UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

August Term, 2003

(Argued: July 12, 2004 Decided: November 2, 2005

As amended: August 10, 2006)

Docket No. 03-7641

In Re: Tamoxifen Citrate Antitrust Litigation

JOBLOVE, ALLIED SERVS., DIV WELFARE FUND, BENNISH, KOONAN, GREAT LAKES HEALTH PLAN INC., LACAVA, DONEGA, SMITH, LOVINGER, WOOLLACOTT, WHITESIDE, PLATT, UNDERWOOD, TEAMSTERS LOCAL 237, LYNCH, CALLAWAY, MALONEY, MECHANICAL CONTRACT, IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN, A.F. OF L.-A.G.C. BUILDING TRADES WELFARE FUND, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE PLAN, LOCAL 1199 NAT'L BENEFIT FUND FOR HEALTH & HUMAN SERVICES, NEW YORK STATEWIDE SENIOR ACTION COUNCIL, MARKS, BLONSTEIN,

Plaintiffs-Appellants,

- v -

BARR LABS. INC., ASTRAZENECA PHARMACEUTICALS LP, ZENECA INC., ASTRAZENECA PLC,

Defendants-Appellees.

Before: POOLER, SACK, and RAGGI, Circuit Judges. Pooler, Circuit Judge, dissents in a separate opinion.

Appeal by consumers of the drug tamoxifen citrate, third-party payor organizations that provide medical benefits for their members which are used to purchase the drug, and consumer advocacy groups 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 allege that the defendants Zeneca, Inc., and AstraZeneca Pharmaceuticals LP entered into an agreement with the defendant Barr Laboratories, Inc., settling litigation among them the terms of which violated federal and state antitrust laws. On appeal, the plaintiffs assert that the district court erred in dismissing the complaint based on its conclusion that the settlement agreement was not a violation of antitrust law and that the plaintiffs did not suffer antitrust injury as a result of the alleged violation.

Affirmed.

J. DOUGLAS RICHARDS, Milberg Weiss Bershad Hynes & Lerach LLP (Michael M. Buchman, Milberg Weiss Bershad & Schulman LLP, New York, NY; Patrick E. Cafferty, Miller Faucher and Cafferty LLP, Ann Arbor, MI; Bernard Persky, Barbara J. Hart, Hollis L. Salzman, Goodkind Labaton Rudoff & Sucharow LLP, New York, NY; Robert S. Schachter, Joseph Lipofsky, Joseph S. Tusa, Zwerling, Schachter & Zwerling, LLP, New York, NY; Robert G. Eisler, Lieff, Cabraser, Heimann & Bernstein, LLP, New York, NY; of counsel), New York, NY, <u>for Plaintiffs-Appellants</u>.

JOEL M. COHEN, Davis Polk & Wardwell (Diem-Suong T. Nguyen, Douglas K. Yatter, Wendy L. Silver, Davis Polk & Wardwell, New York, NY; George C. Lombardi, Christine J. Siwik, Maureen L. Rurka, Winston & Strawn LLP, Chicago, IL; of counsel), New York, NY, <u>for Defendants-Appellees</u>.

Bruce E. Gerstein, Garwin Bronzaft Gerstein & Fisher LLP (Barry S. Taus, Jan Bartelli, Garwin Bronzaft Gerstein & Fisher LLP; Steve D. Shadowen, Monica L. Rebuck, Hangley Aronchick Segal & Pudlin, Harrisburg, PA; of counsel), New York, NY, <u>for Amicus Curiae Louisiana Wholesale Drug Company, Inc., CVS Meridian Inc., and Rite Aid Corporation</u>.

SACK, Circuit Judge:

This appeal, arising 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 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]

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. § 355] is effective with respect to such drug." 21 U.S.C. § 355(a). Subsection (b) describes the process of filing a New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA"), which is typically a costly

[1] A similar description of the relevant statutes and regulations is set forth in the Eleventh Circuit's opinion in Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1296-98 (11th Cir. 2003), cert. denied, 125 S. Ct. 308 (2004), and the District of Columbia Circuit's opinion in Andrx Pharms., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 801-02 (D.C. Cir. 2001), cert. denied, 535 U.S. 931 (2002).

and time-consuming procedure in which the applicant attempts to establish the safety and effectiveness of the drug. Id. § 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. Hatch-Waxman Act § 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. § 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. § 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.

[2] The ANDA process was intended to be available to manufacturers of generic versions of approved drugs. "A generic version . . . contains the same active ingredients, but not necessarily the same inactive ingredients, as the pioneer drug. A generic drug, as the name implies, is ordinarily sold without a brand name and at a lower price." Andrx Pharms., 256 F.3d at 801 n.1. Filing an ANDA allows a generic drug manufacturer to avoid the costly and time-consuming process of demonstrating safety and efficacy, allowing the manufacturer to rely on the FDA's earlier findings concerning the brand-name drug's NDA, and thereby facilitates quicker market entry by generic manufacturers. See id. at 801.

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. § 355(j)(2)(A)(vii).

An ANDA filer that elects a paragraph IV certification must notify each affected patent owner of the certification. Id. § 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. § 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

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[3]

> The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

21 U.S.C. § 355(b)(1).

owner received the requisite notice or until a district court[4] returns a decision as to the validity of the patent or its infringement if it does so before the thirty-month period expires. Id.

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. § 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. § 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").

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[4] At the time of the settlement in this case, the statute did not specify that a district court decision would end the 30-month stay, and the FDA interpreted the statute to require a court decision "from which no appeal can be or has been taken." Ctr. for Drug Evaluation & Research (CDER), Food & Drug Admin., U.S. Dep't of Health & Human Servs., Guidance for Industry: Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act 2 (Mar. 2000) (quoting 21 C.F.R. § 314.107(e)(1) (1999)) (hereinafter CDER, Court Decisions), available at http://www.fda.gov/cder/guidance/3659fnl.pdf (last visited May 12, 2005). In 2000, the FDA changed its interpretation to include any district court decision. See id. at 3-5.

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 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. § 355(j)(5)(B)(iv)(I)-(II).

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. § 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

[5] Like its interpretation of the type of court decision sufficient to end the 30-month stay of final FDA approval described above, at the time of the settlement in this case and until 2000, the FDA interpreted a court decision required to trigger the 180-day period to mean only a court decision "from which no appeal can be or has been taken." See CDER, Court Decisions, supra, at 2 (quoting 21 C.F.R. § 314.107(e)(1) (1999)). That interpretation was subsequently changed in 2000, when the FDA concluded that a patent invalidity decision by a district court would be sufficient to trigger the commencement of the 180-day period. See id. at 3-5.

Pharm. Corp. v. Shalala, 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* (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. § 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®.[6] Tamoxifen is 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 Chem. Indus., PLC v. Barr Labs., Inc., 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 tamoxifen patent invalid based on the court's conclusion that ICI had deliberately withheld

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[6] In 2001, Zeneca's domestic sales of tamoxifen amounted to $442 million.

[7] Soon thereafter, Heumann was dismissed as a defendant after it agreed to be bound by a determination in that case as to the validity of the tamoxifen patent. Compl. ¶ 40.

"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 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®, Barr would change its ANDA paragraph IV certification to a paragraph III certification, thereby agreeing 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 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. ¶ 58. 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 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., No. 92-1403, 1993 WL 118931, at *1, 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 by the Supreme Court, see U.S. Bancorp Mortgage Co. v. Bonner Mall P'ship, 513 U.S. 18, 27-29 (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 filed ANDAs

[8] The rule in U.S. Bancorp does not apply retroactively. See U.S. Philips Corp. v. Sears Roebuck & Co., 55 F.3d 592, 598 (Fed. Cir.), cert. denied, 516 U.S. 1010 (1995).

[9] After the Settlement Agreement was entered into and the vacatur ordered, Barr began to market its licensed version of Zeneca's tamoxifen, selling its product to distributors and

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 the forty-five day time limit provided by 21 U.S.C. § 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

wholesalers at a 15 percent discount to the brand-name price, which translated into a price to consumers about five percent below Zeneca's otherwise identical Nolvadex® brand-name version. Barr soon captured about 80 percent of the tamoxifen market.

[10] Pharmachemie initially filed a paragraph III certification in August 1994, but later amended it to include a paragraph IV certification. See Tamoxifen II, 277 F. Supp. 2d at 126.

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 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 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, 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 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. ¶¶ 61-63 (stating that the 30-month stay for Mylan was scheduled to expire on July 10, 1998, and for Pharmachemie in August 1998); Pharmachemie B.V. v. Barr Labs., Inc., 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., 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 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 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.

