United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued February 12, 2001 Decided July 31, 2001

Nos. 00-5050 & 00-5396

Andrx Pharmaceuticals, Inc.,
Appellee

v.

Biovail Corporation International,
Appellant

Appeals from the United States District Court
for the District of Columbia
(No. 98cv00099)

Richard J. Leighton argued the cause for the appellant. John B. Dubeck, Douglas J. Behr and Eric H. Singer were on brief.

Louis M. Solomon argued the cause for the appellee. Eugene M. Pfeifer, James D. Miller and Peter M. Todaro were on brief.

Before: Henderson, Randolph and Garland, Circuit Judges.

Opinion for the court filed by Circuit Judge Henderson.

Karen LeCraft Henderson, Circuit Judge: Appellant Biovail Corporation (Biovail) appeals two district court decisions. One dismissed with prejudice its antitrust counterclaim against appellee Andrx Pharmaceuticals, Inc (Andrx). The second denied its motion for reconsideration of the court's dismissal. For the reasons that follow, we affirm the district court's dismissal of the counterclaim but reverse its decision to do so with prejudice.

I. Statutory Background

A company wishing to market a new drug must seek the approval of the United States Food & Drug Administration (FDA) by completing a "New Drug Application" (NDA). See American Bioscience, Inc. v. Thompson, 243 F.3d 579, 580 (D.C. Cir. 2001); Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1063 (D.C. Cir. 1998); see also 21 U.S.C. s 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to (b) or (j) of this section is effective with respect to such drug."). An NDA is time-consuming and costly to prepare because it must include data from studies showing the drug's safety and effectiveness. See

Mova, 140 F.3d at 1063. In 1984 the Congress enacted the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act (Amendments) to, inter alia, simplify the procedure for FDA approval. See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in various sections of titles 21, 35 & 42 U.S.C.); see generally Allan M. Fox & Allan R. Bennett, The Legislative History of the Drug and Patent Term Restoration Act of 1984, at 259 (1987); James J. Wheaton, "Generic Competition and Pharmaceutical Innovation: the Drug Price Competition and Patent Term Restoration Act of 1984," 35 Cath. Univ. L. Rev. 433 (1986). Under the Amendments, the original applicant for FDA approval (the "pioneer" applicant)

must still prepare an NDA. Subsequent applicants who wish to manufacture generic versions1 of the pioneer drug, however, need only complete an Abbreviated New Drug Application (ANDA) that relies on the FDA's previous determination that the drug is safe and effective.2 See Mova, 140 F.3d at 1063. The generic drug share of the prescription drug market has grown from 19 per cent in 1983 to over 40 per cent in 1995. See Congressional Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry ix (1998). In addition, almost all of the most popular pioneer drugs with expired patents now have generic versions available. Id. at xii.

Although the Congress was interested in increasing the availability of generic drugs, it also wanted to protect the patent rights of the pioneer applicants. See David A. Balto, "Pharmaceutical Patent Settlements: The Antitrust Risks," 55 Food & Drug L.J. 321, 324 (2000). The Amendments, therefore, require that an NDA contain a list of any patents "which claim[ ] the drug ... or which claim[ ] 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. s 355(b)(1). The FDA maintains a record of such information in its publication entitled Approved Drug Products with Therapeutic Equivalence, commonly known as the Orange Book. See 21 U.S.C. s 355(j)(7)(A). For each patent applicable to the pioneer drug listed in the Orange Book, an ANDA applicant must certify

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1 A generic version of a pioneer drug (often described as a brand-name drug) 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. See United States v. Generix Drug Corp., 460 U.S. 453, 454-55 (1983).

2 Before the Amendments, an earlier version of the ANDA procedure was available to a generic drug manufacturer of a pioneer drug approved before 1962. A generic version of a pioneer drug approved after 1962, however, could be approved only through a full NDA. See Fox & Bennett, supra, at 95.

whether the proposed generic drug would infringe that patent and, if not, why not. An ANDA applicant has four certification options. It may certify (1) that the required patent information has not been filed, (2) that the patent has expired, (3) that the patent has not expired but will expire on a particular date or (4) that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval. See 21 U.S.C. s 355(j)(2)(A)(vii). The last of these options, and the one relevant here, is the Paragraph IV certification. After an applicant makes a Paragraph IV certification, the statute provides a 45-day window during which the patent holder may bring suit against the applicant. If the patent holder brings a timely suit, the statute bars the FDA from approving the applicant's ANDA, or any subsequent ANDA, for thirty months or until the successful resolution of the patent infringement suit, whichever is earlier, at which time the first ANDA applicant is eligible for FDA approval and upon such approval is awarded a 180-day exclusivity period in which to market its generic version. See 21 U.S.C. s 355(j)(5)(B)(iii). The statute permits the court to lengthen or shorten the 30-month waiting period if it determines that either party has failed to "reasonably cooperate in expediting the action." Id.3

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3 The full text of section 355(j)(5)(B)(iii) provides:

> If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that--
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> (I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

II. Background

Hoechst Marion Roussel, Inc. (HMRI) is the manufacturer, marketer and patent holder of the brand name prescription drug Cardizem CD, which consists of a once-daily dosage of the chemical compound dilitiazem hydrochloride. Cardizem CD is widely prescribed for the treatment of chronic chest pains (angina) and hypertension and for the prevention of heart attacks and strokes. See In re Cardizem CD Antitrust Litig., 105 F. Supp. 2d 618, 622 (E.D. Mich. 2000). On September 22, 1995 Andrx filed an ANDA with the FDA

seeking approval to manufacture and sell a generic form of Cardizem CD. On December 31, 1995 it made the Paragraph IV certification with regard to all unexpired patents included in the Orange Book's Cardizem CD entry and certified that its generic form of Cardizem CD did not infringe the patents owned or controlled by HMRI or its affiliates. See 21 U.S.C. s 355(j)(2)(A)(vii)(IV); 21 C.F.R. s 314.94(a)(12)(i)(A)(4). In early 1996 HMRI filed a timely suit against Andrx for patent

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(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of Title 35, or

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of Title 28, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

infringement.4 The filing of the suit triggered the statutory 30-month waiting period during which any subsequent ANDA applicant, including Biovail, could not receive final approval of its generic version of Cardizem CD. See 21 U.S.C. s 355(j)(5)(B)(iii).

In June 1997 Biovail filed an ANDA with the Paragraph IV certification for its generic version of Cardizem CD but HMRI filed no patent infringement suit against it. On September 15, 1997 the FDA issued its tentative approval of Andrx's ANDA.5 Nine days later, on September 24, 1997, HMRI and Andrx entered into an agreement (Agreement or HMRI-Andrx Agreement) purporting to maintain the status quo pending the outcome of HMRI's patent infringement suit against Andrx. Under the terms of the Agreement, Andrx agreed not to sell its generic version of Cardizem CD until a specific time agreed upon by the parties. It also agreed to diligently prosecute its ANDA and not to relinquish or otherwise compromise any right accruing thereunder. HMRI agreed to make interim payments to Andrx in the amount of $40 million per year, payable quarterly, beginning on the date Andrx's generic version of Cardizem CD received FDA approval and ending on the date Andrx either began to sell its generic version or was adjudged liable for patent infringe-

ment.

