466 F.3d at 214. The panel here concluded that rehearing en banc is supported by *Tamoxifen*'s stark error: the FDA does not now and never has awarded the 180-day exclusivity to subsequent challengers. Op. at 18.

Precisely because they are *not* entitled to the 180-day exclusivity (*contra Tamoxifen*, 466 F.3d at 214), subsequent generic challengers take a "wait and see" approach, delaying both their development and litigation costs, as the patent claim against the first generic challenger proceeds.[13] Therefore, when the first generic

[13] *See* A-5864; Hemphill, *Paying For Delay: Pharmaceutical Patent Settlement As A Regulatory Design Problem*, 81 N.Y.U.L. Rev. 1553, 1586, 1605 (2006) (explaining the "serious free-rider problem" subsequent generic challengers face).

challenger settles, the patent is *not* "opened . . . to immediate challenge by other potential generic manufacturers" (*Tamoxifen*, 466 F.3d at 214).

Instead, "[t]he regulatory scheme for pharmaceutical patents means that by settling with an ANDA filer, a patent owner can delay entry by any other generic for three years or more."[14] REDACTED This delay caused the subsequent generic challengers to forego fact-intensive defenses to the patent, with the result that the best defenses to the Bayer patent have never been litigated to this very day. *See* Plaintiffs-Appellants' Brief at 15 (filed May 5, 2008).

The *Tamoxifen* majority also erroneously assumed that the patentee will eventually run out of monopoly profits to pay off subsequent challengers. *See* 466 F.3d at 212. Later challengers have far less to gain by entering and therefore require a correspondingly lower pay-off. *See* A-5826; REDA Consequently, brand manufacturers today are in fact settling with "most or all subsequent filers to guarantee *no* generic entry by anyone."[15]

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[14] Hovenkamp, et al., IP AND ANTITRUST, §7.4 at 7-37 (2007 Supp.); *see also* Hemphill, *Paying for Delay*, at 1586.

[15] Jon Leibowitz, Comm'r, FTC, Remarks at the Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust, *Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck!*, at 6 (Apr. 24, 2006) (emphasis in original); *see also King Drug Co. v. Cephalon*, 2010 WL 1221793 (E.D. Pa. Mar. 29, 2010) (seriatim exclusion payments to four generics).

The *Tamoxifen* majority's erroneous assumption that subsequent generic challenges would ameliorate the anticompetitive effects of exclusion payments was founded on error and the lack of a factual record. The record here shows that later challengers face significant regulatory and economic entry barriers; that brand manufacturers can and do exclude *all* generic competition for years by paying off the first challenger; and that when necessary, brands pay off subsequent challengers as well.

B. *Tamoxifen* Has Permitted Profound Consumer Harm.

As the panel here noted, this is an exceptionally important case because the *Tamoxifen* decision has resulted in a dramatic surge in exclusion payment settlements. Op. at 17. Immediately before *Tamoxifen,* manufacturers settled Hatch-Waxman cases the traditional, competitive way, with licenses granted by the brand to the generic. *Id.* But after *Tamoxifen* gave a green light to exclusion payments, 20 of the next 27[16] settlements with the first generic challengers were via exclusion payments rather than licensed entry. *Id*. at 17.[17] (Some executives have repudiated making exclusion payments because it "violate[s] the antitrust

[16] The panel referred to data for fiscal years 2006 and 2007. In fiscal 2008, 13 of 27 settlements with generic first-filers used exclusion payments to restrict generic entry. FTC, SUMMARY OF AGREEMENTS FILED IN FY 2008, at 5 (Jan. 2010).

[17] If antitrust law permits exclusion payments, the economic incentive for brand and generic manufacturers will always be to eliminate the consumer savings and divide it among themselves via an exclusion payment. A-5809-10.

laws, and it isn't morally right."[18]) This dramatic shift to exclusion payment settlements is costing consumers billions of dollars annually.

The *Tamoxifen* majority thought these consumer losses acceptable because it assumed that manufacturers cannot settle Hatch-Waxman cases without using exclusion payments. 466 F.3d at 212 (disallowing payments would be tantamount to "outlaw[ing] all, or nearly all, settlements of Hatch-Waxman infringement actions").[19] And the litigants' assumed inability to settle Hatch-Waxman cases with traditional early entry licenses "explains the flow of settlement funds." *Id*. at 207.

This key assumption is contrary to fact. After an initial spate of these anticompetitive agreements in the late 1990s, the FTC's aggressive reaction brought them to a halt. From 2000 to 2004, no exclusion payment agreements were reached. Litigants continued to settle Hatch-Waxman cases -- at the same rate as they had before -- but they did so with traditional early-entry licenses. *See* FTC Prepared Statement, at 13.

This real-world experience is confirmed by a comprehensive econometric study showing that exclusion payments are necessary to achieve an efficient

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[18] Bethany Mclean, *A Bitter Pill*, Fortune at p. 5 (August 2001) (A-4791) (quoting Eli Lilly's CEO).

[19] *See also* 466 F.3d at 203 (finding payments unlawful would "severely restrict[] patent settlements" and "forc[e] patent litigation to continue").

settlement in less than 1% of Hatch-Waxman cases.[20] Defendants' experts conceded they had no contrary evidence and knew of no contrary studies. A-6021-22. Indeed, the agreement here provides, as an alternative to the exclusion payments, for settlement via a traditional early-entry license. *See supra* at 8.

The *Tamoxifen* majority correctly noted that the Hatch-Waxman Act often "redistributes the [litigants'] relative risk assessments." 466 F.3d at 207. The brand gets automatic exclusion of the generic for 30 months, and the generic can often litigate validity and infringement without subjecting itself to potential damages. But the *Tamoxifen* majority lept from the premise of altered risk assessments to the assumption that the cases cannot be settled without exclusion payments. That assumption does not follow from the premise, and is contrary to fact.

