

1 UNITED STATES COURT OF APPEALS

2 FOR THE SECOND CIRCUIT

3 August Term, 2003

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

5 As amended: August 10, 2006)

6 Docket No. 03-7641

7 -----
8 In Re: Tamoxifen Citrate Antitrust Litigation

9 JOBLOVE, ALLIED SERVS., DIV WELFARE FUND, BENNISH, KOONAN, GREAT
10 LAKES HEALTH PLAN INC., LACAVA, DONEGA, SMITH, LOVINGER,
11 WOOLLACOTT, WHITESIDE, PLATT, UNDERWOOD, TEAMSTERS LOCAL 237,
12 LYNCH, CALLAWAY, MALONEY, MECHANICAL CONTRACT, IBEW-NECA LOCAL
13 505 HEALTH & WELFARE PLAN, A.F. OF L.-A.G.C. BUILDING TRADES
14 WELFARE FUND, SHEET METAL WORKERS LOCAL 441 HEALTH & WELFARE
15 PLAN, LOCAL 1199 NAT'L BENEFIT FUND FOR HEALTH & HUMAN SERVICES,
16 NEW YORK STATEWIDE SENIOR ACTION COUNCIL, MARKS, BLONSTEIN,

17 Plaintiffs-Appellants,

18 - v -

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

21 Defendants-Appellees.

22 -----
23 Before: POOLER, SACK, and RAGGI, Circuit Judges. Pooler,
24 Circuit Judge, dissents in a separate opinion.

25 Appeal by consumers of the drug tamoxifen citrate,
26 third-party payor organizations that provide medical benefits for
27 their members which are used to purchase the drug, and consumer
28 advocacy groups from a judgment of the United States District
29 Court for the Eastern District of New York (I. Leo Glasser,
30 Judge) dismissing their complaint pursuant to Federal Rule of
31 Civil Procedure 12(b)(6). The plaintiffs allege that the

1 defendants Zeneca, Inc., and AstraZeneca Pharmaceuticals LP
2 entered into an agreement with the defendant Barr Laboratories,
3 Inc., settling litigation among them the terms of which violated
4 federal and state antitrust laws. On appeal, the plaintiffs
5 assert that the district court erred in dismissing the complaint
6 based on its conclusion that the settlement agreement was not a
7 violation of antitrust law and that the plaintiffs did not suffer
8 antitrust injury as a result of the alleged violation.

9 Affirmed.

10 J. DOUGLAS RICHARDS, Milberg Weiss
11 Bershad Hynes & Lerach LLP (Michael M.
12 Buchman, Milberg Weiss Bershad &
13 Schulman LLP, New York, NY; Patrick E.
14 Cafferty, Miller Faucher and Cafferty
15 LLP, Ann Arbor, MI; Bernard Persky,
16 Barbara J. Hart, Hollis L. Salzman,
17 Goodkind Labaton Rudoff & Sucharow LLP,
18 New York, NY; Robert S. Schachter,
19 Joseph Lipofsky, Joseph S. Tusa,
20 Zwerling, Schachter & Zwerling, LLP, New
21 York, NY; Robert G. Eisler, Lieff,
22 Cabraser, Heimann & Bernstein, LLP, New
23 York, NY; of counsel), New York, NY, for
24 Plaintiffs-Appellants.

25 JOEL M. COHEN, Davis Polk & Wardwell
26 (Diem-Suong T. Nguyen, Douglas K.
27 Yatter, Wendy L. Silver, Davis Polk &
28 Wardwell, New York, NY; George C.
29 Lombardi, Christine J. Siwik, Maureen L.
30 Rurka, Winston & Strawn LLP, Chicago,
31 IL; of counsel), New York, NY, for
32 Defendants-Appellees.

33 Bruce E. Gerstein, Garwin Bronzaft
34 Gerstein & Fisher LLP (Barry S. Taus,
35 Jan Bartelli, Garwin Bronzaft Gerstein &
36 Fisher LLP; Steve D. Shadowen, Monica L.
37 Rebeck, Hanglely Aronchick Segal &
38 Pudlin, Harrisburg, PA; of counsel), New
39 York, NY, for Amicus Curiae Louisiana
40 Wholesale Drug Company, Inc., CVS
41 Meridian Inc., and Rite Aid Corporation.

1 SACK, Circuit Judge:

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

10 The plaintiffs appeal from a judgment of the United
11 States District Court for the Eastern District of New York (I.
12 Leo Glasser, Judge) dismissing their complaint pursuant to
13 Federal Rule of Civil Procedure 12(b)(6). The plaintiffs claim
14 that the defendants conspired, under an agreement settling a
15 patent infringement lawsuit among the defendants in 1993 while an
16 appeal in that lawsuit was pending, to monopolize the market for
17 tamoxifen -- the most widely prescribed drug for the treatment of
18 breast cancer -- by suppressing competition from generic versions
19 of the drug. The settlement agreement included, among other
20 things, a so-called "reverse payment" of \$21 million from the
21 defendant patent-holders Zeneca, Inc., AstraZeneca
22 Pharmaceuticals LP, and AstraZeneca PLC (collectively "Zeneca")
23 to the defendant generic manufacturer Barr Laboratories, Inc.
24 ("Barr"), and a license from Zeneca to Barr allowing Barr to sell
25 an unbranded version of Zeneca-manufactured tamoxifen. The
26 settlement agreement was contingent on obtaining a vacatur of the

1 judgment of the district court that had heard the infringement
2 action holding the patent to be invalid.

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

10 **REGULATORY BACKGROUND**

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

14 The Federal Food, Drug, and Cosmetic Act, ch. 675, 52
15 Stat. 1040 (1938) (codified at scattered sections of title 21 of
16 the United States Code), prohibits the introduction or delivery
17 for introduction into interstate commerce of "any new drug,
18 unless an approval of an application filed pursuant to subsection
19 (b) or (j) of [21 U.S.C. § 355] is effective with respect to such
20 drug." 21 U.S.C. § 355(a). Subsection (b) describes the process
21 of filing a New Drug Application ("NDA") with the United States
22 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).

1 and time-consuming procedure in which the applicant attempts to
2 establish the safety and effectiveness of the drug. Id.
3 § 355(b). In 1984, in order to accelerate the approval process
4 for low-cost generic versions of established drugs, Congress
5 enacted the Drug Price Competition and Patent Term Restoration
6 Act of 1984 (the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98
7 Stat. 1585 (codified at scattered sections of titles 21 and 35 of
8 the United States Code). Among other things, the Act added
9 subsection (j) to section 355. Hatch-Waxman Act § 101.
10 Subsection (j) provides for an Abbreviated New Drug Application
11 ("ANDA") to the FDA for the bioequivalent form of a drug already
12 approved for safety and effectiveness. 21 U.S.C. § 355(j)(1),
13 (j)(2)(A), (j)(7)(A). Subsection (j)(7)(A) further provides that
14 the Secretary of the FDA will create and maintain a list of such
15 approved drugs. Id. § 355(j)(7)(A). This list, Approved Drug
16 Products with Therapeutic Equivalence Evaluations, is commonly
17 known as the "Orange Book."² See id.;
18 <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.

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

11 An ANDA filer that elects a paragraph IV certification
12 must notify each affected patent owner of the certification. Id.
13 § 355(j) (2) (B) (i). The patent owner then has forty-five days
14 after the date it receives such notice to bring suit against the
15 ANDA filer for patent infringement. Id. § 355(j) (5) (B) (iii). If
16 no patent owner brings such a lawsuit during this period, the FDA
17 may immediately approve the ANDA. Id. If, however, the patent
18 owner brings suit during this period, the FDA's final approval of
19 the ANDA is stayed for thirty months after the date the patent

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).

1 owner received the requisite notice or until a district court⁴
2 returns a decision as to the validity of the patent or its
3 infringement if it does so before the thirty-month period
4 expires. Id.

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

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.

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

12 Until 1998 (and, therefore, at the time of the
13 settlement that is the subject of this appeal), the 180-day
14 exclusivity period was available to the first ANDA filer to elect
15 a paragraph IV certification, but only if the ANDA filer
16 successfully defended against a lawsuit for infringement of the
17 relevant patent. See 21 C.F.R. § 314.107(c) (1) (1995). This so-
18 called "successful defense" requirement was challenged in 1997 in
19 two separate lawsuits. In each, the circuit court rejected the
20 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.

1 Pharm. Corp. v. Shalala, 140 F.3d 1060, 1076 (D.C. Cir. 1998);
2 Granotec, Inc. v. Shalala, Nos. 97-1873, 97-1874, 1998 WL 153410,
3 at *7, 1998 U.S. App. LEXIS 6685, at *19-*21 (4th Cir. Apr. 3,
4 1998) (unpublished opinion).

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

1 **FACTUAL AND PROCEDURAL BACKGROUND**

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

13 In response, on November 2, 1987 -- within the required
14 forty-five days of Barr's amendment of its ANDA to include a
15 paragraph IV certification -- ICI filed a patent infringement
16 lawsuit against Barr and Barr's raw material supplier, Heumann
17 Pharma GmbH & Co. ("Heumann"), in the United States District
18 Court for the Southern District of New York.⁷ See Imperial Chem.
19 Indus., PLC v. Barr Labs., Inc., 126 F.R.D. 467, 469 (S.D.N.Y.
20 1989). On April 20, 1992, the district court (Vincent L.
21 Broderick, Judge) declared ICI's tamoxifen patent invalid based
22 on the court's conclusion that ICI had deliberately withheld

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.

1 "crucial information" from the Patent and Trademark Office
2 regarding tests that it had conducted on laboratory animals with
3 respect to the safety and effectiveness of the drug. See
4 Imperial Chem. Indus., PLC v. Barr Labs., Inc., 795 F. Supp. 619,
5 626-27 (S.D.N.Y. 1992) ("Tamoxifen I"). Those tests had revealed
6 hormonal effects "opposite to those sought in humans," which, the
7 court found, could have "unpredictable and at times disastrous
8 consequences." Id. at 622.

9 ICI appealed the district court's judgment to the
10 United States Court of Appeals for the Federal Circuit. In 1993,
11 while the appeal was pending, the parties entered into a
12 confidential settlement agreement (the "Settlement Agreement")
13 which is the principal subject of this appeal. In the Settlement
14 Agreement, Zeneca (which had succeeded to the ownership rights of
15 the patent) and Barr agreed that in return for \$21 million and a
16 non-exclusive license to sell Zeneca-manufactured tamoxifen in
17 the United States under Barr's label, rather than Zeneca's
18 trademark Nolvadex®, Barr would change its ANDA paragraph IV
19 certification to a paragraph III certification, thereby agreeing
20 that it would not market its own generic version of tamoxifen
21 until Zeneca's patent expired in 2002. See In re Tamoxifen
22 Citrate Antitrust Litig., 277 F. Supp. 2d 121, 125-26 (E.D.N.Y.
23 2003) ("Tamoxifen II"). Zeneca also agreed to pay Heumann \$9.5
24 million immediately, and an additional \$35.9 million over the
25 following ten years. The parties further agreed that if the
26 tamoxifen patent were to be subsequently declared invalid or

1 unenforceable in a final and (in contrast to the district court
2 judgment in Tamoxifen I) unappealable judgment by a court of
3 competent jurisdiction, Barr would be allowed to revert to a
4 paragraph IV ANDA certification. Thus if, in another lawsuit, a
5 generic marketer prevailed as Barr had prevailed in Tamoxifen I,
6 and that judgment was either not appealed or was affirmed on
7 appeal, Barr would have been allowed to place itself in the same
8 position (but for the 180-day head start, if it was available)
9 that it would have been in had it prevailed on appeal in
10 Tamoxifen I, rather than settling while its appeal was pending in
11 the Federal Circuit.

