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*, 137 S. Ct. 814 (2017). To plead antitrust standing, "a private antitrust plaintiff must plausibly allege that (i) 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 (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 (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

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[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).

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 (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 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

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[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).

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.

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[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

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

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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 (1993).

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, *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 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 (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 (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]

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[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

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 (2009) (citation omitted), and a complaint should not be thrown

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to meet its challenges is not a good reason to dismiss a complaint . . . .").

out for lacking 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.

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