C. Sen. Hatch and Rep. Waxman Reject the *Tamoxifen* Standard.

The panel here notes that rehearing en banc is supported because both Senator Hatch and Representative Waxman have sharply criticized exclusion payment agreements. *See* Op. at 17-18.[21] Before *Tamoxifen*, the brand

[20] Leffler & Leffler, *Settling the Controversy Over Patent Settlements: Payments By the Patent Holder Should Be Per Se Illegal*, 21 Research in Law & Econ. 477, 486 (2004) (A-5678); *see also* A-5811 n. 22.

[21] The legislators' criticisms came both before and after the *Tamoxifen* decision. *See* Op. at 17-18; *Protecting Consumer Access*, at 7 (statement of Rep. Waxman) (exclusion payments "turn[] th[e] fundamental goal of Hatch-Waxman on its head").

manufacturers fended off this criticism by telling Congress that exclusion payments are unlawful under the Sherman Act and that the courts can therefore eliminate them without special legislation.[22] Congress therefore required that all exclusion payment agreements be filed with the FTC so they would be prosecuted.[23]

In the wake of *Tamoxifen* and the new onslaught of exclusion payment settlements, PhRMA and its allies have forestalled corrective Congressional action by arguing that the courts, not Congress, can decide whether "a patent settlement unreasonably restrains trade."[24] Plaintiffs agree that the duty to correct the *Tamoxifen* standard belongs, in the first instance, to this Court rather than Congress. *See Monell v. Dep't of Social Services*, 436 U.S. 658, 695 (1978) (Court should not "place on the shoulders of Congress the burden of the Court's own error.") (citation omitted). This is particularly true under the Sherman Act, where

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[22] *Generic Pharmaceuticals: Marketplace Access and Consumer Issues, Hearing No. 107-1081 Before S. Comm. on Commerce, Science, and Transportation*, 107th Cong. at 71 (Apr. 23, 2002) (PhRMA testified that "those cases [*Cardizem* and *Valley Drug*] outline facts . . . that would have been violations of the antitrust laws and/or the patent laws whether the Hatch-Waxman Act existed or not").

[23] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, at 2462-63; *see* 148 CONG. REC. S7348 (daily ed. July 25, 2002) (Sen. Hatch) ("The FTC is doing the right thing in taking enforcement actions against those who enter into anti-competitive agreements that violate our Nation's antitrust laws").

[24] *Hearing on H.R. 1706, The Protecting Consumer Access to Generic Drugs Act of 2009 Before H. Comm. on Energy and Commerce*, 111th Cong. (Mar. 31, 2009) (statement of Diane E. Bieri , PhRMA General Counsel, at 16).

courts have a clear mandate to shape rules that protect consumers. *See State Oil Co. v. Khan*, 522 U.S. 3, 20 (1997).

D. Antitrust Enforcers Reject the *Tamoxifen* Standard.

The panel here concluded that rehearing en banc is supported because "the United States has itself urged [the Court] to repudiate *Tamoxifen*, arguing that *Tamoxifen* adopted an improper standard that fails to subject reverse exclusionary payment settlements to appropriate antitrust scrutiny." Op. at 16. The United States has rejected the *Tamoxifen* standard under both the current Administration, whose amicus brief is discussed by the panel here (Op. at 16-17), and the Bush Administration, which concluded that *Tamoxifen* "adopted an incorrect standard" because, *inter alia*, the majority "refus[ed] to consider the strength of the infringement claim beyond a determination that the claim was not [a sham]."[25]

Likewise, the FTC has unanimously held that exclusion payments raise significant competitive risks that require more scrutiny than provided by the *Tamoxifen* standard.[26] Every FTC Commissioner in office since 1998, of both

[25] Brief for the United States as Amicus Curiae, *Joblove v. Barr Labs., Inc.*, No. 06-830 at 1, 13-14 (S. Ct. May 2007); *see also id.* at 12, 13 (*Tamoxifen* standard is "insufficiently stringent" and "erroneous"). The United States recommended against certiorari in *Tamoxifen* because issues of mootness made it not "a good vehicle for resolving the [substantive] question presented." *Id.* at 1.

[26] *See In re Schering-Plough Corp.*, 2003 WL 22989651 (FTC Dec. 8, 2003), *rev'd, Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005).

political parties, has reached the same judgment.[27] So have the antitrust enforcement agencies of 36 States;[28] the major consumer groups;[29] dozens of professors of law, business, and economics;[30] and the American Antitrust Institute.[31] Antitrust enforcers know that if the *Tamoxifen* standard is left standing, "[t]he patent-challenge provisions of the Hatch-Waxman Act would be eviscerated, and American consumers would be left to pay the price." AARP Br. at 13.

CONCLUSION

For the reasons stated herein and by the panel, the Court should grant rehearing en banc.

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[27] *See* Thomas Rosch, Comm'r, FTC, *How Pay-For-Delay Settlements Make Consumers and the Federal Government Pay More for Much Needed Drugs,* at 1 (Mar. 31, 2009).

[28] Brief of States As *Amici Curiae* In Support of Federal Trade Commission, *FTC v. Schering-Plough Corp.,* No. 05-273 (S. Ct. Sept. 30, 2005).

[29] Brief of *Amici Curiae* AARP, et al., *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, No. 05-2851, at 13 (2d Cir. May 12, 2008) ["AARP Br."].

[30] Brief *Amici Curiae* of 54 Intellectual Property Law, Antitrust Law, Business, and Economics Professors, et al., *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, No. 08-1194, at 2 (S. Ct. April 24, 2009).

[31] Brief of *Amicus Curiae* American Antitrust Institute, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, No. 05-2851, at 1 (2d Cir. Nov. 30, 2005).