[11] Mylan had agreed to follow the Pharmachemie court decision. See Tamoxifen II, 277 F. Supp. 2d at 127; AstraZemeca UK Ltd., No. 00-2239, slip op. at 2-3.

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 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 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 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 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 (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. "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, 125 S. Ct. 308 (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 Pharms., Inc. v. Kroger Co., 125 S. Ct. 307 (2004)).

The district court was also of the view that the defendants could not be held liable 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 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.

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 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 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.

The United States Court of Appeals for the Federal Circuit has exclusive jurisdiction over an appeal from a federal district court "if the jurisdiction of that court was based, in whole or in part, on section 1338 of [title 28]," with exceptions not pertinent here. 28 U.S.C. § 1295(a)(1). Section 1338, in turn, provides that federal district courts shall have original and exclusive jurisdiction "of any civil action arising under any Act of Congress relating to patents." Id. § 1338(a). Therefore, whether the Federal Circuit has jurisdiction over the instant case "turns on whether this is a case 'arising under' a federal patent statute." Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 807 (1988).

A case "arises under" federal patent law if "a well-pleaded complaint establishes either that federal patent law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims." Id. at 809.[12] This is determined "from what necessarily appears in the plaintiff's statement of his own claim in the bill or declaration, unaided by anything alleged in anticipation or avoidance of defenses which it is thought the defendant may interpose." Id. (internal quotation marks and citation omitted). "[A] case raising a federal patent-law defense does not, for that reason alone, arise under patent law, even if the defense is anticipated in the

[12] The Christianson Court employed the "well-pleaded complaint" test that is routinely applied to determine whether a federal district court has federal-question jurisdiction. See Christianson, 486 U.S. at 808 (quoting Franchise Tax Bd. v. Constr. Laborers Vacation Trust, 463 U.S. 1, 27-28 (1983)); see also, e.g., Aetna Health Inc. v. Davila, 124 S. Ct. 2488, 2494 (2004); Empire HealthChoice Assurance, Inc. v. McVeigh, 396 F.3d 136, 140 (2d Cir. 2005); Bracey v. Bd. of Educ., 368 F.3d 108, 113 (2d Cir. 2004).

plaintiff's complaint, and even if both parties admit that the defense is the only question truly at issue in the case." Id. (internal quotation marks and citation omitted).

Moreover, even if one theory supporting a claim essentially turns on an issue arising under patent law, as long as there is at least one alternative theory supporting the claim that does not rely on patent law, there is no "arising under" jurisdiction under 28 U.S.C. § 1338. In that case, as the Supreme Court concluded in Christianson: "Since there are reasons completely unrelated to the provisions and purposes of federal patent law why petitioners may or may not be entitled to the relief they seek under their monopolization claim, the claim does not arise under federal patent law." Id. at 812 (internal quotation marks, citation, and alterations omitted); see also id. at 810 ("[A] claim supported by alternative theories in the complaint may not form the basis for § 1338(a) jurisdiction unless patent law is essential to each of those theories.").

Applying these principles to the case at hand, we conclude that we have jurisdiction to entertain this appeal. As we explain below, the defendants' contention that "all of [p]laintiffs' claims arise under the patent law because each requires [p]laintiffs to establish that the [tamoxifen] patent was invalid or unenforceable," Appellees' Reply Mem. Supp. Mot. to Transfer Appeal at 2, is mistaken. The theories that would enable the plaintiffs to prevail do not require us to examine whether Judge Broderick's invalidation of the tamoxifen patent would have been upheld on appeal or whether the tamoxifen patent was otherwise enforceable and infringed.

If the plaintiffs alleged facts that, if proved, would establish that the Settlement Agreement provided the defendants with benefits exceeding the scope of the tamoxifen patent, they would succeed in alleging an antitrust violation. And if the plaintiffs plausibly alleged that the defendants entered into an agreement to manipulate the 180-day exclusivity period to the defendants' joint benefit, and if they were able to prove based on the facts alleged that they suffered antitrust injury as a result of that agreement, then that, too, would likely be sufficient to state an antitrust violation. Were they to allege and then prove facts sufficient to support either of these theories, the argument that the Settlement Agreement was unlawful "[e]ven if the [tamoxifen p]atent is presumed valid and enforceable," Compl. ¶ 55, would, in our view, be persuasive.

Because we conclude that there are "reasons completely unrelated to the provisions and purposes of the patent laws why the plaintiff[s] may or may not be entitled to the relief [they] seek[]," Christianson, 486 U.S. at 810 (internal quotation marks, citation, and alterations omitted), we have jurisdiction to entertain this appeal.

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).

"A pleading which sets forth a claim for relief . . . shall contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). "Given the Federal Rules' simplified standard for pleading, a court may dismiss a complaint only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations." Swierkiewicz v. Sorema N.A., 534 U.S. 506, 514 (2002) (internal quotation marks, citation, and alteration omitted). There is no heightened pleading requirement in antitrust cases. See Twombly v. Bell Atl. Corp., 425 F.3d 99, 108-13 (2d Cir. 2005).

In reviewing a decision on a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), we "must accept as true all the factual allegations in the complaint," Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit, 507 U.S. 163, 164 (1993), and "draw all reasonable inferences in plaintiffs' favor," Freedom Holdings Inc. v. Spitzer, 357 F.3d 205, 216 (2d Cir. 2004). To survive a motion to dismiss, a plaintiff bringing suit under section 1 of the Sherman Act need not allege facts that exclude the possibility that the behavior of which complaint is made is legal. See Twombly, 425 F.3d at 111 ("[S]hort of the extremes of 'bare bones' and 'implausibility,' a complaint in an antitrust case need only contain the 'short and plain statement of the claim showing that the pleader is entitled to relief' that Rule 8(a) requires." (citation omitted)). However, "bald assertions and conclusions of law are not adequate [to state a claim] and a complaint consisting only of naked assertions, and setting forth no facts upon which a court could find a violation of the [law], fails to state a claim under Rule 12(b)(6)." Gregory, 243 F.3d at 692 (internal quotation marks and citations omitted). And "[i]t is . . . improper to assume that the plaintiff can prove facts that it has not alleged or that the defendants have violated the antitrust laws in ways that have not been alleged." Todd v. Exxon Corp., 275 F.3d 191, 198 (2d Cir. 2001) (internal quotation marks, citation, and alterations omitted). At the same time, in antitrust cases, "plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each." Cont'l Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 699 (1962).

III. The Plaintiffs' Antitrust Claims

A. The Tension between Antitrust Law and Patent Law

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

[13] "Although the Sherman Act, by its terms, prohibits every agreement 'in restraint of trade,' th[e Supreme] Court has long recognized that Congress intended to outlaw only unreasonable restraints." State Oil Co. v. Khan, 522 U.S. 3, 10 (1997).

U.S.C. § 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. § 2.[14] By contrast, also with the ultimate goal of stimulating competition and innovation, patent law grants an innovator "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing

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Conduct may be deemed an unreasonable restraint of trade in two ways. Conduct may be considered per se unreasonable because it has "such predictable and pernicious anticompetitive effect, and such limited potential for procompetitive benefit." Id.

In most cases, however, conduct will be evaluated under a "rule of reason" analysis, "according to which the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." Id. (citation omitted).

The rule-of-reason analysis has been divided into three steps. First, a plaintiff must demonstrate "that the challenged action has had an actual adverse effect on competition as a whole in the relevant market." Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., 996 F.2d 537, 543 (2d Cir.) (emphasis in original), cert. denied, 510 U.S. 947 (1993). If the plaintiff succeeds in doing so, "the burden shifts to the defendant to establish the 'pro-competitive "redeeming virtues"' of the action." K.M.B. Warehouse Distribs., Inc. v. Walker Mfg. Co., 61 F.3d 123, 127 (2d Cir. 1995) (quoting Capital Imaging Assocs., 996 F.2d at 543). If the defendant succeeds in meeting its burden, the plaintiff then has the burden of "show[ing] that the same pro-competitive effect could be achieved through an alternative means that is less restrictive of competition." Id.