12 The plaintiffs allege that as a part of the Settlement
13 Agreement, Barr "understood" that if another generic manufacturer
14 attempted to market a version of tamoxifen, Barr would seek to
15 prevent the manufacturer from doing so by attempting to invoke
16 the 180-day exclusivity right possessed by the first "paragraph
17 IV" filer. Compl. ¶ 58. According to the plaintiffs, this
18 understanding among the defendants effectively forestalled the
19 introduction of any generic version of tamoxifen, because, five
20 years later -- only a few weeks before other generic
21 manufacturers were to be able to begin marketing their own
22 versions of tamoxifen -- Barr did in fact successfully claim
23 entitlement to the exclusivity period. It thereby prevented
24 those manufacturers from entering the tamoxifen market until 180
25 days after Barr triggered the period by commercially marketing
26 its own generic version of the drug. In fact, Barr had not yet

1 begun marketing its own generic version and had little incentive
2 to do so because, pursuant to the Settlement Agreement, it was
3 already able to market Zeneca's version of tamoxifen.

4 Meanwhile, pursuant to the Settlement Agreement which
5 was contingent on the vacatur of the district court judgment in
6 Tamoxifen I, Barr and Zeneca filed a "Joint Motion to Dismiss the
7 Appeal as Moot and to Vacate the Judgment Below." See Tamoxifen
8 II, 277 F. Supp. 2d at 125. The Federal Circuit granted the
9 motion, thereby vacating the district court's judgment that the
10 patent was invalid. See Imperial Chem. Indus., PLC v. Heumann
11 Pharma GmbH & Co., No. 92-1403, 1993 WL 118931, at *1, U.S. App.
12 LEXIS 14872, at *1-*2 (Fed. Cir. Mar. 19, 1993) (unpublished
13 opinion). Such a vacatur, while generally considered valid as a
14 matter of appellate procedure by courts at the time of the
15 Settlement Agreement, see U.S. Philips Corp. v. Windmere Corp.,
16 971 F.2d 728, 731 (Fed. Cir. 1992), was shortly thereafter held
17 to be invalid in nearly all circumstances by the Supreme Court,
18 see U.S. Bancorp Mortgage Co. v. Bonner Mall P'ship, 513 U.S. 18,
19 27-29 (1994).⁸

20 In the years after the parties entered into the
21 Settlement Agreement and the Federal Circuit vacated the district
22 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

1 with paragraph IV certifications to secure approval of their
2 respective generic versions of tamoxifen: Novopharm Ltd., in June
3 1994, Mylan Pharmaceuticals, Inc., in January 1996, and
4 Pharmachemie, B.V., in February 1996.¹⁰ See Tamoxifen II, 277 F.
5 Supp. 2d at 126-27. Zeneca responded to each of these
6 certifications in the same manner that it had responded to
7 Barr's: by filing a patent infringement lawsuit within the forty-
8 five day time limit provided by 21 U.S.C. § 355(j)(5)(B)(iii).
9 See id. In each case, the court rejected the generic
10 manufacturer's attempt to rely on the vacated Tamoxifen I
11 decision, and -- contrary to the Tamoxifen I judgment -- upheld
12 the validity of Zeneca's tamoxifen patent. See Zeneca Ltd. v.
13 Novopharm Ltd., No. 96-1364, 1997 WL 168318, at *2-*4, 1997 U.S.
14 App. LEXIS 6634, at *4-*11 (Fed. Cir. Apr. 10, 1997) (unpublished
15 opinion) (affirming the judgment of the United States District
16 Court for the District of Maryland declining to give Tamoxifen I
17 collateral estoppel effect or to apply U.S. Bancorp retroactively
18 and deciding that Zeneca's patent was valid); Zeneca Ltd. v.
19 Pharmachemie B.V., No. 96-12413, 2000 WL 34335805, at *15, 2000
20 U.S. Dist LEXIS 22631, at *51-*53 (D. Mass. Sept. 11, 2000)
21 (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.

1 and that the patent was valid); AstraZeneca UK Ltd. v. Mylan
2 Pharms., Inc., No. 00-2239, slip op. at 2-3 (W.D. Pa. Nov. 30,
3 2000) (entering stipulated consent order that FDA approval for
4 Mylan would not be effective before the expiration of the
5 tamoxifen patent).

6 While Mylan and Pharmachemie's lawsuits were pending in
7 district court, the FDA's "successful defense" rule, requiring
8 that a generic manufacturer seeking to market an allegedly
9 patented drug "successfully defend" its patent infringement
10 lawsuit in order to receive the 180-day exclusivity period --
11 which at the time the Settlement Agreement was entered into would
12 have excluded Barr from benefitting from the exclusivity period
13 -- was, as noted, held invalid. See Mova Pharm. Corp. v.
14 Shalala, 955 F. Supp. 128, 130-32 (D.D.C. 1997), aff'd in part
15 and rev'd in part on other grounds, 140 F.3d 1060 (D.C. Cir.
16 1998); Granutec, Inc. v. Shalala, Nos. 97-1873, 97-1874, 1998 WL
17 153410, at *7, 1998 U.S. App. LEXIS 6685, at *19-*21 (4th Cir.
18 Apr. 3, 1998) (unpublished opinion). In June 1998, at the time
19 the FDA removed the requirement, Barr -- armed with the new rule
20 rendering the first ANDA paragraph IV filer eligible for the 180-
21 day exclusivity period even if it had not successfully defended a
22 patent infringement suit -- attempted to block final FDA approval
23 of other generic versions of tamoxifen by claiming entitlement to
24 the 180-day exclusivity period. See Tamoxifen II, 277 F. Supp.
25 2d at 127 (citing "Petition for Stay of Action" filed with the
26 FDA on June 26, 1998).

1 At the time, Pharmachemie had received tentative
2 approval from the FDA to distribute its version of the drug,
3 Mylan was awaiting approval to do the same, and both Pharmachemie
4 and Mylan's thirty-month stays under section 355(j)(5)(B)(iii),
5 triggered by Zeneca's infringement lawsuits, were soon to expire.
6 See Compl. ¶¶ 61-63 (stating that the 30-month stay for Mylan was
7 scheduled to expire on July 10, 1998, and for Pharmachemie in
8 August 1998); Pharmachemie B.V. v. Barr Labs., Inc., 276 F.3d
9 627, 630 (D.C. Cir. 2002) (noting that Pharmachemie was granted
10 tentative approval on April 3, 1997); Mylan Pharms. Inc. v.
11 Henney, 94 F. Supp. 2d 36, 44 (D.D.C. 2000), vacated and
12 dismissed as moot sub nom. Pharmachemie B.V. v. Barr Labs., Inc.,
13 284 F.3d 125 (D.C. Cir. 2002) (per curiam). Because of the rule
14 change, however, the FDA was able to, and on March 2, 1999, did,
15 grant Barr's petition to confirm its entitlement to the
16 exclusivity period despite the fact that it had settled, rather
17 than "successfully defended" against, Zeneca's lawsuit. See
18 Tamoxifen II, 277 F. Supp. 2d at 127. The FDA's action
19 effectively delayed the marketing of other generic versions of
20 tamoxifen unless and until Barr triggered and exhausted its
21 180-day exclusivity period by selling its own generic form of the
22 drug, rather than the version manufactured by Zeneca. As noted,
23 Barr had little incentive to do so because it was already
24 distributing Zeneca's version of tamoxifen.

25 Pharmachemie and Mylan challenged the FDA's decision.
26 On March 31, 2000, in Mylan Pharmaceuticals, the United States

1 District Court for the District of Columbia ruled in
2 Pharmachemie's and Mylan's favor. 94 F. Supp. 2d at 54. It
3 concluded that, although Judge Broderick's ruling of invalidity
4 in Tamoxifen I had been vacated by the Settlement Agreement, that
5 ruling was still a court decision sufficient to trigger Barr's
6 180-day exclusivity period, which therefore had already expired.
7 See Mylan Pharms., 94 F. Supp. 2d at 54. As a result, on June
8 26, 2000, the FDA revoked Barr's claim to the 180-day exclusivity
9 period. See Tamoxifen II, 277 F. Supp. 2d at 127.

10 On appeal, however, the District of Columbia Circuit
11 vacated the district court's decision as moot. Pharmachemie, 276
12 F.3d at 634; Pharmachemie, 284 F.3d at 125. The court noted that
13 subsequent to the FDA's decision to approve Barr's application,
14 the district court had ruled against Pharmachemie in Zeneca's
15 patent infringement lawsuit against it. See Pharmachemie, 276
16 F.3d at 629. Thus, even if, as the district court held in Mylan,
17 Barr's 180-day exclusivity period had run, Pharmachemie and
18 Mylan¹¹ were prohibited by the judgments against them in the
19 patent litigation from marketing their generic versions of
20 tamoxifen until Zeneca's patent expired. Zeneca's patent on
21 tamoxifen expired on August 20, 2002, and generic manufacturers
22 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; AstraZeneca UK Ltd., No. 00-2239, slip op. at 2-3.

1 Proceedings in the District Court

2 While these generic manufacturers were litigating the
3 validity of Zeneca's patent on tamoxifen, consumers and consumer
4 groups in various parts of the United States filed some thirty
5 lawsuits challenging the legality of the 1993 Settlement
6 Agreement between Zeneca and Barr. See Tamoxifen II, 277 F.
7 Supp. 2d at 127. Those lawsuits were subsequently transferred by
8 the Judicial Panel on Multidistrict Litigation to the United
9 States District Court for the Eastern District of New York.
10 Subsequently, a consolidated class action complaint embodying the
11 claims was filed. In re Tamoxifen Citrate Antitrust Litig., 196
12 F. Supp. 2d 1371 (J.P.M.L. 2001); Tamoxifen II, 277 F. Supp. 2d
13 at 127. In the consolidated lawsuit, the plaintiffs alleged that
14 the Settlement Agreement unlawfully (1) enabled Zeneca and Barr
15 to resuscitate a patent that the district court had already held
16 to be invalid and unenforceable; (2) facilitated Zeneca's
17 continuing monopolization of the market for tamoxifen; (3)
18 provided for the sharing of unlawful monopoly profits between
19 Zeneca and Barr; (4) maintained an artificially high price for
20 tamoxifen; and (5) prevented competition from other generic
21 manufacturers of tamoxifen. See Tamoxifen II, 277 F. Supp. 2d at
22 127-28. At the heart of the lawsuit was the contention that the
23 Settlement Agreement enabled Zeneca and Barr effectively to
24 circumvent the district court's invalidation of Zeneca's
25 tamoxifen patent in Tamoxifen I, which, the plaintiffs asserted,
26 would have been affirmed by the Federal Circuit. The result of

1 such an affirmance, according to the plaintiffs, would have been
2 that Barr would have received approval to market a generic
3 version of tamoxifen; Barr would have begun marketing tamoxifen,
4 thereby triggering the 180-day exclusivity period; other generic
5 manufacturers would have introduced their own versions of
6 tamoxifen upon the expiration of the exclusivity period, with
7 Zeneca collaterally estopped from invoking its invalidated patent
8 as a defense; and, as a result, the price for tamoxifen would
9 have declined substantially below the levels at which the Zeneca-
10 manufactured drug in fact sold in the market shared by Zeneca and
11 Barr through the Settlement Agreement. Id. at 128. The
12 defendants moved to dismiss the class action complaint pursuant
13 to Federal Rule of Civil Procedure 12(b)(6) for failure to state
14 a claim upon which relief can be granted.

