17-3486

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

BIOCAD JSC,
Plaintiff-Appellant,

v.

F. HOFFMAN LA ROCHE, GENENTECH, INC.,
R-PHARM JSC, ROCHE HOLDING AG,
Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of New York, No. 1:16cv4226 (RJS)

REPLY BRIEF FOR PLAINTIFF-APPELLANT BIOCAD, JSC

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INTRODUCTION

Biocad plausibly alleges that Defendants successfully conspired to delay or to prevent entirely Biocad from entering the U.S. pharmaceutical market.[1] To support those allegations, Biocad explains Defendants' motive: extending Roche's U.S. monopoly on three extremely lucrative cancer-fighting biological drugs. It explains Defendants' methods: bribery, fraud, product tying, and predatory pricing. And it explains Biocad's injury: Biocad had already invested years of work and millions of dollars in U.S. market entry and then was excluded from the market, or at least delayed, by Defendants' anticompetitive actions.

Defendants assert in response that Biocad cannot establish the intent and preparedness necessary to show antitrust injury because it has failed to plead in sufficient detail that the FDA will probably approve its competing drugs. That argument fails both because there is no rule requiring a blocked pharmaceutical entrant to plead probable FDA approval and because, regardless, Biocad *has* pleaded that FDA approval is probable and has supported that allegation with a substantial body of well-pleaded facts. Among other things, Biocad already makes the drugs it seeks to sell in the United States, already sells them worldwide, has a state-of-the-art, FDA-compliant factory, and spent millions in preparation for U.S.

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[1] In this reply, short forms such as "Biocad," "Defendants," and "FTAIA" have the same meanings given in Biocad's opening brief (ECF No. 47).

market entry – until it was the victim of Defendants' successful conspiracy. Defendants mischaracterize each of these supporting factual allegations or ask this Court to disregard them as conclusory. But this case is governed by ordinary Rule 8 pleading standards; under those standards, Biocad has done more than enough to establish the plausibility of its allegations.

Defendants also claim that the FTAIA bars Biocad's claims because they do not "involve" import commerce. That argument, too, falls short. The FTAIA's import exclusion leaves traditional antitrust law unaltered when Defendants' conduct is directed at import commerce. That test is satisfied here because the object of Defendants' conspiracy was to prevent Biocad from importing its competitive biosimilar drugs into the United States. Defendants' contrary argument is based on a novel reading of the import exclusion – unsupported by statutory text or precedent – that would require Biocad to establish a "direct" effect on imports to state a claim. And Biocad could show a direct effect even if the law required it to do so.

Finally, Defendants say that Biocad's claims do not fit within the FTAIA's domestic-effects exception because Biocad's injury (being excluded from the market) does not count as a direct, substantial, and reasonably foreseeable effect on domestic commerce. As Defendants do not deny, their reading of the FTAIA would make it impossible under that statute for any foreign company to seek relief

for anticompetitive conduct preventing it from entering a domestic market. More than a century of antitrust precedent establishes that excluded competitors may bring Sherman Act claims, and there is no support in the FTAIA for foreclosing this common form of antitrust suit. Defendants also claim that the alleged U.S. effects are insufficiently direct to invoke the domestic-effects exception. But the fact-based challenge they raise to causation cannot be resolved on the pleadings.

The defect that runs through all of Defendants' arguments is that they are thinly veiled challenges to Biocad's well-pleaded factual allegations. On a motion for summary judgment or at trial, it will be appropriate for Defendants to challenge Biocad to come forward with evidence that it was sufficiently prepared to enter the relevant domestic market or that its difficulty in doing so was proximately caused by Defendants' unlawful conduct. On a motion to dismiss, such challenges are not appropriate. The district court was required to accept Biocad's well-pleaded allegations as true, and Defendants cannot defend that court's ruling by ignoring or mischaracterizing those allegations. Because misplaced factual challenges are the sum and substance of their brief, the district court's decision should be reversed and the case remanded so that the parties may develop the facts.

ARGUMENT

I. BIOCAD HAS PLEADED ANTITRUST STANDING

A. Biocad's Preparations To Obtain FDA Approval Support Its Showing Of Intent And Preparedness To Enter

As Biocad showed in its opening brief (at 32-39), it has done all that Federal Rule of Civil Procedure 8 requires to plead an antitrust injury. Under the Clayton Act, the statutory test is whether a plaintiff has been "injured in [its] business or property" by anticompetitive conduct. 15 U.S.C. § 15(a). Where the anticompetitive conduct is exclusion from a market, excluded competitors can establish standing by pleading and proving "intention and preparedness" to enter the market. *American Banana Co. v. United Fruit Co.*, 166 F. 261, 264 (2d Cir. 1908), *aff'd*, 213 U.S. 347 (1909). Courts look to several indicia of preparedness, including background and experience in the field, financial capability to enter, and any "actual and substantial affirmative steps toward entry, such as the consummation of relevant contracts and procurement of necessary facilities and equipment." *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 807 (D.C. Cir. 2001).