[14] "The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." United States v. Grinnell Corp., 384 U.S. 563, 570-71 (1966).

the invention into the United States" for a limited term of years. 35 U.S.C. § 154(a)(1)-(2); see also Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (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 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 (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, 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 (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 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 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 (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, 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 Mortgage Co. v. Bonner Mall P'ship, 513 U.S. 18, 27-29 (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) (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 trade

[15] It is true that had the defendants not settled the underlying patent litigation and had the district court's judgment been affirmed on appeal, Zeneca would have been estopped from asserting the validity of its patent against others seeking to enter the market. See Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313, 350 (1971). However, it is clearly a permissible byproduct of settlement that future hypothetical plaintiffs might be forced to relitigate the same issues involved in the settled case. Furthermore, before 1994, when district court judgments were vacated as a matter of course upon settlement, see U.S. Bancorp, 513 U.S. at 29 (virtually ending this practice), there was similarly and permissibly no collateral estoppel effect accorded these judgments for the benefit of future hypothetical plaintiffs. See Nestle, 756 F.2d at 284 ("Drumbeating about the need to protect other unknown users of the trademark [in question] will ring hollow indeed in the ears of the present defendants if the peril of a reversal is realized. . . . We see no justification to force these defendants, who wish only to settle the present litigation, to act as unwilling private attorneys general and to bear the various costs and risks of litigation.").

that antitrust violations may occur." Duplan Corp., 540 F.2d at 1220.

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 (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 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. Comm'r, 146 F.2d 553 (2d Cir.), aff'd, 326 U.S. 287 (1945)); In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 529 (E.D.N.Y. 2005) ("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 (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 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

[16] It may be worth noting, although in and of itself it seems to us to prove little, that the Federal Circuit reversed district court determinations of patent invalidity at a relatively high rate during the relevant time period. *See* Donald R. Dunner *et al.*, *A Statistical Look at the Federal Circuit's Patent Decisions: 1982-1994*, 5 Fed. Cir. B.J. 151, 154-55 (1995).

underlying patent . . . when deciding whether an agreement concerning the patent violates antitrust law").

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]

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

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[17] We thus think that it was appropriate for the district court to take these decisions into account for the limited purpose of rebutting the plaintiffs' conclusory allegation that the Federal Circuit would have affirmed Judge Broderick's decision invalidating the tamoxifen patent. See Mason v. Am. Tobacco Co., 346 F.3d 36, 39 (2d Cir. 2003) ("[L]egal conclusions, deductions or opinions couched as factual allegations are not given a presumption of truthfulness." (internal quotation marks and citations omitted)), cert. denied, 541 U.S. 1057 (2004); Smith v. Local 819 I.B.T. Pension Plan, 291 F.3d 236, 240 (2d Cir. 2002) ("[C]onclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss." (internal quotation marks and citation omitted)).

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.

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

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[18] Indeed, our Circuit requires civil litigants to go through a pre-argument, Court-sponsored process called the Civil Appeals Management Plan ("CAMP"), see http://www.ca2.uscourts.gov/Docs/Forms/CAMP.pdf and http://www.ca2.uscourts.gov/Docs/Forms/Preargument.pdf, designed in part to facilitate just such post-judgment, pre-appellate argument settlements -- which it accomplishes with significant success. See Gilbert J. Ginsburg, The Case for a Mediation Program in the Federal Circuit, 50 Am. U. L. Rev. 1379, 1383 (2001) (reporting estimate that forty-five to fifty percent of civil cases pending before the Second Circuit settle each year).

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 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.").

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 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) (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 fortymillion-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 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 manufacturing, marketing, or distribution of the potentially infringing generic drug. The prospective generic manufacturer therefore has 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]

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[19] In this case, Barr could not at the time of the Settlement Agreement count on obtaining the 180-day exclusive period from the FDA because, as a settler rather than a "successful defender," it at least appeared that it was unlikely

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

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to be entitled to the period of exclusivity -- in other words, it appeared that, by settling, Barr was trading away its exclusivity period. It is noteworthy, nonetheless, that the 180-day period is of substantial benefit to the generic drug manufacturer who obtains it because it gives that manufacturer a significant head start over other manufacturers. See, e.g., Geneva Pharms. Tech. Corp. v. Barr Labs. Inc., 386 F.3d 485, 494, 510 (2d Cir. 2004) (considering claim that defendant's first-mover status converted a transitory advantage into a permanent one, where plaintiffs provided testimony that "even though its offer price to the Eckerd and CVS drugstore chains was as much as 25 percent below [the first mover's price], neither chain was willing to leave [the first mover] after having devoted substantial time to switching patients and getting their pharmacists comfortable with the new product"); Mova Pharm., 955 F. Supp. at 131 ("All parties recognize that the earliest generic drug manufacturer in a specific market has a distinct advantage over later entrants.").

uncertainty surrounding the validity and scope of the holder's patent.[20]

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]

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[20] It has been observed that even the typical settlement of the ordinary patent infringement suit appears to involve what may be characterized as a reverse payment. See Cipro II, 261 F. Supp. 2d at 252 ("[E]ven in the traditional context, implicit consideration flows from the patent holder to the alleged infringer."); cf. Asahi Glass, 289 F. Supp. 2d at 994 ("[A]ny settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement. If any settlement agreement is thus to be classified as involving a forbidden 'reverse payment,' we shall have no more patent settlements." (emphasis in original)); Daniel A. Crane, Ease Over Accuracy in Assessing Patent Settlements, 88 Minn. L. Rev. 698, 700 (2004) ("It makes no sense to single out exclusion payments for disfavor when the same potential for collusion arises in any settlement involving the defendant's exit."). A blanket rule that all settlements involving reverse payments are unlawful could thus conceivably endanger many ordinary settlements of patent litigation.

[21] The Federal Trade Commission and some commentators have proposed similar or even more stringent rules. See In re Schering-Plough Corp., No. 9297, final order at 4, 2003 WL 22989651, 2003 FTC LEXIS 187 (Fed. Trade Comm'n Dec. 8, 2003) (applying a rule under which generic manufacturers would not be permitted to receive reverse payments that exceeded "the lesser of the [patent] [h]older's expected future litigation costs to

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 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 license. 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.

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resolve the Patent Infringement Claim or $2 million"), vacated, 402 F.3d 1056 (11th Cir. 2005); Hovenkamp et al., supra, at 1759 (proposing that "[i]n an antitrust challenge, a payment from a patentee to an infringement defendant for the latter's exit from the market is presumptively unlawful," and that the "infringement plaintiff can defend by showing both (1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit").

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 over the manufacture and distribution of the patented product.[22]

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[22] The dissent questions what it sees as our reliance on the presumption of validity of the patent at the time of the settlement. Post at **[16-17]**. Even after a district court holds a patent invalid, it is treated as presumptively valid under 35 U.S.C. § 282 on appeal. See Rosco, Inc. v. Mirror Lite Co., 304 F.3d 1373, 1377-78 (Fed. Cir. 2002). But irrespective of whether there was a presumption or where any such presumption lay at the time of settlement, we think that Zeneca was then entitled to protect its tamoxifen patent monopoly through settlement. The question for this Court is whether the settlement extended the patent's scope. If the judgment of the district court against a patent's validity put an end to the patent monopoly that the patent holder was entitled to protect, then any settlement after judgment of the district court holding the patent invalid would extend the patent monopoly beyond the patent's scope and therefore be unlawful. We do not think that to be the law, a view which appears to be consistent with the plaintiffs'. See Appellants' Reply Br. at 4, Heading "B." ("Hatch-Waxman Patent Infringement Litigation Can Be Settled, Even On Appeal, Without

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 of that difference to the generic manufacturer to

Violating The Antitrust Laws.").

[23] There is authority for the proposition that when its patent monopoly is ended, the patent holder might actually raise the price on its branded product, rather than lower it in response to generic competition. See Congr. Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry 29-31 (July 1998), available at http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf (last visited May 12, 2005).

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 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

[24] To illustrate using a vastly oversimplified hypothetical example (ignoring, for example, legal fees and costs): Suppose the patent holder is selling 1,000,000 pills per year at a $1 profit per pill (for a total profit of $1,000,000). The generic manufacturer files a paragraph IV ANDA, and the patent holder responds by bringing suit to protect its patent. If the patent holder projects that, should it lose the suit, it will thereafter sell only 250,000 pills per year at a $.90 profit per pill (for a total profit of $225,000) in the competitive market, and the generic will sell 750,000 pills per year at a profit of $.60 per pill (for a total profit of $450,000) -- so that total market profits are now down from $1,000,000 to $675,000 -- it would make economic sense for the patent holder to pay the generic manufacturer something more than the $450,000 the generic manufacturer would make in a competitive market to settle the litigation. If it paid $500,000 a year to the generic manufacturer -- $50,000 more than the generic manufacturer could earn in the market in a "best case scenario" -- for example, it would thereby retain the ability to make $500,000 per year selling its branded pills ($1,000,000 profit less $500,000 per year paid to the generic), $275,000 more per year than it would earn if it paid nothing to the generic but lost the patent litigation and with it the patent monopoly. It might well be sensible for the patent holder to enter into this sort of settlement, depending in part on its perceived prospects for winning the litigation, and it would seem difficult for the generic manufacturer to refuse. The $325,000 of yearly monopoly profits which accrued to the patent holder before the litigation began would thereafter be divided between the patent holder and the generic manufacturer.

might pay a potential infringer a substantial sum in settlement.").