15 On May 15, 2003, in a thorough and thoughtful opinion,
16 the district court granted the defendants' motion to dismiss.
17 See id. at 140. The court noted that although market-division
18 agreements between a monopolist and a potential competitor
19 ordinarily violate the Sherman Act, they are not necessarily
20 unlawful when the monopolist is a patent holder. Id. at 128-29.
21 Pursuant to a patent grant, the court reasoned, a patent holder
22 may settle patent litigation by entering into a licensing
23 agreement with the alleged infringer without running afoul of the
24 Sherman Act. Id. at 129. Yet, the court continued, a patent
25 holder is prohibited from acting in bad faith "beyond the limits
26 of the patent monopoly" to restrain or monopolize trade. Id.

1 (quoting United States v. Line Material Co., 333 U.S. 287, 308
2 (1948) (internal quotation marks omitted)).

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

25 The district court was also of the view that the
26 defendants could not be held liable for Barr's FDA petition to

1 preserve its 180-day exclusivity period even if this was a term
2 of the defendants' negotiated Settlement Agreement. Id. at 135.
3 It reasoned that at the time of settlement, Barr could not have
4 successfully pursued its FDA application because the FDA
5 continued to apply the "successful defense" rule until 1997.
6 Id. at 134. It was only after 1997 that Barr petitioned the FDA
7 to preserve its exclusivity period. The court concluded that
8 Barr's petition was

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

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

21 The district court also concluded that even if the
22 plaintiffs had stated an antitrust violation, they did not suffer
23 antitrust injury from either Barr's exclusivity period or the
24 Settlement Agreement and the resulting vacatur of the district
25 court's judgment in Tamoxifen I invalidating the tamoxifen
26 patent. Id. at 136-38. The court noted that "[a]ntitrust
27 injury . . . must be caused by something other than the
28 regulatory action limiting entry to the market." Id. at 137.
29 The court attributed "the lack of competition in the market" not
30 to "the deployment of Barr's exclusivity period, but rather [to]

1 the inability of the generic companies to invalidate or design
2 around" the tamoxifen patent, and their consequent loss of the
3 patent litigation against Zeneca. Id. This was so, the district
4 court concluded, even if Barr's petition to the FDA had delayed
5 the approval of Mylan's ANDA. Id. at 137. Any "injury" suffered
6 by the plaintiffs, said the court, "is thus not antitrust injury,
7 but rather the result of the legal monopoly that a patent holder
8 possesses." Id. at 138.

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

24 The district court therefore dismissed the plaintiffs'
25 Sherman Act claims. Id. It also dismissed the plaintiffs'
26 state-law claims, which had alleged violations of the antitrust

1 laws of seventeen states and violations of consumer protection
2 and unfair competition laws of twenty-one states, because those
3 claims were based on the same allegations as the plaintiffs'
4 federal antitrust claims. Id. at 138-40. The plaintiffs appeal
5 the dismissal of their claims.

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

12 **DISCUSSION**

13 I. Jurisdiction

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

22 The United States Court of Appeals for the Federal
23 Circuit has exclusive jurisdiction over an appeal from a federal
24 district court "if the jurisdiction of that court was based, in
25 whole or in part, on section 1338 of [title 28]," with exceptions
26 not pertinent here. 28 U.S.C. § 1295(a)(1). Section 1338, in

1 turn, provides that federal district courts shall have original
2 and exclusive jurisdiction "of any civil action arising under any
3 Act of Congress relating to patents." Id. § 1338(a). Therefore,
4 whether the Federal Circuit has jurisdiction over the instant
5 case "turns on whether this is a case 'arising under' a federal
6 patent statute." Christianson v. Colt Indus. Operating Corp.,
7 486 U.S. 800, 807 (1988).

8 A case "arises under" federal patent law if "a well-
9 pleaded complaint establishes either that federal patent law
10 creates the cause of action or that the plaintiff's right to
11 relief necessarily depends on resolution of a substantial
12 question of federal patent law, in that patent law is a necessary
13 element of one of the well-pleaded claims." Id. at 809.¹² This
14 is determined "from what necessarily appears in the plaintiff's
15 statement of his own claim in the bill or declaration, unaided by
16 anything alleged in anticipation or avoidance of defenses which
17 it is thought the defendant may interpose." Id. (internal
18 quotation marks and citation omitted). "[A] case raising a
19 federal patent-law defense does not, for that reason alone, arise
20 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).

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

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

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

1 would have been upheld on appeal or whether the tamoxifen patent
2 was otherwise enforceable and infringed.

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

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

23 II. Standard of Review

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

1 "A pleading which sets forth a claim for relief . . .
2 shall contain . . . a short and plain statement of the claim
3 showing that the pleader is entitled to relief." Fed. R. Civ. P.
4 8(a)(2). "Given the Federal Rules' simplified standard for
5 pleading, a court may dismiss a complaint only if it is clear
6 that no relief could be granted under any set of facts that could
7 be proved consistent with the allegations." Swierkiewicz v.
8 Sorema N.A., 534 U.S. 506, 514 (2002) (internal quotation marks,
9 citation, and alteration omitted). There is no heightened
10 pleading requirement in antitrust cases. See Twombly v. Bell
11 Atl. Corp., 425 F.3d 99, 108-13 (2d Cir. 2005).

12 In reviewing a decision on a motion to dismiss under
13 Federal Rule of Civil Procedure 12(b)(6), we "must accept as true
14 all the factual allegations in the complaint," Leatherman v.
15 Tarrant County Narcotics Intelligence & Coordination Unit, 507
16 U.S. 163, 164 (1993), and "draw all reasonable inferences in
17 plaintiffs' favor," Freedom Holdings Inc. v. Spitzer, 357 F.3d
18 205, 216 (2d Cir. 2004). To survive a motion to dismiss, a
19 plaintiff bringing suit under section 1 of the Sherman Act need
20 not allege facts that exclude the possibility that the behavior
21 of which complaint is made is legal. See Twombly, 425 F.3d at
22 111 ("[S]hort of the extremes of 'bare bones' and
23 'implausibility,' a complaint in an antitrust case need only
24 contain the 'short and plain statement of the claim showing that

1 the pleader is entitled to relief' that Rule 8(a) requires."
2 (citation omitted). However, "bald assertions and conclusions
3 of law are not adequate [to state a claim] and a complaint
4 consisting only of naked assertions, and setting forth no facts
5 upon which a court could find a violation of the [law], fails to
6 state a claim under Rule 12(b)(6)." Gregory, 243 F.3d at 692
7 (internal quotation marks and citations omitted). And "[i]t
8 is . . . improper to assume that the plaintiff can prove facts
9 that it has not alleged or that the defendants have violated the
10 antitrust laws in ways that have not been alleged." Todd v.
11 Exxon Corp., 275 F.3d 191, 198 (2d Cir. 2001) (internal quotation
12 marks, citation, and alterations omitted). At the same time, in
13 antitrust cases, "plaintiffs should be given the full benefit of
14 their proof without tightly compartmentalizing the various
15 factual components and wiping the slate clean after scrutiny of
16 each." Cont'l Ore Co. v. Union Carbide & Carbon Corp., 370 U.S.
17 690, 699 (1962).

18 III. The Plaintiffs' Antitrust Claims

19 A. The Tension between Antitrust Law and Patent Law

20 With the ultimate goal of stimulating competition and
21 innovation, the Sherman Act prohibits "[e]very contract,
22 combination in the form of trust or otherwise, or conspiracy, in
23 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).

1 U.S.C. § 1, and "monopoliz[ation], or attempt[s] to monopolize,
2 or combin[at]ions] or conspir[acies] . . . to monopolize any part
3 of the trade or commerce among the several States," id. § 2.¹⁴
4 By contrast, also with the ultimate goal of stimulating
5 competition and innovation, patent law grants an innovator "the
6 right to exclude others from making, using, offering for sale, or
7 selling the invention throughout the United States or importing

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).

1 the invention into the United States" for a limited term of
2 years. 35 U.S.C. § 154(a)(1)-(2); see also Dawson Chem. Co. v.
3 Rohm & Haas Co., 448 U.S. 176, 215 (1980) ("[T]he essence of a
4 patent grant is the right to exclude others from profiting by the
5 patented invention."). It is the tension between restraints on
6 anti-competitive behavior imposed by the Sherman Act and grants
7 of patent monopolies under the patent laws, as complicated by the
8 Hatch-Waxman Act, that underlies this appeal. See, e.g., United
9 States v. Singer Mfg. Co., 374 U.S. 174, 196-97 (1963) ("[T]he
10 possession of a valid patent . . . does not give the patentee any
11 exemption from the provisions of the Sherman Act beyond the
12 limits of the patent monopoly.") (internal quotation marks and
13 citation omitted); cf. Andrx Pharms., Inc. v. Biovail Corp.
14 Int'l, 256 F.3d 799, 802 (D.C. Cir. 2001) ("Although the Congress
15 was interested in increasing the availability of generic drugs,
16 it also wanted to protect the patent rights of the pioneer
17 applicants."), cert. denied, 535 U.S. 931 (2002); Schering-Plough
18 Corp. v. F.T.C., 402 F.3d 1056, 1067 (11th Cir. 2005) ("Although
19 the exclusionary power of a patent may seem incongruous with the
20 goals of antitrust law, a delicate balance must be drawn between
21 the two regulatory schemes.").

22 B. The Plaintiffs' Allegations

23 1. Settlement of a Patent Validity Lawsuit. The
24 plaintiffs contend that several factors -- including that
25 Tamoxifen I was settled after the tamoxifen patent had been held

1 invalid by the district court, making the patent unenforceable at
2 the time of settlement -- indicate that if their allegations are
3 proved, the defendants violated the antitrust laws. They argue
4 that the district court in the case before us erred by treating
5 the tamoxifen patent as valid and enforceable. Instead, they
6 say, in accordance with the never-reviewed judgment in Tamoxifen
7 I, the district court in this case should have treated the patent
8 as presumptively invalid for purposes of assaying the sufficiency
9 of the plaintiffs' complaint.

10 We begin our analysis against the backdrop of our
11 longstanding adherence to the principle that "courts are bound to
12 encourage" the settlement of litigation. Gambale v. Deutsche
13 Bank AG, 377 F.3d 133, 143 (2d Cir. 2004). "Where a case is
14 complex and expensive, and resolution of the case will benefit
15 the public, the public has a strong interest in settlement. The
16 trial court must protect the public interest, as well as the
17 interests of the parties, by encouraging the most fair and
18 efficient resolution." United States v. Glens Falls Newspapers,
19 Inc., 160 F.3d 853, 856-57 (2d Cir. 1998). As the Eleventh
20 Circuit recently noted in drug patent litigation similar to the
21 one before us, "There is no question that settlements provide a
22 number of private and social benefits as opposed to the
23 inveterate and costly effects of litigation." Schering-Plough,
24 402 F.3d at 1075.