Here, each of those factors indicates that Biocad intends and is prepared to enter the U.S. market for the drugs. Biocad alleges that it successfully has created biosimilars of the three drugs at issue, that it is Roche's leading competitor in global sales of mAbs, and that it has taken numerous affirmative steps to enter the

U.S. markets for these drugs – including hiring U.S. personnel and constructing a state-of-the-art, FDA-compliant manufacturing facility. A128-29 (¶¶ 56-62); A131 (¶¶ 68-70); A132-35 (¶¶ 74-80). Those detailed allegations are more than sufficient to plead intent and preparedness. *See Anderson News, L.L.C. v. American Media, Inc.*, 680 F.3d 162, 185 (2d Cir. 2012) ("[T]he court is required to proceed 'on the assumption that all the [factual] allegations in the complaint are true.'") (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)) (second alteration in original; emphasis omitted).

Biocad further alleges that Defendants attacked Biocad's business and that their attack was motivated by a desire to prevent Biocad from entering the U.S. market and lowering the price of Roche's blockbuster drugs. A142-44 (¶¶ 117-120); A169 (¶¶ 223-226); A171-72 (¶¶ 235-236). When evaluating antitrust injury, this Court "assume[s] the alleged violation" occurred. *Daniel v. American Bd. of Emergency Med.*, 428 F.3d 408, 437 (2d Cir. 2005). Here, Defendants' violations are alleged thoroughly and in detail. This Court should take as true that they occurred in the way and for the reasons Biocad alleges. And Defendants' actions and motives give rise to a more-than-plausible inference that Defendants believed Biocad would enter the U.S. market if Defendants did not act.

Defendants will be free in discovery, on summary judgment, and at trial to test Biocad's allegations and to press a contrary theory that Biocad was not ready

to enter the U.S. market. But on motion to dismiss, they cannot overcome Biocad's plausible, concrete allegations by ignoring them or inaccurately labeling them conclusory. The Complaint here meets the requirement of a "short and plain statement of [Biocad's] claim showing that [it] is entitled to relief," Fed. R. Civ. P. 8(a)(2), and supporting a plausible inference that Defendants' actions "injured [Biocad] in [its] business or property," 15 U.S.C. § 15(a), by delaying and potentially preventing an otherwise promising market entry.

B. Defendants Fail To Undermine Biocad's Showing Of Intent And Preparedness

Defendants' assertion that Biocad has not pleaded antitrust standing rests on two erroneous premises. *First*, Defendants urge (at 22-25) this Court to adopt a categorical rule that a pharmaceutical-manufacturer plaintiff claiming exclusion from the market must plead that FDA approval of its products is probable (or would have been probable but for the challenged misconduct). No court other than the district court here has recognized such a rule, and this Court should not do so now. *Second*, Defendants contend (at 25-32) that, even though Biocad expressly alleges that FDA approval of its products is probable, that allegation should be disregarded as conclusory. But Biocad's allegation is factual and entitled to an assumption of truth, and it also is supported by many additional, more specific facts. Even if probable FDA approval were strictly required for antitrust standing, Biocad would satisfy that requirement here.

1. Courts have recognized many indicia of intent and preparedness that are relevant to establish an excluded competitor's antitrust standing. Those indicia are factors, not elements, and courts examine them in combination on a case-by-case basis. *See Andrx*, 256 F.3d at 806-07. Many courts treat probable FDA approval as a significant (or even sufficient) intent-and-preparedness factor – and accordingly have noted the absence of such an allegation when ruling on antitrust standing. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 207 (E.D.N.Y. 2003); *Brotech Corp. v. White Eagle Int'l Techs. Grp.*, No. CIV.A.03-232, 2004 WL 1427136, at *6 (E.D. Pa. June 21, 2004). But no court (other than the district court here) has found probable FDA approval to be a necessary requirement for antitrust standing. Defendants err in arguing otherwise.

In *Andrx*, for instance, the D.C. Circuit rejected the argument that an excluded generic manufacturer could not demonstrate antitrust injury without alleging that the FDA had approved its product, holding instead that the generic manufacturer "*could* have alleged its intent and preparedness to enter the market by claiming that FDA approval was probable." 256 F.3d at 808 (emphasis added). Similarly, in *Roxane Laboratories, Inc. v. SmithKline Beecham Corp.*, No. 09-CV-1638, 2010 WL 331704 (E.D. Pa. Jan. 26, 2010), the court treated "the probability of FDA approval as one significant factor to recognize within the intent and preparedness standard" but refused to dismiss merely because the plaintiff did not

allege such probability in express terms. *Id.* at *3-4. *See also Shionogi Pharma, Inc. v. Mylan, Inc.*, Civil No. 10-1077, 2011 WL 3860680, at *5 (D. Del. Aug. 31, 2011) (holding that a plaintiff had alleged intent and preparedness without an express allegation of probable FDA approval).