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May 13, 2010

05-2851-cv(L), 05-2852-cv(CON)
In re: Ciprofloxacin Hydrochloride Antitrust Litigation

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

August Term, 2008

(Argued: April 28, 2009 Decided April 29, 2010)

Docket Nos. 05-2851-cv(L), 05-2852-cv(CON)

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,

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.

Before: NEWMAN, POOLER, PARKER, Circuit Judges.

Plaintiffs appeal from a judgment of the United States District Court for the Eastern District of New York (Trager, J.) granting summary judgment for defendants, manufacturers of the antibiotic ciprofloxacin hydrochloride ("Cipro") or generic bioequivalents of Cipro. Plaintiffs argue that defendants violated Section 1 of the Sherman Act when they settled their dispute concerning the validity of Bayer's Cipro patent by agreeing to a reverse exclusionary payment settlement. Bayer

agreed to pay the generic challengers, and in exchange the generic firms conceded the validity of the Cipro patent.

After the district court entered judgment below, a panel of this Court held that reverse payment settlements of patent lawsuits do not violate antitrust laws. See Joblove v. Barr Labs., Inc., (In re Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187, 208-12 (2d Cir. 2005). Because Tamoxifen is dispositive of plaintiffs' claims, we AFFIRM. However, because of the "exceptional importance" of the antitrust implications of reverse exclusionary payment settlements of patent infringement suits, we invite plaintiffs-appellants to petition for rehearing in banc. See Fed. R. App. P. 35(a)(2).

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CHRISTINE A. VARNEY, Assistant Attorney General, (Philip J. Weiser, Deputy Assistant Attorney General, and Catherine G. O'Sullivan and David Seidman, Attorneys), U.S. Department of Justice, Washington, D.C., for the United States.

PER CURIAM:

Plaintiffs appeal from a judgment of the United States District Court for the Eastern District of New York (Trager, J.) granting summary judgment for defendants. Defendants Bayer AG and its subsidiary Bayer Corporation (collectively "Bayer") own the patent for the active ingredient in the antibiotic ciprofloxacin hydrochloride ("Cipro"). Defendants Barr Laboratories, Inc. ("Barr"), Hoechst Marion Roussel, Inc. ("HMR"), and Watson Pharmaceuticals, Inc. ("Watson") were potential generic manufacturers of Cipro. Plaintiffs are direct purchasers of Cipro, who allege that defendants violated federal antitrust law when they settled a patent infringement lawsuit by entering into collusive agreements that blocked the entry of low-cost generic versions of Cipro into the prescription drug market.

BACKGROUND

Hatch-Waxman Settlement Agreements

Bayer is the owner of the patent relating to the active ingredient in Cipro, which has been described as the most prescribed antibiotic in the world. The Cipro patent, U.S. Patent No. 4,670,444, was issued on June 2, 1987 and was scheduled to expire on December 9, 2003.[1]

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[1]Bayer obtained an additional six-month period of pediatric exclusivity from the Food and Drug Administration (FDA) until June 9, 2004. See 21 U.S.C. § 355a(b)(1)(B)(i)(II).

In 1991, Barr sought to market a generic version of Cipro pursuant to the expedited FDA approval process established by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585. Under the Hatch-Waxman Act, a pharmaceutical company can seek approval to market generic versions of an approved branded drug without having to re-establish the drug's safety and effectiveness by filing an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j)(2)(A), (8)(B). Where, as here, a generic manufacturer seeks to enter the market before the expiration of the branded firm's patent, it must file a pre-expiration challenge ("paragraph IV" or "ANDA-IV" certification). 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The ANDA-IV certification requires the generic firm to demonstrate the bioequivalence of its proposed version of the drug, see 21 C.F.R. § 314.94(a)(9), and to state the basis for its claim of invalidity or noninfringement of the branded firm's patent, see 21 U.S.C. § 355(j)(2)(B)(iv)(II).

An ANDA-IV certification itself constitutes an act of infringement, triggering the branded manufacturer's right to sue. 35 U.S.C. § 271(e)(2)(A). Indeed, the branded manufacturer must sue within 45 days of receiving notice of the ANDA-IV in order to stay the generic firm's entry into the market. 21 U.S.C. § 355(j)(5)(B)(iii).[2] Thus, the Hatch-Waxman Act redistributes the relative risks between the patent holder and the generic manufacturer, allowing generic manufacturers to challenge the validity of the patent without incurring the costs of market entry or the risks of damages from infringement. See Ark. Carpenters Health & Welfare Fund v. Bayer AG (In re Ciprofloxacin

[2]Although this statutory stay is typically called the "thirty-month stay," in fact the stay can last for over four years. Compare 21 U.S.C. § 355(j)(5)(B)(iii) (default maximum duration of stay is thirty months provided notice of ANDA IV is received more than five years after ANDA approval) with § 355(j)(5)(F)(ii) (result of earlier-filed ANDA IV is that stay is lengthened, ending five years plus thirty months after FDA approval of the branded drug).

Hydrochloride Antitrust Litig.), 544 F.3d 1323, 1338 (Fed. Cir. 2008).

The first generic firm to file an ANDA-IV is rewarded with a 180-day exclusive right to market its generic version of the drug. 21 U.S.C. § 355(j)(5)(B)(iv).[3] However, only the first-filed ANDA-IV is eligible for the 180-day exclusivity period: even if the first filer loses, withdraws, or settles its challenge, subsequent filers do not become eligible for the exclusivity period.[4]

The Bayer-Barr Lawsuit

Barr filed an ANDA-IV challenging Bayer's Cipro patent in October 1991.[5] Bayer sued Barr for patent infringement in the Southern District of New York within 45 days of its receipt of notice of Barr's filing, triggering the Hatch-Waxman statutory stay.[6] Barr subsequently entered into an agreement with other defendants herein, also potential generic manufacturers of Cipro, to share the costs and benefits of the patent litigation.

