In Re: Tamoxifen Citrate Antitrust Litigation

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

466 F.3d 187
August 10, 2006, Decided

[*190] SACK, Circuit Judge:

This appeal, arising [**3] out of circumstances surrounding a lawsuit in which a drug manufacturer alleged that its patent for the drug tamoxifen citrate ("tamoxifen") was about to be infringed, and the suit's subsequent settlement, requires us to address issues at the intersection of intellectual property law and antitrust law. Although the particular factual circumstances of this case are unlikely to recur, the issues presented have been much litigated and appear to retain their vitality.

The plaintiffs appeal from a judgment of the United States District Court for the Eastern District of New York (I. Leo Glasser, Judge) dismissing their complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). The plaintiffs claim that the defendants conspired, under an agreement settling a patent infringement lawsuit among the defendants in 1993 while an appeal in that lawsuit was pending, to monopolize the market for tamoxifen -- the most widely prescribed drug for the treatment of breast cancer -- by suppressing competition from generic versions of the drug. The settlement agreement included, among other things, a so-called "reverse payment" of $ 21 million from the defendant patent-holders [**4] Zeneca, Inc., AstraZeneca Pharmaceuticals LP, and AstraZeneca PLC (collectively "Zeneca") to the defendant generic manufacturer Barr Laboratories, Inc. ("Barr"), and a license from Zeneca to Barr allowing Barr to sell an unbranded version of Zeneca-manufactured tamoxifen. The settlement agreement was contingent on obtaining a vacatur of the judgment of the district court that had heard the infringement action holding the patent to be invalid.

The district court in the instant case concluded that the settlement did not restrain trade in violation of the antitrust laws, and that the plaintiffs suffered no antitrust injury from that settlement. Because we conclude that we have jurisdiction to hear the appeal and that the behavior of the defendants alleged in the complaint would not violate antitrust law, we affirm the judgment of the district court.

REGULATORY BACKGROUND

Before setting forth the salient facts of this case and addressing the merits of the plaintiffs' appeal, it may be helpful to outline the relevant regulatory background. [1]

[**5] The Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified at scattered sections of title 21 of the United States Code), prohibits the introduction or delivery for introduction into interstate commerce of "any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of [21 U.S.C. ß 355] is effective with respect to such drug." 21 U.S.C. ß 355(a). Subsection (b) describes the process of filing a New Drug Application ("NDA")

with the United States Food and Drug Administration [*191] ("FDA"), which is typically a costly and time-consuming procedure in which the applicant attempts to establish the safety and effectiveness of the drug. Id. ß 355(b). In 1984, in order to accelerate the approval process for low-cost generic versions of established drugs, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (codified at scattered sections of titles 21 and 35 of the United States Code). Among other things, the Act added subsection (j) to section 355 [**6] . Hatch-Waxman Act ß 101. Subsection (j) provides for an Abbreviated New Drug Application ("ANDA") to the FDA for the bioequivalent form of a drug already approved for safety and effectiveness. 21 U.S.C. ß 355(j)(1), (j)(2)(A), (j)(7)(A). Subsection (j)(7)(A) further provides that the Secretary of the FDA will create and maintain a list of such approved drugs. Id. ß 355(j)(7)(A). This list, Approved Drug Products with Therapeutic Equivalence Evaluations, is commonly known as the "Orange Book." [2] See id.; http://www.fda.gov/cder/orange/default.htm.

[**7] An ANDA filer must certify, with respect to each patent that claims the listed drug for the bioequivalent of which the ANDA filer is seeking approval, [3] either that no patent was filed for the listed drug (a "paragraph I" certification), that the patent has expired (a "paragraph II" certification), that the patent will expire on a specified date and the ANDA filer will not market the drug until that date (a "paragraph III" certification), or that the patent is invalid or would not be infringed by the manufacture, use, or sale of the new drug (a "paragraph IV" certification). 21 U.S.C. ß 355(j)(2)(A)(vii).

[**8] An ANDA filer that elects a paragraph IV certification must notify each affected patent owner of the certification. Id. ß 355(j)(2)(B)(i). The patent owner then has forty-five days after the date it receives such notice to bring suit against the ANDA filer for patent infringement. Id. ß 355(j)(5)(B)(iii). If no patent owner brings such a lawsuit during this period, the FDA may immediately approve the ANDA. Id. If, however, the patent owner brings suit during this period, the FDA's final approval of the ANDA is stayed for thirty months after the date the patent owner received the requisite notice or until a district court [4] returns a decision as to [*192] the validity of the patent or its infringement if it does so before the thirty-month period expires. Id.

[**9] Any approval letter sent by the FDA before the expiration of the prescribed stay and before a court ruling of patent invalidity or non-infringement is tentative. See 21 C.F.R. ß 314.105(d). If before the thirty months expire a court rules that the patent is either invalid or not infringed, the tentative approval of the ANDA is made effective as of the date of judgment. 21 U.S.C. ß 355(j)(5)(B)(iii)(I). If after thirty months there has been no ruling on patent validity or infringement and the stay expires, the ANDA filer can distribute and market the drug but, depending on the court's later patent ruling, an ANDA filer that chooses to follow this course may thereafter become liable for infringement damages if infringement is found. See In re Ciprofloxacin Hydrochloride Antitrust Litig., 166 F. Supp. 2d 740, 744 (E.D.N.Y. 2001) ("Cipro I").

As an incentive for generic manufacturers to choose the paragraph IV certification route and, in the course of pursuing such applications, to challenge weak patents, the Hatch-Waxman Act offers the first ANDA filer with a paragraph IV certification, under certain [**10] conditions, the opportunity to market its generic drug exclusively for 180 days. To this end, the FDA may not approve the ANDA of a subsequent filer until 180 days after the earlier of the date (1) the first ANDA filer commercially markets the generic drug or (2) a court of competent jurisdiction concludes that the patent in question is invalid or not infringed. [5] 21 U.S.C. ß 355(j)(5)(B)(iv)(I)-(II).

[**11] Until 1998 (and, therefore, at the time of the settlement that is the subject of this appeal), the 180-day exclusivity period was available to the first ANDA filer to elect a paragraph IV certification, but only if the ANDA filer successfully defended against a lawsuit for infringement of the relevant patent. See 21 C.F.R. ß 314.107(c)(1) (1995). This so-called "successful defense" requirement was challenged in 1997 in two separate lawsuits. In each, the circuit court rejected the requirement as inconsistent with the Hatch-Waxman Act. See Mova Pharm. Corp. v. Shalala, 329 U.S. App. D.C. 341, 140 F.3d 1060, 1076 (D.C. Cir. 1998); Granutec, Inc. v. Shalala, Nos. 97-1873, 97-1874, 1998 WL 153410, at *7, 1998 U.S. App. LEXIS 6685, at *19-*21 (4th Cir. Apr. 3, 1998) (unpublished opinion).

In June 1998, in response to these decisions, the FDA published a "Guidance for Industry." See Ctr. for Drug Evaluation & Research, Food & Drug Admin., U.S. Dep't of Health and Human Servs., Guidance for Industry: 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act [**12] (June 1998), available at http://www.fda.gov/cder/guidance/2576fnl.pdf (last visited May 12, 2005). In the "Guidance," the FDA expressed its intention to remove the "successful defense" requirement formally through rulemaking and made clear that thereafter even ANDA paragraph IV filers that are not the subject of lawsuits will be eligible for the 180-day exclusivity period. Id. at 4-5. "Until such time as the rulemaking process [was] complete, FDA . . . regulate[d] directly from the statute, and . . . ma[de] decisions on 180-day generic drug exclusivity on a case-by-case basis." Id. at 4. Later that year, the FDA formally revoked the "successful defense" requirement. See Effective Date of Approval of an Abbreviated New Drug Application, 63 Fed. Reg. 59,710, 59,710 (Nov. 5, 1998), 21 C.F.R. ß 314.107 (1999).

FACTUAL AND PROCEDURAL BACKGROUND

Tamoxifen, the patent for which was obtained by Imperial Chemical Industries, PLC, ("ICI") on August 20, 1985, is sold by Zeneca (a former subsidiary of ICI which succeeded to the ownership rights of the tamoxifen patent) under the trade name Nolvadex(R). [6] Tamoxifen is [**13] the most widely prescribed drug for the treatment of breast cancer. Indeed, it is the most prescribed cancer drug in the world. In December 1985, four months after ICI was awarded the patent, Barr filed an ANDA with the FDA requesting the agency's approval for Barr to market a generic version of tamoxifen that it had developed. Barr amended its ANDA in September 1987 to include a paragraph IV certification.

In response, on November 2, 1987 -- within the required forty-five days of Barr's amendment of its ANDA to include a paragraph IV certification -- ICI filed a patent infringement lawsuit against Barr and Barr's raw material supplier, Heumann Pharma GmbH & Co. ("Heumann"), in the United States District Court for the Southern District of New York. [7] See Imperial Chems. Indus., PLC v. Barr Labs., 126 F.R.D. 467, 469 (S.D.N.Y. 1989). On April 20, 1992, the district court (Vincent L. Broderick, Judge) declared ICI's [**14] tamoxifen patent invalid based on the court's conclusion that ICI had deliberately withheld "crucial information" from the Patent and Trademark Office regarding tests that it had conducted on laboratory animals with respect to the safety and effectiveness of the drug. See Imperial Chem. Indus., PLC v. Barr Labs., Inc., 795 F. Supp. 619, 626-27 (S.D.N.Y. 1992) ("Tamoxifen I"). Those tests had revealed hormonal effects "opposite to those sought in humans," which, the court found, could have "unpredictable and at times disastrous consequences." Id. at 622.