Defendants cannot identify a single case that relies on the rule they advocate. They point (at 24-25) to *Bristol-Myers Squibb Co. v. Copley Pharmaceutical, Inc.*, 144 F. Supp. 2d 21 (D. Mass. 2000), on which the district court also relied. But that case turned on the plaintiff's failure to file first at the FDA, which the defendants' actions did not affect. *See id.* at 25. Defendants also point (at 24) to *In re Terazosin Hydrochloride Antitrust Litigation*, 335 F. Supp. 2d 1336 (S.D. Fla. 2004). But in that case – decided at summary judgment – the FDA either had declined to grant tentative approval of the competing manufacturers' Abbreviated New Drug Applications or did not grant tentative approval until after the allegedly frivolous patent litigation ended. *Id.* at 1367-69. Those facts broke the chain of causation for antitrust injury because the FDA, not the defendants, had caused the delay in market entry. Unlike Biocad, the *Terazosin* plaintiffs did not allege that the incumbent manufacturer's exclusionary conduct had delayed its competitors' submissions to the FDA.

Defendants' rule also would break with background principles governing the pleading of causation. The argument that Biocad's competitive biosimilars might

not have received FDA approval is an argument that "the need for approval . . . cut the causal chain," *Bristol-Myers Squibb*, 144 F. Supp. 2d at 24 – that is, an argument that a lack of regulatory approval would be an intervening event that would free Defendants of responsibility for Biocad's injuries. But this Court repeatedly has "observed that where the question, at bottom, is one of intervening events . . . 'the chain of causation is a matter of proof at trial and not to be decided on a Rule 12(b)(6) motion to dismiss.'" *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 187 (2d Cir. 2015) (quoting *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 174 (2d Cir. 2005)). Defendants offer no persuasive reason to depart from that general approach here in favor of an FDA-specific pleading rule that would give incumbent pharmaceutical manufacturers special protection from antitrust claims.

2. In any event, Biocad plausibly alleges that "FDA approval is probable," A120 (¶ 22), and backs up that allegation with concrete factual support. To begin with, Biocad alleges that it now makes the drugs at issue, sells them worldwide, and has already become Roche's primary biosimilar competitor. A128-29 (¶¶ 56-62). As explained in Biocad's opening brief (at 9-11), in the biosimilar industry, developing the drug and establishing a safe, reliable manufacturing process that avoids contamination are the primary challenges that a manufacturer must overcome to bring the product to market. Once those

challenges are overcome, FDA approval can be obtained through an abbreviated statutory process that relies substantially on work already done by the manufacturer of the reference product. Accordingly, Biocad's specific allegations that it has already created its biosimilars and brought them to market in other countries would alone render plausible the FDA's probable approval of Biocad's safe, functional, and popular drugs.

The Complaint also alleges that Biocad has a state-of-the-art factory "to manufacture biosimilars and compete head to head in the U.S. with Roche's three best-selling drugs." A115 (¶ 4) (footnote omitted). Defendants say (at 27) there is no "factual basis for crediting that assertion," but a well-pleaded factual assertion does not require "specific evidence or extra facts beyond what is needed to make the claim plausible," *Arista Records LLC v. Doe 3*, 604 F.3d 110, 120-21 (2d Cir. 2010). And Defendants are incorrect even on their own terms, because the Complaint describes in detail the steps Biocad took to ensure FDA compliance. A132-33 (¶¶ 74-78).

Defendants also suggest (at 27) that Biocad does not "allege[ ] that the facility is capable of producing any of the Drugs" at issue here. That is a willful misreading of the Complaint, which alleges that the facility is "complete[ ]," that it is "FDA-compliant," and (as noted above) that it is the means by which Biocad will "compete head to head in the U.S. with Roche's three best-selling drugs."

A115 (¶¶ 4, 6) (footnote omitted); *see also* A116 (¶ 8) ("By 2016, Plaintiff had . . . [the] necessary facilities, equipment and manufacturing capabilities to import biosimilars into [the] U.S."). The only fair reading of those allegations is that Biocad's new FDA-compliant facility is indeed capable of producing biosimilars that compete with Roche's blockbuster drugs. Biocad stands ready to prove that capacity at summary judgment and at trial.

Biocad alleges other specific steps directed at U.S. market entry, including creating a U.S. subsidiary, transferring personnel to and hiring them in the United States, and leasing premises in Boston. A131 (¶¶ 68-70). It alleges that it has hired consultants to support its efforts at U.S. entry, prepared a timeline and developed a strategy for that entry, and budgeted sums between $60 and $100 million for each product. A131-32 (¶¶ 71, 73). Defendants respond by speculating (at 28) that those investments might relate to "other drugs" rather than to the three blockbuster drugs at issue. Again, that mischaracterizes the Complaint, which states that Biocad has "invested 6 years and a substantial amount of funds and resources to establish operations" as part of its "plan[ ] to . . . dramatically undercut[ ] Roche's price *for Avastin®, Herceptin® and Rituxan®* in the U.S." A135 (¶ 80) (emphasis added); *see also* A115 (¶¶ 4-5) (describing Biocad's plan to "compete . . . with Roche's three best-selling drugs," then setting forth Biocad's "[s]pecific[ ]" steps and investments) (footnote omitted).