In June 1996, the district court denied the parties' cross-motions for summary judgment. In

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[3] This 180-day exclusivity period became law without discussion in the relevant House Report and without debate. See H.R. Rep. No. 98-857, p. 1, at 28 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2661. Moreover, it was apparently not contemplated at the time of passage that the regulatory scheme would facilitate collusion between branded and generic firms. See e.g., S. Rep. No. 107-167, at 4 (2002) ("Agreeing with smaller rivals to delay or limit competition is an abuse of the Hatch-Waxman law . . . .").

[4] In Joblove v. Barr Labs. Inc, (In re Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187 (2d Cir. 2005) (Tamoxifen"), the panel majority suggested otherwise, repeating the district court's claim that the exclusivity period cedes to the first ANDA filer to successfully defend. Compare Tamoxifen, 466 F.3d at 214, with In re Tamoxifen Citrate Antitrust Litig., 277 F. Supp. 2d 121, 134 (E.D.N.Y. 2003). As we discuss in Section 5, infra, this aspect of our Tamoxifen decision was erroneous. See C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement As a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553, 1583-86 (2006).

[5] Barr claimed that the patent was invalid on the following grounds: (1) obviousness; (2) obviousness type double counting; and (3) inequitable conduct.

[6] The parties subsequently agreed to extend the stay until after the entry of final judgment.

January 1997 — approximately two weeks prior to the scheduled trial —

Bayer and Barr entered into a "reverse exclusionary payment" (or "pay-for-delay") settlement: that is, the patent holder (Bayer) agreed to pay the alleged infringer to settle the lawsuit, and in exchange, the alleged infringer agreed not to enter the market.[7] Under the terms of the settlement agreement, Bayer agreed to (1) pay $49.1 million immediately; (2) make quarterly payments of between $12.5 and $17.125 million for the duration of the patent except for the last six months prior to the patent's expiration;[8] and (3) provide the generic manufacturers a guaranteed license to sell brand-name Cipro at a reduced rate for six months prior to the patent's expiration. In exchange, Barr conceded the patent's validity and agreed not to market a generic version of Cipro prior to the patent's expiration.[9]

Plaintiffs' Antitrust Lawsuit

In 2000, direct and indirect purchasers of Cipro filed over thirty antitrust lawsuits against Bayer under federal and state law. These cases were consolidated by the Multi-District Litigation Panel in the Eastern District of New York. See In re Ciprofloxacin Hydrocholoride Antitrust Litig.,

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[7]To be more precise, the parties executed separate settlement agreements between: (1) Bayer and Barr, and (2) Bayer and HMR/Rugby, which was subsequently acquired by Watson. Bayer, Barr, and HMR also executed a supply agreement.

[8]As an alternative to quarterly payments, the settlement gave Bayer the right to either provide Barr with a license to sell Bayer-manufactured Cipro at a royalty rate of 70% of Bayer's average selling price for brand-name Cipro. Bayer elected to make quarterly payments instead. Settlement payments ultimately totaled $398.1 million.

[9]Barr reserved its right to reinstate its ANDA-IV if Bayer's patent were later held to be invalid. Four generic manufacturers – Ranbaxy, Schein, Mylan, and Carlsbad – subsequently challenged the Cipro patent. Ranbaxy's challenge was dismissed as moot in October 1999. Mylan's and Schein's consolidated challenges were dismissed at summary judgment and this dismissal was affirmed on appeal. Bayer AG v. Schein Pharm., Inc., 129 F. Supp. 2d 705 (D.N.J. 2001), aff'd, 301 F.3d 1306 (Fed. Cir. 2002). Carlsbad's challenge was rejected after a nine-day bench trial. Bayer AG v. Carlsbad Tech., Inc., No. Civ. 01-867-B (S.D. Cal. Aug. 26, 2002).

166 F. Supp. 2d 740, 745 (E.D.N.Y. 2001) ("Cipro I"). Plaintiffs allege that defendants' settlement exceeded the scope of Bayer's patent rights because Bayer effectively paid its potential competitors hundreds of millions of dollars not to challenge its patent. Plaintiffs also allege that the agreements were unlawful because Barr was permitted to reclaim the 180-day market exclusivity period if a subsequent challenger was successful in having the patent invalidated, and because the generic manufacturers agreed not to file any ANDA-IV certifications for products that relate to Cipro. But for the challenged agreements, plaintiffs assert that (1) Barr would have entered the market pending resolution of the patent litigation; (2) Barr would have prevailed in the litigation and entered the market; or (3) Bayer would have granted Barr a license to market a generic version of Cipro to avoid a trial on the patent's validity. On cross-motions for summary judgment, the district court granted summary judgment for the defendants. In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 548 (E.D.N.Y. 2005) ("Cipro III"). The court stated:

> The ultimate question – and this is the crux of the matter – is not whether Bayer and Barr had the power to adversely affect competition for ciprofloxacin as a whole, but whether any adverse effects on competition stemming from the Agreements were outside the exclusionary zone of the '444 Patent. It goes without saying that patents have adverse effects on competition. However, any adverse effects within the scope of a patent cannot be redressed by antitrust law.

Id. at 523-24 (citations omitted). In eschewing a "post hoc determination of the potential validity of the underlying patent," the court reasoned that "such an approach would undermine the presumption of validity of patents in all cases, as it could not logically be limited to drug patents, and would work a revolution in patent law." Id. at 529.