In early 1998 Andrx filed suit against the FDA and certain ANDA applicants (including Biovail) to clarify its right as the first to file an ANDA for Cardizem CD. The suit sought injunctive relief requiring the FDA to provide Andrx with "a period of 180 days of marketing exclusivity for its controlled-release generic formulations of the drugs Dilacor XR and Cardizem CD." JA 13. It also requested injunctive relief prohibiting the FDA "from approving any ANDA submitted by defendant Biovail ... for a generic version of Cardizem CD that contains a paragraph 4 certification until 180-days after Andrx begins marketing its generic formulation of Car-

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4 Later in 1996 Faulding Inc. filed an ANDA with a Paragraph IV certification for its generic version of Cardizem CD. In January 1997 HMRI also filed suit against Faulding for patent infringement.

5 The FDA issued tentative, as opposed to final, approval due to the pending infringement suit and the resulting 30-month statutory waiting period.

dizem CD or a court enters a judgment in the patent litigation brought by HMRI in the Southern District of Florida, whichever is earlier." JA 22. Biovail counterclaimed, alleging that Andrx had violated sections 1 and 2 of the Sherman Act as well as New Jersey common law.6

On July 3, 1998 the FDA granted final approval to Andrx's ANDA for a generic version of Cardizem CD. JA 44. By then, the 30-month waiting period had expired and Andrx was no longer restricted under the statutory scheme from marketing and selling its generic drug. Andrx, however, did not do so and on July 9, 1998, pursuant to the Agreement, HMRI began making quarterly payments of $10 million to Andrx. By not marketing its generic version of Cardizem CD, Andrx did not trigger the 180-day market exclusivity period, which in turn prevented the FDA from giving final approval to any subsequently filed applications for competing generic versions of Cardizem CD.

Approximately one year later, HMRI and Andrx terminated their Agreement and entered into a stipulation settling the patent litigation. On June 23, 1999, Andrx then began to market its generic version and its 180-day exclusivity period began to run. In October 1999 the FDA gave tentative approval to Biovail's ANDA and final approval on December

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6 On July 14, 1998 the FDA published a notice entitled "Guidance for Industry on 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act; Availability," interpreting the Hatch-Waxman Amendments so as to give Andrx the relief it sought in its complaint. The Guidance explained that the FDA intended to delete the "successful defense" provisions from s 314.107(c)(1) and that the FDA would not enforce the "successful defense" provisions in the interim. See

63 Fed. Reg. 37,890 (July 14, 1998); see also JA 62 (Federal Defendant's Motion to Dismiss); JA 198 (Notice of Dismissal). Accordingly, the district court subsequently dismissed the complaint. See JA 199. Andrx had earlier moved to dismiss Biovail's counterclaim for failure to state a claim upon which relief may be granted because, inter alia, Biovail lacked standing to assert an antitrust violation.

23, 1999.7 Neither Andrx nor Biovail, however, informed the district court of these developments. On January 6, 2000 the district court granted Andrx's Rule 12(b)(6) motion to dismiss Biovail's counterclaim, the federal antitrust counts with prejudice and the state law claims without prejudice. The court concluded that Biovail did not, and in fact could not, plead an antitrust injury causally linked to Andrx's alleged anticompetitive behavior. Andrx Pharm., Inc. v. Friedman, 83 F. Supp. 2d 179, 185-87 (D.D.C. 2000) ("Court cannot find that Biovail can establish that it has suffered 'antitrust injury.' "). On February 2, 2000 Biovail moved for reconsideration under FRCP 60(b) and on February 4, 2000 it filed a notice of appeal (No. 00-5050). The district court subsequently denied the motion for reconsideration and Biovail noticed its appeal of that decision (No. 00-5396) on November 3, 2000. This court granted Biovail's motion to consolidate the appeals.

III. Analysis

We give de novo review to a Rule 12(b)(6) dismissal. See NRA v. Reno, 216 F.3d 122, 126 (D.C. Cir. 2000); see also Amarel v. Connell, 102 F.3d 1494, 1507 (9th Cir. 1997) (holding that antitrust standing is question of law reviewed de novo). "The complaint should not be dismissed unless plaintiffs can prove no set of facts in support of their claim which would entitle them to relief." Kowal v. MCI Communications Corp., 16 F.3d 1271, 1276 (D.C. Cir. 1994). We liberally construe the complaint in the plaintiff's favor and grant the plaintiff the benefit of all inferences that can be derived from the facts alleged. "However, the court need not accept inferences drawn by plaintiffs if such inferences are unsupported by the facts set out in the complaint. Nor must the court accept legal conclusions cast in the form of factual allegations." Id. The court reviews the denial of the appellant's Rule 60(b) motion for abuse of discretion "unless the decision is 'rooted in an error of law.' " United Mine Work-

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7 In a letter dated October 22, 1999 the FDA explained to Biovail that it had "completed review" of its ANDA and found its generic "safe and effective." JA 322. It gave tentative, rather than final, approval because of "the exclusivity granted by the agency to Andrx." JA 323; see also JA 327.

ers of Am. 1974 Pension v. Pittston Co., 984 F.2d 469, 476 (D.C. Cir. 1993) (citation omitted).

Section 4 of the Clayton Act provides that a private person "injured in his business or property by reason of anything

forbidden in the antitrust laws ... shall recover threefold the damages by him sustained, and the cost of suit, including a reasonable attorney's fee." 15 U.S.C. s 15(a). The Clayton Act includes the Sherman Act8 as one of the "antitrust laws." See 15 U.S.C. s 12. A person "threatened [with] loss or damage by a violation of the antitrust laws" can seek injunctive relief under section 16 of the Clayton Act. 15 U.S.C. s 26. The availability of a private antitrust action, and its accompanying treble damages remedy, serves both to compensate private persons for their injuries and to punish wrongdoers. See 2 Phillip E. Areeda, Herbert Hovenkamp & Roger D. Blair, Antitrust Law p 330, at 273 (2d. ed. 2000). Private enforcement of the nation's antitrust laws also increases the likelihood that violators will be discovered. See Blue Shield of Va. v. McCready, 457 U.S. 465, 473 n.10 (1982) ("Only by requiring violators to disgorge the 'fruits of their illegality' can the deterrent objectives of the antitrust laws be fully served.") (citation omitted). In fact, private enforcement actions account for the overwhelming majority of antitrust litigation in the United States. See William F. Dolan, Developments in Private Antitrust Enforcement in 1999, 1181 PLI/Corp 971, 975 (2000).