Further, just as Biocad alleges that it was expending significant resources to enter the U.S. market, Biocad also alleges that Defendants were expending significant resources to stop that from happening. For antitrust standing analysis, this Court assumes the violation occurred. *Daniel*, 428 F.3d at 437. The reasonable inference from that assumption here is that Defendants believed Biocad would successfully enter the U.S. market; otherwise, they would not spend money to try to stop it. *Cf. Blue Shield of Va. v. McCready*, 457 U.S. 465, 479 (1982) (noting that it is easier to show antitrust injury where the "harm" to the plaintiff "was a necessary step in effecting the ends of the alleged illegal conspiracy"). For all of these reasons, even if Biocad were required to plead that FDA approval is probable, its well-pleaded allegations are more than sufficient.

Defendants make one more attempt to raise the bar. It is not enough, they say (at 25), to plead that FDA approval is probable; an excluded competitor must also support that allegation by pleading "an interaction . . . between itself and the FDA." That argument is another example of a demand that Biocad plead evidence, which Rule 8 does not require. Further, a prospective competitor can easily suffer injury before specific interactions with the FDA. For example, the existing manufacturers of a treatment might collude to prevent hospitals from referring patients to an innovative new competitor's clinical trials. A tying arrangement that excludes others from a market might prevent a new competitor from securing

financing for an FDA-compliant manufacturing facility. *See* X Phillip E. Areeda et al., *Antitrust Law* ¶ 1767a (3d ed. 2010) ("Areeda, *Antitrust Law* (3d ed.)") ("[r]ivals foreclosed from tied-product market"). Or a patent-infringement suit might divert a firm's resources from seeking FDA approval to defending the litigation. Many courts have recognized that an antitrust violation can derail the process of seeking FDA approval.[2] For that reason, Defendants can identify no case that makes contact with the FDA a prerequisite for antitrust standing. This Court should decline their invitation to accept that novel and unjustified rule.

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[2] *See, e.g.*, *Tawfilis v. Allergan, Inc.*, 157 F. Supp. 3d 853, 865-68 (C.D. Cal. 2015) (antitrust standing without application for FDA approval)*; Retrophin, Inc. v. Questcor Pharm., Inc.*, 41 F. Supp. 3d 906, 914-15 (C.D. Cal. 2014) (same); *In re Metoprolol Succinate Direct Purchaser Antitrust Litig.*, No. CIV.A. 06-52 (GMS), 2010 WL 1485328, at *8 (D. Del. Apr. 13, 2010) (dismissal inappropriate where it was unclear whether plaintiffs diverted resources from FDA approval to defending patent suit); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 757 (E.D. Pa. 2003) (it is "reasonable to infer" that "generic companies direct[ ] resources away from FDA approval and toward the defense of [patent] infringement actions and, furthermore, that this reallocation of funds result[s] in a delay of FDA approval" even if the infringement suit is baseless); *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 274 F. Supp. 2d 937, 943-44 (N.D. Ill. 2003) (antitrust standing without application for FDA approval); *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 545 (D.N.J. 2000) (where infringement actions are brought against Paragraph IV filers, "the generic companies are better served to direct their resources toward defense of the infringement action" than toward tentative FDA approval because "approval would be meaningless in the absence of a favorable court ruling"); Biocad Br. 37-38.

II. THE FTAIA DOES NOT BAR BIOCAD'S CLAIMS

A. Biocad Alleges Anticompetitive Conduct Directed At The U.S. Import Market

1. As Biocad's opening brief sets forth (at 42-46), the FTAIA does not apply to – that is, does not preclude – claims where the defendant's conduct "involves import trade or commerce." *Kruman v. Christie's Int'l PLC*, 284 F.3d 384, 395 (2d Cir. 2002) (discussing 15 U.S.C. § 6a). A defendant's conduct involves import commerce if it was "directed at an import market," in the sense that it was intended to and did produce an effect on such a market. *Id.*; *see id.* at 396 (determination rests on whether "the object of the conspiracy was . . . [an] import market"). Here, Biocad alleges that Defendants' conspiracy was intended to and did at least delay (and potentially foreclose) Biocad from importing biosimilars to compete with Roche's three blockbuster drugs. Contrary to Defendants' mischaracterizations, Biocad's claims include allegations of both intent and effects. *See* A173, 176, 179, 181-82 (¶¶ 245, 260, 275, 291) (intent); A169-70 (¶¶ 223-228) (effect). Those allegations fall within the import exclusion.

