942 F.3d 88
United States Court of Appeals, Second Circuit.

BIOCAD JSC, Plaintiff-Appellant,
v.
F. HOFFMANN-LA ROCHE, Genentech, Inc., R-Pharm JSC, Roche Holding AG, Defendants-Appellees. *

Docket No. 17-3486
|
August Term 2018
|
Argued: October 23, 2018
|
Decided: November 5, 2019

Synopsis

Background: Foreign manufacturer of generic cancer treatment drugs brought action against foreign manufacturer of brand-name drugs and its subsidiaries and affiliates alleging that they engaged in foreign anticompetitive conduct that was intended to interfere with generic manufacturer's ability to enter domestic pharmaceutical market upon expiration of exclusivity period for patented drugs, in violation of Sherman Act, Clayton Act, Robinson-Patman Act, and New York's Donnelly Act. The United States District Court for the Southern District of New York, Richard J. Sullivan, J., 2017 WL 4402564, dismissed claims for lack of subject matter jurisdiction and for failure to state a claim. Generic manufacturer appealed.

Holdings: The Court of Appeals, Chin, Circuit Judge, held that:

[1] FTAIA's import exclusion applies when a defendant's actions immediately impact the United States import market and not merely when a defendant subjectively intends to affect the United States import market in the future, and

[2] generic manufacturer failed to state Sherman Act claim.

Affirmed.

Katzmann, Chief Judge, filed concurring opinion.

West Headnotes (15)

[1] **Federal Courts** Pleading
Federal Courts Dismissal for failure to state a claim

The Court of Appeals reviews the grant of a motion to dismiss for failure to state a claim de novo, accepting all factual allegations in the complaint as true and drawing all reasonable inferences in favor of the plaintiff. Fed. R. Civ. P. 12(b)(6).

1 Cases that cite this headnote

[2] **Federal Civil Procedure** Insufficiency in general

Dismissal for failure to state a claim is appropriate when it is clear from the face of the complaint that the plaintiff's claims are barred as a matter of law. Fed. R. Civ. P. 12(b)(6).

1 Cases that cite this headnote

[3] **Antitrust and Trade Regulation** Antitrust and Foreign Trade

The Foreign Trade Antitrust Improvements Act (FTAIA) sets substantive limitations on Sherman Act claims, and the requirements of the FTAIA go to the merits of an antitrust claim rather than to subject matter jurisdiction. Sherman Act § 7, 15 U.S.C.A. § 6a.

[4] **Antitrust and Trade Regulation** Antitrust and Foreign Trade

If a plaintiff's antitrust claims are barred by the Foreign Trade Antitrust Improvements Act (FTAIA), the plaintiff has failed to state a claim for relief as a matter of law. Sherman Act § 7, 15 U.S.C.A. § 6a.

1 Cases that cite this headnote

[5] **Antitrust and Trade Regulation** Causation

While the term "antitrust standing" may give the impression of a jurisdictional obligation, the proximate causation requirement in antitrust standing requires a court to evaluate the merits of the action, and therefore its absence is not a jurisdictional bar to suit, but a failure to state a claim.

1 Cases that cite this headnote

[6] **Antitrust and Trade Regulation** Antitrust and Foreign Trade

The Foreign Trade Antitrust Improvements Act (FTAIA) excludes from the Sherman Act's reach much anticompetitive conduct that causes only foreign injury. Sherman Act § 7, 15 U.S.C.A. § 6a.

[7] **Antitrust and Trade Regulation** Antitrust and Foreign Trade

The Foreign Trade Antitrust Improvements Act (FTAIA) creates two exceptions to the general bar on the extraterritorial application of the Sherman Act: (1) the import exclusion, which applies to conduct involving import trade or import commerce, and (2) the domestic effects exception, which applies to other foreign conduct that has a direct, substantial, and reasonably foreseeable effect on import or domestic commerce and that gives rise to a Sherman Act claim. Sherman Act § 7, 15 U.S.C.A. § 6a.

1 Cases that cite this headnote

[8] **Federal Courts** In general; necessity

It is a general rule that an appellate court will not consider an issue raised for the first time on appeal.

[9] **Federal Courts** Matters of Substance

Foreign manufacturer of generic cancer treatment drugs waived on appeal its argument that Foreign Trade Antitrust Improvements Act's (FTAIA's) domestic effects exception applied to remove bar on extraterritorial application of the Sherman Act, in its action against foreign manufacturer of brand-name drugs and its subsidiaries and affiliates alleging that they engaged in foreign anticompetitive conduct that was intended to interfere with generic manufacturer's ability to enter domestic pharmaceutical market upon expiration of exclusivity period for patented drugs, where generic manufacturer expressly argued in district court that such exception was not relevant. Sherman Act § 7, 15 U.S.C.A. § 6a.

[10] **Antitrust and Trade Regulation** Antitrust and Foreign Trade

The Foreign Trade Antitrust Improvements Act's (FTAIA's) import exclusion to the general bar on the extraterritorial application of the Sherman Act applies when a defendant's actions immediately impact the United States import market and not merely when a defendant subjectively intends to affect the United States import market in the future. Sherman Act § 7, 15 U.S.C.A. § 6a.

[11] **Antitrust and Trade Regulation** Antitrust and Foreign Trade

In determining whether the exclusion under the Foreign Trade Antitrust Improvements Act (FTAIA) for conduct involving import trade or import commerce applies to remove the bar on extraterritorial application of the Sherman Act, the relevant conduct is the defendant's conduct. Sherman Act § 7, 15 U.S.C.A. § 6a.

1 Cases that cite this headnote

[12] **Antitrust and Trade Regulation** Antitrust and Foreign Trade

Term "import," as used in the Foreign Trade Antitrust Improvements Act's (FTAIA's) exclusion to the general bar on the extraterritorial application of the Sherman Act for conduct involving import trade or import commerce, refers to the movement of goods into the United States from a foreign country. Sherman Act § 7, 15 U.S.C.A. § 6a.

1 Cases that cite this headnote

[13] **Antitrust and Trade Regulation** Antitrust and Foreign Trade

Congress enacted the Foreign Trade Antitrust Improvements Act (FTAIA) in part to boost United States exports by making it clear to domestic exporters and to firms doing business abroad that the Sherman Act does not prevent them from entering into anticompetitive business arrangements as long as only foreign markets are adversely affected. Sherman Act § 7, 15 U.S.C.A. § 6a.

[14] **Antitrust and Trade Regulation** Complaint

Foreign manufacturer of generic cancer treatment drugs did not plausibly allege that any anticompetitive conduct by foreign manufacturer of brand-name drugs and its subsidiaries and affiliates fell within Foreign Trade Antitrust Improvements Act's (FTAIA's) exclusion to the general bar on the extraterritorial application of the Sherman Act for conduct involving import trade or import commerce, and, thus, failed to state Sherman Act claim based on such conduct; possibility that defendants' foreign conduct would diminish generic manufacturer's financial circumstances, and, in turn, prevent it from engaging in business in the United States upon expiration of exclusivity period for patented drugs was too remote and speculative. Sherman Act § 7, 15 U.S.C.A. § 6a.