"On its face, s 4 contains little in the way of restrictive language." Reiter v. Sonotone Corp., 442 U.S. 330, 337 (1979). "The statute does not confine its protection to con-

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8 Section 1 of the Sherman Act prohibits contracts, combinations or conspiracies "in restraint of trade or commerce among the several States, or with foreign nations." 15 U.S.C. s 1. Section 2 states that "[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony." 15 U.S.C. s 2. In its counterclaim, Biovail alleged that Andrx violated both sections 1 and 2 of the Sherman Act. JA 20-21.

sumers, or to purchasers, or to competitors, or to sellers.... The Act is comprehensive in its terms and coverage, protecting all who are made victims of the forbidden practices by whomever they may be perpetrated." Mandeville Island Farms, Inc. v. American Crystal Sugar Co., 334 U.S. 219, 236 (1948). The Supreme Court, however, has recognized that "the potency of the remedy implies the need for some care in its application" and does not construe the section 4 language to allow suit by every party affected by an antitrust violator's "ripples of harm." McCready, 457 U.S. at 476-77. An antitrust plaintiff must establish an injury-in-fact or a threatened injury-in-fact caused by the defendant's alleged wrongdoing. See Associated Gen. Contractors of Cal., Inc. v. California State Council of Carpenters, 459 U.S. 519, 535 (1983). Moreover, the injury must affect the plaintiff's business or property and must be the kind of injury the antitrust laws were intended to prevent; it must "flow[ ] from that which makes defendants' acts unlawful." Brunswick Corp. v. Pueblo

Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977). Additional factors to be considered in determining whether the plaintiff has "antitrust standing" include: the directness of the injury, whether the claim for damages is "speculative," the existence of more direct victims, the potential for duplicative recovery and the complexity of apportioning damages. See Associated Gen. Contractors, 459 U.S. at 542-45; see also Adams v. Pan Am. World Airways, Inc., 828 F.2d 24, 26 (D.C. Cir. 1987). We review the district court's decision dismissing Biovail's antitrust counterclaim with prejudice in light of these standing requirements.

A. Injury-in-Fact and Causation

As in any civil action for damages, the plaintiff in a private antitrust lawsuit must show that the defendant's illegal conduct caused its injury. See 2 Areeda et al., supra, p 338, at 316; see also Restatement (Second) of Torts ss 431, 433 (1965). The plaintiff's first step is to plead an injury-in-fact or, in a suit for equitable relief, a threatened injury-in-fact to business or property.9 See Hecht v. Pro-Football, Inc., 570

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9 Section 4 of the Clayton Act authorizes a private suit only for injury to "business or property." 15 U.S.C. s 15; see 2 Areeda et

F.2d 982, 993 (D.C. Cir. 1977). The "burden of proving the fact of damage under s 4 of the Clayton Act is satisfied by [ ] proof of some damage flowing from the unlawful conspiracy; inquiry beyond this minimum point goes only to the amount and not the fact of damage." Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 114 n.9 (1969) (emphasis original). The district court held that Biovail not only failed to plead an injury or a threatened injury but also was unable to do so because Biovail had yet to receive FDA approval for its generic version of Cardizem CD and gave no assurance that it would have entered the market had it gained approval. Cf. Indium Corp. of Am. v. Semi-Alloys, Inc., 781 F.2d 879, 882 (Fed. Cir. 1985) (because plaintiff was not prepared to enter market, defendant's conduct caused no injury).

When competitors violate the antitrust laws and another competitor is forced from a market, the latter suffers an injury-in-fact. A competitor that has not yet entered the market may also suffer injury but courts require a "potential" competitor to demonstrate both its intention to enter the market and its preparedness to do so. See Hecht, 570 F.2d at 987, 994 ("[A] potential competitor cannot achieve standing merely by demonstrating his intention to enter a field; he must also demonstrate his preparedness to do so." (emphasis original)); see Indium Corp., 781 F.2d at 882 (no injury if plaintiff not prepared to enter market). "Indicia of preparedness include adequate background and experience in the new field, sufficient financial capability to enter it, and the taking of actual and substantial affirmative steps toward entry, 'such as the consummation of relevant contracts and procurement of necessary facilities and equipment.' " Hecht, 570 F.2d at

994 (footnote and citation omitted). Thus, in evaluating whether Biovail sufficiently pleaded or can sufficiently plead

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al., supra, p 336, at 303. At the very least, "business or property" includes "commercial interests or enterprises." Hawaii v. Standard Oil Co., 405 U.S. 251, 264 (1972). In Reiter v. Sonotone Corp., the Supreme Court noted that "the word 'property' has a naturally broad and inclusive meaning." Id. at 338. On appeal, the parties do not raise the issue of whether Biovail sufficiently alleged an injury to "business or property."

an injury or threatened injury, we must examine its intent and preparedness to enter the market from which it alleges it was excluded, that is, the Cardizem CD, or controlled-release dilitiazem-based drug, market.

In the pharmaceutical industry, FDA approval is a prerequisite to enter any drug market. See 21 U.S.C. s 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug."). The district court concluded that Biovail suffered no injury as a result of the HMRI-Andrx Agreement "because even today, Biovail could not go to market with a generic version of Cardizem, because it had not received FDA approval."10 Andrx Pharm., 83 F. Supp. 2d at 186 (emphasis original). The only facts Biovail alleged to support its claim of injury were that the Agreement "prevent[ed] generic Cardizem CD products by Biovail and others from reaching the market as soon as they would otherwise be allowed," JA 44 (p 19), and that Biovail had filed an ANDA for a generic version of Cardizem CD, JA 50 (p 41). Biovail did not explicitly allege that it was prepared to bring a generic version of Cardizem CD to market or that it anticipated FDA approval. In addition, when the FDA eventually approved its ANDA, Biovail inexplicably failed to inform the district court. Based on Biovail's failure to plead sufficient intent and preparedness to enter the market, the district court dismissed Biovail's antitrust counterclaim.11 See Andrx Pharm., 83 F. Supp. 2d at 187.

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10 By the time of the district court's decision, however, the FDA had approved Biovail's ANDA for its generic version of Cardizem CD although the court was not apprised of that development.

11 The issues of injury-in-fact and causation are closely linked on this point. By not alleging facts indicating its intent and preparedness to enter the Cardizem CD market, Biovail failed to allege both an injury (no loss of profits because not prepared to enter market) and causation (any damages not related to HMRI-Andrx Agreement because Agreement did not cause loss of profits).

The district court, however, went beyond dismissing the counterclaim based on the pleading's insufficiency. It dismissed Biovail's antitrust counterclaim with prejudice. In so

doing it decided, as a matter of law, that Biovail was unable to set forth any set of facts that would entitle it to the relief it sought. "[D]ismissal with prejudice should be granted only when a trial court determines that 'the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency.' " Jarrell v. United States Post. Serv., 753 F.2d 1088, 1091 (D.C. Cir. 1985) (quoting Bonnano v. Thomas, 309 F.2d 320, 322 (9th Cir. 1962)). The district court did not conclude that Biovail did not intend to enter the market or that it was not sufficiently prepared to do so but instead that it had not sufficiently alleged its intent and capacity to enter the market. See Andrx Pharm., Inc., 83 F. Supp. 2d at 184-85. Its statement that the FDA had not yet approved Biovail's ANDA as of the date of its ruling was understandable in light of the parties' failure to inform the court to the contrary but the statement was nonetheless erroneous and not a ground to dismiss with prejudice.