Defendants respond with a novel definition of the term "involving" based on selectively chosen dictionary definitions. Quoting *Random House* and *Webster's Third*, they argue (at 37-38) that conduct "only *involve[s]* import . . . commerce if" it "'includes'" or "'contains'" import commerce or "'requir[es]'" such commerce as a "'necessary circumstance.'" In doing so, they omit other definitions from the

same sources: to "involve" is also "to have an effect on" or to "affect," "to have within or as part of itself," to "contain" or to "include." *Webster's Third New International Dictionary Unabridged* 1191 (1993); *see Random House Webster's Unabridged Dictionary* 1005 (2d ed. 1997) (to "involve" is "to affect," "to include," "to implicate"). Those meanings squarely encompass the reading of the statute adopted in *Kruman*. And even taking Defendants' cherry-picked definitions at face value, there is no difficulty in saying that a conspiracy "include[s]" its object "as a necessary circumstance," because the conspiracy would not exist without the conspirators' desire to achieve the object.

Defendants extend their argument still further, contending (at 37) that, to fall within the import exclusion, their conduct must "directly constitute [import] commerce or directly act upon" it. That supposed requirement of directness is Defendants' invention. It is not in the text of the import exclusion. It is not in the dictionary definitions Defendants quote. It is not supported by any citation to precedent. It is also not in the legislative history: the source that Defendants cite states that the FTAIA will not apply to "import restraints," H.R. Rep. No. 97-686, at 9 (1982), which is just the conduct Biocad alleges.

The text of the FTAIA instead shows that the import exclusion does *not* require direct action on import commerce. The statute does not use the word "direct" or anything like it in 15 U.S.C. § 6a, where the import exclusion resides.

The next provision – enacted simultaneously – limits the domestic-effects exception to conduct that has "a *direct*, substantial, and reasonably foreseeable effect" on U.S. commerce. *Id.* § 6a(1) (emphasis added). "[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (alteration in original); *see also Gross v. FBL Fin. Servs., Inc.*, 557 U.S. 167, 175 (2009) ("negative implications raised by disparate provisions are strongest" when the provisions were "considered simultaneously").

As the Seventh Circuit has explained, Congress had no reason to include a directness requirement when the challenged conduct affected imports. The FTAIA's removal of much foreign commerce from the Sherman Act's reach "was inspired largely by international comity." *Minn-Chem, Inc. v. Agrium Inc.*, 683 F.3d 845, 854 (7th Cir. 2012) (en banc). "But, by inserting the parenthetical 'other than import trade or import commerce' in the *chapeau*, Congress recognized that there was no need for this self-restraint with respect to imports." *Id.* In other words, where a defendant intends to and does restrain U.S. imports, it is subject to the Sherman Act just as any domestic conduct would be. There is no special FTAIA-imposed requirement of directness; ordinary rules of standing and proximate causation apply (and here, as shown in Part I, are met).

This Court's decision in *Lotes Co. v. Hon Hai Precision Industry Co.*, 753 F.3d 395 (2d Cir. 2014), does not support Defendants' construction of the statute. Defendants quote out of context (at 39) the statement in *Lotes* that "[t]o demand that any domestic effect must follow as an immediate consequence of a defendant's foreign anticompetitive conduct would all but collapse the FTAIA's domestic effects exception into its separate import exclusion." 753 F.3d at 411. That is, all or nearly all domestic effects that are "immediate consequence[s]" of foreign conduct are also effects on imports. But *Lotes* neither said nor implied – as Defendants contend – that the import exclusion covers *only* effects on imports that are "immediate consequence[s]" of foreign conduct.

Even if this Court were to read a directness requirement into the import exclusion, Biocad would meet it. As with disputes about proximate cause, disputes over the directness or indirectness of an effect generally require factual development and cannot be resolved on the pleadings. *See Law Offices of Curtis V. Trinko, L.L.P. v. Bell Atl. Corp.*, 305 F.3d 89, 100 (2d Cir. 2002) ("The plaintiff alleges that it suffered a direct harm, poor phone service, as a result of the defendant's misconduct. While the district court may find otherwise after discovery and a motion for summary judgment, it is too early to conclude on this record that the plaintiff only suffered a wholly derivative injury."), *rev'd on other grounds sub nom. Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S.

398 (2004). Similarly, at the pleading stage, this Court assumes that the alleged antitrust violation occurred. *Daniel*, 428 F.3d at 437. The Complaint stresses that the "sole purpose" of the alleged conspiracy was to prevent Biocad from importing its biosimilars into the United States, A173, 176, 179, 181-82 (¶¶ 245, 260, 275, 291), that Defendants took extensive, expensive steps toward that end, and that they achieved it. Taking those allegations as true, the Defendants' conduct directly involved import commerce. Defendants are free to contest the truth of those allegations and invoke the FTAIA on summary judgment or at trial. *See Trinko*, 305 F.3d at 100. But because Biocad alleges conduct that plausibly involves import commerce, the FTAIA cannot bar its claims at this stage.