ICI appealed the district court's judgment to the United States Court of Appeals for the Federal Circuit. In 1993, while the appeal was pending, the parties entered into a confidential settlement agreement (the "Settlement Agreement") which is the [**15] principal subject of this appeal. In the Settlement Agreement, Zeneca (which had succeeded to the ownership rights of the patent) and Barr agreed that in return for $ 21 million and a non-exclusive license to sell Zeneca-manufactured tamoxifen in the United States under Barr's label, rather than Zeneca's trademark Nolvadex(R), Barr would change its ANDA paragraph IV certification to a paragraph III certification, thereby agreeing [*194] that it would not market its own generic version of tamoxifen until Zeneca's patent expired in 2002. See In re Tamoxifen Citrate Antitrust Litig., 277 F. Supp. 2d 121, 125-26 (E.D.N.Y. 2003) ("Tamoxifen II"). Zeneca also agreed to pay Heumann $ 9.5 million immediately, and an additional $ 35.9 million over the following ten years. The parties further agreed that if the tamoxifen patent were to be subsequently declared invalid or unenforceable in a final and (in contrast to the district court judgment in Tamoxifen I) unappealable judgment by a court of competent jurisdiction, Barr would be allowed to revert to a paragraph IV ANDA certification. Thus if, in another lawsuit, a generic marketer prevailed as Barr had prevailed in [**16] Tamoxifen I, and that judgment was either not appealed or was affirmed on appeal, Barr would have been allowed to place itself in the same position (but for the 180-day head start, if it was available) that it would have been in had it prevailed on appeal in Tamoxifen I, rather than settling while its appeal was pending in the Federal Circuit.

The plaintiffs allege that as a part of the Settlement Agreement, Barr "understood" that if another generic manufacturer attempted to market a version of tamoxifen, Barr would seek to prevent the manufacturer from doing so by attempting to invoke the 180-day exclusivity right possessed by the first "paragraph IV" filer. Compl. P58. According to the plaintiffs, this understanding among the defendants effectively forestalled the introduction of any generic version of tamoxifen, because, five years later -- only a few weeks before other generic manufacturers were to be able to begin marketing their own versions of tamoxifen -- Barr did in fact successfully claim entitlement to the exclusivity period. It thereby prevented those manufacturers from entering the tamoxifen market until 180 days after Barr triggered the period by commercially [**17] marketing its own generic version of the drug. In fact, Barr had not yet begun marketing its own generic version and had little incentive to do so because, pursuant to the Settlement Agreement, it was already able to market Zeneca's version of tamoxifen.

Meanwhile, pursuant to the Settlement Agreement which was contingent on the vacatur of the district court judgment in Tamoxifen I, Barr and Zeneca filed a "Joint Motion to Dismiss the Appeal as Moot and to Vacate the Judgment Below." See Tamoxifen II, 277 F. Supp. 2d at 125. The Federal Circuit granted the motion, thereby vacating the district court's judgment that the patent was invalid. See Imperial Chem. Indus., PLC v. Heumann Pharma GmbH & Co., 991 F.2d 811, No. 92-1403, 1993 WL 118931, at *1, 1993 U.S. App. LEXIS 14872, at *1-*2 (Fed. Cir. Mar. 19, 1993) (unpublished opinion). Such a vacatur, while generally considered valid as a matter of appellate procedure by courts at the time of the Settlement Agreement, see U.S. Philips Corp. v. Windmere Corp., 971 F.2d 728, 731 (Fed. Cir. 1992), was shortly thereafter held to be invalid in nearly all circumstances [**18] by the Supreme Court, see U.S. Bancorp Mortg. Co. v. Bonner Mall Pshp., 513 U.S. 18, 27-29, 115 S. Ct. 386, 130 L. Ed. 2d 233 (1994). [8]

In the years after the parties entered into the Settlement Agreement and the Federal Circuit vacated the district court's judgment, [9] three other generic manufacturers [*195] filed ANDAs with paragraph IV certifications to secure approval of their respective generic versions of tamoxifen:

Novopharm Ltd., in June 1994, Mylan Pharmaceuticals, Inc., in January 1996, and Pharmachemie, B.V., in February 1996. [10] See Tamoxifen II, 277 F. Supp. 2d at 126-27. Zeneca responded to each of these certifications in the same manner that it had responded to Barr's: by filing a patent infringement lawsuit within [**19] the forty-five day time limit provided by 21 U.S.C. ß 355(j)(5)(B)(iii) . See id. In each case, the court rejected the generic manufacturer's attempt to rely on the vacated Tamoxifen I decision, and -- contrary to the Tamoxifen I judgment -- upheld the validity of Zeneca's tamoxifen patent. See Zeneca Ltd. v. Novopharm Ltd., No. 96-1364, 1997 WL 168318, at *2-*4, 1997 U.S. App. LEXIS 6634, at *4-*11 (Fed. Cir. Apr. 10, 1997) (unpublished opinion) (affirming the judgment of the United States District Court for the District of Maryland declining to give Tamoxifen I collateral estoppel effect or to apply U.S. Bancorp retroactively and deciding that Zeneca's patent was valid); Zeneca Ltd. v. Pharmachemie B.V., No. 96-12413, 2000 WL 34335805, at *15, 2000 U.S. Dist LEXIS 22631, at *51-*53 (D. Mass. Sept. 11, 2000) (concluding that Zeneca had not engaged in inequitable conduct and that the patent was valid); AstraZeneca UK Ltd. v. Mylan Pharms., Inc., No. 00-2239, slip op. at 2-3 (W.D. Pa. Nov. 30, 2000) (entering stipulated consent order that FDA approval for Mylan would not be effective before the [**20] expiration of the tamoxifen patent).

While Mylan and Pharmachemie's lawsuits were pending in district court, the FDA's "successful defense" rule, requiring that a generic manufacturer seeking to market an allegedly patented drug "successfully defend" its patent infringement lawsuit in order to receive the 180-day exclusivity period -- which at the time the Settlement Agreement [**21] was entered into would have excluded Barr from benefitting from the exclusivity period -- was, as noted, held invalid. See Mova Pharm. Corp. v. Shalala, 955 F. Supp. 128, 130-32 (D.D.C. 1997), aff'd in part and rev'd in part on other grounds, 329 U.S. App. D.C. 341, 140 F.3d 1060 (D.C. Cir. 1998); Granutec, Inc. v. Shalala, Nos. 97-1873, 97-1874, 1998 WL 153410, at *7, 1998 U.S. App. LEXIS 6685, at *19-*21 (4th Cir. Apr. 3, 1998) (unpublished opinion). In June 1998, at the time the FDA removed the requirement, Barr -- armed with the new rule rendering the first ANDA paragraph IV filer eligible for the 180-day exclusivity period even if it had not successfully defended a patent infringement suit -- attempted to block final FDA approval of other generic versions of tamoxifen by claiming entitlement to the 180-day exclusivity period. See Tamoxifen II, 277 F. Supp. 2d at 127 (citing "Petition for Stay of Action" filed with the FDA on June 26, 1998).

At the time, Pharmachemie had received tentative approval from the FDA to distribute its version of the drug, Mylan was awaiting approval to do the same, and both [**22] Pharmachemie and Mylan's thirty-month stays under section 355(j)(5)(B)(iii), triggered by Zeneca's infringement lawsuits, were soon to expire. See Compl. PP61-63 (stating that the 30-month stay for Mylan was scheduled to expire on July 10, 1998, and for Pharmachemie in August 1998); [*196] Pharmachemie B.V. v. Barr Labs., Inc., 349 U.S. App. D.C. 284, 276 F.3d 627, 630 (D.C. Cir. 2002) (noting that Pharmachemie was granted tentative approval on April 3, 1997); Mylan Pharms. Inc. v. Henney, 94 F. Supp. 2d 36, 44 (D.D.C. 2000), vacated and dismissed as moot sub nom. Pharmachemie B.V. v. Barr Labs., Inc., 350 U.S. App. D.C. 290, 284 F.3d 125 (D.C. Cir. 2002) (per curiam). Because of the rule change, however, the FDA was able to, and on March 2, 1999, did, grant Barr's petition to confirm its entitlement to the exclusivity period despite the fact that it had settled, rather than "successfully defended" against, Zeneca's lawsuit. See Tamoxifen II, 277 F. Supp. 2d at 127. The FDA's action effectively delayed the marketing of other generic versions of tamoxifen unless and until Barr triggered [**23] and exhausted its 180-day exclusivity period by selling its

own generic form of the drug, rather than the version manufactured by Zeneca. As noted, Barr had little incentive to do so because it was already distributing Zeneca's version of tamoxifen.