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. § 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 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 <u>certain</u> 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 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 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 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, 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 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 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 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]

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[25] It seems to us odd for the dissent to urge, in the context of this case, that we have not given proper weight to "the public interest in having the validity of patents litigated." Post at **[9]**. The Settlement Agreement was a virtual invitation to other generic manufacturers to file paragraph IV certifications and thereby court litigation as to the validity of the tamoxifen patent. It was an invitation that was accepted three times leading to three lawsuits, two of them litigated to judgment, as to the validity of the tamoxifen patent. Accepting

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 proprietors. 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]

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

the value of litigating the validity of patents in these circumstances, it has hardly been undermined here.

[26] The dissent "see[s] no reason why the general standard for evaluating an anti-competitive agreement, i.e., its reasonableness, should not govern in this context." Post at **[13]**. We think, such a rule, making every settlement of patent litigation, at least in the Hatch-Waxman Act context, subject to the inevitable, lengthy and expensive hindsight of a jury as to whether the settlement constituted a "reasonable" restraint (and, in this case, whether the Federal Circuit would have affirmed or reversed in a patent appeal), would place a huge damper on such settlements contrary to the law that we have discussed at some length that settlements are not only permitted, they are to be encouraged.

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 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 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 (1993).[27] In

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[27] The reasoning of the dissent, which quotes an excerpt from this statement, post at **[5]**, is, in our view, largely based on a repeated mis-characterization of our views in this regard. We do not, as the dissent states in one form or another many times, see post at **[6]**, **[7 - 9]**,**[13]**, **[16]**, and **[18]**, think that there is a "requirement" that antitrust plaintiffs "must show that the settled litigation was a sham, i.e., objectively baseless, before the settlement can be considered an antitrust violation . . . ," id. at **[6]**. There is no such requirement.

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.

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"

The central criterion as to the legality of a patent settlement agreement is whether it "exceeds the 'scope of the patent's protection.'" As we pointed out at the outset of this discussion, we think that "[i]f the plaintiffs alleged facts that, if proved, would establish that the Settlement Agreement provided the defendants with benefits exceeding the scope of the tamoxifen patent, they would succeed in alleging an antitrust violation." Ante at **[26]**; see also, e.g., post at **[55]** ("[T]he question is whether the "exclusionary effects of the agreement" exceed the 'scope of the patent's protection.' Schering-Plough, 402 F.3d at 1076."). A plaintiff need not allege or prove sham litigation in order to succeed in establishing that a settlement has provided defendants "with benefits exceeding the scope of the tamoxifen patent." Whether there is fraud or baseless litigation may be relevant to the inquiry, but it is hardly, we think, "the . . . standard," post at **[14]**, as the dissent posits in order to take issue with it.

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 payment but also an agreement that the generic manufacturer would not market non-infringing products. See 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"); <u>In re K-Dur Antitrust Litig.</u>, 338 F. Supp. 2d 517, 532 (D.N.J. 2004) (noting, in connection with a private lawsuit involving the same settlement agreements challenged by the FTC in <u>Schering-Plough</u>, 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 <u>any</u> 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 <u>Cipro</u> cases, and unlike the patents at issue in <u>Cardizem</u> and <u>Valley Drug</u>, Zeneca's tamoxifen patent is not a formulation patent, which covers only specific formulations or delivery methods of compounds; rather, it is a patent on a compound that, by its nature, excludes all generic versions of the drug. <u>See</u> Appellees' Br. at 23; <u>Cipro II</u>, 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) 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 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] 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 settlement 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 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 the generic manufacturers "hundreds of millions of dollars," then the patent holder "would

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[28] See Asahi Glass, 289 F. Supp. 2d at 994 (noting that in the typical reverse-payment case, "the settlement leaves the competitive situation unchanged from before the defendant tried to enter the market.").

have issued to [the generic manufacturers] a license for distribution of generic Cipro").

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. ¶ 75, 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. ¶ 75. See also Congr. Budget Office, How Increased Competition from Generic 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 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. ¶ 57. 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" 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. ¶ 58. 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 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 (1961) (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 (1965) ("Joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate

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[29] Of course, as it turned out, Zeneca was successful in subsequently protecting its patent in the courts.

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 to interfere directly with the business relationships of a competitor.'" Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 511 (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 Assocs. v. City of Rutland, 901 F.2d 266, 271-72 (2d Cir. 1990) (stating that when a claimed restraint 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 of a valid patent, we decline to rest our conclusion on the ground of Noerr-Pennington immunity.[30]

We nonetheless do not think that the facts as alleged with respect to Barr's 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

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[30] "The competitive concern is that the 180-day exclusivity provision can be used strategically by a patent holder to prolong its market power in ways that go beyond the intent of the patent laws and the Hatch-Waxman Act by delaying generic entry for a substantial period." Balto, supra, at 331. An agreement that a "generic manufacturer would not relinquish its 180-day exclusivity . . . prevent[s] other generic manufacturers from entering as well." Id. at 335; see also Hovenkamp et al., supra, at 1755 ("It is widely understood that the 180-day exclusivity period offers the potential for collusive settlement arrangements between pioneers and generics. A pioneer could initiate a patent infringement suit against a first generic ANDA filer and settle the litigation with a 'non-entry' payment to the generic, under which the generic would delay commercialization of the generic product, thus postponing the commencement of the 180-day exclusivity period and locking other generics out of the market indefinitely.").

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 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

[31] In Andrx, the defendant attempted unsuccessfully to claim that it was unable to cause any delay in generic entry because the "successful defense" requirement would prevent it from doing so. Andrx Pharms., 256 F.3d at 810. The D.C. Circuit noted that the settlement agreement in that case was signed in September 1997 -- after the district court in Mova issued, in January 1997,

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 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 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]

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a preliminary injunction banning the enforcement of the successful defense requirement. Id. (citing Mova Pharm., 955 F. Supp. at 131-32). Thus, "[t]he timing of the Agreement and of the demise of the successful defense requirement defeats Andrx's argument on this point." Id. In the instant case, however, the Settlement Agreement was executed long before Mova struck down the successful defense requirement.

[32] The dissent says that a reasonable fact-finder might conclude that sophisticated parties would not have included a provision that allowed Barr to re-file under paragraph IV absent an unlawfully anticompetitive purpose because it "had no potential benefit to either of them" apart from an anti-competitive one. Post at **[19]**. We disagree. If another generic manufacturer had been successful in having the tamoxifen patent held invalid, it was strongly and legitimately in Barr's interest to be able to re-file so that it could market tamoxifen without risking a violation of the Settlement Agreement.

Fourth and last, we have grave doubt as to whether, even if the defendants 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 (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 (1983).

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 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 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 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 (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 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.

IV. Leave To Amend

The plaintiffs contend that the district court erred in not addressing, and therefore in effectively denying, their request to amend their complaint to state a claim on which relief could be granted. The defendants reply that the district court acted within its discretion in effectively denying the plaintiffs' request -- which appeared in a footnote in the middle of their brief opposing the defendants' motion to dismiss -- because the request was buried and because it was, in any event, futile.

Federal Rule of Civil Procedure 15(a) provides that "a party may amend the party's pleading . . . by leave of court . . . and leave shall be freely given when justice so requires." A district court has broad discretion to decide whether to grant leave to amend, a decision that we review for an abuse of discretion. <u>Gurary v. Winehouse</u>, 235 F.3d 792, 801 (2d

Cir. 2000). It is within the court's discretion to deny leave to amend implicitly by not addressing the request when leave is requested informally in a brief filed in opposition to a motion to dismiss. See id. Furthermore, where amendment would be futile, denial of leave to amend is proper. See Van Buskirk v. N.Y. Times Co., 325 F.3d 87, 91-92 (2d Cir. 2003).

The plaintiffs' assertion that, if granted leave to amend, they "would be able to redress perceived deficiencies" in their complaint, Appellants' Br. at 56, does not persuade us. Even were plaintiffs to allege -- as they now assert they are able to -- that the defendants were concerned about the possibility that the Settlement Agreement might run afoul of antitrust law, or that the reverse payments were in excess of Zeneca's litigation costs but "less than the substantial losses Zeneca anticipated upon generic competition," or that the defendants "believed the Federal Circuit would likely affirm" the invalidation of the tamoxifen patent, id., in the absence of any plausible allegation that Zeneca's patent infringement lawsuit was baseless or that the Settlement Agreement otherwise restrained competition beyond the scope of the tamoxifen patent, their complaint would fail to state a claim on which relief can be granted.