2. Defendants also mischaracterize Biocad's reading of the import exclusion. "Under Biocad's test," they erroneously claim (at 41), the import exclusion "depends merely on the defendant's subjective 'intentions.'" Defendants' conduct involved import commerce because of the intent behind that conduct (to delay Biocad's import market entry) and the effect of that conduct (actually delaying Biocad's entry). Biocad alleges both, and both matter.

Intent is an essential element of claims, like Biocad's, of conspiracy or attempt. What makes a conspiracy unlawful is always the intent of the conspirators, and what makes an attempt unlawful is the intended illegal result. Intent has always played a role in determining whether foreign conduct falls within

the Sherman Act. *See Hartford Fire Ins. Co. v. California*, 509 U.S. 764, 797 n.24 (1993) ("[T]he Sherman Act covers foreign conduct producing a substantial *intended* effect in the United States.") (emphasis added). For those reasons, intent is relevant to whether conduct "involves" import commerce under the FTAIA – hence this Court's explanation, in *Kruman*, that what matters is whether Defendants' conduct is "directed at an import market," 284 F.3d at 395, and whether "the object of the conspiracy was . . . [an] import market," *id.* at 396.

Defendants err in contending (at 41) that "it is wrong to say that a person's conduct 'involves' a thing merely because the person hopes her conduct will . . . affect that thing." They hypothesize a child who "clean[s] her plate in the hope that she will get dessert," and say that her act of "eating broccoli" would not be "'conduct involving ice cream.'" The reason that case does not sound as though it fits the statute is that Defendants have made the conduct innocent and softened the link between the conduct and its intended effect ("hope" is not "intent"). Suppose instead that the child, after being told she would get ice cream if she ate her broccoli, surreptitiously fed the vegetable to the family dog and presented her parents with a clean plate. It would be fair to say that was conduct (or misconduct) "involving ice cream." And if her parents responded with a month-long ban of ice cream from the house, the child would be unlikely to persuade them that the punishment was unjust for lack of a sufficiently close connection between her

deception and ice cream. Here, the consequence Congress has prescribed for anticompetitive conduct involving U.S. imports is treble-damages liability. Roche cannot escape that consequence by arguing that its chosen means to foreclose import competition was not, in itself, import sales or purchases.

Defendants' more grown-up illustration likewise falls short. Tax fraud, they say (at 41-42), would not become an "'offense involv[ing] a . . . semiautomatic firearm,'" (quoting U.S.S.G. Guidelines Manual § 2k2.1(a)(1)) (alteration by Defendants), because the intended use of the unlawful proceeds was to buy a new gun. But the Supreme Court, addressing a similarly worded statute, has explained that, when a defendant has "ma[de] a material misstatement in order to acquire or sell a gun," the gun is "'involved in'" the transaction and subject to forfeiture, even though the gun is "not 'used' in the offense." *Smith v. United States*, 508 U.S. 223, 235 (1993) (discussing 18 U.S.C. § 922(a)(6) and § 924(d)(1)). The Court explained that Congress chose the "expansive term" "'involved in'" precisely to achieve that result. *Id.* Thus, in firearms as in antitrust, the word "involved" naturally covers the object of misconduct as well as the means.

Finally, Defendants incorrectly suggest (at 42) that the natural reading of the FTAIA's import exclusion set forth above renders the domestic-effects exception "superfluous." The domestic-effects exception brings certain foreign conduct that does not itself involve import commerce back within the reach of the Sherman Act

if that foreign conduct has a "direct, substantial, and reasonably foreseeable effect," 15 U.S.C. § 6a(1), on, among other things, "import trade or import commerce," *id.* § 6a(1)(A). A key difference between conduct covered by § 6a(1)(A) and conduct that falls under the import exclusion is just what Defendants claim is irrelevant: intent. For instance, a conspiracy whose object is to fix prices for semiconductors being shipped to the United States involves import commerce and falls within the import exclusion. A conspiracy unrelated to shipping to the United States – where perhaps the conspirators planned only to suppress semiconductor competition abroad – does not fall within the import exclusion, but still offends the Sherman Act if its effect on imports or domestic semiconductor prices is direct, substantial, and reasonably foreseeable. *See*, *e.g.*, *United States v. Hui Hsiung*, 778 F.3d 738, 759-60 (9th Cir. 2015) (foreign price-fixing fell under domestic-effects exception where price-fixed displays were incorporated into products destined for the U.S. market); *Motorola Mobility LLC v. AU Optronics Corp.*, 775 F.3d 816, 819 (7th Cir. 2015) (foreign price-fixing of components likely to be imported into the United States could constitute a direct, substantial, and reasonably foreseeable domestic effect).