Pharmachemie and Mylan challenged the FDA's decision. On March 31, 2000, in Mylan Pharmaceuticals, the United States District Court for the District of Columbia ruled in Pharmachemie's and Mylan's favor. 94 F. Supp. 2d at 54. It concluded that, although Judge Broderick's ruling of invalidity in Tamoxifen I had been vacated by the Settlement Agreement, that ruling was still a court decision sufficient to trigger Barr's 180-day exclusivity period, which therefore had already expired. See Mylan Pharms., 94 F. Supp. 2d at 54. As a result, on June 26, 2000, the FDA revoked Barr's claim to the 180-day exclusivity period. See Tamoxifen II, 277 F. Supp. 2d at 127.

On appeal, however, the District of Columbia Circuit vacated the district court's decision as moot. Pharmachemie, 276 F.3d at 634; Pharmachemie, 284 F.3d at 125. The court noted that subsequent [**24] to the FDA's decision to approve Barr's application, the district court had ruled against Pharmachemie in Zeneca's patent infringement lawsuit against it. See Pharmachemie, 276 F.3d at 629. Thus, even if, as the district court held in Mylan, Barr's 180-day exclusivity period had run, Pharmachemie and Mylan [11] were prohibited by the judgments against them in the patent litigation from marketing their generic versions of tamoxifen until Zeneca's patent expired. Zeneca's patent on tamoxifen expired on August 20, 2002, and generic manufacturers began marketing their own versions of tamoxifen soon thereafter.

Proceedings in the District Court

While these generic manufacturers were litigating the validity of Zeneca's patent on tamoxifen, consumers and consumer groups in various parts of the United States [**25] filed some thirty lawsuits challenging the legality of the 1993 Settlement Agreement between Zeneca and Barr. See Tamoxifen II, 277 F. Supp. 2d at 127. Those lawsuits were subsequently transferred by the Judicial Panel on Multidistrict Litigation to the United States District Court for the Eastern District of New York. Subsequently, a consolidated class action complaint embodying the claims was filed. In re Tamoxifen Citrate Antitrust Litig., 196 F. Supp. 2d 1371 (J.P.M.L. 2001); Tamoxifen II, 277 F. Supp. 2d at 127. In the consolidated lawsuit, the plaintiffs alleged that the Settlement Agreement unlawfully (1) enabled Zeneca and Barr to resuscitate a patent that the district court had already held to be invalid and unenforceable; (2) facilitated Zeneca's continuing monopolization of the market for tamoxifen; (3) provided [*197] for the sharing of unlawful monopoly profits between Zeneca and Barr; (4) maintained an artificially high price for tamoxifen; and (5) prevented competition from other generic manufacturers of tamoxifen. See Tamoxifen II, 277 F. Supp. 2d at 127-28. At the heart of the lawsuit was the contention [**26] that the Settlement Agreement enabled Zeneca and Barr effectively to circumvent the district court's invalidation of Zeneca's tamoxifen patent in Tamoxifen I, which, the plaintiffs asserted, would have been affirmed by the Federal Circuit. The result of such an affirmance, according to the plaintiffs, would have been that Barr would have received approval to market a generic version of tamoxifen; Barr would have begun marketing tamoxifen, thereby triggering the 180-day exclusivity period; other generic manufacturers would have introduced their own versions of tamoxifen upon the expiration of the exclusivity period, with Zeneca collaterally estopped from invoking its invalidated patent as a defense; and, as a result, the price for tamoxifen would have declined substantially below the levels at which the Zeneca-manufactured drug in fact sold in the market shared by Zeneca and Barr through the Settlement Agreement. Id. at 128. The defendants moved to dismiss the class action complaint pursuant

to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted.

On May 15, 2003, in a thorough and [**27] thoughtful opinion, the district court granted the defendants' motion to dismiss. See id. at 140. The court noted that although market-division agreements between a monopolist and a potential competitor ordinarily violate the Sherman Act, they are not necessarily unlawful when the monopolist is a patent holder. Id. at 128-29. Pursuant to a patent grant, the court reasoned, a patent holder may settle patent litigation by entering into a licensing agreement with the alleged infringer without running afoul of the Sherman Act. Id. at 129. Yet, the court continued, a patent holder is prohibited from acting in bad faith "beyond the limits of the patent monopoly" to restrain or monopolize trade. Id. (quoting United States v. Line Material Co., 333 U.S. 287, 308, 68 S. Ct. 550, 92 L. Ed. 701 (1948) (internal quotation marks omitted)).

Analyzing the terms and impact of the Settlement Agreement, the district court concluded that the agreement permissibly terminated the litigation between the defendants, which "cleared the field for other generic manufacturers to challenge the patent." Id. at 133 [**28] . "Instead of leaving in place an additional barrier to subsequent ANDA filers, the Settlement Agreement in fact removed one possible barrier to final FDA approval -- namely, the existence of ongoing litigation between an existing ANDA filer and a subsequent filer." Id. To the court, this factor distinguished the case from similar cases in which other circuits had held settlement agreements to be unlawful, where the agreement in question did not conclude the underlying litigation and instead prolonged the period during which other generic manufacturers could not enter the market. Id. (distinguishing the Settlement Agreement from the agreements addressed in In re Terazosin Hydrochloride Antitrust Litig., 164 F. Supp. 2d 1340, 1346-47 (S.D. Fla. 2000), rev'd sub nom. Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294 (11th Cir. 2003), cert. denied, 543 U.S. 939, 125 S. Ct. 308, 160 L. Ed. 2d 248 (2004), and In re Cardizem CD Antitrust Litig., 105 F. Supp. 2d 618, 632 (E.D. Mich. 2000), aff'd, 332 F.3d 896 (6th Cir. 2003), cert. denied sub nom. Andrx Pharm., Inc. v. Kroger Co., 543 U.S. 939, 125 S. Ct. 307, 160 L. Ed. 2d 248 (2004)) [**29] .

The district court was also of the view that the defendants could not be held liable [*198] for Barr's FDA petition to preserve its 180-day exclusivity period even if this was a term of the defendants' negotiated Settlement Agreement. Id. at 135. It reasoned that at the time of settlement, Barr could not have successfully pursued its FDA application because the FDA continued to apply the "successful defense" rule until 1997. Id. at 134. It was only after 1997 that Barr petitioned the FDA to preserve its exclusivity period. The court concluded that Barr's petition was

> an attempt to petition a governmental body in order to protect an arguable interest in a statutory right based on recent developments in the court and at the FDA. As such, the FDA Petition was protected activity under the First Amendment, and long-settled law established that the Sherman Act, with limited exceptions, does not apply to petitioning administrative agencies.

Id. at 135. The court concluded that the plaintiffs' complaint therefore did not sufficiently allege a bad-faith settlement in violation of the Sherman [**30] Act. Id. at 136.

The district court also concluded that even if the plaintiffs had stated an antitrust violation, they did not suffer antitrust injury from either Barr's exclusivity period or the Settlement Agreement and the resulting vacatur of the district court's judgment in Tamoxifen I invalidating the tamoxifen patent. Id. at 136-38. The court noted that "[a]ntitrust injury . . . must be caused by something other than the regulatory action limiting entry to the market." Id. at 137. The court attributed "the lack of competition in the market" not to "the deployment of Barr's exclusivity period, but rather [to] the inability of the generic companies to invalidate or design around" the tamoxifen patent, and their consequent loss of the patent litigation against Zeneca. Id. This was so, the district court concluded, even if Barr's petition to the FDA had delayed the approval of Mylan's ANDA. Id. at 137. Any "injury" suffered by the plaintiffs, said the court, "is thus not antitrust injury, but rather the result of the legal monopoly that a patent holder possesses." Id. at 138 [**31] .

The district court also rejected the plaintiffs' contention that "the settlement and vacatur deprived other generic manufacturers of the ability to make the legal argument that the [Tamoxifen I] judgment (if affirmed) would collaterally estop Zeneca from claiming the [tamoxifen] patent was valid in future patent litigation with other ANDA filers." Id. It reasoned that there is no basis for the assertion that "forcing other generic manufacturers to litigate the validity of the [tamoxifen] patent[] is an injury to competition." Id. The court also referred to the other generic manufacturers' subsequent litigation against Zeneca over the validity of the tamoxifen patent, in which Zeneca prevailed, as additional reason to reject the plaintiffs' assertion that the Federal Circuit would have affirmed Judge Broderick's judgment invalidating the tamoxifen patent. Id.

The district court therefore dismissed the plaintiffs' Sherman Act claims. Id. It also dismissed the plaintiffs' state-law claims, which had alleged violations of the antitrust laws of seventeen states and violations of consumer protection and unfair competition laws of twenty-one states, because [**32] those claims were based on the same allegations as the plaintiffs' federal antitrust claims. Id. at 138-40. The plaintiffs appeal the dismissal of their claims.

On July 28, 2003, the defendants moved in this Court to transfer the appeal to the Federal Circuit on the ground that that court alone has jurisdiction to entertain this appeal. For the reasons stated below, we deny the defendants' motion and affirm [*199] the district court's judgment dismissing the plaintiffs' complaint.