As its motion for reconsideration manifests, Biovail can allege facts sufficient to indicate its intent and preparedness. See JA 297, 300-02. And even before the FDA approved Biovail's ANDA, Biovail could have alleged its intent and preparedness to enter the market by claiming that FDA approval was probable. Andrx's original suit, which sought to enjoin the FDA from approving Biovail's ANDA, suggests that Biovail (or so Andrx believed) may have intended and been sufficiently prepared to enter the market. See Zenith Radio, 395 U.S. at 130 ("[Section 16] authorizes injunctive relief upon the demonstration of 'threatened' injury. That remedy is characteristically available even though the plaintiff has not yet suffered actual injury; he need only demonstrate a significant threat of injury from an impending violation of the antitrust laws or from a contemporary violation likely to continue or recur.") (citation and footnote omitted); L.A. Mem'l Coliseum Comm'n v. National Football League, 468 F. Supp. 154, 159 (C.D. Cal. 1979). And unlike the plaintiffs in Confederate Memorial Association, Inc. v. Hines, 995 F.2d

295 (D.C. Cir. 1993), where this court upheld the trial court's dismissal with prejudice of the plaintiffs' RICO claims because the plaintiffs failed to allude to facts "entitling them to recover," Biovail has (in its motion for reconsideration) alluded to facts--FDA approval and intent to enter market--that may entitle it to relief. Id. at 299; cf. Askins v. District of Columbia, 877 F.2d 94, 99 (D.C. Cir. 1989) (dismissal with prejudice of unripe legal claim is legal error). Because Biovail may be able to cure its pleading deficiency, we conclude that dismissal with prejudice was erroneously granted.

Andrx responds, however, that an independent legal ground supports dismissal with prejudice. It argues Biovail is unable to allege causation. To sufficiently plead causation, a plaintiff must allege that the defendant violated the antitrust laws, that the defendant's alleged violation "had a tendency to injure" the plaintiff's business or property, Amerinet, Inc. v. Xerox Corp., 972 F.2d 1483, 1495 (8th Cir. 1992),

and that the plaintiff suffered a decline in its business or property "not shown to be attributable to other causes." Bigelow v. RKO Radio Pictures, Inc., 327 U.S. 251, 264 (1945). The Supreme Court has explained "[i]t is enough that the illegality is shown to be a material cause of the injury; a plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury under [section 4 of the Clayton Act]." Zenith Radio, 395 U.S. at 114 n.9.

The district court found that Biovail failed to establish the requisite causal connection between its injury and the alleged anticompetitive conduct. It concluded that any injury Biovail may have suffered was caused not by the HMRI-Andrx Agreement but instead by the lack of FDA approval of its generic version of Cardizem CD and by the delay period prescribed by the Hatch-Waxman Amendments. We disagree. Although we affirm the district court's dismissal to the extent Biovail failed to allege an injury-in-fact, we disagree with its conclusion that any injury Biovail might plead would be caused by "the existence of a troublesome statutory scheme that prohibits it from marketing a drug until the first ANDA recipient goes to market, and which places no restrictions on when, or even whether, that applicant must to [sic]

go to market." Andrx Pharms., 83 F. Supp. 2d at 185. We also reject Andrx's argument that any rational actor like itself would not market its generic drug until the patent infringement suit against it was resolved, making any loss of profits caused by Biovail's exclusion from the market a result of the statutory scheme, not Andrx's conduct. A reasonable juror could conclude that Andrx's argument contradicts the very premise of the HMRI-Andrx Agreement. Under the Agreement, HMRI paid Andrx 10 million dollars per quarter effectively not to enter the market. One can fairly infer from these facts, which were alleged in the counterclaim, that but for the Agreement, Andrx would have entered the market. As one commentator has noted, "[a] payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties in entering the agreement and the rent-preserving effect of that agreement." Balto, supra, at 335.

Andrx, however, argues that it "did nothing other than to act in accordance with rights granted to it under the Hatch-Waxman [Amendments]. The exercise of these statutory rights, exclusionary though they may be, cannot support a claim under the antitrust laws." Appellee Br. 31. Andrx may be correct that "[a] plaintiff cannot be injured in fact by private conduct excluding him from the market when a statute prevents him from entering that market in any event." City of Pittsburgh v. West Penn Power Co., 147 F.3d 256, 268 (3d Cir. 1998) (quoting Philip E. Areeda & Herbert Hovenkamp, Antitrust Law, p 363(b) at 222 (1995)). Although the Hatch-Waxman Amendments provide a 180-day period of market exclusivity to the first applicant to file an ANDA for a generic version of a pioneer drug, see 21 U.S.C.

s 355(j)(5)(B)(iv),12 through the Amendments, "Congress

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12 Section 355(j)(5)(B)(iv) provides:

> If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after--

sought to get generic drugs into the hands of patients at reasonable prices--fast." In re Barr Lab., Inc., 930 F.2d 72, 76 (D.C. Cir. 1991). We disagree with Andrx that "its conduct was not only permitted under but clearly contemplated by the Hatch-Waxman" Amendments. Appellee Br. 32. Although it is true that the first to file an ANDA is permitted to delay marketing as long as it likes, the statutory scheme does not envision the first applicant's agreeing with the patent holder of the pioneer drug to delay the start of the 180-day exclusivity period. See Mova Pharm., 140 F.3d at 1072 (acknowledging and describing as anomaly fact situation here presented).13

By accepting payments from HMRI, Andrx received the benefit of the 180-day exclusivity period without starting the clock. By agreeing with HMRI to share HMRI's profits from the sale of Cardizem CD, it was able to exclude other competitors from entering the market. Andrx's commitment

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> (I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
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> (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,
> whichever is earlier.

13 The court stated in a footnote:

> An amicus brief filed by Biovail Corporation International dramatically illustrates an analogous risk, not necessarily involving collusion. Biovail was the second applicant to file a paragraph IV ANDA for a generic version of a heart medication. Biovail was not sued by the pioneer drug company. The first applicant and the pioneer drug company are now in litigation, and, Biovail claims, the pioneer is paying the first applicant some $10 million per quarter in exchange for the first applicant's agreement not to sell its product after the 30-month waiting period expires. Under these circumstances, neither party would seem to have maximum incentive to bring the litigation to a close.

Id. at 1072 n.14.

not to trigger the running of the 180-day exclusivity period

could have caused Biovail's injury (assuming FDA approval was probable and it was sufficiently prepared to enter the market) by denying it the ability to proceed to market with its own generic version. Although the 180-day provision of the Hatch-Waxman Amendments legally barred it from selling its product, Andrx's manipulation of the exclusivity period trigger date extended the legal bar.