B. Biocad's Claims Also Arise From Direct, Substantial, And Reasonably Foreseeable Effects On U.S. Commerce

The FTAIA's domestic-effects exception applies to foreign conduct that has a "direct, substantial, and reasonably foreseeable effect" on U.S. domestic or

import commerce, 15 U.S.C. §§ 6a(1)(A), 6a(2), as long as "the defendants' foreign conduct caused [such a] domestic effect" and "that effect caused the plaintiff's injury," *Lotes*, 753 F.3d at 414. Biocad alleges that Defendants' conduct has excluded it from the domestic market or at least delayed its entry. It alleges that effect was direct, substantial, and reasonably foreseeable – indeed, intentional. And exclusion from the market (resulting in lost profits) is a familiar antitrust injury. *See American Banana*, 166 F. at 264 ("it is as unlawful to prevent a person from engaging in business as it is to drive a person out of business"); *Retrophin*, 41 F. Supp. 3d at 912-15 (approving exclusion theory of harm for pharmaceutical manufacturer); *Amgen, Inc. v. F. Hoffmann-La Roche Ltd.*, 480 F. Supp. 2d 462, 468 (D. Mass. 2007) (same); *Xechem*, 274 F. Supp. 2d at 941-44 (same for delay in entering market); *see also BNLfood Invs. Ltd. SARL v. Martek Biosciences Corp.*, Civil No. WDQ-11-0446, 2011 WL 6439451, at *4 (D. Md. Dec. 14, 2011) (exclusion); *Metoprolol Succinate*, 2010 WL 1485328, at *7-8 (delay). The FTAIA does not bar this common form of antitrust suit.

Defendants respond by mischaracterizing the Complaint and Biocad's opening brief. They say (at 49, 55) that the anticompetitive effect that Biocad challenges is the increased "cost to U.S. consumers" that will occur as a result of Biocad's exclusion from the market. It is quite true that Defendants' conduct has harmed and will continue to harm consumers in this way, and Biocad has pointed

to that harm to show the anticompetitive nature of the conduct. But the higher prices paid by consumers are not the anticompetitive effect for which Biocad seeks relief – as should be obvious, because Biocad is not a consumer. As Biocad has explained (at 50-51), the relevant domestic effect is "[p]reventing or delaying Biocad's U.S. market entry"; and "[t]he effect that Biocad challenges – delaying entry or entirely excluding Biocad from the market – also 'gives rise,' 15 U.S.C. § 6a(2), to Biocad's claims because Biocad's injury is the business (and profits) it has lost in the United States."[3]

For this reason, Defendants err in contending (at 54-55) that Biocad impermissibly relies on a different "effect" for § 6a(1)(A) and § 6a(2). There is one effect that Biocad challenges – its exclusion from the domestic market. A174 (¶ 248) (challenged effect was being "delayed and excluded from entering the Relevant [U.S.] Markets"); A172-82 (¶¶ 237-295) (seeking damages exclusively

[3] Defendants show that they understand Biocad's actual theory under the domestic-effects exception by addressing it in their brief (at 55), but nevertheless argue in the same breath that Biocad has not made the argument they address. As set forth above, Biocad's position is presented at pages 50-51 of its opening brief. Defendants also argue (at 55-56 n.17) that the district court did not pass upon Biocad's claim that the relevant domestic effect was Biocad's exclusion from the market. But Biocad made clear from the first paragraph of its Complaint that it was seeking relief for "Defendants' continuing pattern of anticompetitive and illegal conduct aimed at delaying and preventing altogether Plaintiff's entry on the U.S. market with cheaper lifesaving cancer drugs." A114 (¶ 1). The idea that Biocad was seeking relief for higher prices paid by consumers is not a fair reading of its allegations. This Court should thus address Biocad's position on its merits.

for lost profits in the United States, not for injuries in Russia). That is the "direct, substantial, and reasonably foreseeable effect" on domestic or import commerce, 15 U.S.C. § 6a(1), that "gives rise" to Biocad's claims, *id.* § 6a(2).

Defendants also fail to show (at 47-52) that Biocad's exclusion from the U.S. market is an insufficiently "direct" result of their conduct to fall within the domestic-effects exception. Biocad alleges facts demonstrating a causal connection between Defendants' attacks on its Russian business and the delay of its entry into the U.S. market. The attacks resulted in less business and lost sales for Biocad in its home market of Russia. A146-47 (¶¶ 125-127) (lower prices); A151-52 (¶¶ 145, 147) (inability to bid on auctions); A156-57 (¶¶ 164-168) (lost sales from unlawful payments); A163-65 (¶¶ 192-205) (lost sales from tying). Those losses damaged Biocad's finances to the point where it was forced to lay off U.S. employees and delay the expenditures needed to enter the U.S. market. A135, 170-72 (¶¶ 81, 229-236). Those concrete allegations set out a plausible claim.