DISCUSSION

I. Jurisdiction

The defendants argue that this Court does not have jurisdiction to hear this appeal because the case arises under federal patent law and the Federal Circuit has exclusive appellate jurisdiction over such appeals. The plaintiffs respond that we, rather than the Federal Circuit, have appellate jurisdiction because this case does not, on the basis of their well-pleaded complaint, substantially turn on issues of federal patent law. We agree with the plaintiffs….

II. Standard of Review

We review a decision on a motion to dismiss de novo. Gregory v. Daly, 243 F.3d 687, 691 (2d Cir. 2001)….

III. The Plaintiffs' Antitrust Claims

A. The Tension between Antitrust Law and Patent Law

[**40] With the ultimate goal of stimulating competition and innovation, the Sherman Act prohibits "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States," [13] 15 U.S.C. ß 1, and "monopoliz[ation], or attempt[s] to monopolize, or combin[ations] or conspir[acies] . . . to monopolize any part of the trade or commerce among the several States," id. ß 2. [14] By contrast, also with the ultimate goal of stimulating competition and innovation, patent law grants an innovator "the right to exclude others [*202] from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States" for a limited term of years. 35 U.S.C. ß 154(a)(1)-(2); see also Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215, 100 S. Ct. 2601, 65 L. Ed. 2d 696 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention."). It is the tension between restraints on anti-competitive behavior imposed by the Sherman Act and [**41] grants of patent monopolies under the patent laws, as complicated by the Hatch-Waxman Act, that underlies this appeal. See, e.g., United States v. Singer Mfg. Co., 374 U.S. 174, 196-97, 83 S. Ct. 1773, 10 L. Ed. 2d 823, 1963 Dec. Comm'r Pat. 547 (1963) ("[T]he possession of a valid patent . . . does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly.") (internal quotation marks and citation omitted); cf. Andrx Pharms., Inc. v. Biovail Corp. Int'l, 347 U.S. App. D.C. 178, 256 F.3d 799, 802 (D.C. Cir. 2001) ("Although the Congress was interested in increasing the availability of generic drugs, it also wanted to protect the patent rights of the pioneer applicants."), cert. denied, 535 U.S. 931, 122 S. Ct. 1305, 152 L. Ed. 2d 216 (2002); Schering-Plough Corp. v. F.T.C., 402 F.3d 1056, 1067 (11th Cir. 2005) ("Although the exclusionary power of a patent may seem incongruous with the goals of antitrust law, a delicate balance must be drawn between the two regulatory schemes.").

B. The Plaintiffs' Allegations

1. Settlement of a Patent Validity Lawsuit. The plaintiffs contend that several factors -- including that Tamoxifen I was settled after the tamoxifen patent had been held invalid by the district court, making the patent unenforceable at the time of settlement -- indicate that if their allegations are proved, the defendants violated the antitrust laws. They argue that the district court in the case before us erred by treating the tamoxifen patent as valid and enforceable. Instead, they say, in accordance with the never-reviewed judgment in Tamoxifen I, the district court in this case should [**43] have treated the patent as presumptively invalid for purposes of assaying the sufficiency of the plaintiffs' complaint.

We begin our analysis against the backdrop of our longstanding adherence to the principle that "courts are bound to encourage" the settlement of litigation. Gambale v. Deutsche Bank AG, 377 F.3d 133, 143 (2d Cir. 2004). "Where a case is complex and expensive, and resolution of the case will benefit the public, the public has a strong interest in settlement. The trial court must protect the public interest, as well as the interests of the parties, by encouraging the most fair and efficient resolution." United States v. Glens Falls Newspapers, Inc., 160 F.3d 853, 856-57 (2d Cir. 1998). As the Eleventh Circuit recently noted in drug patent litigation similar to the one before us, "There is

no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation." Schering-Plough, 402 F.3d at 1075.

It is well settled that "[w]here there are legitimately conflicting [patent] claims . . ., a settlement by agreement, rather than litigation, is not [**44] precluded by the [Sherman] Act," although such a settlement may ultimately have an adverse effect on competition. Standard Oil Co. v. United States, 283 U.S. 163, 171, 51 S. Ct. 421, 75 L. Ed. 926 (1931); cf. Flex-Foot, Inc. v. CRP, Inc., 238 F.3d 1362, 1369 (Fed. Cir. 2001) ("[W]hile the federal patent laws favor full and free competition in the use of ideas in the public domain over the technical requirements of contract doctrine, [*203] settlement of litigation is more strongly favored by the law."); Nestle Co. v. Chester's Mkt., Inc., 756 F.2d 280, 284 (2d Cir. 1985) ("[T]he district court imposed the heavy burden on trademark defendants of having to continue to litigate when they would prefer to settle, a ruling without precedent."), overruled on other grounds, U.S. Bancorp Mortg. Co. v. Bonner Mall Pshp., 513 U.S. 18, 27-29, 115 S. Ct. 386, 130 L. Ed. 2d 233 (1994); Duplan Corp. v. Deering Milliken, Inc., 540 F.2d 1215, 1220 (4th Cir. 1976) ("[T]he settlement of patent litigation, in and of itself, does not violate the antitrust laws."); Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003) [**45] (Posner, J., sitting by designation) ("The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.").

Rules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation. See Valley Drug, 344 F.3d at 1308; Daniel A. Crane, Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications, 54 Fla. L. Rev. 747, 749 (2002). Although forcing patent litigation to continue might benefit consumers in some instances, "patent settlements can . . . promote efficiencies, resolving disputes that might otherwise block or delay the market entry of valuable inventions." Joseph F. Brodley & Maureen A. O'Rourke, Preliminary Views: Patent Settlement Agreements, Antitrust, Summer 2002, at 53. [15] As the Fourth Circuit has observed, "It is only when settlement agreements are entered into in bad faith and are utilized as part of a scheme to restrain or monopolize [**46] trade that antitrust violations may occur." Duplan Corp., 540 F.2d at 1220.

[**47] We cannot judge this post-trial, pre-appeal settlement on the basis of the likelihood vel non of Zeneca's success had it not settled but rather pursued its appeal. As the Supreme Court noted in another context, "[i]t is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case." Whitmore v. Arkansas, 495 U.S. 149, 159-60, 110 S. Ct. 1717, 109 L. Ed. 2d 135 (1990). Similarly, "[n]o one can be certain that he will prevail in a patent suit." Asahi Glass, 289 F. Supp. 2d at 993 (emphasis in original). We cannot guess with any degree of assurance what the Federal Circuit would have done on an appeal from the district court's judgment in Tamoxifen I. Cf. In re Ciprofloxacin [*204] Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188, 200-01 (E.D.N.Y. 2003) ("Cipro II") (noting that courts should not speculate about the outcome of litigation) (citing Boehm v. Commissioner, 146 F.2d 553 (2d Cir.), aff'd, 326 U.S. 287, 66 S. Ct. 120, 90 L. Ed. 78, 1945 C.B. 353 (1945)); In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 529 (E.D.N.Y. 2005) [**48] ("Cipro III ") ("[M]aking the legality of a patent settlement agreement, on pain of treble damages, contingent on a later court's assessment of the patent's validity might chill patent settlements altogether."). And because in this case any such guess is retrospective, it would in any event be of limited value in assessing the behavior of the defendants at the relevant time: when they were entering into the Settlement Agreement. See Valley Drug, 344 F.3d at 1306 ("[T]he reasonableness of agreements under the antitrust

laws are to be judged at the time the agreements are entered into.") (citing, inter alia, SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1207 (2d Cir. 1981), cert. denied, 455 U.S. 1016, 102 S. Ct. 1708, 72 L. Ed. 2d 132 (1982)).

As the plaintiffs correctly point out, the Federal Circuit would have reviewed Judge Broderick's factual findings underlying his conclusion of invalidity with considerable deference, rather than engaging in a presumption of validity. See Shelcore, Inc. v. Durham Indus., Inc., 745 F.2d 621, 624-25 (Fed. Cir. 1984) ("The presumption of validity does not guide our [**49] analysis on appeal. Rather, we review the findings and conclusions of a district court under the appropriate standards of review."). But it takes no citation to authority to conclude that appellants prevail with some frequency in federal courts of appeals even when a high degree of deference is accorded the district courts from which the appeals are taken. [16] Accordingly, it does not follow from the deference that was due by the Federal Circuit to the district court in Tamoxifen I that Zeneca would have been unsuccessful on appeal. See Cipro III, 363 F. Supp. 2d at 529 (noting that with few exceptions "courts assessing the legality of patent settlement agreements have not engaged in a post hoc determination of the potential validity of the underlying patent . . . when deciding whether an agreement concerning the patent violates antitrust law").

[**50] The facts of this case provide an additional reason for us to embrace the general rule that we will ordinarily refrain from guessing what a court will hold or would have held. As noted earlier, federal district courts in later lawsuits seeking to enforce the tamoxifen patent concluded, contrary to the court in Tamoxifen I, that the patent was, in fact, valid. While we do not think that these results enable us to estimate the chances that the Federal Circuit would have reversed the judgment of the district court in Tamoxifen I, they at least suggest the extent to which the outcome of such proceedings may be unpredictable. [17]

[**51] [*205] The fact that the settlement here occurred after the district court ruled against Zeneca seems to us to be of little moment. There is a risk of loss in all appeals that may give rise to a desire on the part of both the appellant and the appellee to settle before the appeal is decided. [18] Settlements of legitimate disputes, even antitrust and patent disputes of which an appeal is pending, in order to eliminate that risk, are not prohibited. That Zeneca had sufficient confidence in its patent to proceed to trial rather than find some means to settle the case first should hardly weigh against it.