1 It is well settled that "[w]here there are legitimately
2 conflicting [patent] claims . . . , a settlement by agreement,
3 rather than litigation, is not precluded by the [Sherman] Act,"
4 although such a settlement may ultimately have an adverse effect
5 on competition. Standard Oil Co. v. United States, 283 U.S. 163,
6 171 (1931); cf. Flex-Foot, Inc. v. CRP, Inc., 238 F.3d 1362, 1369
7 (Fed. Cir. 2001) ("[W]hile the federal patent laws favor full and
8 free competition in the use of ideas in the public domain over
9 the technical requirements of contract doctrine, settlement of
10 litigation is more strongly favored by the law."); Nestle Co. v.
11 Chester's Mkt., Inc., 756 F.2d 280, 284 (2d Cir. 1985) ("[T]he
12 district court imposed the heavy burden on trademark defendants
13 of having to continue to litigate when they would prefer to
14 settle, a ruling without precedent."), overruled on other
15 grounds, U.S. Bancorp Mortgage Co. v. Bonner Mall P'ship, 513
16 U.S. 18, 27-29 (1994); Duplan Corp. v. Deering Milliken, Inc.,
17 540 F.2d 1215, 1220 (4th Cir. 1976) ("[T]he settlement of patent
18 litigation, in and of itself, does not violate the antitrust
19 laws."); Asahi Glass Co. v. Pentech Pharms., Inc., 289 F. Supp.
20 2d 986, 991 (N.D. Ill. 2003) (Posner, J., sitting by designation)
21 ("The general policy of the law is to favor the settlement of
22 litigation, and the policy extends to the settlement of patent
23 infringement suits").

24 Rules severely restricting patent settlements might
25 also be contrary to the goals of the patent laws because the
26 increased number of continuing lawsuits that would result would

1 heighten the uncertainty surrounding patents and might delay
2 innovation. See Valley Drug, 344 F.3d at 1308; Daniel A. Crane,
3 Exit Payments in Settlement of Patent Infringement Lawsuits:
4 Antitrust Rules and Economic Implications, 54 Fla. L. Rev. 747,
5 749 (2002). Although forcing patent litigation to continue might
6 benefit consumers in some instances, "patent settlements
7 can . . . promote efficiencies, resolving disputes that might
8 otherwise block or delay the market entry of valuable
9 inventions." Joseph F. Brodley & Maureen A. O'Rourke,
10 Preliminary Views: Patent Settlement Agreements, Antitrust,
11 Summer 2002, at 53.¹⁵ As the Fourth Circuit has observed, "It is
12 only when settlement agreements are entered into in bad faith and
13 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.").

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

3 We cannot judge this post-trial, pre-appeal settlement
4 on the basis of the likelihood vel non of Zeneca's success had it
5 not settled but rather pursued its appeal. As the Supreme Court
6 noted in another context, "[i]t is just not possible for a
7 litigant to prove in advance that the judicial system will lead
8 to any particular result in his case." Whitmore v. Arkansas, 495
9 U.S. 149, 159-60 (1990). Similarly, "[n]o one can be certain
10 that he will prevail in a patent suit." Asahi Glass, 289 F.
11 Supp. 2d at 993 (emphasis in original). We cannot guess with any
12 degree of assurance what the Federal Circuit would have done on
13 an appeal from the district court's judgment in Tamoxifen I. Cf.
14 In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp.
15 2d 188, 200-01 (E.D.N.Y. 2003) ("Cipro II") (noting that courts
16 should not speculate about the outcome of litigation) (citing
17 Boehm v. Comm'r, 146 F.2d 553 (2d Cir.), aff'd, 326 U.S. 287
18 (1945)); In re Ciprofloxacin Hydrochloride Antitrust Litig., 363
19 F. Supp. 2d 514, 529 (E.D.N.Y. 2005) ("Cipro III") ("[M]aking the
20 legality of a patent settlement agreement, on pain of treble
21 damages, contingent on a later court's assessment of the patent's
22 validity might chill patent settlements altogether."). And
23 because in this case any such guess is retrospective, it would in
24 any event be of limited value in assessing the behavior of the
25 defendants at the relevant time: when they were entering into the
26 Settlement Agreement. See Valley Drug, 344 F.3d at 1306 ("[T]he

1 reasonably of agreements under the antitrust laws are to be
2 judged at the time the agreements are entered into.") (citing,
3 inter alia, SCM Corp. v. Xerox Corp., 645 F.2d 1195, 1207 (2d
4 Cir. 1981), cert. denied, 455 U.S. 1016 (1982)).

5 As the plaintiffs correctly point out, the Federal
6 Circuit would have reviewed Judge Broderick's factual findings
7 underlying his conclusion of invalidity with considerable
8 deference, rather than engaging in a presumption of validity.
9 See Shelcore, Inc. v. Durham Indus., Inc., 745 F.2d 621, 624-25
10 (Fed. Cir. 1984) ("The presumption of validity does not guide our
11 analysis on appeal. Rather, we review the findings and
12 conclusions of a district court under the appropriate standards
13 of review."). But it takes no citation to authority to conclude
14 that appellants prevail with some frequency in federal courts of
15 appeals even when a high degree of deference is accorded the
16 district courts from which the appeals are taken.¹⁶ Accordingly,
17 it does not follow from the deference that was due by the Federal
18 Circuit to the district court in Tamoxifen I that Zeneca would
19 have been unsuccessful on appeal. See Cipro III, 363 F. Supp. 2d
20 at 529 (noting that with few exceptions "courts assessing the
21 legality of patent settlement agreements have not engaged in a
22 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).

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

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

13 The fact that the settlement here occurred after the
14 district court ruled against Zeneca seems to us to be of little
15 moment. There is a risk of loss in all appeals that may give
16 rise to a desire on the part of both the appellant and the

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)).

1 appellee to settle before the appeal is decided.¹⁸ Settlements
2 of legitimate disputes, even antitrust and patent disputes of
3 which an appeal is pending, in order to eliminate that risk, are
4 not prohibited. That Zeneca had sufficient confidence in its
5 patent to proceed to trial rather than find some means to settle
6 the case first should hardly weigh against it.

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

13 2. Reverse Payments. Payments pursuant to the
14 settlement of a patent suit such as those required under the
15 Settlement Agreement are referred to as "reverse" payments
16 because, by contrast, "[t]ypically, in patent infringement cases
17 the payment flows from the alleged infringer to the patent
18 holder." David A. Balto, Pharmaceutical Patent Settlements: The
19 Antitrust Risks, 55 Food & Drug L.J. 321, 335 (2000). Here, the

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).

1 patent holder, which, if its patent is valid, has the right to
2 prevent the alleged infringer from making commercial use of it,
3 nonetheless pays that party not to do so. Seeking to supply the
4 "something more" than the fact of settlement that would render
5 the Settlement Agreement unlawful, the plaintiffs allege that the
6 value of the reverse payments from Zeneca to Barr thereunder
7 "greatly exceeded the value of Barr's 'best case scenario' in
8 winning the appeal . . . and entering the market with its own
9 generic product." Appellants' Br. at 27.

10 It is the size, not the mere existence, of Zeneca's
11 reverse payment that the plaintiffs point to in asserting that
12 they have successfully pleaded a Sherman Act cause of action. In
13 explaining our analysis, though, it is worth exploring the notion
14 advanced by others that the very existence of reverse payments
15 establishes unlawfulness. See Balto, supra, at 335 ("A payment
16 flowing from the innovator to the challenging generic firm may
17 suggest strongly the anticompetitive intent of the parties in
18 entering the agreement and the rent-preserving effect of that
19 agreement."); Herbert Hovenkamp et al., Anticompetitive
20 Settlement of Intellectual Property Disputes, 87 Minn. L. Rev.
21 1719, 1751 (2003) ("[T]he problem of exclusion payments can arise
22 whenever the patentee has an incentive to postpone determination
23 of the validity of its patent.").

24 Heeding the advice of several courts and commentators,
25 we decline to conclude (and repeat that the plaintiffs do not ask
26 us to conclude) that reverse payments are per se violations of

1 the Sherman Act such that an allegation of an agreement to make
2 reverse payments suffices to assert an antitrust violation. We
3 do not think that the fact that the patent holder is paying to
4 protect its patent monopoly, without more, establishes a Sherman
5 Act violation. See Valley Drug, 344 F.3d at 1309 (concluding
6 that the presence of a reverse payment, by itself, does not
7 transform an otherwise lawful settlement into an unlawful one);
8 Asahi Glass, 289 F. Supp. 2d at 994 (asserting that "[a] ban on
9 reverse-payment settlements would reduce the incentive to
10 challenge patents by reducing the challenger's settlement options
11 should he be sued for infringement, and so might well be thought
12 anticompetitive," and observing that if the parties decided not
13 to settle, and the patent holder ultimately prevailed in the
14 infringement lawsuit, there would be the same level of
15 competition as in the reverse payment case); Thomas F. Cotter,
16 Refining the "Presumptive Illegality" Approach to Settlements of
17 Patent Disputes Involving Reverse Payments: A Commentary on
18 Hovenkamp, Janis & Lemley, 87 Minn. L. Rev. 1789, 1807 (2003)
19 (noting that "the plaintiff often will have an incentive to pay
20 the defendant not to enter the market, regardless of whether the
21 former expects to win at trial," which "suggests that reverse
22 payments should not be per se illegal, since they are just as
23 consistent with a high probability of validity and infringement
24 as they are with a low probability. It also suggests that
25 reverse payments should not be per se legal for the same
26 reason."). But see Cardizem, 332 F.3d at 911 (calling a forty-

1 million-dollar reverse payment to a generic manufacturer "a
2 naked, horizontal restraint of trade that is per se illegal
3 because it is presumed to have the effect of reducing competition
4 in the market for Cardizem CD and its generic equivalents to the
5 detriment of consumers").

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

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

1 into a settlement in which it pays a significant amount to the
2 patent holder to rid itself of the risk of losing the litigation.

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

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

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

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

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

14 Under these circumstances, we see no sound basis for
15 categorically condemning reverse payments employed to lift the

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.").

1 uncertainty surrounding the validity and scope of the holder's
2 patent.²⁰

3 3. "Excessive" Reverse Payments. As we have noted,
4 although there are those who contend that reverse payments are in
5 and of themselves necessarily unlawful, the plaintiffs are not
6 among them. They allege instead that "[t]he value of the
7 consideration provided to keep Barr's product off the
8 market . . . greatly exceeded the value Barr could have realized
9 by successfully defending its trial victory on appeal and
10 entering the market with its own competitive generic product."
11 Appellants' Br. at 15. The plaintiffs assert that it is that
12 excessiveness that renders the Settlement Agreement unlawful.²¹

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

1 We agree that even if "reverse payments are a natural by-product
2 of the Hatch-Waxman process," Cipro II, 261 F. Supp. 2d at 252,
3 it does not follow that they are necessarily lawful, see
4 Hovenkamp et al., supra, at 1758 ("We do not think it follows
5 that because it is rational for the patentee to agree to an
6 exclusion payment, that payment cannot be anticompetitive. Far
7 from it."). But

8 [o]nly if a patent settlement is a device for
9 circumventing antitrust law is it vulnerable
10 to an antitrust suit. Suppose a seller
11 obtains a patent that it knows is almost
12 certainly invalid (that is, almost certain
13 not to survive a judicial challenge), sues
14 its competitors, and settles the suit by
15 licensing them to use its patent in exchange
16 for their agreeing not to sell the patented
17 product for less than the price specified in
18 the license. In such a case, the patent, the
19 suit, and the settlement would be devices --
20 masks -- for fixing prices, in violation of
21 antitrust law.

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

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").

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

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

1 If the patent holder loses its patent monopoly as a
2 result of defeat in patent litigation against the generic
3 manufacturer, it will likely lose some substantial portion of the
4 market for the drug to that generic manufacturer and perhaps
5 others. The patent holder might also (but will not
6 necessarily)²³ lower its price in response to the competition.
7 The result will be, unsurprisingly, that (assuming that lower
8 prices do not attract significant new purchasers for the drug)
9 the total profits of the patent holder and the generic
10 manufacturer on the drug in the competitive market will be lower
11 than the total profits of the patent holder alone under a patent-
12 conferred monopoly. In the words of the Federal Trade
13 Commission: "The anticipated profits of the patent holder in the
14 absence of generic competition are greater than the sum of its
15 profits and the profits of the generic entrant when the two
16 compete." In re Schering-Plough Corp., No. 9297, slip op. at 27,
17 2003 WL 22989651, 2003 FTC LEXIS 187 (Fed. Trade Comm'n Dec. 8,
18 2003), vacated, 402 F.3d 1056 (11th Cir. 2005). It might
19 therefore make economic sense for the patent holder to pay some
20 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).

