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

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

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August Term, 2008

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

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

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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.

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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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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.