"[I]t appears beyond doubt that the plaintiff[s] can prove no set of facts in support of [their] claim which would entitle [them] to relief." Conley v. Gibson, 355 U.S. 41, 45-46

(1957). The district court therefore did not abuse its discretion in denying the plaintiffs' request for leave to amend.

CONCLUSION

For the foregoing reasons, the judgment of the district court is affirmed.

POOLER, Circuit Judge:

I respectfully dissent. I believe that the opinion of the court, which dismisses plaintiffs' complaint at the Rule 12(b)(6) stage, shortcuts a process necessary to balance the interests at stake in this litigation. These interests include, on one side, the encouragement of innovation fostered by the patent laws, the public and private interest in amicable settlements, and judicial economy; and, on the other side, an interest in vigorous competition protected by the Sherman Act as well as the interest of consumers in having the validity of a patent litigated. I agree with the majority that balancing is required but differ from them as to (1) the proper balancing analysis, and (2) the ability to perform this analysis without further development of the factual record. In my view, plaintiffs' allegations were sufficient to allow discovery and, thereafter, a more fully informed balancing analysis.

BACKGROUND

I. Plaintiffs' relevant allegations.

Plaintiffs allege that the various agreements described in the majority opinion are a cover for an agreement to allow Zeneca[1] and Barr to monopolize and allocate the tamoxifen market. In support of this proposition, plaintiffs further allege that (1) at the time the two drug manufacturers entered into

[1] Like the majority, I use "Zeneca" to refer collectively to defendants Zeneca, Inc., Astrazeneca Pharmaceuticals LP, and AstraZeneca, Inc. "Barr" refers to defendant Barr Labs, Inc.

their agreements, Zeneca's patent had been declared invalid by a district court and Zeneca's appeal was fully briefed before the Federal Circuit; (2) Zeneca agreed to pay Barr $21 million and Barr's supplier $45.4 million in return for Barr's agreement to withdraw its challenge to Zeneca's patent and refrain from entering the generic market until Zeneca's patent expired in 2002; (3) the amount paid to Barr exceeded the amount that Barr could have earned by successfully defending its judgment because the 180-day period during which Barr would have been the only generic manufacturer would have been followed immediately by a highly competitive generic market; (4) although the agreement required Barr to convert its paragraph IV certification to a paragraph III certification, it also provided that Barr could revert to a paragraph IV certification if Zeneca's patent was later declared invalid, which would allow Barr and Zeneca to delay the entry of any subsequent generic challenger into the market; (5) in order to render the agreement effective, Barr was required to join Zeneca in moving for vacatur of the judgment, which motion resulted in the vacatur of the district court's determination that the patent was not valid; (6) subsequent generic challengers faced a thirty-month stay before they could enter the market; (7) Barr did indeed employ its exclusivity period against another generic manufacturer, Mylan Pharmaceuticals, when the latter was poised to enter the market; and (8) the savings to end purchasers who bought the tamoxifen that Barr obtained from Zeneca was only about 5% as compared to the 30% to 80% discount typically available where there is true generic competition.

II. The majority's analysis.

The majority's resolution of this appeal rests on a series of premises. First, the majority states that the Sherman Act aims to encourage competition by prohibiting agreements that unreasonably restrain trade. Majority op. at **[29-30 & n.13]**. The majority next states that the patent laws also ultimately aim to stimulate competition and innovation, but that they do so through a system that grants an inventor a time-limited exclusive right in her invention or formulation. Id. at **[30]**. These contrasting goals, the majority posits, create a tension in cases where patent and antitrust overlap and require "a delicate balance." Id. at **[30-31]** (quoting Schering-Plough Corp. v FTC, 402 F.3d 1056, 1067 (11th Cir. 2005).

After thus recognizing the inherent tension between antitrust and patent law, the majority goes on to articulate principles that it believes should be used to resolve this tension in the context of an antitrust challenge to a Hatch-Waxman settlement agreement. First, it notes the general principle that settlements, including patent settlements in the pharmaceutical area, are to be encouraged because they promote the public interest and the interests of the parties. Id. at **[31-32]**. In addition, the majority relies on the Supreme Court's recognition that "'where there are legitimately conflicting [patent] claims . . . a settlement by agreement rather than litigation, is not precluded by the Sherman Act.'" Id. **[at 32]** (quoting Standard Oil Co. v. United States, 283 U.S. 163, 171 (1931).

The majority then suggests that rules that severely restrict patent settlements create undue uncertainty concerning patents and thus might delay the entry of innovative products into the market. It also reasons that, although forcing patent litigation to continue might be pro-competitive in some cases, resolving disputes may also allow the entry into the market of valuable inventions. Id. at **[33-34]**.

Turning to the agreements at issue in this case, the majority states that it cannot find them unreasonable based on the likelihood that Barr would maintain its victory on appeal because courts are ill positioned to predict the outcome of litigation. Id. **[at 34]**. Puzzlingly, after noting that the validity of a settlement agreement must be judged from the viewpoint of the time in which it was made, id. at **[35]**, the majority relies on the fact that other district courts reached a different conclusion from that of the Southern District of New York to show that it is difficult to assess Barr's likelihood of success on appeal, id. at **[36]**. It finds "of little moment" the fact that the parties reached settlement "after the district court ruled against Zeneca" because all parties have a motivation to eliminate risk on appeal, but finds it significant "[t]hat

Zeneca had sufficient confidence in its patent to proceed to trial rather than find some means to settle the case first." Id. at **[37]**.

The court concludes "that without alleging something more than the fact that Zeneca settled after it lost to Barr in the district court," plaintiffs have not alleged an antitrust violation. Id. at **[37]**. The first "something more" that the majority considers is the $21-million reverse payment Zeneca made to Barr in return for the latter's agreement to stay out of the generic market for tamoxifen and to cooperate in vacating its favorable judgment. It finds no per se bar to reverse payments, indicating that "the fact that the patent holder is paying to protect its patent monopoly [does not], without more, establish[] a Sherman Act violation." Id. at **[39]**. The majority also posits that reverse payments are to be expected in the drug patent context because Hatch-Waxman shifted the risk of a lawsuit from an infringer to a patent holder. Id. at 40-43.

Next, after conceding that reverse payments that, like the one alleged here, exceed the profits the generic might expect to make if it prevailed in the underlying litigation look suspicious, the majority holds that such excessive reverse payments are not unlawful, explaining that "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 over the manufacture and distribution of the patented product." Id. at **[45]**.

The court then articulates its standard for judging whether a Hatch-Waxman settlement agreement violates the antitrust laws: "[A]bsent an extension of the monopoly beyond the patent's scope . . . and absent fraud . . . 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.'" Id. at **[54]** (quoting Prof'l Real Estate Investors, Inc. v. Columbia Pictures, Inc., 508 U.S. 49, 60 (1993)). The majority then holds that plaintiffs did not and cannot—in light of Zeneca's subsequent litigation victories—establish that Zeneca's infringement suit against Barr was objectively baseless. Id. at **[55]**.

The majority next considers whether the exclusionary effects of the agreements exceed the patent's scope and concludes that they do not because (1) the agreements did not bar the introduction of any non-infringing products; (2) they ended all litigation between Zeneca and Barr, thus opening the field to other generic challengers; and (3) they did not entirely foreclose competition because they allowed Barr to market Zeneca's version of Tamoxifen. Id. at **[56-62]**. Finally, the majority considers plaintiffs' allegations concerning Barr's manipulation of the exclusivity period. It concludes that although "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 of a valid patent," id. at **[65]**, because the agreements themselves did not exceed the scope of Zeneca's lawful patent, Barr's actions could not be unlawful as in furtherance of an original conspiracy, id. at **[65-66]**.

