

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 Errata Filed: January 3, 2006)  
6 Docket No. 03-7641

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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  
32 defendants Zeneca, Inc., and AstraZeneca Pharmaceuticals LP

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

8 Affirmed.

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

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

32 Bruce E. Gerstein, Garwin Bronzaft  
33 Gerstein & Fisher LLP (Barry S. Taus,  
34 Jan Bartelli, Garwin Bronzaft Gerstein &  
35 Fisher LLP; Steve D. Shadowen, Monica L.  
36 Rebuck, Hanglely Aronchick Segal &  
37 Pudlin, Harrisburg, PA; of counsel), New  
38 York, NY, for Amicus Curiae Louisiana  
39 Wholesale Drug Company, Inc., CVS  
40 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.<sup>1</sup>

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

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

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<sup>2</sup> 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,<sup>3</sup> 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

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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 court<sup>4</sup>  
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").

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<sup>4</sup> 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.<sup>5</sup> 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

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<sup>5</sup> 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 requirement as inconsistent with the Hatch-Waxman Act. See Mova  
2 Pharm. Corp. v. Shalala, 140 F.3d 1060, 1076 (D.C. Cir. 1998);  
3 Granutec, Inc. v. Shalala, Nos. 97-1873, 97-1874, 1998 WL 153410,  
4 at \*7, 1998 U.S. App. LEXIS 6685, at \*19-\*21 (4th Cir. Apr. 3,  
5 1998) (unpublished opinion).

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

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<sup>6</sup> In 2001, Zeneca's domestic sales of tamoxifen amounted to \$442 million.

<sup>7</sup> 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).<sup>8</sup>

20           In the years after the parties entered into the  
21 Settlement Agreement and the Federal Circuit vacated the district  
22 court's judgment,<sup>9</sup> three other generic manufacturers filed ANDAs

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<sup>8</sup> 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).

<sup>9</sup> 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.<sup>10</sup> 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

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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.

<sup>10</sup> 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 Mylan<sup>11</sup> 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.

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<sup>11</sup> 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.<sup>12</sup> 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

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<sup>12</sup> 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,"<sup>13</sup> 15

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<sup>13</sup> "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.<sup>14</sup>  
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

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

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

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

<sup>14</sup> "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.<sup>15</sup> 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

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<sup>15</sup> 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.<sup>16</sup> 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

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<sup>16</sup> 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.<sup>17</sup>

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

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<sup>17</sup> 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.<sup>18</sup> 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

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<sup>18</sup> 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.<sup>19</sup>

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<sup>19</sup> 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

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

1 uncertainty surrounding the validity and scope of the holder's  
2 patent.<sup>20</sup>

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.<sup>21</sup>

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<sup>20</sup> 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.

<sup>21</sup> 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.

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

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.<sup>22</sup>

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<sup>22</sup> 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)<sup>23</sup> 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

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Violating The Antitrust Laws.").

<sup>23</sup> 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.<sup>24</sup> 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

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<sup>24</sup> 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.)<sup>25</sup>

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<sup>25</sup> 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.<sup>26</sup>

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

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

<sup>26</sup> 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).<sup>27</sup> In

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<sup>27</sup> 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"

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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, Barr  
16 ensured (under procedures in effect at the time) that it was not  
17 eligible for the exclusivity period. See Cipro II, 261 F. Supp.  
18 2d at 242-43 (emphasizing that the settlement in that case  
19 extinguished the litigation between Barr and Bayer and that Barr  
20 thereby relinquished its claim to the 180-day exclusivity period,  
21 thus removing any "bottleneck" to future generic entrants). The  
22 Agreement thus avoided a "bottleneck" of the type created by the  
23 agreements in Valley Drug and Cardizem, which prevented other  
24 generic manufacturers from obtaining approval for their own  
25 generic versions from the FDA. Rather than resolve the  
26 litigation, the settlements in those cases prolonged it by

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

16 The disadvantage purportedly suffered by the plaintiffs  
17 is not that Barr somehow prevented others from challenging the  
18 patent and obtaining FDA approval; nor is it that no other  
19 generic manufacturer tried to do so. It is instead that each of  
20 the subsequent challenges failed. While it is true that, had the  
21 district court's decision in Zeneca's patent infringement lawsuit  
22 against Barr been affirmed, other generic manufacturers would  
23 have been allowed to market their drugs, there is no legal  
24 requirement that parties litigate an issue fully for the benefit  
25 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,<sup>28</sup> 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

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<sup>28</sup> 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."<sup>29</sup> 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

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<sup>29</sup> 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.<sup>30</sup>

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

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<sup>30</sup> "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.<sup>31</sup> Accordingly, even if Barr might have

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<sup>31</sup> 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.<sup>32</sup>

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

<sup>32</sup> 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.