The district court also found that the agreements did not allow Barr to manipulate the

exclusivity period to obstruct subsequent challengers of the patent. Id. at 540-41; see also Cipro II, 261 F. Supp. 2d at 243-47. The court summarized as follows:

> [I]n the absence of any evidence that the Agreements created a bottleneck on challenges to the '444 Patent, or that they otherwise restrained competition beyond the scope of the claims of the '444 Patent, the Agreements have not had any anti-competitive effects on the market for ciprofloxacin beyond that which are permitted under the '444 Patent. The fact that Bayer paid what in absolute numbers is a handsome sum to Barr to settle its lawsuit does not necessarily reflect a lack of confidence in the '444 Patent, but rather the economic realities of what was at risk. There is simply no precedent for plaintiffs' argument that the parties to a settlement are required to preserve the public's interest in lower prices. Such a rule would only result in parties being less likely to reach settlements, aside from undermining well-settled principles of patent law. Finally, to even attempt to quantify the public's interest in a patent settlement between private parties would require devaluing patents across the board, a result that would contravene the presumption of validity afforded by Congress and impact the very way patent licenses are handled in countless daily transactions.

Cipro III , 363 F. Supp. 2d at 540-41.

Plaintiffs timely appealed. This Court retained jurisdiction over the direct purchaser plaintiffs' appeals, but transferred the indirect purchaser plaintiffs' appeal to the Federal Circuit.[10]

DISCUSSION

We review the district court's grant of summary judgment de novo, construing evidence in the manner most favorable to the nonmoving party. Horvath v. Westport Library Ass'n, 362 F.3d 147,

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[10]The indirect purchaser plaintiffs amended their complaint to add state-law, Walker Process antitrust claims, so-called based on the Supreme Court's decision in Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., which recognized an antitrust claim when patents are obtained by fraud. 382 U.S. 172, 177 (1965). Because the Walker Process claims are preempted by patent law, see Cipro III, 363 F. Supp. 2d at 543-44, we transferred the indirect purchaser plaintiffs' appeal to the Federal Circuit, while retaining jurisdiction over the direct purchaser plaintiffs' appeals. The Federal Circuit ultimately affirmed the district court on the indirect purchaser plaintiffs' claims, agreeing with the district court's conclusion that the settlement did not restrain competition beyond the exclusionary zone of the Cipro patent. 544 F.3d 1323, 1333 (Fed. Cir. 2008).

151 (2d Cir. 2004) (citation omitted). Summary judgment is appropriate only where "there is no genuine issue as to any material fact and . . . the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

1. Section 1 of the Sherman Act

The Sherman Act provides that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal." 15 U.S.C. § 1. Although by its terms, the Act prohibits "every" restraint of trade, the Supreme Court "has long recognized that Congress intended to outlaw only unreasonable restraints." State Oil Co. v. Khan, 522 U.S. 3, 10 (1997). Agreements that have a "predictable and pernicious anticompetitive effect, and . . . limited potential for procompetitive benefit" are deemed per se unlawful. Id. Most conduct, however, is subject to so-called "rule of reason" analysis. See Texaco Inc. v. Dagher, 547 U.S. 1, 5 (2006).

Rule of reason analysis proceeds in three steps. First, the plaintiff bears the initial burden of showing that the defendant's conduct "had an actual adverse effect on competition as a whole in the relevant market." Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., Inc., 996 F.2d 537, 543 (2d Cir. 1993) (emphasis in original). If plaintiff satisfies this burden, the burden then shifts to defendant to offer evidence that its conduct had pro-competitive effects. Id. If defendant is able to offer such proof, the burden shifts back to plaintiff, who must prove that any legitimate competitive effects could have been achieved through less restrictive alternatives. Id.

2. Reverse Exclusionary Payment Settlements, Antitrust Law, and Tamoxifen

Plaintiffs argue that when Bayer paid Barr to withdraw its challenge to the Cipro patent, defendants effectively entered into a market-sharing agreement in restraint of trade. Patent

settlements, like all private contracts, are subject to antitrust scrutiny. Cf. Standard Oil Co. v. United States, 283 U.S. 163, 169 (1931) ("The limited monopolies granted to patent owners do not exempt them from the prohibitions of the Sherman Act . . . ."); see also B. Braun Med., Inc. v. Abbott Labs., 124 F.3d 1419, 1426-27 (Fed. Cir. 1997) (the Sherman Act prevents patentees from obtaining a greater monopoly than was inherent in the relevant patent grant). Thus, like ordinary contracts, patent settlements cannot take the form of "market-sharing agreements." See Palmer v. BRG of Georgia, Inc., 498 U.S. 46, 49 (1990) (per curiam) (market-sharing agreement is unlawful on its face); United States v. Sealy, Inc., 388 U.S. 350, 357-58 (1967) (same); see also 12 Herbert Hovenkamp, Antitrust Law ¶ 2030b, at 213 (2d ed. 2005) ("[T]he law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition").

The question, therefore, is whether patent settlements in which the generic firm agrees to delay entry into the market in exchange for payment fall within the scope of the patent holder's property rights, or whether such settlements are properly characterized as illegal market-sharing agreements. Authorities are divided on this question. The Federal Trade Commission ("FTC"), the U.S. antitrust enforcement agency charged with supervising the pharmaceutical industry, has long insisted that reverse exclusionary payment settlements violate antitrust law and has challenged numerous agreements as unreasonable restraints of trade.[11] Although it initially took a different view,

[11] E.g. Anticompetitive Patent Settlements in the Pharmaceutical Industry: The Benefits of a Legislative Solution: Hearing Before the S. Comm. on the Judiciary, 110th Cong. (2007) (statement of Jon Leibowitz, FTC Commissioner), available at http://www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_ senate.pdf (criticizing the "extremely lenient view" taken by some toward reverse exclusionary agreements and alleging that reverse exclusionary agreements result in massive wealth transfers from consumers to pioneer drug producers); see also Concurring Statement of Commissioner Jon Leibowitz, FTC v. Watson Pharmaceuticals et. al. (Feb. 2, 2009), available at http://ftc.gov/speeches/leibowitz/090202watsonpharm.pdf.