Andrx maintains that the Agreement was not a restraint cognizable under the antitrust laws because, under the FDA regulations in effect at the time, it could not have caused the delay of FDA approval of Biovail's ANDA. In September 1997 (when the Agreement was signed) Andrx contends that the FDA regulations provided that the first ANDA applicant to file a Paragraph IV certification would not be granted a 180-day exclusivity period unless it had "successfully defended" any patent infringement action brought by the patent holder "before a subsequent applicant's ANDA was ready to be approved." Appellee Br. 37-38 (citing 21 C.F.R. s 314.107(c)(i) (1997)). We rejected the FDA's "successful defense" regulation in Mova Pharm., 140 F.3d at 1076. Andrx argues that before the court invalidated the regulation, it could have done nothing to prolong its exclusivity period by delaying FDA approval of Biovail's ANDA because it was entitled to the exclusionary period only if it successfully defended the patent litigation before the FDA approved a subsequent applicant's ANDA. Had the FDA approved Biovail's ANDA, Andrx asserts, the Agreement would not have prevented Biovail from entering the market under the old regulation.

We reject this argument. On January 23, 1997 the district court in Mova issued a preliminary injunction against the FDA, holding that its "successful defense" regulation was inconsistent with the plain language of the statute and therefore unenforceable. See Mova Pharm. Corp. v. Shalala, 955 F. Supp. 128, 131-32 (D.D.C. 1997). HMRI and Andrx did not enter into their agreement until September 1997, almost nine months after the court's ruling. On April 14, 1998 this court affirmed the district court. Mova, 140 F.3d at 1076.

The Agreement did not go into effect until three months later, in July 1998. The timing of the Agreement and of the demise of the successful defense requirement defeats Andrx's argument on this point.

Andrx nevertheless relies on the holding in Polk Bros., Inc. v. Forest City Enters., Inc., 776 F.2d 185 (7th Cir. 1985). In Polk Bros., two companies, one that sold appliances and home furnishings and the other that sold building materials, lumber, tools and related products, reached an agreement to build on a large parcel of land one building, partitioned on the interior, to house both stores. Id. at 187. The arrangement was attractive to both firms due to the complementary nature of their products. They feared, however, that one day competition might replace cooperation so they negotiated a covenant restricting the products each could sell. Id. Years later

one of the firms wanted to sell certain products in violation of the covenant and challenged the covenant on antitrust grounds when the other firm sought to enforce it. Id. at 187-88. Although the case arose under Illinois antitrust law, state law used federal antitrust law as a guide. Id. at 188. The Seventh Circuit upheld the validity of the covenant on the ground that, although "naked" restraints on trade are unlawful per se, ancillary restraints that facilitate productive activity are not. The court provided the following example:

> If A hires B as a salesman and passes customer lists to B, then B's reciprocal covenant not to compete with A is "ancillary." At the time A and B strike their bargain, the enterprise (viewed as a whole) expands output and competition by putting B to work. The covenant not to compete means that A may trust B with broader responsibilities, the better to compete against third parties. Covenants of this type are evaluated under the Rule of Reason as ancillary restraints, and unless they bring a large market share under a single firm's control they are lawful. See United States v. Addyston Pipe & Steel Co., 85 F. 271, 280-83 (6th Cir. 1898) (Taft, J.), aff'd, 172 U.S. 211 (1899).

Id. at 189. Thus even were we to adopt Andrx's characterization of the Agreement as "designed to preserve the status quo by duplicating relief that the court could have ordered had HMR[I] proceeded with" its motion for a preliminary injunction in the patent infringement litigation, the Agreement's allegedly anticompetitive provisions, including Andrx's pledge to continue to pursue its ANDA so as to forestall other applicants from receiving final FDA approval, were not necessarily ancillary restraints but rather could reasonably be viewed as an attempt to allocate market share and preserve monopolistic conditions.

Finally, Andrx contends that there were reasonable alternatives available to Biovail that could have avoided the exclusionary effect of the Agreement by triggering the 180-day period. Andrx relies on CBS Broad. Sys., Inc. v. ASCAP, 620 F.2d 930, 935 (2d Cir. 1980), which held that "a practice that is not a per se violation ... does not restrain trade when the complaining consumer elects to use it in preference to realistically available marketing alternatives." There the court found that to avoid injury, the consumer plaintiff had only to do nothing "more extraordinary than offer to buy from competing sellers." Id. at 936. Andrx argues that Biovail had two alternatives in lieu of waiting for Andrx to market its generic version of Cardizem CD. First, Biovail could have triggered the start of the 180-day exclusivity period itself under the "court decision" prong of the Hatch-Waxman Amendments, 21 U.S.C. s 355(j)(5)(B)(iv)(II), by seeking a declaratory judgment of non-infringement or invalidity of HMRI's patent. The successful resolution (or dismissal) of the declaratory judgment action would have started the 180-day exclusivity period. See Teva Pharm. USA, Inc. v. FDA, 182 F.3d 1003, 1007-08 (D.C. Cir. 1999). Alternatively, Bio-

vail could have petitioned the FDA to nullify Andrx's 180-day exclusivity period. FDA regulations provide that "if FDA concludes that the applicant submitting the first application is not actively pursuing approval of its abbreviated application, FDA will make the approval of subsequent abbreviated applications immediately effective if they are otherwise eligible for an immediately effective approval." 21 C.F.R. s 314.107(c)(3).

The CBS holding is easily distinguishable; the language on which Andrx relies appears in the context of determining whether an agreement determined not to be per se unlawful nonetheless restrains trade on the facts. There the agreement benefitted the consumer by bundling various music copyright licenses, relieving the consumer of having to negotiate licenses with every individual artist. Andrx has cited no consumer benefit here. Biovail could have sought a declaratory judgment; however, as evidenced by the HMRI-Andrx patent infringement litigation, the time involved to obtain such a judgment made this option less than "fully available." CBS, 620 F.2d at 935. Likewise, as long as Andrx was pursuing FDA approval, Biovail could not use 21 C.F.R. s 314.107(c)(3) to revoke the 180-day exclusivity period. Indeed, according to the HMRI-Andrx Agreement, Andrx was to continue to pursue approval, which prevented the FDA from denying it the 180-day exclusivity period. Accordingly, we conclude the district court erred in dismissing with prejudice Biovail's counterclaim for failure to plead injury caused by Andrx's alleged unlawful restraint of trade. See supra note 8.

B. Antitrust Injury

"A private antitrust plaintiff does not acquire standing merely by showing that it was injured in a proximate and reasonably measurable way by conduct of the defendant violating the antitrust laws (injury-in-fact). Nor is it enough that the injury be causally connected to the acts that violate the antitrust laws (causation)." 2 Areeda et al., supra, p 337a, at 305. In Brunswick, the Supreme Court explained that "[p]laintiffs must [also] prove antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." 429 U.S. at 489 (emphasis original). "The injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation. It should, in short, be 'the type of loss that the claimed violations ... would be likely to cause.' " Id. (quoting Zenith Radio, 395 U.S. at 125).14 The Supreme Court has declared that the antitrust laws "were enacted for 'the protection of competition not competitors.' " Id. at 488 (quoting Brown Shoe Co. v. United States, 370 U.S. 294, 320 (1962)) (emphasis original). Thus a competitor may not claim an injury resulting from competition even when such competition was actually caused by conduct that violates the antitrust laws. See 2 Areeda et

al., supra, p 337, at 306; see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 596 n.20 (1986) (competitors suffer no harm from conspiracy to raise prices); J. Truett Payne Co. v. Chrysler Motors Corp., 451 U.S. 557, 568 (1981) (violation of antitrust laws not enough to confer standing).