The court dismisses as speculative any claim by plaintiffs that Barr and Zeneca entered into a side agreement that Barr would use its exclusivity period in the way it did, claiming that "[a]lthough 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 time, to construe the provision as a conscious and unlawful attempt to manipulate the exclusivity period." Id. at **[67]**. The law to which the majority refers is a former federal regulation requiring that in order to obtain an exclusivity period, the generic manufacturer must successfully defend a patent infringement suit. See Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1065 (D.C. Cir. 1998) (citing former 21 C.F.R. 314.107(c)(1)). The majority also argues that Barr's deployment of the exclusionary period is adequately explained "by [its] own interest in protecting itself from competition through a petition to the FDA for a statutorily described benefit" and that nothing in the complaint suggests a conspiracy. Id. at **[67]**. Alternatively, the majority suggests that it has grave doubts that the injury plaintiffs allege is antitrust injury because the injury stemmed from the scope of Zeneca's patent and from the inability of other generics to defeat Zeneca's patent. Id. **[at 68-71]**

DISCUSSION

I differ with both the majority's standard for pleading a Hatch-Waxman-settlement antitrust violation and with several subsidiary holdings, conclusions, or assumptions. The requirement that—unless an antitrust plaintiff demonstrates that a settlement agreement exceeds the scope of the patent—it must show that the settled litigation was a sham, i.e., objectively baseless, before the settlement can be considered an antitrust violation is not soundly grounded in Supreme Court precedent and is insufficiently protective of the consumer interests safeguarded by the Hatch-Waxman Act and the antitrust laws. Beyond that overarching difference, the majority has, in my view, wrongly (1) accorded dispositive deference to Zeneca's patent rights when its patent had been declared invalid at the time of the settlement; (2) focused on subsequent litigation concerning patent validity rather than the litigation posture at the time of settlement; (3) held that the district court could not assess the likelihood that Zeneca would succeed on appeal; (4) held that plaintiffs insufficiently alleged a conspiracy between Barr and Zeneca to deploy Barr's paragraph IV certification when it would delay the market entry of another generic manufacturer; and (5) failed to recognize that whether plaintiffs' injuries stem from the alleged Barr/Zeneca conspiracy or from the failure of other generics to invalidate the patent cannot be resolved on the pleadings.

I. The pleading standard.

Relying principally on Professional Real Estate Investors, the majority concludes that, in order to attack a Hatch-Waxman settlement on antitrust grounds, plaintiffs must allege either that the agreement gave the patent holder benefits beyond the scope of the patent or that the agreement was a sham, that it was "objectively baseless in the sense that no reasonable litigant would realistically expect success on the merits." Majority op. at **[54]** (quoting 508 U.S. at 60). I agree that a settlement agreement that confers on the patent holder a greater monopoly benefit than does the patent itself is illegal. However, I do not agree that, absent a showing of benefits exceeding the scope of the patent, the antitrust plaintiff must show that the settled litigation was objectively baseless.

Professional Real Estate Investors is not apposite because it did not involve the settlement of Hatch-Waxman patent litigation. Rather, plaintiffs brought a copyright infringement case, and defendants countersued, alleging that the suit was a sham and a violation of §§ 1 and 2 of the Sherman Act. 508 U.S. at 52. The district court held that while no infringement occurred, no antitrust violation occurred either because the plaintiffs were entitled to immunity under Eastern Railroad

Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961), as their litigation "was clearly a legitimate effort and therefore not a sham." 508 U.S. at 53 (quoting Columbia Pictures Indus., Inc. v. Prof'l Real Estate Investors, Inc., 1990 WL 56166 at * 1 (C.D. Cal. 1990). Both the Court of Appeals and the Supreme Court agreed, and the Supreme Court defined "sham" for the purposes of defeating Noerr-Pennington immunity,[2] as the majority does here. Id. at 60. The Court was not called upon to decide and did not decide the standard for pleading an antitrust violation; it simply defined "sham," in a context in which it was already clear that the required standard was sham litigation. It is ill-advised, I think, to import the definition of "sham" used where a party must concededly establish that litigation was "sham" to avoid a well-established immunity from antitrust liability to a context in which we are defining antitrust liability in the first instance. Although Zeneca's original suit was likely protected under the standard set out in Professional Real Estate Investors, it does not necessarily follow that the settlement of that suit should be judged on the same grounds.

In fact, other leading cases cited in the majority opinion suggest, although I concede they do not mandate, a contrary conclusion. See Standard Oil, 283 U.S. at 180 (noting in the context of upholding cross-licensing agreements for patents against an antitrust challenge that a "master found,

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[2] Noerr-Pennington immunity derives from both Noerr and United Mine Workers of Am. v. Pennington, 381 U.S. 657 (1965).

after an elaborate review of the entire art, that the presumption of validity attaching to the patents had not been negatived in any way; that they merited a broad interpretation; that they had been acquired in good faith; and that the scope of the several groups of patents overlapped sufficiently to justify the threats and fears of litigation."); United States v. Singer Mf'g Co., 374 U.S. 174, 197 (1963) (White, Justice, concurring) (noting that the majority had not reached issue of whether "collusive termination of a Patent Office interference proceeding pursuant to an agreement between [certain parties] to help one another to secure as broad a patent monopoly as possible, invalidity considerations, notwithstanding" was sufficient, standing alone, to state an antitrust claim and indicating that he believed it was). Both the majority opinion in Standard Oil and the concurrence in Singer suggest that an antitrust court must go beyond deciding that a lawsuit was not a sham, that is objectively baseless, before it can dismiss an antitrust challenge to the lawsuit's settlement—as opposed to the initiation of the lawsuit—and, in fact, must consider the strength of the patent.

Holding that a Hatch-Waxman settlement agreement cannot violate antitrust laws unless the underlying litigation was a sham also ill serves the public interest in having the validity of patents litigated. See United States v. Glaxo Group Ltd., 410 U.S. 52, 57 (1973). This interest exists because "[i]t is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly."[3] Id. at 58. Litigating the validity of drug company patents is critically important to the general well being in light of the recent trend toward capping the maximum amounts insurers and public benefit plans will spend on medications.

A Hatch-Waxman settlement, by definition, protects the parties' interests as they see them. Whether it also promotes the public's interest depends on the facts. If the validity of the patent is clear, and the generic company receives a license to market the patent holder's product, competition is increased. However, if, as in this case, the patent has already been shown to be vulnerable to attack and the generic manufacturer is paid to keep its generic product off the market, it is hard to see how the public benefits.

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[3] The majority suggests, **[majority op. at 53 n.25]** that this interest was adequately protected through the subsequent suits by other generics. I disagree. This position ignores the time gap between the Barr-Zeneca litigation and the subsequent litigation. During this period, had Barr maintained its victory on appeal, which, as I explain below, was quite likely, very ill consumers would have had access to low cost generic tamoxifen. In addition, once Zeneca's patent protection was gone with respect to Zeneca, it was gone with respect to all generic manufacturers, which would have produced a very competitive market at the close of the 180-day exclusivity period. Thus, it was very important to the public interest that Barr and Zeneca allow the appeal to proceed. This does not mean, as the majority suggests at 49 n.25 that any settlement of patent litigation after the challenger prevails at trial is an antitrust violation. As I discuss at **[13-14]** below, a Hatch-Waxman settlement agreement, even on appeal from a judgment declaring the patent invalid, is not a per se antitrust violation. Rather, a reviewing court must assess the reasonability of the settlement by weighing various factors including the strength of the patent as it appeared at the time of settlement.

The Hatch-Waxman Act provides an incentive for the second kind of agreement that other patent laws do not provide. Patent litigation other than Hatch-Waxman patent litigation generally proceeds along familiar lines. A patent holder sues an alleged infringer, and the infringer either chooses to go to trial to vindicate its view that the patent is invalid or pays the patent holder money as compensation for damages the patent holder has suffered or as the price of a license. In this context, one can perhaps assume that the parties' relative views on the strength of a patent will result in a pro-competitive or neutral result. If the patent holder believes its patent is strong, it will proceed to trial, knowing that it can collect damages at the end. The generic manufacturer, if it believes the patent holder's patent is weak, may be willing to risk damages and market its product during the litigation, thereby promoting competition. And if the claims are in relative equipoise, a licensing arrangement may well result.

In contrast, a generic competitor subject to Hatch-Waxman cannot enter the market for the first thirty months after litigation is commenced against it. See 21 U.S.C. § 355(j)(5)(B)(iii). In addition, whether its attack against the patent is strong or weak, the benefit it will obtain by successfully litigating to the finish is not great. At best, it will obtain 180 days in which it will be the exclusive generic on the market. See 21 U.S.C. § 355(j)(5)(B)(iv). On the other hand, the benefits to the public from the completion of litigation can be enormous if the generic challenger prevails as it did, at least initially, here. Once the 180-day exclusivity period is over, any generic that wishes to market a generic product and that can establish its product is bioequivalent to the patented product can enter the market, thus providing increased competition.