[15] **Antitrust and Trade Regulation** Construction

New York's Donnelly Act is modeled after the Sherman Act and should generally be construed in light of federal precedent. Sherman Act, § 1 et seq., 15 U.S.C.A. § 1 et seq.; N.Y. General Business Law § 340 et seq.

***91** ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

Attorneys and Law Firms

David C. Frederick (Gregory G. Rapawy and Julius P. Taranto, on the brief), Kellogg, Hansen, Todd, Figel & Frederick, P.L.L.C, Washington, DC, and Albert Feinstein, Feinstein & Partners, P.L.L.C., New York, New York, for Plaintiff-Appellant.

Daniel M. Wall (Amanda P. Reeves, Roman Martinez, Benjamin W. Snyder, and Lawrence E. Buterman, on the brief), Latham & Watkins LLP, New York, New York; San Francisco, California; and Washington, DC, for Defendant-Appellee Genentech, Inc.

Paul Spagnoletti (Andrew S. Gehring, on the brief), Davis Polk & Wardell LLP, New York, New York, for Defendants-Appellees F. Hoffmann-La Roche Ltd and Roche Holding AG.

Caitlin J. Halligan, Eric J. Stock, and Alejandro A. Herrera, Gibson, Dunn & Crutcher LLP, New York, New York, for Defendant-Appellee R-Pharm JSC.

Before: Katzmann, Chief Judge, and Kearse and Chin, Circuit Judges.

Opinion

Chief Judge Katzmann concurs in a separate opinion.

Chin, Circuit Judge:

Plaintiff-appellant Biocad JSC ("Biocad") and defendants-appellees Roche Holding AG ("Roche"), F. Hoffmann-La Roche Ltd. ("La Roche"), Genentech, Inc. ("Genentech"), and R-Pharm JSC ("R-Pharm") (collectively, "Defendants") are manufacturers of cancer treatment drugs. Biocad alleges that Defendants engaged in anticompetitive conduct in Russia -- price fixing, illegal tying, and price discrimination -- that was intended to interfere with its ability to enter the pharmaceutical market for cancer treatment drugs in the United States.

Biocad commenced this action pursuant to the Sherman Act, 15 U.S.C. §§ 1 and 2; the Clayton Act, 15 U.S.C. §§ 15 and 26; the Robinson-Patman Act, 15 U.S.C. § 13; and the Donnelly Act, N.Y. Gen. Bus. Law § 340 *et seq*. The district

court granted Defendants' motions to dismiss all of Biocad's claims for lack of subject matter jurisdiction and failure to state a claim, pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). The district court dismissed Biocad's Sherman Act claims because it concluded that Biocad had not sufficiently pleaded antitrust injury. The district court also ruled that Biocad's Sherman Act claims were barred by the Foreign Trade Antitrust Improvements Act (the "FTAIA"), 15 U.S.C. § 6a, because the foreign nature of its claims placed them beyond the reach of United States antitrust laws. The district court dismissed the claims under Section 16 of the Clayton Act and the Donnelly Act for largely the same reasons.[2] On review, we ***92** agree that Biocad's claims are barred by the FTAIA. Accordingly, the judgment of the district court is affirmed on that basis.

BACKGROUND

A. *The Allegations of Anticompetitive Conduct*[3]

Biocad is a pharmaceutical company with its principal place of business in Saint Petersburg, Russia. It also has a subsidiary in the United States. Roche is a Swiss, multinational healthcare corporation, which owns Switzerland-based La Roche as well as La Roche's American-based affiliate Genentech. In Russia, Roche distributes its drug products through the independent and Russia-based pharmaceutical company, R-Farm JSC ("R-Farm"). In turn, R-Farm conducts business in the United States through its own subsidiary, R-Pharm US LLC. La Roche conducts all of its American business operations and activities through Genentech.

In recent years, monoclonal antibodies ("mAbs") -- laboratory-produced molecules that mimic naturally produced antibodies -- have been used successfully in cancer treatment in the United States. Roche is the sole United States seller of three key mAbs, *bevacizumab*, *trastuzumab*, and *rituximab* (collectively, the "Drugs"), the patents for which have expired or will expire soon. Biocad has created biosimilar drugs to compete with existing, brand name mAbs that are produced by companies like Roche.[4] Biosimilars are priced substantially below their brand-named counterparts, and price competition ensues once the first biosimilar product enters the market.

As of 2016, Biocad was the only pharmaceutical company to successfully produce biosimilars of the Drugs and it "intended and [was] prepared to enter the U.S. market" for mAbs once Roche's exclusivity rights expired. J. App'x 128-29. Biocad, however, has never participated in the American market for mAbs.

Faced with impending competition from Biocad, Defendants "hatched a scheme to restrict [the] U.S. market" and "delay or preclude altogether [Biocad's] imports into [the] U.S." so that Roche could maintain its control over the Drugs beyond the exclusivity period. J. App'x 142-43. The conspiracy included the following: (1) creating a predatory and discriminatory pricing scheme by increasing Roche's American prices for the Drugs by on average 19% while decreasing costs in Russia by on average 76%; (2) underwriting the independent, third-party distributor R-Farm by permitting R-Farm to sell the Drugs at below Roche's costs incurred for distribution in Russia; (3) operating an illegal kickback system involving the Russian government's hospitals, doctors, and other healthcare professionals to bolster Roche's drug sales while excluding Biocad from Russian government programs; (4) limiting Genentech's United States distribution of Roche's drug samples, which Biocad needed for pre-Food and Drug Administration approval testing of its biosimilars; (5) maintaining an illegal tying and bundling ***93** scheme between *trastuzumab* and another Roche-manufactured drug sold in Russia; (6) submitting fraudulent, below-cost bids at Russian government auctions; and (7) globally manipulating drug dosages to force patients into purchasing and eventually discarding more drugs than necessary. Defendants' goal was to cripple Biocad financially so that Biocad could not afford to enter the United States market. Biocad recognizes that Roche's alleged anticompetitive behavior was conducted through its foreign operations, acknowledging that "Biocad had no active U.S. business with which to interfere" because of Roche's patent-based monopolies. Pl. Appellant's Br. at 17.

B. *The District Court Proceedings*

Biocad commenced this action on June 7, 2016, and filed the Complaint on October 24, 2016. On December 12, 2016, Defendants moved to dismiss the Complaint pursuant to Rules 12(b)(1) and 12(b)(6). The district court issued an Opinion and Order on September 30, 2017, dismissing the Complaint and denying Biocad's request for leave to amend.

The district court ruled that Biocad failed to state a claim as a matter of law because it failed to sufficiently allege antitrust standing. The district court also ruled that, even assuming Biocad had adequately pleaded antitrust injury, "the foreign locus of [Biocad's] allegations would still defeat each of

its causes of action." S. App'x 7. Thus, the district court dismissed Biocad's claims.