[**52] We conclude, then, that without alleging something more than the fact that Zeneca settled after it lost to Barr in the district court that would tend to establish that the Settlement Agreement was unlawful, the assertion that there was a bar -- antitrust or otherwise -- to the defendants' settling the litigation at the time that they did is unpersuasive.

2. Reverse Payments. Payments pursuant to the settlement of a patent suit such as those required under the Settlement Agreement are referred to as "reverse" payments because, by contrast, "[t]ypically, in patent infringement cases the payment flows from the alleged infringer to the patent holder." David A. Balto, Pharmaceutical Patent Settlements: The Antitrust Risks, 55 Food & Drug L.J. 321, 335 (2000). Here, the patent holder, which, if its patent is valid, has the right to prevent the alleged infringer from making commercial use of it, nonetheless pays that party not to do so. Seeking to supply the "something more" than the fact of settlement that would render the Settlement Agreement unlawful, the plaintiffs allege that the value of the reverse payments from Zeneca to Barr thereunder "greatly exceeded [**53] the value of Barr's 'best case scenario' in winning the appeal . . . and entering the market with its own generic product." Appellants' Br. at 27.

It is the size, not the mere existence, of Zeneca's reverse payment that the plaintiffs point to in asserting that they have successfully pleaded a Sherman Act cause of action. In explaining our analysis, though, it is worth exploring the notion advanced by others that the very existence of reverse payments establishes unlawfulness. See Balto, supra, at 335 ("A payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties in entering the agreement and the rent-preserving effect of that agreement."); Herbert Hovenkamp et al., Anticompetitive Settlement of Intellectual Property Disputes, 87 Minn. L. Rev. 1719, 1751 (2003) ("[T]he problem of exclusion payments can arise whenever the patentee has an incentive to postpone determination of the validity of its patent.").

[*206] Heeding the advice of several courts and commentators, we decline to conclude (and repeat that the plaintiffs do not ask us to conclude) that reverse payments are [**54] per se violations of the Sherman Act such that an allegation of an agreement to make reverse payments suffices to assert an antitrust violation. We do not think that the fact that the patent holder is paying to protect its patent monopoly, without more, establishes a Sherman Act violation. See Valley Drug, 344 F.3d at 1309 (concluding that the presence of a reverse payment, by itself, does not transform an otherwise lawful settlement into an unlawful one); Asahi Glass, 289 F. Supp. 2d at 994 (asserting that "[a] ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive," and observing that if the parties decided not to settle, and the patent holder ultimately prevailed in the infringement lawsuit, there would be the same level of competition as in the reverse payment case); Thomas F. Cotter, Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley, 87 Minn. L. Rev. 1789, 1807 (2003) [**55] (noting that "the plaintiff often will have an incentive to pay the defendant not to enter the market, regardless of whether the former expects to win at trial," which "suggests that reverse payments should not be per se illegal, since they are just as consistent with a high probability of validity and infringement as they are with a low probability. It also suggests that reverse payments should not be per se legal for the same reason."). But see Cardizem, 332 F.3d at 911 (calling a forty-million-dollar reverse payment to a generic manufacturer "a naked, horizontal restraint of trade that is per se illegal because it is presumed to have the effect of reducing competition in the market for Cardizem CD and its generic equivalents to the detriment of consumers").

As other courts have noted, moreover, reverse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them. See Cipro II, 261 F. Supp. 2d at 252 (noting that the Hatch-Waxman Act "has the unintended consequence of altering the litigation risks of patent lawsuits" and concluding that "reverse payments [**56] are a natural by-product of the Hatch-Waxman process"); accord Schering-Plough, 402 F.3d at 1074.

In the typical patent infringement case, the alleged infringer enters the market with its drug after the investment of substantial sums of money for manufacturing, marketing, legal fees, and the like. The patent holder then brings suit against the alleged infringer seeking damages for, inter alia, its lost profits. If the patent holder wins, it receives protection for the patent and money damages for the infringement. And in that event, the infringer loses not only the opportunity to continue in the business of making and selling the infringing product, but also the investment it made to enter the market for that product in the first place. And it must pay damages to boot. It makes sense in such a

circumstance for the alleged infringer to enter into a settlement in which it pays a significant amount to the patent holder to rid itself of the risk of losing the litigation.

By contrast, under the Hatch-Waxman Act, the patent holder ordinarily brings suit shortly after the paragraph IV ANDA has been filed -- before the filer has spent substantial sums on the [**57] manufacturing, marketing, or distribution of the potentially infringing generic drug. The prospective generic manufacturer therefore has [*207] relatively little to lose in litigation precipitated by a paragraph IV certification beyond litigation costs and the opportunity for future profits from selling the generic drug. Conversely, there are no infringement damages for the patent holder to recover, and there is therefore little reason for it to pursue the litigation beyond the point at which it can assure itself that no infringement will occur in the first place.

Accordingly, a generic marketer has few disincentives to file an ANDA with a paragraph IV certification. The incentive, by contrast, may be immense: the profits it will likely garner in competing with the patent holder without having invested substantially in the development of the drug, and, in addition, possible entitlement to a 180-day period (to be triggered at its inclination) during which it would be the exclusive seller of the generic drug in the market. [19]

[**58] The patent holder's risk if it loses the resulting patent suit is correspondingly large: It will be stripped of its patent monopoly. At the same time, it stands to gain little from winning other than the continued protection of its lawful monopoly over the manufacture and sale of the drug in question.

"Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. Because of the Hatch-Waxman scheme, [the generic challengers] gain[] considerable leverage in patent litigation: the exposure to liability amount[s] to litigation costs, but pale[s] in comparison to the immense volume of generic sales and profits." Schering-Plough, 402 F.3d at 1074 (citation omitted).

Under these circumstances, we see no sound basis for categorically condemning reverse payments employed to lift the uncertainty surrounding the validity and scope of the holder's patent. [20]

[**59] [*208] 3. "Excessive" Reverse Payments. As we have noted, although there are those who contend that reverse payments are in and of themselves necessarily unlawful, the plaintiffs are not among them. They allege instead that "[t]he value of the consideration provided to keep Barr's product off the market . . . greatly exceeded the value Barr could have realized by successfully defending its trial victory on appeal and entering the market with its own competitive generic product." Appellants' Br. at 15. The plaintiffs assert that it is that excessiveness that renders the Settlement Agreement unlawful. [21] We agree that even if "reverse payments are a natural by-product of the Hatch-Waxman process," Cipro II, 261 F. Supp. 2d at 252, it does not follow that they are necessarily lawful, see Hovenkamp et al., supra, at 1758 ("We do not think it follows that because it is rational for the patentee to agree to an exclusion payment, that payment cannot be anticompetitive. Far from it."). But

> [o]nly if a patent settlement is a device for circumventing antitrust law is it vulnerable to an antitrust suit. Suppose a seller obtains a patent that [**60] it knows is almost certainly invalid (that is, almost certain not to survive a judicial challenge), sues its competitors, and settles the suit by licensing them to use its patent in exchange for their agreeing not to sell the patented product for less than the price specified in the li-

> cense. In such a case, the patent, the suit, and the settlement would be devices -- masks -- for fixing prices, in violation of antitrust law.

Asahi Glass, 289 F. Supp. 2d at 991. "If, however, there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation." Id. at 992.

[**61] There is something on the face of it that does seem "suspicious" about a patent holder settling patent litigation against a potential generic manufacturer by paying that manufacturer more than either party anticipates the manufacturer would earn by winning the lawsuit and entering the newly competitive market in competition with the patent holder. Why, after all -- viewing the settlement through an antitrust lens -- should the potential competitor be permitted to receive such a windfall at the ultimate expense of drug purchasers? We think, however, that the suspicion abates upon reflection. In such a case, so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly [*209] over the manufacture and distribution of the patented product. [22]

[**62] If the patent holder loses its patent monopoly as a result of defeat in patent litigation against the generic manufacturer, it will likely lose some substantial portion of the market for the drug to that generic manufacturer and perhaps others. The patent holder might also (but will not necessarily) [23] lower its price in response to the competition. The result will be, unsurprisingly, that (assuming that lower prices do not attract significant new purchasers for the drug) the total profits of the patent holder and the generic manufacturer on the drug in the competitive market will be lower than the total profits of the patent holder alone under a patent-conferred monopoly. In the words of the Federal Trade Commission: "The anticipated profits of the patent holder in the absence of generic competition are greater than the sum of its profits and the profits of the generic entrant when the two compete." In re Schering-Plough Corp., No. 9297, slip op. at 27, 2003 WL 22989651, 2003 FTC LEXIS 187 (Fed. Trade Comm'n Dec. 8, 2003), vacated, 402 F.3d 1056 (11th Cir. 2005). It might therefore make economic sense for the patent holder to pay some portion [**63] of that difference to the generic manufacturer to maintain the patent-monopoly market for itself. And, if that amount exceeds what the generic manufacturer sees as its likely profit from victory, it seems to make obvious economic sense for the generic manufacturer to accept such a payment if it is offered. [24] We think [*210] we can safely assume that the patent holder will seek to pay less if it can, but under the circumstances of a paragraph IV Hatch-Waxman filing, as we have discussed, the ANDA filer might well have the whip hand. Cf. Valley Drug, 344 F.3d at 1310 ("Given the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.").