Moreover, the thirty-month stay provides an incentive to the patent holder to pay its generic competitor more than the generic company could have realized from winning the lawsuit. This is so because once the settlement is reached and the litigation dismissed, another generic manufacturer will have to wait at least thirty months after litigation is commenced against it to begin production.[4] Thus, the patent holder will be protected against all generic competition for thirty months after the first lawsuit is terminated. This problem is aggravated when the agreement between the putative competitors provides that the generic company can deploy its exclusivity period after sitting on it until another ANDA applicant attempts to enter the market. These anti-competitive effects—and others not present in this case—have caused antitrust scholars to propose various analytical frameworks for determining whether an antitrust violation has occurred when a patent holder makes a

[4] Of course, other generic challengers could file Paragraph IV certifications before the first litigation is resolved, but a second generic manufacturer has little incentive to incur the cost of litigation. Even if it wins, it will have to wait until after the first generic challenger's exclusivity period has expired to market its product.

reverse payment to settle patent litigation. The analytical frameworks proposed vary both as to burden of proof and as to the evidence necessary to find a reverse payment illegal.

For instance, Herbert Hovenkamp, Mark Janis, and Mark A. Lemly propose that a Hatch Waxman Act settlement that includes a reverse payment be presumed illegal with the patent holder being allowed to rebut this presumption "by showing both (1) that the ex ante likelihood of prevailing in its infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of litigation and collateral costs attending the lawsuit." Herbert Hovenkamp et al, Anticompetitive Settlement of Intellectual Property Disputes, 87 Minn. L. Rev. 1719, 1759 (2004).

Daniel A. Crane urges a standard somewhat more favorable to the settling parties. See Daniel A. Crane, Ease Over Acuracy in Assessing Patent Settlements, 88 Minn. L. Rev. 698, 709 (2004) (urging that the dispositive factor should be "the ex ante likelihood that the defendant would be excluded from the market if the case was finally adjudicated"). Id. at 709. Because the settling parties will typically have the most documentation relevant to the issue, he contends that "there is relatively little social cost in requiring the settling parties to retain documents going to the core issues in the patent infringement lawsuit." Id. However, to avoid unduly chilling patent settlements, Crane, unlike Hovenkamp et al, would not shift the burden of proof to the settling parties. Id.

Thomas F. Cotter's approach occupies the middle ground. Cotter would leave on the antitrust defendants the burden of demonstrating the legality of a reverse-payment settlement, but he does not adopt Hovenkamp's position that the reverse payment must be limited to litigation costs. See Thomas F. Cotter, Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis and Lemley, 87 Minn. L. Rev. 1789, 1795–97, 1802 (2003). Rather, he argues that "when the antitrust defendants can show that the payment is below the expected amount of the patent defendant's loss if an injunction were to issue, the burden of proving validity and infringement should be somewhat easier to satisfy than at a full-blown infringement trial." Id. at 1814. Cotter rejects, and the other commentators implicitly reject, the approach adopted by the majority. See id. at 1811 (noting that requiring antitrust plaintiffs to show that patent litigation is a sham "would permit too many anticompetive settlements to escape scrutiny. A suit with only a 25% chance of success may not be a sham, but a settlement based upon such a low probability estimate reduces consumer welfare for no apparent offsetting benefit.") (footnote omitted).

Thus, commentators, precedent, and policy suggest the majority's requirement that an antitrust plaintiff show that a Hatch-Waxman lawsuit settled by agreement was a sham—assuming that the agreement did not convey benefits beyond the scope of the patent—is unjustified. A more searching inquiry and a less stringent standard are required to properly protect all interests. I see no reason why the general standard for evaluating an anti-competitive agreement, i.e., its reasonableness, should not govern in this context.[5] See Clorox. Co. v. Winthrop, Inc., 117 F.3d 50, 56 (2d Cir. 1997). In assessing reasonableness, the fact-finder must consider all the circumstances affecting a restrictive agreement. Id. Of course, the strength of the patent must be central to any antitrust analysis involving a patent. Thus, in assessing the reasonability of a Hatch-Waxman settlement, I would rely primarily on the strength of the patent as it appeared at the time at which the parties settled and secondarily on (a) the amount the patent holder paid to keep the generic manufacturer from marketing its product, (b) the amount the generic manufacturer stood to earn during its period of exclusivity, and

[5] The majority argues that applying the general rule of reasonableness would "mak[e] every settlement of patent litigation, at least in the Hatch-Waxman Act context, subject to the inevitable, lengthy and expensive hindsight of a jury as to whether the settlement constituted a 'reasonable' restraint (and, in this case, whether the Federal Circuit would have affirmed or reversed in a patent appeal)" and thus "place a huge damper on such settlements." Majority op. at **[53 n.26]**. I doubt that this doomsday scenario would, in fact, take place. Courts would eventually develop rules for judging the reasonableness of a settlement, and as with other litigation, the majority of cases would be resolved in motion practice. Moreover, the majority again emphasizes the acknowledged interest in settlements without acknowledging the absent party in Hatch Waxman litigation settlements, the consumer of medicines. Those consumers have no ability to affect the settlement, which, in some cases, may benefit both parties beyond any expectation they could have from the litigation itself while harming the consumer. There is a panglossian aspect to the majority's tacit assumption that the settling parties will not act to injure the consumer or competition.

(c) any ancillary anti-competitive effects of the agreement including the presence or absence of a provision allowing the parties to manipulate the generic's exclusivity period. Because plaintiffs allege that the district court's determination of patent invalidity would have been upheld on appeal; that Barr received more than it would have through a victory on appeal; and that Barr and Zeneca agreed that Barr would deploy its paragraph IV certification to defeat other potential generic entrants, I believe that their pleading is adequate.

II. Ancillary issues.

A. Capacity of the district court to evaluate Zeneca's likelihood of success on appeal.

It appears that the court may have been motivated to adopt the "sham" or objectively baseless standard because it overestimated the difficulty of estimating Zeneca's chance of prevailing on appeal. See Majority op. at **[34]** (citing principally Whitmore v. Arkansas, 495 U.S. 149, 159–60 (1990), for the proposition that is impossible to predict the likelihood that Barr would have maintained its patent victory on appeal). Whitmore, is inapposite; there the Court considered a challenge to one inmate's death sentence from a different inmate, Whitmore, who also had been sentenced to death. 495 U.S. at 153. Whitmore argued that he had standing because Arkansas's Supreme Court compared the circumstances of any capital case currently before it to prior capital cases to determine whether the death penalty had been arbitrarily applied. Id. at 156. Whitmore claimed that if he obtained federal habeas relief in the future and if he were again convicted and sentenced to death and appealed to the Arkansas Supreme Court, the failure to include the first inmate's heinous crime in the data base the Arkansas Supreme Court considered would prejudice the review of his sentence. Id. at 156–57. The Court dismissed as speculative the probability of Whitmore's obtaining federal habeas relief, the odds that he would be retried, convicted and sentenced to death once more, and the odds "that the addition of [the first inmate's] crimes to a comparative review 'data base' would lead the Supreme Court of Arkansas to set aside a death sentence for Whitmore." Id. at 157. To find that the sequence of events Whitmore alleged would actually occur indeed requires multiple layers of speculation. In contrast, by the time of the settlement, Barr had already prevailed at the district court level. The record in that case is presumably available, the standards of review the appellate court would have employed are well known, and it is not outside the bounds of the district court's competence to predict whether Barr would have prevailed on appeal.[6] Judges and juries

[6] The majority also relies on Boehm v. Comm'r, 146 F.2d 553 (2d Cir. 1945), aff'd, 326 U.S. 287 (1945). This case also is strikingly inapposite; the Boehm court held only that a taxpayer must claim a loss in the year it becomes obvious and cannot rely on the inherently speculative outcome of litigation seeking to recover some of that loss to justify claiming it in a later year. 146 F.2d at 555. The relevance of that principle to the case at hand is not immediately obvious to me. It is also interesting to note that the Supreme Court affirmed not on the impossibility of predicting litigation outcome but rather because the Tax Court had found that the suit had "no substantial value" and "[t]here

routinely perform an analogous, but more difficult, task in legal malpractice cases in which they must estimate whether, absent attorney error, a party would have prevailed at trial. Estimating the possibility of success on appeal with the assistance of the full record and the parties' briefs is much simpler. Certainly the review would not be so difficult as to justify a sham litigation test.