the United States has since maintained that reverse exclusionary payment settlements may violate antitrust laws. See Brief for the United States as Amicus at 12, Joblove v. Barr Labs., Inc., No. 06-830, 2007 WL 1511527 (U.S. May 23, 2007). Many academic commentators share the United States's view.[12]

Most courts, by contrast, including this Court, Joblove v. Barr Labs. Inc, (In re Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187, 216 (2d Cir. 2005) ("Tamoxifen"), have held that the right to enter into reverse exclusionary payment agreements fall within the terms of the exclusionary grant conferred by the branded manufacturer's patent. See In re Ciprofloxacin Antitrust Litig., 544 F.3d at 1333; Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1076 (11th Cir. 2005). But see La. Wholesale Drug Co. v. Hoechst Marion Roussel, Inc. (In re Cardizem CD Antitrust Litig.), 332 F.3d 896, 908 (6th Cir. 2003) (holding such agreements to be per se illegal); In re Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279 (S.D. Fla. 2005) (same).

Particularly relevant here is this Court's decision in Tamoxifen. The plaintiffs in Tamoxifen challenged a reverse exclusionary payment settlement between Zeneca and Barr that the parties entered into after a district court had declared Zeneca's patent invalid. 466 F.3d at 193. At the 12(b)(6) stage, Tamoxifen rejected as speculative plaintiffs' allegation that Barr would have

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[12]See, e.g., C. Scott Hemphill, Paying for Delay, 81 N.Y.U. L. Rev. at 1561-62 (2006) (arguing that a settlement should be accorded a presumption of illegality if the settlement both restricts the generic firm's ability to market a competing drug and includes compensation from the innovator to the generic firm); Herbert Hovenkamp, Mark Janis, & Mark A. Lemley, Anticompetitive Settlement of Intellectual Property Disputes, 87 Minn. L. Rev. 1719, 1759-60 (2003) (proposing that a defendant would overcome the presumptive unlawfulness of a reverse payment settlement by "showing both (1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit"). But see Alan Devlin, The Stochastic Relationship Between Patents and Antitrust, 5 J. Competition L. & Econ. 75, 108 (2009) ("uncritical application of standard principles of competition law to information markets may be myopic.").

prevailed on appeal but for the settlement agreement. Id. at 203-04. Assuming the truth of plaintiffs' allegation that the exclusion payments exceeded the profits Barr would have obtained upon entering the market as a generic competitor, the Tamoxifen court determined that the plaintiffs had no antitrust claim because a patent holder is entitled to protect its "lawful monopoly over the manufacture and distribution of the patented product." Id. at 205, 208-09.

Notably, Tamoxifen expressly adopted aspects of the lower court's summary judgment decision in this case, holding:

> Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.

Id. at 213 (citing Cipro III, 363 F. Supp. 2d at 535). The Tamoxifen court ruled that the settlement agreement did not exceed the scope of the patent where (1) there was no restriction on marketing non-infringing products; (2) a generic version of the branded drug would necessarily infringe the branded firm's patent; and (3) the agreement did not bar other generic manufacturers from challenging the patent. Id. at 213-15; cf. Cipro III, 363 F. Supp. 2d at 540-41; Cipro II, 261 F. Supp. 2d at 241-47.

Since Tamoxifen rejected antitrust challenges to reverse payments as a matter of law, we are bound to review the Cipro court's rulings under the standard adopted in Tamoxifen. See 466 F.3d at 208-12. We therefore proceed to evaluate plaintiffs' claims under Tamoxifen.[13] Plaintiffs do not argue that the patent infringement lawsuit was a sham or that the Cipro patent was procured by fraud. Thus, the only reasonable basis for distinguishing Tamoxifen would be if plaintiffs demonstrated that

[13]Our jurisdiction over plaintiffs' claims is also established by Tamoxifen. See 466 F.3d at 199-200.

the settlement agreement here, unlike in Tamoxifen, exceeded the scope of the Cipro patent. Plaintiffs cannot establish this because a generic version of Cipro would necessarily infringe Bayer's patent. Tamoxifen explained that unlike "formulation patents," which cover only specific formulations or delivery methods for a compound, a "compound patent" "by its nature, excludes all generic versions of the drug." 466 F.3d at 214. Bayer's Cipro patent is a compound patent. Id. Thus, Barr's agreement to refrain from manufacturing generic Cipro encompasses only conduct that would infringe Bayer's patent rights.

Plaintiffs also claim that the challenged agreements contained ancillary restraints outside the scope of the patent: (1) Barr was permitted under the agreements to manipulate its rights to the 180-day market exclusivity period; and (2) Barr and HMR agreed to refrain from filing future ANDA-IV certifications related to Cipro.[14] Tamoxifen recognized that a plaintiff can have antitrust claims where a Hatch-Waxman settlement allows the generic manufacturer to manipulate the 180-day exclusivity period in a manner that bars subsequent challenges to the patent or precludes the generic manufacturer from marketing non-infringing products unrelated to the patent. See Tamoxifen, 466 F.3d at 213-19; see also Cardizem CD, 332 F.3d at 907-09. In this case, however, plaintiffs have not shown that the settlement agreements allowed manipulation of the exclusivity period or prohibited the marketing of non-infringing products.