1 maintain the patent-monopoly market for itself. And, if that
2 amount exceeds what the generic manufacturer sees as its likely
3 profit from victory, it seems to make obvious economic sense for
4 the generic manufacturer to accept such a payment if it is
5 offered.²⁴ We think we can safely assume that the patent holder
6 will seek to pay less if it can, but under the circumstances of a
7 paragraph IV Hatch-Waxman filing, as we have discussed, the ANDA
8 filer might well have the whip hand. Cf. Valley Drug, 344 F.3d
9 at 1310 ("Given the asymmetries of risk and large profits at
10 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.

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

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

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

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

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

14 This case is illustrative. It is understandable that
15 however sure Zeneca was at the outset that its patent was valid,
16 settlement might have seemed attractive once it lost in the
17 district court, especially in light of the deferential standard
18 the Federal Circuit was expected to apply on review. But its
19 desire to settle does not necessarily belie Zeneca's confidence
20 in the patent's validity. Indeed, Zeneca's pursuit of subsequent
21 litigation seeking to establish the tamoxifen patent's validity,
22 and the success of that litigation, strongly suggest that such
23 confidence persisted and was not misplaced. Neither do we think
24 that the settlement's entry after the district court rendered a
25 judgment against Zeneca should counsel against the settlement's
26 propriety. It would be odd to handicap the ability of Zeneca to

1 settle after it had displayed sufficient confidence in its patent
2 to risk a finding of invalidity by taking the case to trial.

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

22 It strikes us, in other words, as pointless to permit
23 parties to enter into an agreement settling the litigation
24 between them, thereby protecting the patent holder's monopoly
25 even though it may be based on a relatively weak patent, but to

1 limit the amount of the settlement to the amount of the generic
2 manufacturer's projected profits had it won the litigation.

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

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

17 If courts do not discount the exclusionary
18 power of the patent by the probability of the
19 patent's being held invalid, then the patents
20 most likely to be the subject of exclusion
21 payments would be precisely those patents
22 that have the most questionable validity.
23 This concern, on its face, is quite powerful.
24 But the answer to this concern lies in the
25 fact that, while the strategy of paying off a
26 generic company to drop its patent challenge
27 would work to exclude that particular
28 competitor from the market, it would have no
29 effect on other challengers of the patent,
30 whose incentive to mount a challenge would
31 also grow commensurately with the chance that
32 the patent would be held invalid.

33 Cipro III, 363 F. Supp. 2d at 534. There is, of course, the
34 possibility that the patent holder will continue to buy out

1 potential competition such that a settlement with one generic
2 manufacturer protecting the patent holder's ill-gotten patent
3 monopoly will be followed by other settlements with other generic
4 manufacturers should a second, third, and fourth rise to
5 challenge the patent. We doubt, however, that this scenario is
6 realistic.

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

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

1 An alternative rule is, of course, possible. As
2 suggested above, the antitrust laws could be read to outlaw all,
3 or nearly all, settlements of Hatch-Waxman infringement actions.
4 Patent holders would be required to litigate each threatened
5 patent to final, unappealable judgment. Only patents that the
6 courts held were valid would be entitled to confer monopoly power
7 on their proprietors. But such a requirement would be contrary
8 to well-established principles of law. As we have rehearsed at
9 some length above, settlement of patent litigation is not only
10 suffered, it is encouraged for a variety of reasons even if it
11 leads in some cases to the survival of monopolies created by what
12 would otherwise be fatally weak patents. It is too late in the
13 journey for us to alter course.²⁶

14 We generally agree, then, with the Eleventh Circuit
15 insofar as it held in Valley Drug that "'simply because a brand-
16 name pharmaceutical company holding a patent paid its generic
17 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.

1 antitrust law,' unless the 'exclusionary effects of the
2 agreement' exceed the 'scope of the patent's protection.'" Cipro
3 III, 363 F. Supp. 2d at 538 (quoting Schering-Plough, 402 F.3d at
4 1076 (alteration omitted)). Whatever damage is done to
5 competition by settlement is done pursuant to the monopoly
6 extended to the patent holder by patent law unless the terms of
7 the settlement enlarge the scope of that monopoly. "Unless and
8 until the patent is shown to have been procured by fraud, or a
9 suit for its enforcement is shown to be objectively baseless,
10 there is no injury to the market cognizable under existing
11 antitrust law, as long as competition is restrained only within
12 the scope of the patent." Cipro III, 363 F. Supp. 2d at 535.

13 We further agree with the Cipro III court that absent
14 an extension of the monopoly beyond the patent's scope, an issue
15 that we address in the next section of this opinion, and absent
16 fraud, which is not alleged here, the question is whether the
17 underlying infringement lawsuit was "objectively baseless in the
18 sense that no reasonable litigant could realistically expect
19 success on the merits." Prof'l Real Estate Investors, Inc. v.
20 Columbia Pictures Indus., Inc., 508 U.S. 49, 60 (1993).²⁷ In

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.

1 this case, the plaintiffs do not contend that they can -- and we
2 conclude that in all likelihood they cannot -- establish that
3 Zeneca's patent litigation was baseless, particularly in light of
4 the subsequent series of decisions upholding the validity of the
5 same patent. Cf. id. at 60 n.5 ("A winning lawsuit is by
6 definition a reasonable effort at petitioning for redress and
7 therefore not a sham."). Payments, even "excessive" payments, to
8 settle the dispute were therefore not necessarily unlawful.

9 4. The Terms of the Settlement Agreement. Inasmuch as
10 we conclude that neither the fact of settlement nor the amount of
11 payments made pursuant thereto as alleged by the plaintiffs would
12 render the Settlement Agreement unlawful, we must assess its
13 other terms to determine whether they do. As we have explained
14 in the previous section of this opinion, we think that the
15 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.

1 exceed the "scope of the patent's protection." Schering-Plough,
2 402 F.3d at 1076. Looking to other courts that have addressed
3 similar cases for guidance, and accepting the plaintiffs'
4 allegations as true, we conclude that the Settlement Agreement
5 did not unlawfully extend the reach of Zeneca's tamoxifen patent.

6 First, the Settlement Agreement did not extend the
7 patent monopoly by restraining the introduction or marketing of
8 unrelated or non-infringing products. It is thus unlike the
9 agreement the Sixth Circuit held per se illegal in Cardizem, 332
10 F.3d at 908, which included not only a substantial reverse
11 payment but also an agreement that the generic manufacturer would
12 not market non-infringing products. See id. at 902, 908 & n.13
13 (quoting the court in Cipro II, 261 F. Supp. 2d at 242, which
14 observed that the Cardizem district court, in condemning the
15 settlement agreement in that case, "'emphasized that the
16 agreement [there] restrained Andrx from marketing other
17 bioequivalent or generic versions of Cardizem that were not at
18 issue in the pending litigation, Thus, the court found
19 that the agreement's restrictions extended to noninfringing
20 and/or potentially noninfringing versions of generic Cardizem.'" (alterations in original)); see also Valley Drug, 344 F.3d at
21 1306 n.18 (observing that if the agreement "also prohibited the
22 marketing of non-infringing terazosin products, prohibited [the
23 generic manufacturer] from marketing infringing products beyond
24 the date a district court held the [relevant] patent invalid, and
25 prohibited [the generic manufacturer] from waiving its 180-day
26

1 exclusivity period" then the agreement "may be beyond the scope
2 of [the patent holder's] lawful right to exclude and, if so,
3 would expose appellants to antitrust liability"); In re K-Dur
4 Antitrust Litig., 338 F. Supp. 2d 517, 532 (D.N.J. 2004) (noting,
5 in connection with a private lawsuit involving the same
6 settlement agreements challenged by the FTC in Schering-Plough,
7 that the plaintiffs "alleged that [the generic manufacturer] not
8 only agreed not to enter the market with the allegedly infringing
9 generic drug at issue in the patent litigation, but agreed not to
10 enter the market with any generic competitor drug, irrespective
11 of whether it infringed the patent" and that another potential
12 distributor of generic equivalents also agreed to delay marketing
13 a generic competitor drug and "agreed not to conduct, sponsor,
14 file or support any study of a generic drug's bioequivalence to
15 [the patented drug] before the expiration of the [relevant]
16 patent," and concluding: "These agreements, as alleged, grant
17 rights to Schering in excess of what is granted by the [relevant]
18 patent alone." (emphasis in original)).

19 Like the patent for the compound ciprofloxacin
20 hydrochloride, which was the subject of dispute in the Cipro
21 cases, and unlike the patents at issue in Cardizem and Valley
22 Drug, Zeneca's tamoxifen patent is not a formulation patent,
23 which covers only specific formulations or delivery methods of
24 compounds; rather, it is a patent on a compound that, by its
25 nature, excludes all generic versions of the drug. See
26 Appellees' Br. at 23; Cipro II, 261 F. Supp. 2d at 249-50

1 (observing that the patent in that case covered all formulations
2 and the generic manufacturer could not have avoided it). Because
3 Zeneca's patent therefore precludes all generic versions of
4 tamoxifen, so that any such competing version would, as we
5 understand it, necessarily infringe the patent, the Settlement
6 Agreement did not, by precluding the manufacture of a generic
7 version of tamoxifen, restrain the marketing of any non-
8 infringing products.

9 Second, the Settlement Agreement ended all litigation
10 between Zeneca and Barr and thereby opened the tamoxifen patent
11 to immediate challenge by other potential generic manufacturers,
12 which did indeed follow -- spurred by the additional incentive
13 (at the time) of potentially securing the 180-day exclusivity
14 period available upon a victory in a subsequent infringement
15 lawsuit, since by vacating the district court judgment and
16 amending its ANDA to remove its paragraph IV certification, Barr
17 appeared to ensure (under procedures in effect at the time) that
18 it was not eligible for the exclusivity period. See Cipro II,
19 261 F. Supp. 2d at 242-43 (emphasizing that the settlement in
20 that case extinguished the litigation between Barr and Bayer and
21 that Barr agreed to withdraw its paragraph IV certification, thus
22 removing any "bottleneck" to future generic entrants). The
23 Agreement thus avoided a "bottleneck" of the type created by the
24 agreements in Valley Drug and Cardizem, which prevented other
25 generic manufacturers from obtaining approval for their own
26 generic versions from the FDA. Rather than resolve the

1 litigation, the settlements in those cases prolonged it by
2 providing incentives to the defendant generic manufacturers not
3 to pursue the litigation avidly. In Cardizem, for example, the
4 settlement included periodic payments to the generic manufacturer
5 during the pendency of the lawsuit in exchange for its promise
6 not to market a generic drug for which it had already received
7 FDA approval, thereby delaying the market entry of other generic
8 manufacturers "who could not enter until the expiration of [the
9 first-moving generic manufacturer's] 180-day period of marketing
10 exclusivity, which [the generic] had agreed not to relinquish or
11 transfer." Cardizem, 332 F.3d at 907; see also Cipro II, 261 F.
12 Supp. 2d at 243 (noting that in Valley Drug, the generic
13 manufacturer had obtained final FDA approval, yet the settlement
14 agreement "delayed triggering [the generic manufacturer's] 180-
15 day exclusivity period, effectively holding up FDA approval of
16 other generic manufacturers' ANDA IVs.").