[**65] Of course, the law could provide that the willingness of the patent holder to settle at a price above the generic manufacturer's projected profit betrays a fatal disbelief in the validity of the patent or the likelihood of infringement, and that the patent holder therefore ought not to be allowed to maintain its monopoly position. Perhaps it is unwise to protect patent monopolies that rest on such dubious patents. But even if large reverse payments indicate a patent holder's lack of confidence in its patent's strength or breadth, we doubt the wisdom of deeming a patent effectively invalid on the basis of a patent holder's fear of losing it.

> [T]he private thoughts of a patentee, or of the alleged infringer who settles with him, about whether the patent is valid or whether it has been infringed is not the issue in an antitrust case. A firm that has received a patent from the patent office (and not by fraud . . .), and thus enjoys the presumption of validity that attaches to an issued patent, 35 U.S.C. ß 282, is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them, whatever its private doubts, unless [**66] a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment. It is not "bad faith" to assert patent rights that one is not certain will be upheld in a suit for infringement pressed to judgment and to settle the suit to avoid risking the loss of the rights. No one can be certain that he will prevail in a patent suit.

Asahi Glass, 289 F. Supp. 2d at 992-93 (citation omitted) (emphasis in original).

Such a rule would also fail to give sufficient consideration to the patent holder's incentive to settle the lawsuit without reference to the amount the generic manufacturer might earn in a competitive market, even when it is relatively confident of the validity of its patent -- to insure against the possibility that its confidence is misplaced, or, put another way, that a reviewing court might (in its view) render an erroneous decision. Cf. Schering-Plough, 402 F.3d at 1075-76. Whatever the degree of the patent holder's certainty, there is always some risk of loss that the patent holder [**67] might wish to insure against by settling.

This case is illustrative. It is understandable that however sure Zeneca was at the outset that its patent was valid, settlement might have seemed attractive once it lost in the district court, especially in light of the deferential standard the Federal Circuit was expected to apply on review. But its desire to settle does not necessarily [*211] belie Zeneca's confidence in the patent's validity. Indeed, Zeneca's pursuit of subsequent litigation seeking to establish the tamoxifen patent's validity, and the success of that litigation, strongly suggest that such confidence persisted and was not misplaced. Neither do we think that the settlement's entry after the district court rendered a judgment against Zeneca should counsel against the settlement's propriety. It would be odd to handicap the ability of Zeneca to settle after it had displayed sufficient confidence in its patent to risk a finding of invalidity by taking the case to trial.

We are unsure, too, what would be accomplished by a rule that would effectively outlaw payments by patent holders to generic manufacturers greater than what the latter would be able to earn in the market were they [**68] to defend successfully against an infringement claim. A patent holder might well prefer such a settlement limitation -- it would make such a settlement cheaper -- while a generic manufacturer might nonetheless agree to settle because it is less risky to accept in settlement all the profits it expects to make in a competitive market rather than first to defend and win a lawsuit, and then to enter the marketplace and earn the profits. If such a limitation had been in place here, Zeneca might have saved money by paying Barr the maximum such a rule might allow -- what Barr was likely to earn if it entered the market -- and Barr would have received less than it could have if it were free to negotiate the best deal available -- as it did here. But the resulting level of competition, and its benefit to consumers, would have been the same. The monopoly would have nonetheless endured -- but, to no apparent purpose, at less expense to Zeneca and less reward for Barr.

It strikes us, in other words, as pointless to permit parties to enter into an agreement settling the litigation between them, thereby protecting the patent holder's monopoly even though it may be based on a relatively weak patent, [**69] but to limit the amount of the settlement to the amount of the generic manufacturer's projected profits had it won the litigation.

We are not unaware of a troubling dynamic that is at work in these cases. The less sound the patent or the less clear the infringement, and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder by allowing it to retain the patent. But the law allows the settlement even of suits involving weak patents with the presumption that the patent is valid and that settlement is merely an extension of the valid patent monopoly. So long as the law encourages settlement, weak patent cases will likely be settled even though such settlements will inevitably protect patent monopolies that are, perhaps, undeserved.

We also agree with the Cipro III court's observation that:

> If courts do not discount the exclusionary power of the patent by the probability of the patent's being held invalid, then the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity. This concern, on its face, is [**70] quite powerful. But the answer to this concern lies in the fact that, while the strategy of paying off a generic company to drop its patent challenge would work to exclude that particular competitor from the market, it would have no effect on other challengers of the patent, whose incentive to mount a challenge would also grow commensurately with the chance that the patent would be held invalid.

Cipro III, 363 F. Supp. 2d at 534. There is, of course, the possibility that the patent [*212] holder will continue to buy out potential competition such that a settlement with one generic manufacturer protecting the patent holder's ill-gotten patent monopoly will be followed by other settlements with other generic manufacturers should a second, third, and fourth rise to challenge the patent. We doubt, however, that this scenario is realistic.

Every settlement payment to a generic manufacturer reduces the profitability of the patent monopoly. The point will come when there are simply no monopoly profits with which to pay the new generic challengers. "[I]t is unlikely that the holder of a weak patent could stave off all possible challengers with exclusion payments [**71] because the economics simply would not justify it." Cipro III, 363 F. Supp. 2d at 535 (emphasis supplied). We note in this regard that Zeneca settled its first tamoxifen lawsuit against the first generic manufacturer, Barr, but did not settle, and, as far as we know, did not attempt to settle, the litigation it brought against the subsequent challenging generics, Novopharm, Pharmachemie, and Mylan. (To be sure, the settlement with Barr came after a judgment against Zeneca, while the judgments in Novopharm, Pharmachemie, and Mylan's challenges were for Zeneca.) [25]

[**72] An alternative rule is, of course, possible. As suggested above, the antitrust laws could be read to outlaw all, or nearly all, settlements of Hatch-Waxman infringement actions. Patent holders would be required to litigate each threatened patent to final, unappealable judgment. Only patents that the courts held were valid would be entitled to confer monopoly power on their pro-

prietors. But such a requirement would be contrary to well-established principles of law. As we have rehearsed at some length above, settlement of patent litigation is not only suffered, it is encouraged for a variety of reasons even if it leads in some cases to the survival of monopolies created by what would otherwise be fatally weak patents. It is too late in the journey for us to alter course. [26]

[**73] We generally agree, then, with the Eleventh Circuit insofar as it held in Valley Drug that "'simply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law,' unless the 'exclusionary effects of the agreement' exceed the 'scope of the patent's protection.'" Cipro III, 363 F. Supp. 2d at 538 (quoting Schering-Plough, 402 F.3d at 1076 (alteration omitted)). Whatever damage is done to competition by settlement is done pursuant to [*213] the monopoly extended to the patent holder by patent law unless the terms of the settlement enlarge the scope of that monopoly. "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." Cipro III, 363 F. Supp. 2d at 535.

We further agree with the Cipro III court that absent an extension of the monopoly beyond the patent's scope, an issue that we address in the next section of [**74] this opinion, and absent fraud, which is not alleged here, the question is whether the underlying infringement lawsuit was "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60, 113 S. Ct. 1920, 123 L. Ed. 2d 611 (1993). [27] In this case, the plaintiffs do not contend that they can -- and we conclude that in all likelihood they cannot -- establish that Zeneca's patent litigation was baseless, particularly in light of the subsequent series of decisions upholding the validity of the same patent. Cf. id. at 60 n.5 ("A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham."). Payments, even "excessive" payments, to settle the dispute were therefore not necessarily unlawful.

[**75] 4. The Terms of the Settlement Agreement. Inasmuch as we conclude that neither the fact of settlement nor the amount of payments made pursuant thereto as alleged by the plaintiffs would render the Settlement Agreement unlawful, we must assess its other terms to determine whether they do. As we have explained in the previous section of this opinion, we think that the question is whether the "exclusionary effects of the agreement" exceed the "scope of the patent's protection." Schering-Plough, 402 F.3d at 1076. Looking to other courts that have addressed similar cases for guidance, and accepting the plaintiffs' allegations as true, we conclude that the Settlement Agreement did not unlawfully extend the reach of Zeneca's tamoxifen patent.