Plaintiffs contend that Barr's insistence on its right to reclaim the 180-day exclusivity period caused other generic manufacturers to delay subsequent challenges. Specifically, they maintain that Mylan delayed its challenge because it perceived Barr's continued assertion of a right to the 180-day

[14]Plaintiffs argued below that the agreements were unlawful because Barr and HMR conceded the validity of several additional patents related to Cipro. See Cipro II, 261 F. Supp. 2d at 254. Plaintiffs do not press this argument on appeal.

exclusivity as an obstruction to their entry into the market. This argument is unpersuasive. Although the settlement agreement allows Barr to reinstate its ANDA-IV if a subsequent patent challenge were successful, a reinstated ANDA-IV certification would not have entitled Barr to the 180-day exclusivity period based on the law in effect at the time of settlement.[15] Thus, the district court properly determined that Barr forfeited its challenge to the patent and thus any right to 180-day exclusivity, and that other generic manufacturers were able to subsequently challenge the Cipro patent. See Cipro II, 261 F. Supp.2d at 243;[16] cf. Tamoxifen, 466 F.3d at 218-19 (rejecting a claim that Barr manipulated the 180-day exclusivity period based on similar analysis).

Finally, plaintiffs argue that Barr and HMR unlawfully agreed to refrain from filing ANDA-

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[15]When Bayer and Barr entered the settlement in January 1997, an ANDA filer's right to 180-day exclusivity was contingent on their "successful defense" of a patent infringement suit. See 21 C.F.R. § 314.107(c)(1). Since Barr did not successfully defend the lawsuit by entering a settlement, the court found it had no claim to the exclusivity period. Cipro II, 261 F. Supp. 2d at 243, 247. After courts rejected the FDA's "successful defense" requirement, see, e.g., Mova Pharm. Corp. v. Shalala, 140 F.3d 1060 (D.C. Cir. 1998), the FDA permanently removed it. See Effective Date and Approval of an Abbreviated New Drug Application, 63 Fed. Reg. 59710, 57911 (Nov. 5, 1998). But this occurred after the agreements in this case were executed. Plaintiffs argue that the questionable validity of the regulation suggests that Barr tried to exploit it in order to keep other manufacturers from the market, but Tamoxifen specifically rejected this argument. 466 F.3d at 218-19. Plaintiffs assert that the Tamoxifen panel did not consider a district court case that found an earlier FDA exclusivity requirement contrary to the Hatch-Waxman statute. See Inwood Labs., Inc. v. Young, 723 F. Supp. 1523 (D.D.C. 1989), vacated as moot, 43 F.3d 712 (D.C. Cir. 1989). However, this argument is unavailing because the FDA promulgated the "successful defense" requirement in effect at the time of the agreements here after the Inwood Labs decision. See Abbreviated New Drug Application Regulations; Patent and Exclusivity Provision, 59 Fed. Reg. 50338 (Oct. 3, 1994). The established law at the time of the agreement precluded Barr from retaining a right to exclusivity.

[16]Plaintiffs contend that the district court erred in Cipro III when it admitted that, based on its ruling in Cipro II, it need not consider this claim "anew." See 363 F. Supp. 2d at 540 (citing Cipro II, 261 F. Supp. 2d at 243-47). Cipro II considered the claim in the context of plaintiffs' motion for partial summary judgment. When addressing defendants' motion for summary judgment in Cipro III, the district court was required to view the evidence in plaintiffs' favor. Because the district court's analysis is consistent with Tamoxifen, which was decided at the 12(b)(6) stage, the district court did not err by incorporating its analysis from Cipro II.

IVs even after the Cipro patent expired. The agreement states that Barr and HMR are "not to . . . file any [ANDA] relating to Cipro with . . . a certification made pursuant to Paragraph IV of the Act." The district court reasonably interpreted the agreement to mean that Barr and HMR would not file any ANDA-IV certifications challenging the validity of the Cipro patent. See Cipro II, 261 F. Supp. 2d at 253. This reading was consistent with Barr's concession of validity and with the fact that there could not be an ANDA-IV certification for a non-infringing version of the drug since Bayer had a compound patent.

Plaintiffs contend that Tamoxifen is distinguishable because, by relying on the district court's Cipro III decision, Tamoxifen adopted an erroneous view of the facts of this case i.e.22, Tamoxifen was based on an erroneous view of the facts of Cipro. This argument is not persuasive. Tamoxifen relied on Cipro III not for its facts, but rather for its legal and policy analysis. The Tamoxifen majority urged against addressing the probability that a patent was invalid and deferred to a patent holder's desire to settle patent challenges, concluding that a patent holder could reasonably decide to pay money, even more than a generic manufacturer would make on the market, to guarantee protection of its patent. See Tamoxifen, 466 F.3d at 210 ("[A] rule [limiting the amount of exclusion payments] would . . . fail to give sufficient consideration to the patent holder's incentive to settle . . . .").

Plaintiffs and amici also argue that Tamoxifen runs afoul of the purpose of the Hatch-Waxman Act. The purpose of the Hatch-Waxman Act, 21 U.S.C. § 355, was "to make available more low cost generic drugs." H.R. Rep. No. 98-857, pt. 1, at 14 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647. The Act sought to accomplish this objective by providing an incentive through the ANDA-IV certification procedure for generic manufacturers to challenge presumptively

valid patents, which, if successful, would result in exclusivity for the first successful challenger and the entry of generic drugs into the market. The market entry of generic drugs arising from successful Hatch-Waxman challenges can result in significant savings to consumers. See Brief for AARP as Amicus at 8-9 (discussing generic manufacturers' challenges to the Prozac patent and Paxil patent where generic entry resulted in $2.5 and $2 billion in consumer savings, respectively).[17]

These policy arguments cannot be addressed here. As defendants note, this panel is bound by Tamoxifen "absent a change in law by higher authority or by way of an in banc proceeding." United States v. Snow, 462 F.3d 55, 65 n.11 (2d Cir. 2006). However, there are several reasons why this case might be appropriate for reexamination by our full Court.