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

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

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

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.").

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

3 The Settlement Agreement almost certainly resulted in
4 less price competition than if Barr had introduced its own
5 generic version, of course. The plaintiffs allege that the Barr-
6 distributed, Zeneca-manufactured tamoxifen sold at retail for
7 just five percent less than the Zeneca-branded version, Compl.
8 ¶ 75, compared with what the plaintiffs allege is a typical
9 initial drop of sixteen percent or more, see Oral Argument Tr.,
10 July 12, 2004, at 5, and an eventual drop in a truly competitive
11 market of thirty to eighty percent, Compl. ¶ 75. See also Congr.
12 Budget Office, How Increased Competition from Generic Drugs Has
13 Affected Prices and Returns in the Pharmaceutical Industry 32
14 (July 1998), available at
15 <http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf> (last visited May
16 12, 2005) (describing one study that estimated that the average
17 price of a generic drug fell from sixty percent of the brand-name
18 price to thirty-four percent of the brand-name price as the
19 number of generic manufacturers increased from one to ten). This
20 was competition nonetheless. It was certainly more competition
21 than would have occurred had there been no settlement and had
22 Zeneca prevailed on appeal. Cf. Nestle, 756 F.2d at 284 (noting
23 that the district court erred by not placing more weight on the
24 consequences of requiring the litigation to go forward, such as
25 the fact that "the appellees will be forced to bear the costs and

1 risks of further litigation, including the non-trivial risk of a
2 reversal on the merits").

3 We conclude that the facts as alleged in the
4 plaintiffs' complaint, if proved, would not establish that the
5 terms of the Settlement Agreement violated the antitrust laws.
6 In the absence of any plausible allegation that the reverse
7 payment provided benefits to Zeneca outside the scope of the
8 tamoxifen patent, the plaintiffs have not stated a claim for
9 relief with respect to the Settlement Agreement. See Twombly,
10 425 F.3d at 111.

11 5. Barr's 180-Day Exclusivity Period. The plaintiffs
12 also advance allegations regarding actions that Barr took with
13 respect to the 180-day exclusivity period to which the first
14 paragraph IV filer is entitled under the Hatch-Waxman Act. We
15 confess that it is not altogether clear to us what the import of
16 those allegations is. The plaintiffs contend that Barr's attempt
17 to assert its exclusivity period in 1998, five years after the
18 date of the Settlement Agreement, should be viewed as
19 "circumstantial evidence demonstrating the anticompetitive
20 consequences of [the] agreement[]" among the defendants.
21 Appellants' Reply Br. at 13. They allege that the Settlement
22 Agreement was drafted "careful[ly] to preserve Barr's" ability to
23 "strategically deploy[]" its claim to the exclusivity period.
24 Compl. ¶ 57. And they further allege the existence of an
25 understanding among the defendants as to when and under what
26 circumstances "Barr would assert its claimed exclusivity period

1 rights to prevent . . . FDA approval" of other generic
2 manufacturers' ANDA applications, "even if Zeneca was
3 unsuccessful in using patent litigation to keep another generic
4 competitor off the market."²⁹ Id. ¶ 58. They also contend that
5 because they have alleged an unlawful conspiracy, the issue is
6 only "whether Barr's conduct in blocking generic entry was in
7 furtherance of that alleged conspiracy." Appellants' Br. at 35
8 (emphasis omitted).

9 The defendants contend in response that any
10 consequences of the 180-day exclusivity period resulted from
11 Barr's petition to the FDA, and that Barr's actions in claiming
12 the 180-day exclusivity period were therefore immune from
13 antitrust scrutiny under the Noerr-Pennington doctrine, which
14 immunizes parties from antitrust liability for injuries resulting
15 from government action prompted by the parties' petitioning
16 activities. See E.R.R. Presidents Conference v. Noerr Motor
17 Freight, Inc., 365 U.S. 127, 136 (1961) (stating that "the
18 Sherman Act does not prohibit two or more persons from
19 associating together in an attempt to persuade the legislature or
20 the executive [or an agency or a court] to take particular action
21 with respect to a law that would produce a restraint or a
22 monopoly"); United Mine Workers of Am. v. Pennington, 381 U.S.
23 657, 670 (1965) ("Joint efforts to influence public officials do
24 not violate the antitrust laws even though intended to eliminate

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

1 competition."). Such immunity does not disappear even if the
2 petitioning activity is intended to harm competitors. See Noerr,
3 365 U.S. at 138-39. In this case, the defendants assert, because
4 Barr's petitioning activity was protected under Noerr-Pennington,
5 it cannot be the basis for antitrust liability.

6 We are not so sure. Although Noerr-Pennington immunity
7 may lend Barr's actions some protection, it does not immunize all
8 actions with respect to the 180-day exclusivity period from
9 antitrust scrutiny. The doctrine does not extend protection to
10 the defendants "where the alleged conspiracy 'is a mere sham to
11 cover what is actually nothing more than an attempt to interfere
12 directly with the business relationships of a competitor.'" Cal.
13 Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 511 (1972)
14 (quoting Noerr, 365 U.S. at 144). And it "does not authorize
15 anticompetitive action in advance of [the] government's adopting
16 the industry's anticompetitive proposal. The doctrine applies
17 when such action is the consequence of legislation or other
18 governmental action, not when it is the means for obtaining such
19 action." In re Brand Name Prescription Drugs Antitrust Litig.,
20 186 F.3d 781, 789 (7th Cir. 1999) (emphasis in original); see
21 also Juster Assocs. v. City of Rutland, 901 F.2d 266, 271-72 (2d
22 Cir. 1990) (stating that when a claimed restraint is the
23 consequence of government action, it falls within the purview of
24 Noerr-Pennington immunity, but when the restraint is the means by
25 which the defendants seek to obtain favorable government action,
26 it does not). Because we think that an agreement to time the

1 deployment of the exclusivity period to extend a patent's
2 monopoly power might well constitute anticompetitive action
3 outside the scope of a valid patent, we decline to rest our
4 conclusion on the ground of Noerr-Pennington immunity.³⁰

5 We nonetheless do not think that the facts as alleged
6 with respect to Barr's claim to the 180-day exclusivity period
7 amount to an antitrust violation.

8 First, as we have explained, our review of the
9 Settlement Agreement convinces us that, accepting the plaintiffs'
10 allegations as true, the defendants did not violate the antitrust
11 laws merely by entering into it. Therefore, even if we were to
12 view Barr's actions with regard to the 180-day exclusivity period
13 as somehow constituting "evidence" -- "circumstantial" or
14 otherwise -- of the "anticompetitive consequences" of the
15 Settlement Agreement, it would not affect our conclusion. The
16 Agreement is no doubt "anticompetitive" -- the plaintiffs need no

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.").

1 additional proof of that. It limited competition between generic
2 tamoxifen and Zeneca's branded product. But, as we have seen,
3 because it did not exceed the scope of the tamoxifen patent, it
4 was not an unlawful anticompetitive agreement.

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

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

19 At the time the Settlement Agreement was entered into,
20 the established law was that a generic manufacturer must
21 "successfully defend" a patent infringement lawsuit in order to
22 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,

1 suspected that the FDA would drop its "successful defense"
2 requirement, it had, at the time, no claim to the exclusionary
3 period. Although the Agreement in this case did include a
4 provision allowing Barr to revert its paragraph III certification
5 back to a paragraph IV certification in the event another generic
6 manufacturer successfully invalidated the patent, it seems
7 farfetched, in light of the law at the time, to construe that
8 provision as a conscious and unlawful attempt to manipulate the
9 exclusivity period.

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

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.

1 Fourth and last, we have grave doubt as to whether,
2 even if the defendants agreed to deploy the exclusionary period
3 to protect their shared monopoly power, the injury that the
4 defendants allege they suffered in this regard constitutes
5 "antitrust injury."

6 To state a claim under the Sherman Act, a plaintiff, in
7 addition to stating an antitrust violation, must allege facts
8 sufficient to prove that it suffered "antitrust injury, which is
9 to say injury of the type the antitrust laws were intended to
10 prevent and that flows from that which makes defendants' acts
11 unlawful." Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S.
12 477, 489 (1977) (emphasis omitted); see also George Haug Co.,
13 Inc. v. Rolls Royce Motor Cars Inc., 148 F.3d 136, 139 (2d Cir.
14 1998). "The injury should reflect the anticompetitive effect
15 either of the violation or of anticompetitive acts made possible
16 by the violation." Brunswick, 429 U.S. at 489. "Harm to the
17 antitrust plaintiff is sufficient to satisfy the constitutional
18 standing requirement of injury in fact." Associated Gen.
19 Contractors, Inc. v. Cal. State Council of Carpenters, 459 U.S.
20 519, 535 n.31 (1983).

21 Accepting for the sake of argument that the plaintiffs
22 have stated an antitrust violation by alleging an agreement or
23 understanding between Barr and Zeneca to manipulate the 180-day
24 exclusivity period, we are inclined to agree with the district
25 court's conclusion that any injury that the plaintiffs suffered
26 nonetheless resulted from Zeneca's valid patent and from the

1 inability of other generic manufacturers to establish that the
2 patent was either invalid or not infringed -- and not from any
3 agreement between Barr and Zeneca that Barr should employ its
4 exclusivity powers to exclude competition. See Tamoxifen II, 277
5 F. Supp. 2d at 136-38.

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

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

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

25 Therefore, the plaintiffs could not have suffered any
26 antitrust injury with regard to an exclusivity period for Barr
27 from the time the defendants signed the Settlement Agreement
28 until the time the regulations were changed in 1997-1998. During
29 that period, as far as all parties were concerned, the Settlement
30 Agreement had indeed "cleared the field" so that other generic

1 challengers could enter the market. Accordingly, any injury
2 suffered by the plaintiffs during that time period was the result
3 of Zeneca's legitimate patent monopoly -- which remained intact
4 as a result of the lawful Settlement Agreement -- and not the
5 result of any steps that Barr took.

6 The plaintiffs also suffered no antitrust injury from
7 the time the "successful defense" requirement was eliminated
8 until, in 2000, the FDA rejected Barr's claim to the exclusivity
9 period, because the other ANDA filers with a paragraph IV
10 certification ultimately lost their infringement suits against
11 Zeneca. Even if Barr had not successfully petitioned the FDA,
12 other generic manufacturers would not have been able to enter the
13 market with their generic versions without infringing the
14 tamoxifen patent. As the district court rightly noted, this
15 allegation of injury is "based on the lack of competition that
16 could have only existed by illegally infringing on the [tamoxifen
17 p]atent." Id. at 137-38. Thus, the plaintiffs did not suffer
18 antitrust injury then either. See, e.g., Axis, S.p.A. v. Micafil,
19 Inc., 870 F.2d 1105, 1111 (6th Cir.), cert. denied, 493 U.S. 823
20 (1989) (finding no antitrust injury where plaintiffs had stated
21 an antitrust violation, but where the alleged injury would have
22 resulted even in the absence of the antitrust violation, because
23 of the existence of patents preventing market entry).

24 Finally, there is clearly no antitrust injury with
25 regard to Barr's use of the exclusivity period after the FDA
26 rejected Barr's claim to the exclusivity period in 2000. From

1 that time on, no one could have thought that Barr had a claim to
2 an exclusivity period. Any injury suffered by the plaintiffs
3 arose from Zeneca's patent monopoly, which remained valid until
4 its expiration in 2002, after which other generic manufacturers
5 did, in fact, enter the market.