As relevant here, in considering Biocad's Sherman Act claims, the district court ruled that the claims were effectively barred under the import exclusion and domestic effects exception to the FTAIA. *See* 15 U.S.C. § 6a. With respect to the import exclusion, the district court concluded that the relationship between Defendants' acts and their effect on American import commerce was "too attenuated for Defendants' acts to be considered 'directed at' a U.S. import market," and Biocad's allegations instead indicated that "Defendants' alleged conduct was targeted at the domestic Russian pharmaceutical market." S. App'x 10. With respect to the domestic effects exception, the district court noted that Biocad expressly waived that argument, S. App'x 12 & n.7, but still reached the question, reasoning that Biocad's "alleged injuries flow from Defendants' allegedly anticompetitive foreign conduct, not the domestic effect of that conduct, and is therefore the type of 'independently caused foreign injury' that falls outside of the reach" of the exclusion, S. App'x 13 (quoting *Lotes Co. v. Hon Hai Precision Indus. Co.*, 753 F.3d 395, 414 (2d Cir. 2014)). Biocad's Donnelly Act claim and request for injunctive relief under the Clayton Act were also dismissed based largely on the same reasoning.

This appeal followed.

DISCUSSION

[1] **[2]** We review the grant of a motion to dismiss for failure to state a claim *de novo*, accepting all factual allegations in the complaint as true and drawing all reasonable inferences in favor of the plaintiff. *Mantikas v. Kellogg Co.*, 910 F.3d 633, 636 (2d Cir. 2018); *see* Fed. R. Civ. P. 12(b)(6). Dismissal is appropriate when "it is clear from the face of the complaint ... that the plaintiff's claims are barred as a matter of law." *Parkcentral Glob. Hub Ltd. v. Porsche Auto. Holdings SE*, 763 F.3d 198, 208-09 (2d Cir. 2014) (quoting *Conopco, Inc. v. Roll Int'l*, 231 F.3d 82, 86 (2d Cir. 2000)).

[3] **[4]** The FTAIA sets substantive limitations on Sherman Act claims, and "the requirements of the FTAIA go to the merits of an antitrust claim rather than to ***94** subject matter jurisdiction." *Lotes*, 753 F.3d at 405. Hence, if a plaintiff's claims are barred by the FTAIA, the plaintiff has failed to state a claim for relief as a matter of law.

[5] On appeal, Biocad contends that the district court erred in dismissing the Complaint on the grounds that (1) Biocad lacks antitrust standing, and (2) the antitrust claims are barred by the FTAIA. We do not reach the question of antitrust standing as we agree with the district court that the foreign nature of Biocad's alleged injuries places its claims beyond the reach of United States antitrust laws. [5]

I. *Applicable Law*

A. *The FTAIA Generally*

[6] The FTAIA "excludes from the Sherman Act's reach much anticompetitive conduct that causes only foreign injury." *F. Hoffmann-La Roche Ltd. v. Empagran S.A.*, 542 U.S. 155, 158, 124 S.Ct. 2359, 159 L.Ed.2d 226 (2004). It does so first by "lay[ing] down a general rule placing *all* (nonimport) activity involving foreign commerce outside the Sherman Act's reach." *Id.* at 162, 124 S.Ct. 2359. The FTAIA then creates exceptions to the general rule, bringing back within the Sherman Act's reach conduct that meets certain statutory requirements. *Id.* at 161-62, 124 S.Ct. 2359 (quoting 15 U.S.C. § 6a). *See generally Lotes*, 753 F.3d at 404.

The FTAIA provides:

> [The Sherman Act] shall not apply to conduct involving trade or commerce (other than import trade or import commerce) with foreign nations unless --
>
> (1) such conduct has a direct, substantial, and reasonably foreseeable effect--
>
> (A) on trade or commerce which is not trade or commerce with foreign nations, or on import trade or import commerce with foreign nations; or
>
> (B) on export trade or export commerce with foreign nations, of a person engaged in such trade or commerce in the United States; and
>
> (2) such effect gives rise to a claim under the provisions of sections 1 to 7 of this title, other than this section.

15 U.S.C. § 6a.

[7] In simpler terms, the FTAIA creates two exceptions to the general bar on the extraterritorial application of the Sherman Act: (1) the import exclusion, which applies to "conduct involving ... import trade or import commerce," 15 U.S.C. § 6a; and (2) the domestic effects exception, which

applies to other foreign conduct that has a direct, substantial, and reasonably foreseeable effect on import or domestic commerce and that gives rise to a Sherman Act claim, *id.* § 6a(1)-(2); *see Maricultura Del Norte v. World Bus. Capital, Inc.*, 159 F. Supp. 3d 368, 382 (S.D.N.Y. 2015) (citing courts referring to "the 'import exception' (or 'import exclusion') ***95** and the 'domestic effects exception' "); *see also Minn-Chem, Inc. v. Agrium, Inc.*, 683 F.3d 845, 855 (7th Cir. 2012) (referring to "import commerce exclusion"); *Animal Sci. Prods. Inc. v. China Minmetals Corp.*, 654 F.3d 462, 471 n.11 (3d Cir. 2011) (referring to "import exception"). Courts have understood this statutory scheme "to clarify, perhaps to limit, but not to expand in any significant way, the Sherman Act's scope as applied to foreign commerce." *Lotes*, 753 F.3d at 404 (quoting *Empagran*, 542 U.S. at 169, 124 S.Ct. 2359).

The conduct at issue here clearly "involv[es] trade or commerce ... with foreign nations," 15 U.S.C. § 6a, as Biocad complains principally of actions by foreign entities in a foreign country. Consequently, the question is whether the challenged conduct falls within either the import exclusion or the domestic effects exception to the general bar on the application of the Sherman Act to foreign commerce.

[8] **[9]** In the district court, however, Biocad waived its reliance on the domestic effects exception by expressly arguing that it was not relevant to this case. "It is a well-established general rule that an appellate court will not consider an issue raised for the first time on appeal." *Moll v. Telesector Res. Grp., Inc.*, 760 F.3d 198, 204 (2d Cir. 2014) (brackets omitted). While we have the discretion, as a prudential matter, to consider arguments not raised below, *Sniado v. Bank Austria AG*, 378 F.3d 210, 213 (2d Cir. 2004), we have disfavored "an exercise of discretion to address new arguments on appeal where those arguments were available to the parties below and they proffer no reason for their failure to raise the arguments below," *United States ex rel. Keshner v. Nursing Pers. Home Care*, 794 F.3d 232, 234 (2d Cir. 2015) (quoting *In re Nortel Networks Corp. Sec. Litig.*, 539 F.3d 129, 133 (2d Cir. 2008)). Here, while Biocad urges this Court to consider its claims under the domestic effects exception because the district court passed upon the issue, it does not explain why it failed to press the argument below. Accordingly, we decline to consider Biocad's theory of injury under the domestic effects exception, and we limit our discussion to whether Defendants' conduct falls within the import exclusion.

B. The Import Exclusion

[10] Biocad argues that the conduct here was "directed at import commerce and was intended to (and did) have a substantial effect in the United States" in that it was intended to prevent or delay Biocad "from entering the U.S. import market for pharmaceuticals." Pl. Appellant's Br. at 44. The argument thus raises the issue of whether foreign conduct involves import trade or commerce where there is no actual current effect on United States markets, but where the defendant intends to impact import commerce in the future. We conclude, based on the language, structure, and purpose of the FTAIA, that the import exclusion applies when a defendant's actions immediately impact the United States import market and not merely when a defendant subjectively intends to affect the United States import market in the future. *See, e.g.*, *Abramski v. United States*, 573 U.S. 169, 179, 134 S.Ct. 2259, 189 L.Ed.2d 262 (2014) ("[W]e must (as usual) interpret the relevant words not in a vacuum, but with reference to the statutory context, 'structure, history, and purpose.' " (quoting *Maracich v. Spears*, 570 U.S. 48, 76, 133 S.Ct. 2191, 186 L.Ed.2d 275 (2013))).