First, the United States has itself urged us to repudiate Tamoxifen, arguing that Tamoxifen adopted an improper standard that fails to subject reverse exclusionary payment settlements to appropriate antitrust scrutiny. Brief for the United States as Amicus at 6, 14-15;[18] see also Brief for the United States as Amicus in Joblove v. Barr Labs., Inc., No. 06-830, 2007 WL 1511527, at *1 (U.S. May 23, 2007) (describing the Tamoxifen standard as "incorrect"). In the pending case, the United States argues:

> This Court's Tamoxifen standard inappropriately permits patent holders to contract their way out of the statutorily imposed risk that patent litigation could lead to invalidation of the patent while claiming antitrust immunity for that private contract. . . . [T]his standard effectively bars considering whether the agreement might violate the antitrust laws, and so offers no protection

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[17]One study found that generic manufacturers prevailed in 73% of the Hatch-Waxman lawsuits that were tried to verdict. See Brief for American Antitrust Institute ("AAI") as Amicus at 3 (citing Generic Drug Entry Prior to Patent Expiration, at vii (2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf).

[18]The Department of Justice provided a brief at the request of the panel. Though the United States argues that our Tamoxifen decision was wrongly decided, it "takes no position on the ultimate merits of this appeal." Brief for the United States as Amicus at 9.

to the public interest in eliminating undeserved patents.

Brief for the United States as Amicus at 14-15.[19] While acknowledging that patent-holders are entitled to settle disputes over the validity of their patent, the United States proposes that excessive reverse payment settlements be deemed presumptively unlawful unless a patent-holder can show that settlement payments do not greatly exceed anticipated litigation costs. Id. at 27-32.

Second, there is evidence that the practice of entering into reverse exclusionary payment settlements has increased since we decided Tamoxifen. Prior to our Tamoxifen decision, there were fourteen settlements of Hatch-Waxman lawsuits, none of which involved reverse payments to a generic manufacturer. Brief for American Antitrust Institute as Amicus at 3 (citing Fed. Trade Comm'n, Generic Drug Entry: Prior to Patent Expiration 31-32, 34 (July 2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf). After Tamoxifen, however, plaintiffs represent that twenty of twenty-seven Hatch-Waxman settlements have involved reverse payments.

Third, after Tamoxifen was decided, a principal drafter of the Hatch-Waxman Act criticized the settlement practice at issue here. See 148 Cong. Rec. S7565 (July 30, 2002) (remarks of Sen. Hatch) ("As coauthor of the [Hatch-Waxman Act], I can tell you that I find these type[s] of reverse payment collusive arrangements appalling"); see also 146 Cong. Rec. E1538-02 (Sept 20, 2000) (remarks of Rep. Waxman) ("[R]equir[ing] companies seeking to reach secret, anticompetitive

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[19]Amici similarly argue that the Tamoxifen court's permissive approach to reverse payments offers protection to patent holders beyond that envisioned by patent law, is inconsistent with the principle that antitrust cases be decided "based upon demonstrable economic effect rather than . . . formalistic line drawing," Brief for AAI as Amicus at 5, (quoting Continental T.V., Inc. v. GTE Sylvania, Inc., 433 U.S. 36 (1977)), and did not give sufficient consideration to the public interest in "authoritative testing of patent validity." Brief for Nat'l Assoc. of Chain Drug Stores, Inc. as Amicus at 20 (quoting Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313, 343 (1971)).

agreements to disclose them to the FTC . . . . [would] ensure that existing antitrust and drug approval laws are enforced to the letter.").[20]

Fourth and finally, Tamoxifen relied on an unambiguous mischaracterization of the Hatch-Waxman Act. Tamoxifen was based in no small part on the panel majority's belief that reverse exclusionary settlements "open[] the [relevant] patent to immediate challenge by other potential generic manufacturers . . . spurred by the additional incentive . . . of potentially securing the 180-day exclusivity period available upon a victory in a subsequent infringement lawsuit." 466 F.3d at 214. The panel majority's claim that the statutory exclusivity period cedes to the first ANDA filer to successfully defend was erroneous. See C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement As a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553, 1583-86 (2006). Contrary to our suggestion in Tamoxifen, later ANDA-IV filers are not eligible for the 180-day exclusivity period. Id. at 1584; cf. 21 C.F.R. § 314.107(c)(1)-(2) (only first-filer eligible for exclusivity period); 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42,873, 42,874 (Aug. 6, 1999) (revisiting and re-endorsing FDA interpretation of exclusivity provisions); 21 U.S.C. § 355(j)(5)(D)(iii) (codifying FDA interpretation).

In addition, unlike Tamoxifen, which was decided at the 12(b)(6) stage, this case involves a summary judgment decision based on a full record. This case could provide our full Court with an opportunity to revisit the issues in play in Tamoxifen and to analyze the competing interests that

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[20]We are not insensitive to "the oft-repeated warning that the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one." Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc., 447 U.S. 102, 117 (1980) (quotation marks omitted). However, remarks by an Act's author do not trigger the typical concern about post-enactment legislative history, namely that "the losers in the legislative arena hope to persuade the courts to give them the victory after all." Richard A. Posner, How Judges Think 344 (2008).

underlie antitrust challenges to reverse payment settlements in light of the full record and the arguments of the parties and amici, including the United States, that have been raised in this appeal. We therefore invite plaintiffs-appellants to petition for in banc rehearing.

CONCLUSION

In sum, as long as Tamoxifen is controlling law, plaintiffs' claims cannot survive. Accordingly, we AFFIRM the judgment of the district court. However, we believe there are compelling reasons to revisit Tamoxifen with the benefit of the full Court's consideration of the difficult questions at issue and the important interests at stake. We therefore invite the plaintiffs-appellants to petition for rehearing in banc.