In asserting that Biovail cannot assert an antitrust injury, Andrx compares it to the Brunswick plaintiffs. In Brunswick, the plaintiffs, three bowling alleys, complained that the defendant's acquisition of several financially troubled bowling centers violated section 7 of the Clayton Act. In seeking damages, the plaintiffs "attempted to show that had [the defendant] allowed the defaulting centers to close, [the plaintiffs'] profits would have increased." Brunswick, 429 U.S. at 481. The Supreme Court held that even though the plaintiffs' injury--loss of profits--was caused by the defendant's potentially unlawful acquisitions, the plaintiffs suffered no antitrust injury because the increased competition resulting from the defendant's purchase and operation of competing bowling alleys was not an injury antitrust laws were designed to prevent. Id. at 488. The Court explained that the plaintiffs' injury resulted from competitive, not anticompetitive, conduct. Further, because the plaintiffs would have suffered the same injury had their rivals been lawfully acquired by some-

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14 In a suit for equitable relief under section 16 of the Clayton Act, the plaintiff must also establish an antitrust injury, although the injury need only be threatened. See Zenith Radio, 395 U.S. 130 (section 16 "invokes traditional principles of equity and authorizes injunctive relief upon the demonstration of 'threatened' injury"); see also Cargill, Inc. v. Monfort of Colo., Inc., 479 U.S. 104, 122 (1986).

one else, their injury did not occur " 'by reason of anything forbidden in the antitrust laws': while [plaintiffs'] loss occurred 'by reason of' the unlawful acquisitions, it did not occur 'by reason of' that which made the acquisitions unlawful." Id. Unlike the Brunswick plaintiffs' injury, Biovail's alleged injury is the type the antitrust laws were designed to prevent. If Biovail's allegations are correct, the Andrx-HMRI Agreement neither enhanced competition nor benefitted consumers; if anything, it accomplished just the opposite by preserving HMRI's monopoly. Moreover, Biovail alleged that its exclusion from the market occurred not only by reason of the unlawful Agreement but also by reason of that which made the Agreement unlawful, that is, an illegal restraint of trade. See Brunswick, 429 U.S. at 488.

Andrx next argues that it could have lawfully excluded Biovail from the Cardizem CD market by deciding, on its own, to delay marketing of its generic version of Cardizem CD and therefore Biovail's alleged injury does not constitute an antitrust injury. It contends that because its underlying conduct was legal, the fact that it combined to act that way cannot give rise to an antitrust violation. See ES Dev., Inc. v.

RWM Enters., Inc., 939 F.2d 547, 553 (8th Cir. 1991) (explaining that "[t]he evidence must also establish that the alleged participants combined or conspired to 'achieve an unlawful objective' "). Under the Hatch-Waxman Amendments, Andrx was lawfully entitled to unilaterally delay marketing its product until the patent infringement claims against it were resolved. Although its unilateral decision not to market its generic version of Cardizem CD would have prevented others, including Biovail, from entering the market, the counterclaim alleges that Andrx entered into an anticompetitive agreement with HMRI in order to exclude others; HMRI's ten million dollar quarterly payments were presumably in return for something that Andrx would not otherwise do, that is, delay marketing of its generic. Andrx's argument that any rational actor would wait for resolution of the patent infringement suit is belied by the quid of HMRI's quo. See 54 Fed. Reg. 42,873, 42,882-83 ("[I]t can be mutually beneficial for the innovator and the generic company that is awarded 180 days

of generic exclusivity to enter into agreements that block generic competition for extended periods. This delayed competition harms consumers by slowing the introduction of lower priced products into the market and thwarts the intent of the Hatch-Waxman Amendments.").15

Antitrust law looks at entry into the market as one mechanism to limit and deter exploitation of market power by those who may temporarily possess it. "Existing firms know that if they collude or exercise market power to charge supracompetitive prices, entry by firms currently not competing in the market becomes likely, thereby increasing the pressure on them to act competitively." FTC v. H.J. Heinz Co., 246 F.3d 708, 717 n.13 (D.C. Cir. 2001). The FDA acknowledges that "[u]nder current regulatory provisions, the first generic applicant to file a substantially complete ANDA with a paragraph IV certification can delay generic competition by entering into certain commercial arrangements with an innovator company." 64 Fed. Reg. 42,882.16 Such an arrangement can

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15 The statutorily granted monopoly of patent rights is similar. Like a drug's 180-day exclusive market period, a patent grant in and of itself is "an exception to the general rule against monopolies and to the right to a free and open market." Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 177 (1965) (quoting Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co., 324 U.S. 806, 816 (1945)). But even a patent-right holder is not immune from antitrust liability. In United States v. Singer Mfg. Co., 374 U.S. 174 (1963), two competitors, Singer and Gegauf, entered into a cross-licensing agreement to settle a Patent Office interference proceeding involving their conflicting patent claims. Although Singer (like Andrx) had no obligation to pursue a patent grant and could have, on its own, withdrawn from the interference proceeding, it nevertheless acted unlawfully when it agreed with a competitor to settle the dispute, suppress information and exclude others from the market. See id. at 196; see also American Cyanimid Co., 72 F.T.C. 623 (1967), aff'd sub nom.

Charles Pfizer & Co. v. FTC, 401 F.2d 574 (6th Cir. 1968) (Tetracycline case).

16 The FDA has proposed a "triggering period" during which there must exist either a favorable court decision regarding the

manipulate the statutory grant of a monopoly to bar competitive entries. See Balto, supra, at 331 ("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."). Andrx argues that the Agreement merely preserved the status quo--in effect a stipulated preliminary injunction--until the conclusion of the patent infringement suit. When the court grants preliminary injunctive relief, however, it does so only after considering the public interest and the likelihood of success on the merits. See Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc., 559 F.2d 841, 842-43 (D.C. Cir. 1977); accord Serono Labs., Inc. v. Shalala, 158 F.3d 1313, 1317-18 (D.C. Cir. 1998); CityFed Fin. Corp. v. Office of Thrift Supervision, 58 F.3d 738, 746-47 (D.C. Cir. 1995).17 Moreover, even if Andrx's agreement to maintain the status quo was lawful, its commitment to continue to prosecute its ANDA and do nothing to jeopardize its 180-day exclusivity period went beyond preserving the status quo. "To be ancillary, and hence exempt from the per se rule, an agreement eliminating competition must be subor-

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alleged infringed patent or the first applicant must begin commercial marketing. If the first applicant does neither, it forfeits its 180-day exclusivity period. See 64 Fed. Reg. 42,877. "In most cases, the triggering period would begin to run on the day a subsequent ANDA applicant with a paragraph IV certification receives a tentative approval stating that but for the first applicant's exclusivity, the subsequent ANDA would receive final approval." Id. The triggering period would also begin to run upon expiration of any 30-month stay in place.