1. *Statutory Language*

We start with the words of the statute. The FTAIA is cumbersomely worded, as it provides that the Sherman Act "shall not ***96** apply to conduct involving trade or commerce (other than import trade or import commerce) with foreign nations." 15 U.S.C. § 6a.

[11] **[12]** The relevant "conduct" is the defendant's conduct. *Kruman v. Christie's Int'l PLC*, 284 F.3d 384, 398 (2d Cir. 2002), *abrogated on other grounds by Empagran*, 542 U.S. 155, 124 S.Ct. 2359. The word "import" refers to the movement of goods into the United States from a foreign country. *See Minn-Chem*, 683 F.3d at 855. The word "involving" is less clear. The most common meaning of "involving" is including (or having) as a necessary feature, accompaniment, or consequence, but "involving" could also mean influencing or affecting. *See Involve*, Oxford English Dictionary (2d ed. 1989) (defining "involve" as "[t]o include as a necessary (and therefore unexpressed) feature, circumstance, antecedent condition, or consequence" or "[t]o include or affect in its operation"); *Involve*, American Heritage College Dictionary (3d ed. 1997) (defining "involve" as "[t]o have as a necessary feature or consequence" or "[t]o influence or affect"). Hence, the words "conduct involving ... import trade or import commerce" could encompass, as Biocad argues, foreign conduct intended

to influence or affect domestic markets; or the words could mean, as Defendants argue, conduct that constitutes or directly acts upon import commerce.

We think the latter is the more natural reading of the words. Taken together, the words suggest that the Sherman Act applies to a defendant's conduct abroad that constitutes, includes, or has as a necessary consequence the movement of goods into this country. *See Minn-Chem*, 683 F.3d at 854 ("The applicability of U.S. law to transactions in which a good or service is being sent directly into the United States, with no intermediate stops, is both fully predictable to foreign entities and necessary for the protection of U.S. consumers."). That the statutory language contemplates conduct that directly interferes with the act of importing goods or services to the United States is supported by the legislative history, as the House Report repeatedly refers to import "transactions" in its discussion of the import exclusion. *See* H. R. Rep. No. 97-686, at 2-3, 9-10 (1982), 1982 U.S.C.C.A.N., 2487, 2488, 2494–2495 ("House Report").[6] Indeed, courts have applied the import exclusion where plaintiffs alleged that defendants interfered with the introduction of goods or services into the United States. *See, e.g.*, *Minn-Chem*, 683 F.3d at 855 (holding that import exclusion applied because transactions in which plaintiffs purchased potash directly from foreign cartel members constitute import commerce); *Carrier Corp. v. Outokumpu Oyj*, 673 F.3d 430, 438 n.3, 440 (6th Cir. 2012) (holding that ***97** import exclusion applied because "the result of that agreement [with foreign conspirators] was to raise prices artificially for ACR copper tubing for transactions between the co-conspirators and buyers in the United States"); *Maricultura*, 159 F. Supp. 3d at 384 (holding that the import exclusion applied because "Plaintiffs allege[d] that Defendants' actions ... substantially impaired Plaintiffs' exports of Bluefin Tuna into the United States thereby impacting United States import trade and commerce" (internal quotation marks and emphasis omitted)). Conduct does not "involve" import commerce if it has no direct or immediate consequence for domestic markets and is intended merely to have a domestic impact in the future. Nothing in the text of the FTAIA otherwise suggests an intent-based analysis.

As suggested above, the word "involving" can be read more expansively and, in some circumstances, we have interpreted statutory provisions using the word more broadly. *See, e.g.*, *United States v. King*, 325 F.3d 110, 113 (2d Cir. 2003) ("The word 'involving' has expansive connotations."). And both the Department of Justice and the Federal Trade Commission endorse a somewhat broader reading of the import exclusion to include conduct that does not immediately act upon import transactions. According to the government's reading of the import exclusion, "[c]onduct may 'involve' import commerce even if it is not directed specifically or exclusively at import commerce." *See* U.S. Dep't of Justice & Fed. Trade Comm'n, *Antitrust Guidelines for International Enforcement and Cooperation* 19 (Jan. 13, 2017) ("Guidelines"), https://www.justice.gov/atr/internationalguidelines/download.

That may be so, as it is possible that conduct specifically directed at foreign commerce can have a direct impact on domestic commerce. Foreign conduct that is "closely connected to the importation of goods into the United States," *id*. at 20, such as, for example, foreign defendants fixing global shipping prices, could fall within the import exclusion even though it is not directed specifically at import commerce, as such conduct could have a direct effect on domestic competition for imported goods, s*ee id.* at 19-20. The import exclusion, however, would not include cases where a foreign defendant fixes the price of goods sold to a foreign intermediary, with an intent to interfere with that competitor's American business, but with no demonstrable effect on the United States. *Cf. Empagran*, 542 U.S. at 164, 124 S.Ct. 2359 (holding domestic effects exception does not apply where "price-fixing conduct significantly and adversely affects both customers outside the United States and customers within the United States, but the adverse foreign effect is independent of any adverse domestic effect"). In such a case, the intended effect is too removed, and the word "involving" cannot be read so broadly as to encompass conduct that is undertaken with the subjective hope or desire to have a domestic impact at some point in the future.

In arguing for an intent-based test, Biocad relies on our decision in *Kruman*, where we noted that the alleged conspiracy was not "directed at an import market" and imports were not "the object of the conspiracy." 284 F.3d at 395-96. While the use of the words "directed at" and "object of the conspiracy" in the decision arguably suggest an intent-based analysis, we did not adopt such a test in *Kruman*. Rather, we evaluated the nature and effect of the conduct at issue and recognized that the commerce concerned fixed commissions on goods purchased and sold in foreign auctions, and not the trade in or movement of those goods after purchase and sale even though some of the goods might eventually be imported into the United States. *Id*. ***98** The import exclusion did not apply, we concluded, because "the object of the conspiracy was the price that the defendants

charged for their auction services, not any import market for those goods." *Id.* at 396. This reasoning is consistent with our historical view that "it is the situs of the effects, as opposed to the conduct, that determines whether United States antitrust law applies." *Id.* at 395 (quoting House Report at 5, and citing *United States v. Aluminum Co. of Am.*, 148 F.2d 416, 444 (2d Cir. 1945) ("[W]e shall assume that "[The Sherman Act] does not cover agreements, even though intended to affect [American] imports or exports, unless its performance is shown actually to have had some effect upon them."); *accord Turicentro, S.A. v. Am. Airlines Inc.*, 303 F.3d 293, 305 (3d Cir. 2002), *overruled on other grounds by Animal Sci. Prod.*, 654 F.3d 462; *see Republic of Philippines v. Marcos*, 818 F.2d 1473, 1491 (9th Cir. 1987) (Hall, *J.*, concurring in part and dissenting in part). The conclusion that the statutory text supports an effects-based rather than an intent-based analysis is confirmed by the FTAIA's structure and Congress's goals in enacting the statute.