B. The strength of Zeneca's patent.

As the majority states, the reasonableness of agreements under antitrust law must be judged by the circumstances existing at the time when the agreements were made. Majority op. at **[35]**; cf. SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1207 (2d Cir. 1981) ("Because the essence of a patent is the monopoly or exclusionary power it confers upon the holder; analyzing the lawfulness of the acquisition of the patent [within an antitrust analysis] necessitates that we primarily focus upon the circumstances of the acquiring party and the status of the

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was no evidence in the stipulation of the merits of the suit, the probability of recovery or any assurance of collection of an amount sufficient to pay the creditors' claim . . . and to provide a sufficient surplus for stockholders." 326 U.S. at 294. The majority's additional reliance on Asahi Glass Co. v. Pentech Pharms, 289 F.Supp. 2d 986, 993 (N.D. Il. 2003), and In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d. 188, 200-01 (E.D.N.Y. 2003), requires little discussion. The statement quoted from Asahi Glass that "[n]o one can be certain that he will prevail in a patent suit"—is irrelevant to the capacity of skilled corporate counsel and district court judges to evaluate the likelihood that a determination of patent invalidity will be upheld, and the discussion in Ciprofloxacin relies primarily on Whitmore and Boehm, which I have already discussed.

relevant product and geographic markets at the time of acquisition."). When the agreements here were reached, Judge Broderick had found by clear and convincing evidence that Zeneca's patent was invalid. Therefore, the patent could no longer be considered presumptively valid. See Shelcore, Inc. v. Durham Indus., Inc., 745 F.2d 621, 624-25 (Fed. Cir. 1984) ("The presumption of validity does not guide our analysis on appeal. Rather, we review the findings and conclusions of a district court under the appropriate standard of review.")

The majority, citing Rosco, Inc. v. Mirror Lite Co., 304 F.3d F.3d 1373, 1377-78 (Fed. Cir. 2002), appears to suggest that Shelcore is no longer good law and that patents are presumed valid on appeal even if they have been declared invalid by the district court. See majority op. at 45 n.22. I respectfully suggest that the majority places too much weight on Rosco. The Rosco court simply reiterated the statutory language indicating that patents are presumed valid. 304 F.3d at 1377. It then held that the district court had improperly found that plaintiffs produced clear and convincing evidence to overcome this presumption and thus reversed its finding of validity as to one patent. Id. at 1378-79. This analysis is a far cry from a statement that a patent must be presumed valid on appeal because the latter holding would imply—contrary to Shelcore and Federal Rule of Civil Procedure 52(a)—that the district court's factual findings in support of its ultimate conclusion of invalidity are entitled to no deference.

Alternatively the majority suggests that it is not important where the presumption of validity lay at the moment of appeal because the patent holder was still entitled to protect its monopoly. Majority op. at 45 n.22. However, even assuming, contrary to my view, that most patent settlements should be subject to the "sham litigation" standard, surely there are strong policy reasons for applying more searching scrutiny where a court of competent jurisdiction has found the patent to be invalid.

C. The majority's reliance on Zeneca's subsequent litigation victories.

The majority also focuses on the subsequent litigation between other generics and Zeneca to demonstrate that plaintiffs cannot support a claim that Zeneca's litigation against Barr was sham litigation. Of course, in my view, plaintiffs need not plead or prove sham or objectively baseless litigation. But, in addition, the majority's discussion of the later litigation appears to violate its own acknowledgment of the basic principle that "the reasonableness of agreements under the antitrust laws are to be judged at the time they are entered into." Majority op. at **[35]** (quoting Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294, 1306 (11th Cir. 2003) (citing, inter alia, SCM Corp., 645 F.2d at 1207)). At the time Zeneca and Barr settled the appeal, the existing facts made it fairly likely, if not certain, that Barr would prevail. Judge Broderick had judged the crediblity of the witnesses and found that Zeneca willfully withheld information from the FDA. That finding is quintessentially factual. Thus, the Federal Circuit could have set it aside only for clear error. Fed. R. Civ. P. 52(a). Without the record, I cannot say that the Federal Circuit would have been required to affirm, but, as I am sure the majority will concede, it is the rare case in which an appellate court sets aside a trial court's credibility findings.[7] Had Barr prevailed, on appeal, as I expect it would have, Zeneca would have been estopped from asserting the validity of its patent in any subsequent litigation. Therefore, there is a certain unfairness in using the subsequent litigation, which would not have existed had Barr prevailed on appeal, to demonstrate that plaintiffs cannot establish that Barr would have prevailed on appeal.[8]

D. Conspiracy to use Barr's paragraph IV certification in an anticompetive manner.

I turn now to the majority's expressed belief that the complaint cannot be read to plausibly allege a conspiracy between Barr and Zeneca to deploy Barr's putative exclusivity period to their joint benefit and to the detriment of other

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[7] I do not find persuasive the statistics the majority cites on the frequency of reversal in the Federal Circuit. These statistics would include decisions construing the patent and making other legal determinations. Therefore, they do nothing to show how frequently the Federal Circuit reverses credibility determinations on appeal.

[8] I recognize that it makes more sense to use the subsequent litigation to argue that plaintiffs could not prove the Zeneca lawsuit was not a sham. However, as noted, I do not believe this is an appropriate test.

potential competitors and consumers. A complaint need "include only 'a short and plain statement of the claim showing the pleader is entitled to relief.'" Swierkiewicz v. Sorema, 534 U.S. 506, 512 (2002) (quoting Fed. R. Civ. P. 8(a)(2)). A simplified notice pleading standard is acceptable because "liberal discovery rules and summary judgment motions" allow the parties "to define disputed facts and issues and to dispose of unmeritorious claims." Id. The majority requires more than Swierkiewicz mandates when it complains of plaintiffs' failure to plead evidentiary facts that create an inference of conspiracy.

The court additionally attacks the plausibility of plaintiffs' allegations because, at the time Barr and Zeneca entered into their agreements, a generic enjoyed the benefit of the exclusivity period only if it had successfully defended an infringement lawsuit. See Mova Pharm., 140 F.3d at 1065 (citing former 21 C.F.R. § 314.107(c)(1)). This regulation was struck down after the agreements at issue. See id. at 1076. Because the regulation was in effect when Barr and Zeneca finalized their agreement, the majority finds it implausible that they could have envisioned any anti-competitive effect from the portion of the agreement allowing Barr to deploy its exclusivity period if another generic manufacturer succeeded in invalidated Zeneca's patent. That inference is certainly one that a reasonable fact finder could draw from the facts alleged to date. However, a reasonable fact-finder could also conclude that it is quite unlikely that sophisticated parties would include in their agreement a provision that had no potential benefit to either of them. Is it not at least as likely that the parties were conscious that the regulation was vulnerable to attack and that they wished to add another layer of protection against potential competitors in the event the regulation was invalidated? Discovery would presumably produce materials relevant to determining whether this provision was part of an antitrust conspiracy between Barr and Zeneca. Among other things, the parties may have had written communications concerning the purpose of the exclusionary-period clause. If not, the corporate employees who negotiated the agreement could be deposed. And, the parties could explore the state of legal discussion concerning the successful-defense requirement at the time of the agreement. Thus, it is premature to reject out of hand plaintiffs' claim that Barr and Zeneca agreed to the exclusivity-period provision because they wanted to further restrict other generic manufacturers' ability to market Tamoxifen.

E. Antitrust injury.

In addition to affirming dismissal of the paragraph IV certification claim because plaintiffs did not adequately describe an antitrust violation, the majority states that it has "grave doubt as to whether, even if the defendants 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.'" Majority op. at **[68]**. The majority's doubt stems, in part, from Zeneca's victories in subsequent patent litigation. Id. at **[69]** Because these victories could not have existed if (1) the settlement agreement had not been signed and (2) Barr had prevailed on appeal, they are not finally determinative of causation. Therefore, it is necessary to assess the strength of Zeneca's patent in order to decide whether the injuries were really caused by the patent itself or by the agreements.

III. The inappropriateness of dismissal at the Rule 12(b)(6) stage.

Applying the reasonableness inquiry that I suggest requires a factual record not yet in existence. We have no sense of the value to Barr of the exclusivity period it gave up or the relationship of the value of this period to the reverse payment Zeneca made. Nor do we have any sense of the negotiations between the parties concerning the provision that allowed Barr to revivify its Paragraph IV certification.   Finally no judge or appellate panel has attempted to discern whether Judge Broderick's findings of facts were clearly erroneous.   Allowing the parties to develop a record and make summary judgment motions would give the district court information it needs to assess the reasonableness of the agreements.

However, even under the majority's newly articulated standard, I believe that it was wrong to affirm the dismissal. At a minimum, the plaintiffs should be allowed to develop a factual record to demonstrate that Zeneca's litigation was sham because they had no reason to anticipate the standard articulated here. I note that the courts that have finally rejected antitrust challenges to Hatch-Waxman settlements have done so after reviewing a full record. See Schering-Plough, 402 F.3d at 1058 (granting a petition for review of and reversing an agency decision made upon a full record that granted injunctive relief against certain Hatch-Waxman settlements); In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 517 (E.D.N.Y. 2005) (granting summary judgment motion).

CONCLUSION

Because I disagree with the majority's test for judging whether a Hatch-Waxman agreement violates antitrust law, and because I believe it was inappropriate to dismiss plaintiffs' complaint without allowing discovery, I respectfully dissent.