17 By contrast, a private agreement purporting to maintain the status quo may not be in the public interest or may have little likelihood of success on review. See generally Sheila F. Anthony, Prepared Remarks before the ABA "Antitrust and Intellectual Property: The Crossroads" Program, Riddles and Lessons from the Prescription Drug Wars: Antitrust Implications of Certain Types of Agreements Involving Intellectual Property (June 1, 2000), available at www.ftc.gov/speeches/anthony/sfip000601.htm.

dinate and collateral to a separate, legitimate transaction.... If [the restraint] is so broad that part of the restraint suppresses competition without creating efficiency, the restraint is, to that extent, not ancillary." Rothery Storage & Van Co. v. Atlas Van Lines, Inc., 792 F.2d 210, 224 (D.C. Cir. 1986). As Biovail has pleaded the facts, HMRI and Andrx combined to achieve an unlawful objective, namely, the extension of the exclusivity period granted under the Hatch-

Waxman Amendments. Accordingly, we conclude that Biovail can allege an antitrust injury, that is, one the antitrust laws were designed to prevent and that flows from that which makes the defendant's conduct unlawful.

C. Speculative Nature of Harm

Standing may yet be denied if damages "rest[ ] at bottom on some abstract conception or speculative measure of harm." McCready, 457 U.S. at 475 n.11. In Associated General Contractors, the Court denied standing because the plaintiff's damages claim was "highly speculative." 459 U.S. at 542; accord Adams, 828 F.2d at 30. It noted that the plaintiff union did not allege (1) that any of its collective bargaining agreements were terminated as a result of the defendant's alleged anticompetitive acts, (2) that union firms' aggregate share of the contracting market had been diminished and (3) that its revenue from dues and initiation fees had decreased. On the other hand, in Bigelow, the Court held that the plaintiff's damages were not too speculative to support the jury's verdict of damages. 327 U.S. at 265. There, the movie theater owner plaintiffs claimed that defendant distributors and affiliated movie theaters conspired to prevent the plaintiffs from obtaining movies for their theaters until after the defendant theaters had shown them. Id. at 254. The Court permitted the jury to consider evidence of decline in prices, profits and values not shown to be attributable to other causes to calculate the quantum of damage caused by the defendants' unlawful acts. Id. at 264.

We find Biovail's damages claim, assuming it can plead its intent and preparedness to enter the market, more like that in Bigelow than in Associated General Contractors. According to its counterclaim, Biovail was not an inexperienced newcomer; it already manufactured generic pharmaceuticals. It had already developed its product and, once FDA gave tentative approval to its ANDA, was simply waiting out Andrx's 180-day exclusivity period.18 Although damages may be difficult to quantify, "[t]he most elementary conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which his own wrong has created." Bigelow, 327 U.S. at 265; see Story Parchment Co. v. Paterson Parchment Paper Co., 282 U.S. 555, 562 (1931). Biovail may ultimately fail to establish the amount of damages beyond a nominal amount, see Associated Gen. Contractors, 459 U.S. at 544-45, but Biovail could continue to seek (if not moot) injunctive relief. See Blue Cross & Blue Shield of Wis. v. Marshfield Clinic, 152 F.3d 588, 595 (7th Cir. 1998).19

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18 Biovail received tentative approval in October 1999. On November 5, 1999 Andrx petitioned for reconsideration and for a stay of the FDA's tentative approval. The parties dispute the effect of the petition on the timing of Biovail's final approval on December 23, 1999. Even if Biovail's damages period were relatively short, Biovail would nevertheless be able to seek recovery. Moreover,

"[d]ifficulty of ascertainment [should not be] confused with right of recovery." McCready, 457 U.S. at 475 n.11 (quoting Bigelow, 327 U.S. at 265).

19 Antitrust standing also requires proximity between the alleged cause and the alleged injury. See Associated Gen. Contractors, 459 U.S. at 540; McCready, 457 U.S. at 476-77 (" '[D]espite the broad wording of s 4 there is a point beyond which the wrongdoer should not be held liable.' " (citation omitted)); 2 Areeda et al., supra, p 339, at 325-26. In evaluating whether an injury is too remote, "we look (1) to the physical and economic nexus between the alleged violation and the harm to the plaintiff, and (2), more particularly, to the relationship of the injury alleged with those forms of injury about which Congress was likely to have been concerned in making defendant's conduct unlawful and in providing a private remedy under s 4." McCready, 457 U.S. at 478; see In re Multidistrict Vehicle Air Pollution M.D.L., 481 F.2d 122, 129 (9th Cir. 1973). In McCready, the Supreme Court held that health insurance subscribers had standing to sue their insurance company for colluding with physicians and psychiatrists to deny them reimbursement for pay-

D. Existence of More Appropriate Plaintiff

In evaluating standing, courts also consider whether there exists a more directly injured plaintiff to vindicate the public interest. See Associated Gen. Contractors, 459 U.S. at 544. "Inferiority" to another plaintiff does not necessitate that we deny standing but it is a relevant factor. See 2 Areeda et al., supra, p 339, at 332. We are more likely to find no standing if the plaintiff's injury both derives from and is measured by another's more direct injury. See Adams, 828 F.2d at 30-31 (existence of superior plaintiffs--employer airline as well as consumers of transatlantic air transportation--militated against employees' standing). Additionally, lack of standing is more likely as layers of superior plaintiffs increase. See 2 Areeda et al., supra, p 339, at 332.

The district court held that "[t]hose most directly affected by [Andrx's] violation would be the consumers faced to pay artificially high prices for Cardizem." Andrx Pharm., 83 F. Supp. 2d at 186. It reasoned that "[i]f Andrx's activity violates the antitrust laws, it is because it is keeping others out of the market and thereby maintaining artificially high costs for generic drugs." Id. But Biovail's alleged injury is not derived from or measured by the injury to consumers; instead it is measured by the loss of profits it would have otherwise made had it not been excluded from the market. See Story Parchment, 282 U.S. at 562-64; Eastman Kodak Co. v. Southern Photo Co., 273 U.S. 359, 378-79 (1927).

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ments made to psychologists. The Court acknowledged that while the psychologists (not the patients) were the targets of the conspiracy, standing "cannot reasonably be restricted to those competitors whom the conspirators hoped to eliminate from the market." McCready, 457 U.S. at 479. It thus affirmed the subscribers' standing. Applying the same reasoning, we conclude that Biovail's

alleged injury is "so integral an aspect" of the alleged anticompetitive behavior, "there can be no question but that the loss was precisely 'the type of loss that the claimed violations ... would be likely to cause.' " Id. (quoting Brunswick, 429 U.S. at 489). When a competitor is excluded from a market by the collusive acts of its rivals, its loss of profits is directly caused by that anticompetitive behavior.

Biovail does not seek damages for profits it would have earned at higher, less competitive prices. See, e.g., Atlantic Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 337 (1990); Brunswick, 429 U.S. at 487-89. It seeks damages to compensate for profits it would have earned by competing in the market. Irrespective of consumer injury, an excluded competitor like Biovail suffers a distinct injury if it is prevented from selling its product. "[A] rival has clear standing to challenge the conduct of rival(s) that is illegal precisely because it tends to exclude competitors from the market." 2 Areeda et al., supra, p 348, at 387. Unlike the "high probability of substantial overlap" the Adams court found between the injury the plaintiffs there alleged (employees' lost jobs and lower wages) and those of more direct victims (company's loss of profits and transatlantic passengers' increased airfare), Biovail's alleged injury is not measured by or derived from consumer plaintiffs. Adams, 828 F.2d at 30 n.12. And to the extent Biovail seeks injunctive relief, its standing is plainly not derivative.