2. *Structure of the FTAIA*

The structure of the FTAIA also provides us with guidance as to the interpretation of the import exclusion. We conclude that an interpretation of the exclusion that turns on the subjective intent of the defendant is inconsistent with the statutory scheme. *See Abramski*, 573 U.S. at 179, 134 S.Ct. 2259.

The FTAIA provides two exemptions from its general rule that the Sherman Act does not apply to conduct involving foreign trade or commerce. The first is for import trade or commerce and the second is for certain *nonimport* trade or commerce. *See Lotes*, 753 F.3d at 404. The first exemption is the simpler of the two -- described simply as "import trade or import commerce," or, more fully, as "conduct involving ... import trade or import commerce." 15 U.S.C. § 6a. The domestic effects exception is more complicated as it encompasses other foreign conduct that has "a direct, substantial, and reasonably foreseeable effect" on the United States market. *Id.* § 6a(1). It is apparent that Congress had in mind a simple, bright-line exception for import trade and commerce and an additional, more flexible exception for other conduct that would require a more fact-specific analysis.

Biocad's intent-based analysis would blur the two exceptions. If we read "involving" as expansively as Biocad suggests, to include foreign conduct merely intended to have a domestic impact in the future, the direct effects exception would be rendered superfluous. *See, e.g.*, *Bilski v. Kappos*, 561 U.S. 593, 607-08, 130 S.Ct. 3218, 177 L.Ed.2d 792 (2010) (stating that courts should not "interpret[ ] any statutory provision in a manner that would render another provision superfluous"); *see also Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 386, 133 S.Ct. 1166, 185 L.Ed.2d 242 (2013) ("[T]he canon against surplusage is strongest when an interpretation would render superfluous another part of the same statutory scheme."). Under Biocad's suggestion, any conduct intended to have a domestic impact would be excepted from the coverage of the Sherman Act, even if the conduct did not in fact have a "direct, substantial, and reasonably foreseeable" effect on domestic, import, or export commerce.

In *Lotes*, we cautioned against "collaps[ing] the FTAIA's domestic effects exception into its separate import exclusion." 753 F.3d at 411. For that reason, we held that "direct," within the meaning of the domestic effects exception, only requires ***99** "a reasonably proximate causal nexus," akin to common-law proximate causation principles. *Id.* We distinguished that interpretation of "direct" from one that required the effect on commerce to occur as an immediate consequence of the defendant's conduct because the latter interpretation was narrowly focused on the "spatial and temporal separation between the defendant's conduct and the relevant effect." *Id.* at 412. We thereby implied that the import exclusion requires "that any domestic effect must follow as an immediate consequence of a defendant's foreign anticompetitive conduct." *Id.* at 411.

Indeed, Congress accounted for conduct that immediately affects domestic commerce by excluding import commerce from the FTAIA at the outset. *See id.* An intent-based test would require courts to probe defendants' remote, as opposed to direct, conduct targeted at foreign markets to discern whether it was aimed at affecting American imports. But, as discussed above, foreign commercial conduct that does not immediately affect domestic commerce would be covered by the separate domestic effects exception for conduct that might have a substantial downstream effect on domestic, import, or export commerce and give rise to a Sherman Act claim. *See* 15 U.S.C. § 6a (1)-(2).

Finally, we note that an intent-based test could place domestic anticompetitive conduct outside the reach of the Sherman Act. The word "involving" is not limited to the import exclusion as it appears in the introductory language of Section 6a and therefore applies to the FTAIA, including the domestic effects exception. Under an intent-based test, conduct that occurred domestically could conceivably fall

outside the scope of the Sherman Act if the intent was to affect trade with foreign nations, and the conduct did not have a "direct, substantial, and reasonably foreseeable" effect on the markets. While such conduct could be characterized in some cases as conduct directed toward an export market, the anticompetitive conduct would occur domestically, and we cannot endorse an interpretation of "involving" that could exempt such anticompetitive activities from the Sherman Act's reach.

3. *Purposes of the FTAIA*

[13] Finally, an intent-based test is inconsistent with the FTAIA's purposes. First, Congress enacted the FTAIA in part "to boost" American exports by making it clear to American exporters and to firms doing business abroad that the Sherman Act does not prevent them from entering into anticompetitive business arrangements as long as only foreign markets are adversely affected. *Lotes*, 753 F.3d at 404 (citing *Empagran*, 542 U.S. at 161, 124 S.Ct. 2359). Second, Congress sought to clarify when American antitrust laws govern foreign conduct, "to promote certainty in assessing the applicability of American antitrust law to international business transactions." House Report at 9; *see Lotes*, 753 F.3d at 404.

An intent-based test would inject further uncertainty into an already complex statutory scheme. Significantly, there is some evidence that Congress was keen on adopting an objective jurisdictional test for the FTAIA. House Report at 9. For instance, Congress used the "reasonable foreseeability" standard for the domestic effects exception to avoid complicated inquiries into intent. *Id.* ("The Subcommittee chose a formulation based on *foreseeability* rather than *intent* to make the standard an objective one and to avoid -- at least at the jurisdictional stage -- inquiries into the actual, subjective motives of defendants."). Congress was also concerned about practicality. *Id.* (explaining that the term "[r]easonably connotes ... practicality" ***100** and "[t]he test is whether the effects would have been evident to a reasonable person making practical business judgments, not whether ... intent can be shown"). These considerations of clarity, objectivity, and practicality would be undermined if the applicability of the import exclusion turned on the subjective intent of companies doing business abroad.

* * *

Accordingly, we hold that "conduct ... involving import trade or import commerce" is not determined by reference to a defendant's subjective intent to affect import commerce. Rather, the import exclusion applies to conduct by a defendant that has a direct or immediate effect on import commerce.

II. *Application*

A. *The Sherman Act*

[14] We conclude that Biocad has not plausibly alleged that Defendants' purportedly anticompetitive conduct in Russia falls within the exception for conduct involving import commerce.

As a threshold matter, the alleged anticompetitive conduct does not directly involve the importing of drugs into the United States. Rather, the bulk of the alleged conduct occurred in Russia, consisting of actions taken by foreign entities in combination with, or against, other foreign entities.[7] For instance, Biocad accuses Roche, a Swiss company, of underwriting R-Farm, an independent Russian distributor, and engaging in illegal kickback and auction-rigging schemes in Russia orchestrated by the Russian government. None of this conduct has a nexus to imports into the United States. In fact, Biocad has not alleged that it has ever imported any product or biosimilar to the United States and admits that it "had no active U.S. business with which to interfere" because Roche's exclusivity periods had not yet expired. Pl. Appellant's Br. at 17; *see Turicentro*, 303 F.3d at 303 (holding that defendants were not engaged in import trade or commerce because conspiring to set rates that foreign travel agents could charge for their services did not include directly bringing items or services into the United States).