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

10 IV. Leave To Amend

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

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

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

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

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

1 (1957). The district court therefore did not abuse its
2 discretion in denying the plaintiffs' request for leave to amend.

3 **CONCLUSION**

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

1 POOLER, Circuit Judge:

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

17 **BACKGROUND**

18 **I. Plaintiffs' relevant allegations.**

19 Plaintiffs allege that the various agreements
20 described in the majority opinion are a cover for an agreement to
21 allow Zeneca¹ and Barr to monopolize and allocate the tamoxifen
22 market. In support of this proposition, plaintiffs further allege
23 that (1) at the time the two drug manufacturers entered into

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

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

1 the 30% to 80% discount typically available where there is true
2 generic competition.

3 **II. The majority's analysis.**

4 The majority's resolution of this appeal rests on
5 a series of premises. First, the majority states that the
6 Sherman Act aims to encourage competition by prohibiting
7 agreements that unreasonably restrain trade. Majority op. at
8 **[29-30 & n.13]**. The majority next states that the patent laws
9 also ultimately aim to stimulate competition and innovation, but
10 that they do so through a system that grants an inventor a time-
11 limited exclusive right in her invention or formulation. Id. at
12 **[30]**. These contrasting goals, the majority posits, create a
13 tension in cases where patent and antitrust overlap and require
14 "a delicate balance." Id. at **[30-31]** (quoting Schering-Plough
15 Corp. v FTC, 402 F.3d 1056, 1067 (11th Cir. 2005)).

16 After thus recognizing the inherent tension
17 between antitrust and patent law, the majority goes on to
18 articulate principles that it believes should be used to resolve
19 this tension in the context of an antitrust challenge to a Hatch-
20 Waxman settlement agreement. First, it notes the general
21 principle that settlements, including patent settlements in the
22 pharmaceutical area, are to be encouraged because they promote
23 the public interest and the interests of the parties. Id. at
24 **[31-32]**. In addition, the majority relies on the Supreme Court's
25 recognition that "where there are legitimately conflicting

1 [patent] claims . . . a settlement by agreement rather than
2 litigation, is not precluded by the Sherman Act.'" Id. [at 32]
3 (quoting Standard Oil Co. v. United States, 283 U.S. 163, 171
4 (1931)).

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

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

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

4 The court concludes “that without alleging
5 something more than the fact that Zeneca settled after it lost
6 to Barr in the district court,” plaintiffs have not alleged an
7 antitrust violation. Id. at [37]. The first “something more”
8 that the majority considers is the \$21-million reverse payment
9 Zeneca made to Barr in return for the latter’s agreement to stay
10 out of the generic market for tamoxifen and to cooperate in
11 vacating its favorable judgment. It finds no per se bar to
12 reverse payments, indicating that “the fact that the patent
13 holder is paying to protect its patent monopoly [does not],
14 without more, establish[] a Sherman Act violation.” Id. at
15 [39]. The majority also posits that reverse payments are to be
16 expected in the drug patent context because Hatch-Waxman shifted
17 the risk of a lawsuit from an infringer to a patent holder. Id.
18 at 40-43.

19 Next, after conceding that reverse payments that,
20 like the one alleged here, exceed the profits the generic might
21 expect to make if it prevailed in the underlying litigation look
22 suspicious, the majority holds that such excessive reverse
23 payments are not unlawful, explaining that “so long as the patent
24 litigation is neither a sham nor otherwise baseless, the patent
25 holder is seeking to arrive at a settlement in order to protect
26 that to which it is presumably entitled: a lawful monopoly over

1 the manufacture and distribution of the patented product.” Id.
2 at [45].

3 The court then articulates its standard for
4 judging whether a Hatch-Waxman settlement agreement violates the
5 antitrust laws: “[A]bsent an extension of the monopoly beyond
6 the patent’s scope . . . and absent fraud . . . the question is
7 whether the underlying infringement lawsuit was ‘objectively
8 baseless in the sense that no reasonable litigant could
9 realistically expect success on the merits.’” Id. at [54]
10 (quoting Prof’l Real Estate Investors, Inc. v. Columbia Pictures,
11 Inc., 508 U.S. 49, 60 (1993)). The majority then holds that
12 plaintiffs did not and cannot—in light of Zeneca’s subsequent
13 litigation victories—establish that Zeneca’s infringement suit
14 against Barr was objectively baseless. Id. at [55].

15 The majority next considers whether the
16 exclusionary effects of the agreements exceed the patent’s scope
17 and concludes that they do not because (1) the agreements did not
18 bar the introduction of any non-infringing products; (2) they
19 ended all litigation between Zeneca and Barr, thus opening the
20 field to other generic challengers; and (3) they did not entirely
21 foreclose competition because they allowed Barr to market
22 Zeneca’s version of Tamoxifen. Id. at [56-62]. Finally, the
23 majority considers plaintiffs’ allegations concerning Barr’s
24 manipulation of the exclusivity period. It concludes that
25 although “an agreement to time the deployment of the exclusivity

1 period to extend a patent's monopoly power might well constitute
2 anticompetitive action outside the scope of a valid patent," id.
3 at [65], because the agreements themselves did not exceed the
4 scope of Zeneca's lawful patent, Barr's actions could not be
5 unlawful as in furtherance of an original conspiracy, id. at [65-
6 66].

7 The court dismisses as speculative any claim by
8 plaintiffs that Barr and Zeneca entered into a side agreement
9 that Barr would use its exclusivity period in the way it did,
10 claiming that "[a]lthough the Agreement in this case did include
11 a provision allowing Barr to revert its paragraph III
12 certification back to a paragraph IV certification in the event
13 another generic manufacturer successfully invalidated the patent,
14 it seems farfetched, in light of the law at the time, to construe
15 the provision as a conscious and unlawful attempt to manipulate
16 the exclusivity period." Id. at [67]. The law to which the
17 majority refers is a former federal regulation requiring that in
18 order to obtain an exclusivity period, the generic manufacturer
19 must successfully defend a patent infringement suit. See Mova
20 Pharm. Corp. v. Shalala, 140 F.3d 1060, 1065 (D.C. Cir. 1998)
21 (citing former 21 C.F.R. 314.107(c)(1)). The majority also
22 argues that Barr's deployment of the exclusionary period is
23 adequately explained "by [its] own interest in protecting itself
24 from competition through a petition to the FDA for a statutorily
25 described benefit" and that nothing in the complaint suggests a
26 conspiracy. Id. at [67]. Alternatively, the majority suggests

1 that it has grave doubts that the injury plaintiffs allege is
2 antitrust injury because the injury stemmed from the scope of
3 Zeneca's patent and from the inability of other generics to
4 defeat Zeneca's patent. Id. [at 68-71]

5 **DISCUSSION**

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

1 the alleged Barr/Zeneca conspiracy or from the failure of other
2 generics to invalidate the patent cannot be resolved on the
3 pleadings.

4 **I. The pleading standard.**

5 Relying principally on Professional Real Estate
6 Investors, the majority concludes that, in order to attack a
7 Hatch-Waxman settlement on antitrust grounds, plaintiffs must
8 allege either that the agreement gave the patent holder benefits
9 beyond the scope of the patent or that the agreement was a sham,
10 that it was "objectively baseless in the sense that no reasonable
11 litigant would realistically expect success on the merits."

12 Majority op. at [54] (quoting 508 U.S. at 60). I agree that a
13 settlement agreement that confers on the patent holder a greater
14 monopoly benefit than does the patent itself is illegal.

15 However, I do not agree that, absent a showing of benefits
16 exceeding the scope of the patent, the antitrust plaintiff must
17 show that the settled litigation was objectively baseless.

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

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

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

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

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

21 Holding that a Hatch-Waxman settlement agreement
22 cannot violate antitrust laws unless the underlying litigation
23 was a sham also ill serves the public interest in having the
24 validity of patents litigated. See United States v. Glaxo Group
25 Ltd., 410 U.S. 52, 57 (1973). This interest exists because "[i]t
26 is as important to the public that competition should not be

1 repressed by worthless patents, as that the patentee of a really
2 valuable invention should be protected in his monopoly.”³ Id. at
3 58. Litigating the validity of drug company patents is
4 critically important to the general well being in light of the
5 recent trend toward capping the maximum amounts insurers and
6 public benefit plans will spend on medications.

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

1 ³ The majority suggests, [**majority op. at 53 n.25**] that this
2 interest was adequately protected through the subsequent suits by
3 other generics. I disagree. This position ignores the time gap
4 between the Barr-Zeneca litigation and the subsequent litigation.
5 During this period, had Barr maintained its victory on appeal,
6 which, as I explain below, was quite likely, very ill consumers
7 would have had access to low cost generic tamoxifen. In
8 addition, once Zeneca’s patent protection was gone with respect
9 to Zeneca, it was gone with respect to all generic manufacturers,
10 which would have produced a very competitive market at the close
11 of the 180-day exclusivity period. Thus, it was very important
12 to the public interest that Barr and Zeneca allow the appeal to
13 proceed. This does not mean, as the majority suggests at 49 n.25
14 that any settlement of patent litigation after the challenger
15 prevails at trial is an antitrust violation. As I discuss at
16 [**13-14**] below, a Hatch-Waxman settlement agreement, even on
17 appeal from a judgment declaring the patent invalid, is not a per
18 se antitrust violation. Rather, a reviewing court must assess
19 the reasonability of the settlement by weighing various factors
20 including the strength of the patent as it appeared at the time
21 of settlement.

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

18 In contrast, a generic competitor subject to
19 Hatch-Waxman cannot enter the market for the first thirty months
20 after litigation is commenced against it. See 21 U.S.C. §
21 355(j) (5) (B) (iii). In addition, whether its attack against the
22 patent is strong or weak, the benefit it will obtain by
23 successfully litigating to the finish is not great. At best, it
24 will obtain 180 days in which it will be the exclusive generic on
25 the market. See 21 U.S.C. § 355(j) (5) (B) (iv). On the other
26 hand, the benefits to the public from the completion of

1 litigation can be enormous if the generic challenger prevails as
2 it did, at least initially, here. Once the 180-day exclusivity
3 period is over, any generic that wishes to market a generic
4 product and that can establish its product is bioequivalent to
5 the patented product can enter the market, thus providing
6 increased competition.

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

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

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

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

14 Daniel A. Crane urges a standard somewhat more
15 favorable to the settling parties. See Daniel A. Crane, Ease
16 Over Accuracy in Assessing Patent Settlements, 88 Minn. L. Rev.
17 698, 709 (2004) (urging that the dispositive factor should be
18 "the ex ante likelihood that the defendant would be excluded from
19 the market if the case was finally adjudicated"). Id. at 709.
20 Because the settling parties will typically have the most
21 documentation relevant to the issue, he contends that "there is
22 relatively little social cost in requiring the settling parties
23 to retain documents going to the core issues in the patent
24 infringement lawsuit." Id. However, to avoid unduly chilling
25 patent settlements, Crane, unlike Hovenkamp et al, would not
26 shift the burden of proof to the settling parties. Id.

1 Thomas F. Cotter's approach occupies the middle
2 ground. Cotter would leave on the antitrust defendants the
3 burden of demonstrating the legality of a reverse-payment
4 settlement, but he does not adopt Hovenkamp's position that the
5 reverse payment must be limited to litigation costs. See Thomas
6 F. Cotter, Refining the "Presumptive Illegality" Approach to
7 Settlements of Patent Disputes Involving Reverse Payments: A
8 Commentary on Hovenkamp, Janis and Lemley, 87 Minn. L. Rev. 1789,
9 1795-97, 1802 (2003). Rather, he argues that "when the antitrust
10 defendants can show that the payment is below the expected amount
11 of the patent defendant's loss if an injunction were to issue,
12 the burden of proving validity and infringement should be
13 somewhat easier to satisfy than at a full-blown infringement
14 trial." Id. at 1814. Cotter rejects, and the other commentators
15 implicitly reject, the approach adopted by the majority. See id.
16 at 1811 (noting that requiring antitrust plaintiffs to show that
17 patent litigation is a sham "would permit too many anticompetitive
18 settlements to escape scrutiny. A suit with only a 25% chance of
19 success may not be a sham, but a settlement based upon such a low
20 probability estimate reduces consumer welfare for no apparent
21 offsetting benefit.") (footnote omitted).