E. Duplicative Recovery and Complex Apportionment of Damages

In Illinois Brick Co. v. Illinois, 431 U.S. 720 (1977), the Supreme Court held that antitrust suits brought by indirect purchasers increased both the risk of multiple recoveries and the difficulty of apportionment of damages. The Court explained that in addition to adding complexity to the case, apportionment pares the direct purchasers' recovery, thereby diminishing their incentive to bring treble damage actions under section 4 of the Clayton Act. Id. at 737-47; see McCready, 457 U.S. at 475 n.11.

The district court concluded that the existence of both consumer suits and Biovail's own suit against HMRI raised "the potential here for duplicative recoveries and inconsistent holdings." Id. As we have explained, however, Biovail's injuries are neither derived from nor measured by injuries consumers may have suffered. Any injury to consumers would result from paying a supracompetitive price for Cardizem CD. Biovail's injury, on the other hand, is the result of

foregone profits, i.e., the difference between the competitive market price it would have charged had it been in the market and its total costs. See Eastman Kodak, 273 U.S. at 378-79. Moreover, Biovail has settled its suit with HMRI. See Biovail Corp. Int'l v. Aktiengesellschaft, Civ. No. 98-1434 (D.N.J. Jan. 31, 2001).20

F. Noerr-Pennington Doctrine

Having concluded that dismissal with prejudice was erroneously granted, we must consider Andrx's claim that the Agreement is litigation-related conduct exempted from antitrust liability by the Noerr-Pennington doctrine. The Noerr-Pennington doctrine insulates from antitrust challenge competitors' decision to combine to petition the government, even if their underlying intention is to restrain competition or gain advantage over competitors. See United Mine Workers of Am. v. Pennington, 381 U.S. 657, 670 (1965); see also City of Columbia v. Omni Outdoor Adver., Inc., 499 U.S. 365, 379-80 (1991) ("The federal antitrust laws also do not regulate the conduct of private individuals in seeking anticompetitive action from the government."). The doctrine is rooted in First Amendment law and "rests ultimately upon a recognition that the antitrust laws, 'tailored as they are for the business world, are not at all appropriate for application in the political arena.' " Omni, 499 U.S. at 380 (citation omitted).21

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20 Moreover, the Federal Trade Commission has withdrawn its complaint against HMRI and Andrx and entered into consent agreements with both manufacturers prospectively barring them from entering into certain anticompetitive agreements and requiring that future interim settlements of patent litigation be approved by the court with notice to the Commission. See 66 Fed. Reg. 18,636 (proposed consent decree).

21 The doctrine derives its name from two Supreme Court decisions. The first, Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961), held that the antitrust laws do not apply to conduct resulting from valid government actions. The Supreme Court held that attempts by railroads to influence legislation designed to restrict competition from the trucking industry were exempt from antitrust liability. The Court remarked, "no

In California Motor Transport Co. v. Trucking Unlimited, the Court extended the right to petition all departments of the government, including the "courts, the third branch of Government." 404 U.S. 508, 510 (1972) ("The right of access to the courts is indeed but one aspect of the right of petition."). Whether conduct falls with "[t]he scope of this protection depends, however, on the source, context, and nature of the anticompetitive restraint at issue." Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 499 (1988). If anticompetitive harm is caused by the decision of a court, even though granted at the request of a private party, no private restraint of trade occurs because the intervening government action breaks the causal chain. See 1 Phillip Areeda & Herbert Hovenkamp, Antitrust Law p 202c, at 159-62 (2d ed. 2000).

Andrx argues that its Agreement should receive the same protection as threatened litigation or an offer of settlement. See, e.g., Coastal States Mktg., Inc. v. Hunt, 694 F.2d 1358, 1367 (5th Cir. 1983) (extending doctrine to cover activities not

necessarily part of petitioning process, but reasonably incident or normally attendant to it, e.g., genuine litigation threat); McGuire Oil Co. v. Mapco, Inc., 958 F.2d 1552, 1560 (11th Cir. 1992) (same).22 We disagree. Although certain

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violation of the [Sherman] Act can be predicated upon mere attempts to influence the passage or enforcement of laws." Id. at 135. The Court came to the same conclusion in Pennington, 381 U.S. 657 (1965). There, mine operators and workers petitioned the Executive Branch to induce the Tennessee Valley Authority to curtail spot market purchases and to increase minimum wages. The Court explained that "[j]oint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition. Such conduct is not illegal, either standing alone or as a part of a broader scheme itself violative of the Sherman Act." Id. at 670.

22 See also 1 Areeda & Hovenkamp, supra, p 205e, at 238 ("Most lawsuits are prefaced by various communications, such as demand letters that expressly or impliedly threaten suit unless the addressee alters its conduct or provides other relief. Such prelitigation communications provide useful notice and facilitate the resolution of

litigation conduct is protected under the doctrine, it does not extend to the HMRI-Andrx Agreement. See California Motor Transp., 404 U.S. at 512-13 (examples of unprotected litigation conduct include perjury by witnesses and fraudulently obtained patent); cf. Omni, 499 U.S. at 380 ("sham" petitioning such as filing frivolous objections to license application of a competitor to impose expense and delay not protected). In In re Cardizem CD Antitrust Litigation, 105 F. Supp. 2d 618, the district court found the alleged anticompetitive harm stemming from the Agreement separate from any anticompetitive effects that may have resulted from resolution of the HMRI patent infringement suit. The harm, the court declared, was not the result of a court decision. "Rather, it is the result of purely private conduct and thus constitutes a private restraint of trade subject to liability under the antitrust laws." Id. at 635; see also In re Brand Name Prescription Drugs Antitrust Litig., 186 F.3d 781, 789 (7th Cir. 1999) ("[T]he doctrine does not authorize anticompetitive action in advance of government's adopting the industry's anticompetitive proposal. The doctrine applies when such action is the consequence of legislation or other governmental action, not when it is the means for obtaining such action (or in this case inaction)." (emphasis original)). The Agreement is not unlike a final, private settlement agreement resolving the patent infringement litigation by substituting a market allocation agreement. Such a settlement agreement would not enjoy Noerr-Pennington immunity and neither does the Agreement here.

IV. Conclusion

In sum, although the district court correctly dismissed Biovail's antitrust counterclaim for failure to sufficiently al-

lege injury caused by the HMRI-Andrx Agreement, it should have granted the dismissal without prejudice to allow Biovail the opportunity to replead. Accordingly, appeal No. 00-5050

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controversies. It would be foolish to adopt antitrust rules encouraging suit before communication by penalizing the communication but not the suit.").

is remanded to the district court for proceedings not inconsistent with this opinion. In light of our holding, we dismiss as moot appeal No. 00-5396.

So ordered.