Moreover, even assuming the "sole purpose" of Defendants' actions was to delay Biocad's entry into the United States market, Biocad has not alleged that Defendants engaged in any conduct that otherwise immediately or directly affected import trade or commerce. Pl. Appellant's Br. at 44; *see Carpet Grp. Int'l v. Oriental Rug Importers Ass'n, Inc.*, 227 F.3d 62, 72 (3d Cir. 2000) (holding that import exclusion applied to defendants' attempts at foreign trade shows to exclude American retailers from importing rugs to the United States), *overruled on other grounds by Animal Sci. Prods., Inc. v. China Minmetals Corp.*, 654 F.3d 462 (3d Cir. 2011); *Maricultura*, 159 F. Supp 3d at 383-84 (import exclusion applied where defendants' actions limited plaintiff's ability to capture, farm, and export tuna to the United States). Defendants' immediate objective was to impair Biocad's

ability to compete in the Russian market for the Drugs. The possibility that Defendants' conduct would diminish Biocad's financial circumstances, and, in turn, prevent it from engaging in business in the United States when it was at some point ready to do so is too remote and speculative to plausibly affect imports to the United States with the directness necessary to invoke the import exclusion. Further, as ***101** in *Kruman*, the fact that some of Defendants' goods might end up in the stream of imports to the United States is insignificant because the effect on import trade is too removed and the harm to the Russian markets precedes any eventual effect on American imports. *See* 284 F.3d at 395-96; *see also Empagran*, 542 U.S. at 164, 124 S.Ct. 2359. In short, Biocad's claims do not fall within the import exclusion to the FTAIA, and, therefore, its claims fall outside the scope of the Sherman Act.

B. *The Donnelly and Clayton Act Claims*

[15] Biocad cannot advance its claims under New York's Donnelly Act because the state statute is modeled after the Sherman Act and "should generally be construed in light of Federal precedent." *Gatt Commc'ns, Inc. v. PMC Assocs., LLC*, 711 F.3d 68, 81 (2d Cir. 2013) (quoting *X.L.O. Concrete Corp. v. Rivergate Corp.*, 83 N.Y.2d 513, 518, 611 N.Y.S.2d 786, 634 N.E.2d 158 (1994)); *see also Global Reins. Corp. U.S. Branch v. Equitas Ltd.*, 18 N.Y.3d 722, 735, 946 N.Y.S.2d 71, 969 N.E.2d 187 (2012). As Biocad has not stated a plausible claim for relief under the Sherman Act, its Donnelly Act claim similarly fails.

Further, Biocad briefly argues that we should reinstate its claims for injunctive relief under Section 16 of the Clayton Act because "neither [the] antitrust standing doctrine nor the FTAIA bars Biocad's claims." Pl. Appellant's Br. at 53-54. Biocad, however, is not entitled to injunctive relief pursuant to Section 16 of the Clayton Act because the FTAIA bars Biocad's Sherman Act claims, and, consequently, Biocad cannot point to a violation of antitrust laws that would cause it injury, actual or threatened. *See* 15 U.S.C. § 26; *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 130 & n.24, 89 S.Ct. 1562, 23 L.Ed.2d 129 (1969) (holding that even where a plaintiff "has not yet suffered actual injury," injunctive relief is available if the plaintiff "demonstrate[s] a significant threat of injury from an impending violation of the antitrust laws or from a contemporary violation likely to continue or recur."); *Kruman*, 284 F.3d at 397 ("[The Clayton Act] sets forth the requirement that a plaintiff must suffer an injury or be threatened with an injury caused by a Sherman Act violation in order to bring suit."). Thus, the claim under Section 16 of the Clayton Act fails as well.

CONCLUSION

For the reasons set forth above, we **AFFIRM** the judgment of the district court.

Katzmann, Chief Judge, concurring:

I agree that Biocad's claims are barred by the FTAIA, and I join in full the excellent majority opinion. I also agree that we can affirm the district court without reaching the issue of antitrust standing. Were we to reach that issue, however, I would respectfully have to part company with the district court's determination that a potential entrant to a pharmaceutical market must show at the motion to dismiss stage that FDA approval of its products was probable. I write separately to explain why the probability of FDA approval should be considered as a significant, but not dispositive, factor in a broader preparedness inquiry at the motion-to-dismiss stage.

I.

Antitrust plaintiffs must plead both constitutional and antitrust standing. *Gelboim v. Bank of Am. Corp.*, 823 F.3d 759, 770 (2d Cir. 2016), *cert. denied*, —— U.S. ——, 137 S. Ct. 814, 196 L.Ed.2d 599 (2017). To plead antitrust standing, "a private antitrust plaintiff must plausibly allege that (i) ***102** it suffered an antitrust injury and (ii) it is an acceptable plaintiff to pursue the alleged antitrust violations." *In re Aluminum Warehousing Antitrust Litig.*, 833 F.3d 151, 157 (2d Cir. 2016). Only the first prong, antitrust injury, is at issue in this case. [1] "Congress did not intend to allow every person tangentially affected by an antitrust violation to maintain an action to recover threefold damages for the injury to his business or property." *Blue Shield of Va. v. McCready*, 457 U.S. 465, 477, 102 S.Ct. 2540, 73 L.Ed.2d 149 (1982). Hence, Biocad must plausibly allege that the injury it suffered is "of the type the antitrust laws were intended to prevent and that flows from that which makes [Defendants'] acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489, 97 S.Ct. 690, 50 L.Ed.2d 701 (1977). The question is whether Biocad must allege that its biosimilars had come far enough along in the FDA process that approval was probable, or whether actions beyond that process suffice to show that Biocad was prepared to receive approval and enter the market.

Usually, antitrust injury is limited to active "participants" in the defendant's market. *In re Aluminum Warehousing*, 833 F.3d at 158. Yet this court has long held that "it is as unlawful to prevent a person from engaging in business as it is to drive a person out of business." *Am. Banana Co. v. United Fruit Co.*, 166 F. 261, 264 (2d Cir. 1908) (quoting *Thomsen v. Union Castle Mail S.S. Co.*, 166 F. 251, 253 (2d Cir. 1908)), *aff'd* 213 U.S. 347, 29 S.Ct. 511, 53 L.Ed. 826 (1909). Thus, nascent businesses or potential market entrants may also demonstrate antitrust injury. To do so, the plaintiff must "state facts showing an intention and preparedness to engage in business." *Id.* Defendants and the district court both faulted Biocad on preparedness grounds.

As with many totality-of-circumstances tests, the *American Banana* standard requires courts to gather together the many dots of information spread across the canvas of a plaintiff's complaint and ask whether, like a pointillist painting, the dots resolve themselves into a coherent image. *Cf.* Stephen Sondheim & James Lapine, *Sunday in the Park with George* (1984) ("White. A blank page or canvass. The challenge: bring order to the whole."). We have provided few guideposts to channel this inquiry—in the 111 years since *American Banana*, this Court has not fleshed out the "intention and preparedness" standard any further.[2] But *American Banana* itself, as well as a companion case decided the same day, *Pennsylvania Sugar Refining Co. v. American Sugar Refining Co.*, 166 F. 254 (2d Cir. 1908), provided some factual analysis to undergird the standard.