First, the Settlement Agreement did not extend the patent monopoly by restraining the introduction or marketing of unrelated or non-infringing products. It is thus unlike the agreement the Sixth Circuit held per se illegal in Cardizem, 332 F.3d at 908, which included not only a substantial reverse [*214] payment but also an agreement that the generic manufacturer would not market non-infringing products. See [**76] id. at 902, 908 & n.13 (quoting the court in Cipro II, 261 F. Supp. 2d at 242, which observed that the Cardizem district court, in condemning the settlement agreement in that case, "'emphasized that the agreement [there] restrained Andrx from marketing other bioequivalent or generic versions of Cardizem that were not at issue in the pending litigation, ... Thus, the court found that the agreement's restrictions extended to noninfringing and/or potentially noninfringing versions of generic Cardizem.'" (alterations in original)); see also Valley Drug,

344 F.3d at 1306 n.18 (observing that if the agreement "also prohibited the marketing of non-infringing terazosin products, prohibited [the generic manufacturer] from marketing infringing products beyond the date a district court held the [relevant] patent invalid, and prohibited [the generic manufacturer] from waiving its 180-day exclusivity period" then the agreement "may be beyond the scope of [the patent holder's] lawful right to exclude and, if so, would expose appellants to antitrust liability"); In re K-Dur Antitrust Litig., 338 F. Supp. 2d 517, 532 (D.N.J. 2004) [**77] (noting, in connection with a private lawsuit involving the same settlement agreements challenged by the FTC in Schering-Plough, that the plaintiffs "alleged that [the generic manufacturer] not only agreed not to enter the market with the allegedly infringing generic drug at issue in the patent litigation, but agreed not to enter the market with any generic competitor drug, irrespective of whether it infringed the patent" and that another potential distributor of generic equivalents also agreed to delay marketing a generic competitor drug and "agreed not to conduct, sponsor, file or support any study of a generic drug's bioequivalence to [the patented drug] before the expiration of the [relevant] patent," and concluding: "These agreements, as alleged, grant rights to Schering in excess of what is granted by the [relevant] patent alone." (emphasis in original)).

Like the patent for the compound ciprofloxacin hydrochloride, which was the subject of dispute in the Cipro cases, and unlike the patents at issue in Cardizem and Valley Drug, Zeneca's tamoxifen patent is not a formulation patent, which covers only specific formulations or delivery methods of [**78] compounds; rather, it is a patent on a compound that, by its nature, excludes all generic versions of the drug. See Appellees' Br. at 23; Cipro II, 261 F. Supp. 2d at 249-50 (observing that the patent in that case covered all formulations and the generic manufacturer could not have avoided it). Because Zeneca's patent therefore precludes all generic versions of tamoxifen, so that any such competing version would, as we understand it, necessarily infringe the patent, the Settlement Agreement did not, by precluding the manufacture of a generic version of tamoxifen, restrain the marketing of any non-infringing products.

Second, the Settlement Agreement ended all litigation between Zeneca and Barr and thereby opened the tamoxifen patent to immediate challenge by other potential generic manufacturers, which did indeed follow -- spurred by the additional incentive (at the time) of potentially securing the 180-day exclusivity period available upon a victory in a subsequent infringement lawsuit, since by vacating the district court judgment and amending its ANDA to remove its paragraph IV certification, Barr appeared to ensure (under procedures in effect at the time) [**79] that it was not eligible for the exclusivity period. See Cipro II, 261 F. Supp. 2d at 242-43 (emphasizing that the settlement in that case extinguished the litigation between Barr and Bayer and [*215] that Barr agreed to withdraw its paragraph IV certification, thus removing any "bottleneck" to future generic entrants). The Agreement thus avoided a "bottleneck" of the type created by the agreements in Valley Drug and Cardizem, which prevented other generic manufacturers from obtaining approval for their own generic versions from the FDA. Rather than resolve the litigation, the settlements in those cases prolonged it by providing incentives to the defendant generic manufacturers not to pursue the litigation avidly. In Cardizem, for example, the settlement included periodic payments to the generic manufacturer during the pendency of the lawsuit in exchange for its promise not to market a generic drug for which it had already received FDA approval, thereby delaying the market entry of other generic manufacturers "who could not enter until the expiration of [the first-moving generic manufacturer's] 180-day period of marketing exclusivity, which [the generic] [**80] had agreed not to relinquish or transfer." Cardizem, 332 F.3d at 907; see also Cipro II, 261 F. Supp. 2d at 243 (noting that in Valley Drug, the generic manufacturer had obtained final FDA approval, yet the set-

tlement agreement "delayed triggering [the generic manufacturer's] 180-day exclusivity period, effectively holding up FDA approval of other generic manufacturers' ANDA IVs.").

The disadvantage purportedly suffered by the plaintiffs is not that Barr somehow prevented others from challenging the patent and obtaining FDA approval; nor is it that no other generic manufacturer tried to do so. It is instead that each of the subsequent challenges failed. While it is true that, had the district court's decision in Zeneca's patent infringement lawsuit against Barr been affirmed, other generic manufacturers would have been allowed to market their drugs, there is no legal requirement that parties litigate an issue fully for the benefit of others. See, e.g., Nestle, 756 F.2d at 284.

Thus the stated terms of the Settlement Agreement include nothing that would place it beyond the legitimate exclusionary scope of Zeneca's [**81] patent: The Settlement Agreement did not have an impact on the marketing of non-infringing or unrelated products, and the Agreement fully resolved the litigation between Zeneca and Barr, clearing the way for other generic manufacturers to seek to enter the market.

Finally, the Settlement Agreement did not entirely foreclose competition in the market for tamoxifen. It included a license from Zeneca to Barr that allowed Barr to begin marketing Zeneca's version of tamoxifen eight months after the Settlement Agreement became effective. The license ensured that money also flowed from Barr to Zeneca, decreasing the value of the reverse payment. By licensing tamoxifen to Barr, Zeneca added a competitor to the market, however limited the competition may have been. Unlike reverse payment settlements that leave the competitive situation as it was prior to the litigation, [28] the reverse payment in this case was pursuant to an agreement that increased competition in the market for tamoxifen -- even if only a little -- almost nine years before the tamoxifen patent was to expire. Cf. Cipro II, 261 F. Supp. 2d at 209 (noting that if the patent holder had not agreed to pay [**82] the generic manufacturers "hundreds of millions of dollars," then the patent holder "would have issued to [the generic manufacturers] a license for distribution of generic Cipro").

[*216] The Settlement Agreement almost certainly resulted in less price competition than if Barr had introduced its own generic version, of course. The plaintiffs allege that the Barr-distributed, Zeneca-manufactured tamoxifen sold at retail for just five percent less than the Zeneca-branded version, Compl. P75, compared with what the plaintiffs allege is a typical initial drop of sixteen percent or more, see Oral Argument Tr., July 12, 2004, at 5, and an eventual drop in a truly competitive market of thirty to eighty percent, Compl. P75. See also Congr. Budget Office, How Increased Competition from Generic [**83] Drugs Has Affected Prices and Returns in the Pharmaceutical Industry 32 (July 1998), available at http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf (last visited May 12, 2005) (describing one study that estimated that the average price of a generic drug fell from sixty percent of the brand-name price to thirty-four percent of the brand-name price as the number of generic manufacturers increased from one to ten). This was competition nonetheless. It was certainly more competition than would have occurred had there been no settlement and had Zeneca prevailed on appeal. Cf. Nestle, 756 F.2d at 284 (noting that the district court erred by not placing more weight on the consequences of requiring the litigation to go forward, such as the fact that "the appellees will be forced to bear the costs and risks of further litigation, including the non-trivial risk of a reversal on the merits").

We conclude that the facts as alleged in the plaintiffs' complaint, if proved, would not establish that the terms of the Settlement Agreement violated the antitrust laws. In the absence of any plausible allegation that the reverse payment provided benefits to Zeneca outside [**84] the scope of the tamoxifen patent, the plaintiffs have not stated a claim for relief with respect to the Settlement Agreement. See Twombly, 425 F.3d at 111.

5. Barr's 180-Day Exclusivity Period. The plaintiffs also advance allegations regarding actions that Barr took with respect to the 180-day exclusivity period to which the first paragraph IV filer is entitled under the Hatch-Waxman Act. We confess that it is not altogether clear to us what the import of those allegations is. The plaintiffs contend that Barr's attempt to assert its exclusivity period in 1998, five years after the date of the Settlement Agreement, should be viewed as "circumstantial evidence demonstrating the anticompetitive consequences of [the] agreement[]" among the defendants. Appellants' Reply Br. at 13. They allege that the Settlement Agreement was drafted "careful[ly] to preserve Barr's" ability to "strategically deploy[]" its claim to the exclusivity period. Compl. P57. And they further allege the existence of an understanding among the defendants as to when and under what circumstances "Barr would assert its claimed exclusivity period rights to prevent . . . FDA approval" [**85] of other generic manufacturers' ANDA applications, "even if Zeneca was unsuccessful in using patent litigation to keep another generic competitor off the market." [29] Id. P58. They also contend that because they have alleged an unlawful conspiracy, the issue is only "whether Barr's conduct in blocking generic entry was in furtherance of that alleged conspiracy." Appellants' Br. at 35 (emphasis omitted).