22 Thus, commentators, precedent, and policy
23 suggest the majority's requirement that an antitrust plaintiff
24 show that a Hatch-Waxman lawsuit settled by agreement was a
25 sham—assuming that the agreement did not convey benefits beyond
26 the scope of the patent—is unjustified. A more searching inquiry

1 and a less stringent standard are required to properly protect
2 all interests. I see no reason why the general standard for
3 evaluating an anti-competitive agreement, i.e., its
4 reasonableness, should not govern in this context.⁵ See Clorox.
5 Co. v. Winthrop, Inc., 117 F.3d 50, 56 (2d Cir. 1997). In
6 assessing reasonableness, the fact-finder must consider all the
7 circumstances affecting a restrictive agreement. Id. Of course,
8 the strength of the patent must be central to any antitrust
9 analysis involving a patent. Thus, in assessing the
10 reasonability of a Hatch-Waxman settlement, I would rely
11 primarily on the strength of the patent as it appeared at the
12 time at which the parties settled and secondarily on (a) the
13 amount the patent holder paid to keep the generic manufacturer
14 from marketing its product, (b) the amount the generic
15 manufacturer stood to earn during its period of exclusivity, and

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

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

10 **II. Ancillary issues.**

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

13 It appears that the court may have been motivated
14 to adopt the "sham" or objectively baseless standard because it
15 overestimated the difficulty of estimating Zeneca's chance of
16 prevailing on appeal. See Majority op. at [34] (citing
17 principally Whitmore v. Arkansas, 495 U.S. 149, 159-60 (1990),
18 for the proposition that is impossible to predict the likelihood
19 that Barr would have maintained its patent victory on appeal).
20 Whitmore, is inapposite; there the Court considered a challenge
21 to one inmate's death sentence from a different inmate, Whitmore,
22 who also had been sentenced to death. 495 U.S. at 153. Whitmore
23 argued that he had standing because Arkansas's Supreme Court
24 compared the circumstances of any capital case currently before
25 it to prior capital cases to determine whether the death penalty

1 had been arbitrarily applied. Id. at 156. Whitmore claimed that
2 if he obtained federal habeas relief in the future and if he were
3 again convicted and sentenced to death and appealed to the
4 Arkansas Supreme Court, the failure to include the first inmate's
5 heinous crime in the data base the Arkansas Supreme Court
6 considered would prejudice the review of his sentence. Id. at
7 156-57. The Court dismissed as speculative the probability of
8 Whitmore's obtaining federal habeas relief, the odds that he
9 would be retried, convicted and sentenced to death once more, and
10 the odds "that the addition of [the first inmate's] crimes to a
11 comparative review 'data base' would lead the Supreme Court of
12 Arkansas to set aside a death sentence for Whitmore." Id. at
13 157. To find that the sequence of events Whitmore alleged would
14 actually occur indeed requires multiple layers of speculation.
15 In contrast, by the time of the settlement, Barr had already
16 prevailed at the district court level. The record in that case
17 is presumably available, the standards of review the appellate
18 court would have employed are well known, and it is not outside
19 the bounds of the district court's competence to predict whether
20 Barr would have prevailed on appeal.⁶ Judges and juries

1 ⁶ The majority also relies on Boehm v. Comm'r, 146 F.2d 553
2 (2d Cir. 1945), aff'd, 326 U.S. 287 (1945). This case also is
3 strikingly inapposite; the Boehm court held only that a taxpayer
4 must claim a loss in the year it becomes obvious and cannot rely
5 on the inherently speculative outcome of litigation seeking to
6 recover some of that loss to justify claiming it in a later year.
7 146 F.2d at 555. The relevance of that principle to the case at
8 hand is not immediately obvious to me. It is also interesting to
9 note that the Supreme Court affirmed not on the impossibility of
10 predicting litigation outcome but rather because the Tax Court
11 had found that the suit had "no substantial value" and "[t]here

1 routinely perform an analogous, but more difficult, task in legal
2 malpractice cases in which they must estimate whether, absent
3 attorney error, a party would have prevailed at trial.

4 Estimating the possibility of success on appeal with the
5 assistance of the full record and the parties' briefs is much
6 simpler. Certainly the review would not be so difficult as to
7 justify a sham litigation test.

8 *B. The strength of Zeneca's patent.*

9 As the majority states, the reasonableness of
10 agreements under antitrust law must be judged by the
11 circumstances existing at the time when the agreements were made.
12 Majority op. at [35]; cf. SCM Corp. v. Xerox Corp., 645 F.2d
13 1195, 1207 (2d Cir. 1981) ("Because the essence of a patent is
14 the monopoly or exclusionary power it confers upon the holder;
15 analyzing the lawfulness of the acquisition of the patent [within
16 an antitrust analysis] necessitates that we primarily focus upon
17 the circumstances of the acquiring party and the status of the

1 was no evidence in the stipulation of the merits of the suit, the
2 probability of recovery or any assurance of collection of an
3 amount sufficient to pay the creditors' claim . . . and to
4 provide a sufficient surplus for stockholders." 326 U.S. at 294.
5 The majority's additional reliance on Asahi Glass Co. v. Pentech
6 Pharms, 289 F.Supp. 2d 986, 993 (N.D. Il. 2003), and In re
7 Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d.
8 188, 200-01 (E.D.N.Y. 2003), requires little discussion. The
9 statement quoted from Asahi Glass that "[n]o one can be certain
10 that he will prevail in a patent suit"—is irrelevant to the
11 capacity of skilled corporate counsel and district court judges
12 to evaluate the likelihood that a determination of patent
13 invalidity will be upheld, and the discussion in Ciprofloxacin
14 relies primarily on Whitmore and Boehm, which I have already
15 discussed.

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

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

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

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

12 The majority also focuses on the subsequent
13 litigation between other generics and Zeneca to demonstrate that
14 plaintiffs cannot support a claim that Zeneca's litigation
15 against Barr was sham litigation. Of course, in my view,
16 plaintiffs need not plead or prove sham or objectively baseless
17 litigation. But, in addition, the majority's discussion of the
18 later litigation appears to violate its own acknowledgment of the
19 basic principle that "the reasonableness of agreements under the
20 antitrust laws are to be judged at the time they are entered
21 into." Majority op. at [35] (quoting Valley Drug Co. v. Geneva
22 Pharms., Inc., 344 F.3d 1294, 1306 (11th Cir. 2003) (citing,
23 inter alia, SCM Corp., 645 F.2d at 1207)). At the time Zeneca
24 and Barr settled the appeal, the existing facts made it fairly
25 likely, if not certain, that Barr would prevail. Judge Broderick
26 had judged the credibility of the witnesses and found that Zeneca

1 willfully withheld information from the FDA. That finding is
2 quintessentially factual. Thus, the Federal Circuit could have
3 set it aside only for clear error. Fed. R. Civ. P. 52(a).
4 Without the record, I cannot say that the Federal Circuit would
5 have been required to affirm, but, as I am sure the majority will
6 concede, it is the rare case in which an appellate court sets
7 aside a trial court's credibility findings.⁷ Had Barr prevailed,
8 on appeal, as I expect it would have, Zeneca would have been
9 estopped from asserting the validity of its patent in any
10 subsequent litigation. Therefore, there is a certain unfairness
11 in using the subsequent litigation, which would not have existed
12 had Barr prevailed on appeal, to demonstrate that plaintiffs
13 cannot establish that Barr would have prevailed on appeal.⁸

14 *D. Conspiracy to use Barr's paragraph IV certification*
15 *in an anticompetitive manner.*

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

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

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

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

12 The court additionally attacks the plausibility of
13 plaintiffs' allegations because, at the time Barr and Zeneca
14 entered into their agreements, a generic enjoyed the benefit of
15 the exclusivity period only if it had successfully defended an
16 infringement lawsuit. See Mova Pharm., 140 F.3d at 1065
17 (citing former 21 C.F.R. § 314.107(c)(1)). This regulation was
18 struck down after the agreements at issue. See id. at 1076.
19 Because the regulation was in effect when Barr and Zeneca
20 finalized their agreement, the majority finds it implausible that
21 they could have envisioned any anti-competitive effect from the
22 portion of the agreement allowing Barr to deploy its exclusivity
23 period if another generic manufacturer succeeded in invalidated
24 Zeneca's patent. That inference is certainly one that a
25 reasonable fact finder could draw from the facts alleged to date.
26 However, a reasonable fact-finder could also conclude that it is

1 quite unlikely that sophisticated parties would include in their
2 agreement a provision that had no potential benefit to either of
3 them. Is it not at least as likely that the parties were
4 conscious that the regulation was vulnerable to attack and that
5 they wished to add another layer of protection against potential
6 competitors in the event the regulation was invalidated?
7 Discovery would presumably produce materials relevant to
8 determining whether this provision was part of an antitrust
9 conspiracy between Barr and Zeneca. Among other things, the
10 parties may have had written communications concerning the
11 purpose of the exclusionary-period clause. If not, the corporate
12 employees who negotiated the agreement could be deposed. And,
13 the parties could explore the state of legal discussion
14 concerning the successful-defense requirement at the time of the
15 agreement. Thus, it is premature to reject out of hand
16 plaintiffs' claim that Barr and Zeneca agreed to the exclusivity-
17 period provision because they wanted to further restrict other
18 generic manufacturers' ability to market Tamoxifen.

19 *E. Antitrust injury.*

20 In addition to affirming dismissal of the
21 paragraph IV certification claim because plaintiffs did not
22 adequately describe an antitrust violation, the majority states
23 that it has "grave doubt as to whether, even if the defendants
24 agreed to deploy the exclusionary period to protect their shared
25 monopoly power, the injury that the defendants allege they
26 suffered in this regard constitutes 'antitrust injury.'" Majority

1 op. at [68]. The majority's doubt stems, in part, from Zeneca's
2 victories in subsequent patent litigation. Id. at [69] Because
3 these victories could not have existed if (1) the settlement
4 agreement had not been signed and (2) Barr had prevailed on
5 appeal, they are not finally determinative of causation.
6 Therefore, it is necessary to assess the strength of Zeneca's
7 patent in order to decide whether the injuries were really caused
8 by the patent itself or by the agreements.

9 **III. The inappropriateness of dismissal at the Rule**
10 **12(b)(6) stage.**

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

23 However, even under the majority's newly
24 articulated standard, I believe that it was wrong to affirm the
25 dismissal. At a minimum, the plaintiffs should be allowed to

1 develop a factual record to demonstrate that Zeneca's litigation
2 was sham because they had no reason to anticipate the standard
3 articulated here. I note that the courts that have finally
4 rejected antitrust challenges to Hatch-Waxman settlements have
5 done so after reviewing a full record. See Schering-Plough, 402
6 F.3d at 1058 (granting a petition for review of and reversing an
7 agency decision made upon a full record that granted injunctive
8 relief against certain Hatch-Waxman settlements); In re
9 Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d
10 514, 517 (E.D.N.Y. 2005) (granting summary judgment motion).

12 **CONCLUSION**

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