The *Pennsylvania Sugar Refining* plaintiff had previously been in the market and had bought a sugar refining facility in anticipation of rejoining that market. *Id.* at 260. The court contrasted this situation with that of the *American Banana* plaintiff, which did not allege that it "had made any preparations to engage in the business ***103** of buying bananas ... as a separate and independent business," or that it had "invested any money in preparing to engage in any such independent business." *Am. Banana*, 166 F. at 264. The *American Banana* plaintiff also did not allege "the extent to which, nor even the country in which, it desired or intended to engage" in business. *Id.* The result: a cause of action in *Pennsylvania Sugar Refining*, 166 F. at 260, and none in *American Banana*, 166 F. at 264. Thus, allegations of investment, and details regarding where and how the plaintiff intends to enter the market, are relevant to the antitrust injury analysis.

While we have not since addressed the standing requirements for potential market participants, other circuit courts have adopted the *American Banana* standard, looking at both the "sincerity of [the plaintiff's] ambitions" to enter the market and the plaintiff's ability to act on its intent. *E.g.*, *Sanger Ins. Agency v. HUB Int'l, Ltd.*, 802 F.3d 732, 738 (5th Cir. 2015). Those circuits have identified four indicia of preparedness: (1) the plaintiff's background and experience in the prospective business; (2) the ability to finance entry, and particularly to finance facilities and equipment; (3) the consummation of contracts related to the potential entry; and (4) other affirmative action by the plaintiff to engage in the proposed business or new market.[3] *See* 2A Phillip E. Areeda et al., *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 349, at 260-61 (4th ed. 2014) (summarizing the requirements for nascent-firm antitrust injury using these tests). A succession of district courts in this Circuit have looked to the same indicia. *See, e.g.*, *Fido's Fences, Inc. v. Radio Sys. Corp.*, 999 F. Supp. 2d 442, 450 (E.D.N.Y. 2014); *Jade Aircraft Sales, Inc. v. City of Bridgeport*, No. CIV. B-83-454 WWE, 1990 WL 128573, at *2 (D. Conn. July 9, 1990); *Indium Corp. of Am. v. Semi-Alloys, Inc.*, 611 F. Supp. 379, 385 (N.D.N.Y. 1985), *aff'd*, 781 F.2d 879 (Fed. Cir. 1985); *Waldron v. British Petro. Co.*, 231 F. Supp. 72, 81-82 (S.D.N.Y. 1964). In an appropriate case, this Court should join the other circuits that have adopted this four-factor standard, which grew out of and elucidates our decision in *American Banana*.

II.

In its thoughtful opinion, the district court did not rely on these four factors to analyze antitrust injury. Rather, it determined that Biocad could not establish injury because it had not plausibly alleged that FDA approval of its biosimilars was probable. As the district court understood, this Court has never held that plaintiffs seeking antitrust standing as entrants into the pharmaceutical market must make such a showing, and neither has the Supreme Court. The district court instead relied principally on a D.C. Circuit case, ***104** *Andrx Pharmaceuticals, Inc. v. Biovail Corp. International*, 256 F.3d 799, to support two propositions that were key to the district court's decision: first, that "[c]ourts ... require a plaintiff to allege that FDA approval of the potential drug is at least 'probable,' " *Biocad, JSC v. F. Hoffman-La-Roche, Ltd.*, No. 16 CIV. 4226, 2017 WL 4402564, at *4 (S.D.N.Y. Sept. 30, 2017); and second, that "plaintiffs alleging intent and preparedness to enter a pharmaceutical market typically

include facts regarding the stage of the FDA-approval process their product has reached or the steps the plaintiff has taken (or plans to take) to secure approval," *id.* at *5.

However, *Andrx* arguably does not stand for these propositions. In *Andrx*, a district court dismissed an antitrust counterclaim with prejudice, holding that Biovail could not plead antitrust injury because the FDA had not yet approved its biosimilar. *See* 256 F.3d at 807. The D.C. Circuit reversed, finding that Biovail "*can* allege facts sufficient to indicate its intent and preparedness." *Id.* at 808. The court then noted that, even before the FDA approved Biovail's drug, Biovail "could have alleged its intent and preparedness to enter the market by claiming that FDA approval was probable." *Id.* This statement is the source of the supposed rule that the district court adopted below. As other courts have noted, though, the *Andrx* decision "does not declare that a specific allegation regarding probability of FDA approval is an absolute requirement of the intent and preparedness standard." *Roxane Labs., Inc. v. SmithKline Beecham Corp.*, No. CIV.A. 09-CV-1638, 2010 WL 331704, at *3 (E.D. Pa. Jan. 26, 2010); *accord BNLfood Invs. Ltd. SARL v. Martek Biosciences Corp.*, No. CIV. WDQ-11-0446, 2011 WL 6439451, at *4 & n.17 (D. Md. Dec. 14, 2011); *see Amgen, Inc. v. F. Hoffmann-La Roche Ltd.*, 480 F. Supp. 2d 462, 468 (D. Mass. 2007) (stating that *Andrx* "clarified that the *anticipation* of FDA approval may suffice since all that is necessary is demonstration of intent and preparedness to enter a market" (emphasis added)). It stated that an allegation of probable approval was sufficient, not that it was necessary.

Other statements in *Andrx* underscore this point. The *Andrx* court faulted Biovail's initial counterclaim in part because Biovail "did not explicitly allege ... that it *anticipated* FDA approval," *Andrx*, 256 F.3d at 807 (emphasis added), a standard more subjective and less demanding than probable approval. The court also suggested, directly after its probable approval language, that the *defendant's* beliefs can prove intention and preparedness. *Id.* at 808 ("Andrx's original suit ... 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."). Read as a whole, *Andrx* requires neither probable approval nor specific facts about the plaintiff's approval process.

Even if it did, though, this Court should not adopt a rigid probable FDA approval requirement. True, there is some logic to the idea. "That a regulatory or legislative bar can break the chain of causation in an antitrust case is beyond fair dispute." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165 (3d Cir. 2017). Courts often find a lack of antitrust injury when it views a regulatory barrier, rather than the defendant's alleged anticompetitive activities, as the cause of the plaintiff's inability to enter the market. *See, e.g.*, *In re Canadian Imp. Antitrust Litig.*, 470 F.3d 785, 791 (8th Cir. 2006); *RSA Media, Inc. v. AK Media Grp., Inc.*, 260 F.3d 10, 15 (1st Cir. 2001); *City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 268 (3d Cir. 1998). And "the Supreme Court has made clear that '[a]ntitrust analysis must always be attuned to *105 the particular structure and circumstances of the industry at issue.' " *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 658 (2d Cir. 2015) (quoting *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411, 124 S.Ct. 872, 157 L.Ed.2d 823 (2004)). As the *Andrx* court notes, "FDA approval is a prerequisite to enter *any* drug market." 256 F.3d at 807; *see* 21 U.S.C. § 355(a); 42 U.S.C. § 262(a)(1)(A). It is therefore unlikely that a pharmaceutical company could prove that it is prepared to enter the market unless it pleads facts showing that it can surpass the FDA's barriers. *Cf.* 2A Areeda et al., *supra*, ¶ 349, at 264 ("[T]he absence of a license should not block recovery when the plaintiff can show that it very likely would have received the license.").