The defendants contend in response that any consequences of the 180-day exclusivity period resulted from Barr's petition to [*217] the FDA, and that Barr's actions in claiming the 180-day exclusivity period were therefore immune from antitrust scrutiny under the Noerr-Pennington doctrine, which immunizes parties from antitrust liability for injuries resulting from government action prompted by the parties' petitioning activities. See E.R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 136, 81 S. Ct. 523, 5 L. Ed. 2d 464 (1961) [**86] (stating that "the Sherman Act does not prohibit two or more persons from associating together in an attempt to persuade the legislature or the executive [or an agency or a court] to take particular action with respect to a law that would produce a restraint or a monopoly"); United Mine Workers of Am. v. Pennington, 381 U.S. 657, 670, 85 S. Ct. 1585, 14 L. Ed. 2d 626 (1965) ("Joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition."). Such immunity does not disappear even if the petitioning activity is intended to harm competitors. See Noerr, 365 U.S. at 138-39. In this case, the defendants assert, because Barr's petitioning activity was protected under Noerr-Pennington, it cannot be the basis for antitrust liability.

We are not so sure. Although Noerr-Pennington immunity may lend Barr's actions some protection, it does not immunize all actions with respect to the 180-day exclusivity period from antitrust scrutiny. The doctrine does not extend protection to the defendants "where the alleged conspiracy 'is a mere sham to cover what is actually nothing more than an attempt [**87] to interfere directly with the business relationships of a competitor.'" Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 511, 92 S. Ct. 609, 30 L. Ed. 2d 642 (1972) (quoting Noerr, 365 U.S. at 144). And it "does not authorize anticompetitive action in advance of [the] government's adopting the industry's anticompetitive proposal. The doctrine applies when such action is the consequence of legislation or other governmental action, not when it is the means for obtaining such action." In re Brand Name Prescription Drugs Antitrust Litig., 186 F.3d 781, 789 (7th Cir. 1999) (emphasis in original); see also Juster Assoc. v. Rutland, 901 F.2d 266, 271-72 (2d Cir. 1990) (stating that when a claimed re-

straint is the consequence of government action, it falls within the purview of Noerr-Pennington immunity, but when the restraint is the means by which the defendants seek to obtain favorable government action, it does not). Because we think that an agreement to time the deployment of the exclusivity period to extend a patent's monopoly power might well constitute anticompetitive action outside the scope [**88] of a valid patent, we decline to rest our conclusion on the ground of Noerr-Pennington immunity. [30]

[**89] We nonetheless do not think that the facts as alleged with respect to Barr's [*218] claim to the 180-day exclusivity period amount to an antitrust violation.

First, as we have explained, our review of the Settlement Agreement convinces us that, accepting the plaintiffs' allegations as true, the defendants did not violate the antitrust laws merely by entering into it. Therefore, even if we were to view Barr's actions with regard to the 180-day exclusivity period as somehow constituting "evidence" -- "circumstantial" or otherwise -- of the "anticompetitive consequences" of the Settlement Agreement, it would not affect our conclusion. The Agreement is no doubt "anticompetitive" -- the plaintiffs need no additional proof of that. It limited competition between generic tamoxifen and Zeneca's branded product. But, as we have seen, because it did not exceed the scope of the tamoxifen patent, it was not an unlawful anticompetitive agreement.

Second, because we have concluded that the Settlement Agreement was not itself an unlawful conspiracy, Barr's "block[ing of] generic entry" would not be unlawful as "in furtherance of" an unlawful conspiracy. There would have to be an unlawful [**90] conspiracy before Barr's actions could contribute to it.

Third, "[t]he factual predicate that is pleaded does need to include [an unlawful] conspiracy among the realm of plausible possibilities. Twombly, 425 F.3d at 111 (footnote omitted). Assuming that the plaintiffs intended to allege a separate agreement among the defendants relating to Barr's manipulation of its exclusivity period in order to protect the defendants from competition from other generic manufacturers, the pleaded conspiracy seems to us to be "implausible."

At the time the Settlement Agreement was entered into, the established law was that a generic manufacturer must "successfully defend" a patent infringement lawsuit in order to obtain exclusivity. [31] Accordingly, even if Barr might have suspected that the FDA would drop its "successful defense" requirement, it had, at the time, no claim to the exclusionary period. Although the Agreement in this case did include a provision allowing Barr to revert its paragraph III certification back to a paragraph IV certification in the event another generic manufacturer successfully invalidated the patent, it seems farfetched, in light of the law at the [**91] time, to construe that provision as a conscious and unlawful attempt to manipulate the exclusivity period.

Moreover, the fact that Barr acted as it did with respect to the deployment [**92] of the exclusionary period is easily explained by Barr's own interest in protecting itself from competition through a petition to the FDA for a statutorily prescribed benefit. Nothing that we can draw from the facts alleged in the complaint indicates how Barr's actions in this regard suggest that it was in league with Zeneca. [32]

[*219] Fourth and last, we have grave doubt as to whether, even if the defendants [**93] agreed to deploy the exclusionary period to protect their shared monopoly power, the injury that the defendants allege they suffered in this regard constitutes "antitrust injury."

To state a claim under the Sherman Act, a plaintiff, in addition to stating an antitrust violation, must allege facts sufficient to prove that it suffered "antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489, 97 S. Ct. 690, 50 L. Ed. 2d 701 (1977) (emphasis omitted); see also George Haug Co., Inc. v. Rolls Royce Motor Cars Inc., 148 F.3d 136, 139 (2d Cir. 1998). "The injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation." Brunswick, 429 U.S. at 489. "Harm to the antitrust plaintiff is sufficient to satisfy the constitutional standing requirement of injury in fact." Associated Gen. Contractors, Inc. v. Cal. State Council of Carpenters, 459 U.S. 519, 535 n.31, 103 S. Ct. 897, 74 L. Ed. 2d 723 (1983) [**94] .

Accepting for the sake of argument that the plaintiffs have stated an antitrust violation by alleging an agreement or understanding between Barr and Zeneca to manipulate the 180-day exclusivity period, we are inclined to agree with the district court's conclusion that any injury that the plaintiffs suffered nonetheless resulted from Zeneca's valid patent and from the inability of other generic manufacturers to establish that the patent was either invalid or not infringed -- and not from any agreement between Barr and Zeneca that Barr should employ its exclusivity powers to exclude competition. See Tamoxifen II, 277 F. Supp. 2d at 136-38.

As we have noted, at the time that Zeneca and Barr entered into the Settlement Agreement and caused the district court's judgment of patent invalidity to be vacated, Barr was not entitled to the 180-day period of exclusivity. It was only after the FDA announced that it was abandoning the "successful defense" requirement that Barr asserted its claim to the exclusivity period. See Tamoxifen II, 277 F. Supp. 2d at 135. As the district court noted:

> Barr did not seek similar relief when Novopharm [**95] filed its ANDA and challenged the [tamoxifen] patent between 1994 and 1997. Only after the events in 1997 and 1998 . . . did Barr attempt to assert its rights. If Barr intended to protect its exclusivity period on behalf of itself and Zeneca pursuant to the Settlement Agreement, Barr's inactivity during the pendency of the Novopharm litigation is inexplicable.

Id. at 134 n.9 (emphasis in original).

Therefore, the plaintiffs could not have suffered any antitrust injury with regard to an exclusivity period for Barr from the time the defendants signed the Settlement Agreement until the time the regulations were changed in 1997-1998. During that period, as far as all parties were concerned, the Settlement Agreement had indeed "cleared the field" so that other generic challengers could enter the market. Accordingly, any injury suffered by the plaintiffs during that time period was the result of Zeneca's legitimate patent monopoly -- which remained intact as a result [*220] of the lawful Settlement Agreement -- and not the result of any steps that Barr took.

The plaintiffs also suffered no antitrust injury from the time the "successful defense" requirement [**96] was eliminated until, in 2000, the FDA rejected Barr's claim to the exclusivity period, because the other ANDA filers with a paragraph IV certification ultimately lost their infringement suits against Zeneca. Even if Barr had not successfully petitioned the FDA, other generic manufacturers would not have been able to enter the market with their generic versions without infringing the tamoxifen patent. As the district court rightly noted, this allegation of injury is "based on the lack of competition that could have only existed by illegally infringing on the [tamoxifen p]atent."

Id. at 137-38. Thus, the plaintiffs did not suffer antitrust injury then either. See, e.g, Axis, S.p.A. v. Micafil, Inc., 870 F.2d 1105, 1111 (6th Cir.), cert. denied, 493 U.S. 823, 110 S. Ct. 83, 107 L. Ed. 2d 49 (1989) (finding no antitrust injury where plaintiffs had stated an antitrust violation, but where the alleged injury would have resulted even in the absence of the antitrust violation, because of the existence of patents preventing market entry).

Finally, there is clearly no antitrust injury with regard to Barr's use of the exclusivity period [**97] after the FDA rejected Barr's claim to the exclusivity period in 2000. From that time on, no one could have thought that Barr had a claim to an exclusivity period. Any injury suffered by the plaintiffs arose from Zeneca's patent monopoly, which remained valid until its expiration in 2002, after which other generic manufacturers did, in fact, enter the market.

For the foregoing reasons, we conclude that the plaintiffs have not sufficiently stated an antitrust claim arising out of the defendants' actions with regard to Barr's 180-day exclusionary period….

[The dissenting opinion of Circuit Judge Pooler is omitted.]