However, the Supreme Court has also emphasized that "antitrust standing ... was developed by courts over time in response to myriad concerns presented in particular cases" and thus "cannot easily be reduced to a 'black-letter rule that will dictate the result in every case.' " *Daniel v. Am. Bd. of Emergency Med.*, 428 F.3d 408, 437 (2d Cir. 2005) (quoting *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 536, 103 S.Ct. 897, 74 L.Ed.2d 723 (1983)); *see Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 922 (3d Cir. 1999) (stating that "lower courts should avoid applying brightline rules" to the antitrust injury question "and instead should analyze the circumstances of each case, focusing on certain key factors"). Application of the four-factor test outlined above seems a better way to achieve the fact-bound analysis required for antitrust cases than does a rigid rule setting some threshold probability of approval. This is particularly so "[b]ecause licensors seldom address the suitability of firms not then seeking a license." 2A Areeda et al., *supra*, ¶ 349, at 264. Given that reality, "the antitrust tribunal can only estimate the likelihood of such a license." *Id.* This factual inquiry may be difficult for a court to undertake without discovery. [4]

Rather than a strict requirement, probability of FDA approval should be treated simply as a significant factor in the broader preparedness inquiry. At the motion-to-dismiss stage, preparedness is best inferred from the four-factor test itself, which already asks about the very indicia that would best predict whether a pharmaceutical company is likely to seek and receive FDA approval. The standard on a motion to dismiss is whether the plaintiff's factual allegations give rise to a plausible claim of antitrust injury, not a probable one. *See In re Aluminum Warehousing*, 833 F.3d at 157. The proper test at this stage, then, is whether the allegations in the complaint, taken as true, create a plausible inference that Biocad intended to, and would be able to, receive FDA approval and enter the market but for Defendants' alleged actions. Claims that a plaintiff filed for approval, or specifics about where the plaintiff stands in the approval process, are particularly probative of this question. But "the pleading standard Rule 8 announces does not require 'detailed factual allegations,' " *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009) (citation omitted), and a complaint should not be thrown out for lacking ***106** these particular forms of evidence. Even more so since "early exclusion may be far cheaper than ruining or disciplining a recent entrant who has become established." 2A Areeda et al., *supra*, ¶ 349, at 258. Too strict a pleading requirement for preparedness could make it easier for monopolistic firms to avoid antitrust liability by identifying and undermining potential competitors before they can file with the FDA.

* * *

For these reasons, I would not impose a rigid "probable FDA approval" requirement for nascent pharmaceutical market participants to plead antitrust injury.

All Citations

942 F.3d 88, 2019-2 Trade Cases P 80,981

Footnotes

* The Clerk of the Court is directed to amend the caption to conform to that above.

2 The district court also dismissed claims under the Robinson-Patman Act and Section 4 of the Clayton Act. Biocad does not appeal from those rulings.

3 The facts alleged in the First Amended Complaint (the "Complaint") are assumed to be true on this review of a motion to dismiss. *Biro v. Conde Nast*, 807 F.3d 541, 544 (2d Cir. 2015) ("We ... accept[ ] as true the factual allegations in the complaint.").

4 A "biosimilar" is a "biological product [that] is highly similar to the reference product notwithstanding minor differences in clinically inactive components"; and a biosimilar has "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." 42 U.S.C. § 262(i)(2)(A)-(B).

5 While the term "antitrust standing" may give the impression of a jurisdictional obligation, "the proximate causation requirement in antitrust standing requires a court to evaluate the merits of the action," and therefore "its absence is not a jurisdictional bar to suit, but a failure to state a claim." *Lerner v. Fleet Bank, N.A.*, 318 F.3d 113, 129 (2d Cir. 2003), *abrogation on other grounds recognized by Am. Psych. Ass'n v. Anthem Health Plans, Inc.*, 821 F.3d 352 (2d Cir. 2016); *see Am. Psych. Ass'n*, 821 F.3d at 359 ("The Supreme Court has recently clarified ... that what has been called 'statutory standing' in fact is not a standing issue, but simply a question of whether the particular plaintiff 'has a cause of action under the statute.' " (quoting *Lexmark Int'l, Inc. v. Static Control Components, Inc.* 572 U.S. 118, 128, 134 S.Ct. 1377, 188 L.Ed.2d 392 (2014))). We therefore need not pass upon the antitrust standing question before determining the applicability of the FTAIA.

6 As the Supreme Court explained in *Empagran*, the FTAIA originated in a bill that initially referred only to "export trade or export commerce." 542 U.S. at 163, 124 S.Ct. 2359 (quoting H.R. 5235, 97th Cong., 1st Sess., § 1 (1981)). The House Report states:

> The Subcommittee's "export" commerce limitation appeared to make the amendments inapplicable to transactions that were neither import nor export, *i.e.*, transactions within, between, or among other nations.
>
> .... Such foreign transactions should, for the purposes of this legislation, be treated in the same manner as export transactions -- that is, there should be no American antitrust jurisdiction absent a direct, substantial and reasonably foreseeable effect on domestic commerce or a domestic competitor. The Committee amendment therefore deletes references to "export" trade, and substitutes phrases such as "other than import" trade. It is thus clear that wholly foreign transactions as well as export transactions are covered by the amendment, but that import transactions are not.

House Report at 9-10 (citations omitted).

7 As the district court noted, the Complaint does refer to conduct that allegedly occurred in the United States, but it does not allege that those activities caused an injury in the United States import market.

1 The antitrust injury requirement stems from Section Four of the Clayton Act, which provides the right of action that allows private parties to sue for antitrust violations. Section Four reads, in relevant part:

> [A]ny person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court of the United States ... without respect to the amount in controversy, and shall recover threefold the damages by him sustained, and the cost of suit, including a reasonable attorney's fee.

15 U.S.C. § 15(a).

2 This Court has only cited *American Banana* once, for an unrelated proposition related to international comity. *See Hewitt v. Speyer*, 250 F. 367, 370 (2d Cir. 1918).

3 *See Sanger*, 802 F.3d at 739; *Ashley Creek Phosphate Co. v. Chevron USA, Inc.*, 315 F.3d 1245, 1254-55 (10th Cir. 2003); *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 806-07 (D.C. Cir. 2001); *In re Dual-Deck Video Cassette Recorder Antitrust Litig.*, 11 F.3d 1460, 1465 (9th Cir. 1993); *Gas Utils. Co. of Ala. v. S. Nat. Gas Co.*, 996 F.2d 282, 283 (11th Cir. 1993) (per curiam) (focusing on first three factors); *Bubis v. Blanton*, 885 F.2d 317, 319 (6th Cir. 1989); *see also Cent. Telecommc'ns, Inc. v. TCI Cablevision, Inc.*, 800 F.2d 711, 728-29 (8th Cir. 1986) (recognizing these standards as the "majority view," with which a prior Eighth Circuit case "is consistent"); *Grip-Pak, Inc. v. Illinois Tool Works, Inc.*, 694 F.2d 466, 475 (7th Cir. 1982) (adopting the intention and preparedness test without "having to explore its precise dimensions"), *disapproved of on other grounds by Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 113 S.Ct. 1920, 123 L.Ed.2d 611 (1993).

4 The Seventh Circuit allowed a case similar to this one to move forward for precisely that reason. *See Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 902 (7th Cir. 2004) ("[A company] cannot recover damages unless it can show that (and when) it would have entered the market in the absence of anticompetitive practices, and how much money it would have made. ... But a prediction that the plaintiff will be unable to meet its challenges is not a good reason to dismiss a complaint ....").