Defendants' "directness" challenge is really a challenge to proximate cause, as they more or less admit (at 49) by arguing that Biocad's allegations involve "a highly attenuated chain of causation" and rely on connections that are "speculative, remote, and distant." That kind of challenge cannot properly be resolved at this stage of the litigation. Courts have long recognized that proximate-cause disputes are far more suited to summary judgment or trial than to motions on

the pleadings. *See Loreley Fin.*, 797 F.3d at 187; *Trinko*, 305 F.3d at 100; *Norfolk Cty. Ret. Sys. v. Community Health Sys., Inc.*, 877 F.3d 687, 696 (6th Cir. 2017) (proximate cause was "for the parties to dispute at the summary-judgment stage or at trial, rather than for us to decide on the pleadings here"), *petition for cert. filed*, No. 17-1453 (U.S. filed Apr. 20, 2018); *Estate of Bailey v. County of York*, 768 F.2d 503, 511 (3d Cir. 1985) ("Ordinarily, proximate cause cannot be determined on the basis of pleadings but instead requires a factual development at trial."); *Wilshire Oil Co. of Tex. v. Riffe*, 409 F.2d 1277, 1284 (10th Cir. 1969) (improper to resolve causation challenge on motion to dismiss an antitrust case). Biocad need not do more at this stage than offer concrete allegations that Defendants intended to and did preclude it from entering the domestic market on time. It has done so.

Finally, Defendants make (at 48, 56) the remarkable claim that excluding a competitor is not anticompetitive. But even Defendants acknowledge (at 48) that "decreases in output" are a classic anticompetitive effect. *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 238 (2d Cir. 2003). Excluding a competitor like Biocad decreases output and raises prices. And excluding a competitor through exclusive dealing (via fraud and bribery), tying, and predatory pricing is exactly the kind of anticompetitive conduct that the antitrust laws police. *See* IIIA Phillip E. Areeda, et al., *Antitrust Law* ¶ 723 (4th ed. 2014) ("Areeda, *Antitrust Law* (4th ed.)") (predatory pricing); IX Areeda, *Antitrust Law* (3d ed.) ¶¶ 1703-1718 (tying

arrangements); XI Areeda, *Antitrust Law* (3d ed.) ¶¶ 1800-1807 (exclusive dealing).

Moreover, Defendants' argument runs headlong into more than a century of antitrust precedent permitting suits by excluded competitors.[4] As discussed above and in Biocad's opening brief, excluded-competitor suits are common in exactly the present circumstance – where an incumbent drug manufacturer unlawfully delays a competitor's market entry. *See supra* p. 22 (collecting cases). Biocad's claims thus seek a remedy for the kind of injury the antitrust laws were intended and have long been understood to prevent.

Defendants do not contest that their interpretation of the FTAIA will categorically preclude excluded competitors from availing themselves of the

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[4] *See American Banana*, 166 F. at 264 (recognizing suits by excluded competitors); *Martin v. Phillips Petroleum Co.*, 365 F.2d 629, 633 (5th Cir. 1966) (same); *International Rys. of Cent. Am. v. United Brands Co.*, 532 F.2d 231, 248 (2d Cir. 1976) (same); *Blackburn v. Sweeney*, 53 F.3d 825, 830 (7th Cir. 1995) (same) ("[B]ecause the harm suffered by a consumer forced to pay inflated prices, and the harm inflicted on an excluded competitor[,] . . . both result from the anti-competitive effect of the cartel agreement, they are both antitrust injuries."); *Serfecz v. Jewel Food Stores*, 67 F.3d 591, 597 (7th Cir. 1995) (same) ("When the plaintiff's injury is linked to the injury inflicted upon the market, such as when consumers pay higher prices because of a market monopoly or when a competitor is forced out of the market, the compensation of the injured party promotes the designated purpose of the antitrust law – the preservation of competition."); *Andrx*, 256 F.3d at 806 (same); *Bourns Inc. v. Raychem Corp.*, 331 F.3d 704, 711 (9th Cir. 2003) (same); *Sanger Ins. Agency v. HUB Int'l, Ltd.*, 802 F.3d 732, 738 (5th Cir. 2015) (same); IIA Areeda, *Antitrust Law* ¶ 349a (4th ed.) (same).

domestic-effects exception. Defendants claim instead (at 57), without any authority, that "[i]t is hardly surprising that Congress would have wanted" that result. But if Congress had meant the FTAIA to bar such a common form of antitrust injury, it would have said so; and, at some point, some court or commentator would have at least raised that possibility. Defendants point to none that has. They instead argue for a novel and significant restriction on the domestic-effects exception based on vague, unsupported statements about Congress's internationalist preferences. This Court has no reason to assume that those purported preferences here override Congress's other preferences, and long-standing policies, of protecting American consumers and competition by offering a remedy to excluded competitors.[5]

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[5] Defendants suggest (at 58 n.19) that the doctrine of comity is an alternative basis for affirming the district court's judgment. That was neither pressed nor passed upon below, and this Court should not address it in the first instance. Further, Defendants mention comity only in a footnote, which is insufficient to present an argument for this Court's review. *See United States v. Restrepo*, 986 F.2d 1462, 1463 (2d Cir. 1993) ("We do not consider an argument mentioned only in a footnote to be adequately raised or preserved for appellate review."). In any event, Defendants' two citations for that proposition are easily distinguished. In *F. Hoffmann-La Roche Ltd. v. Empagran S.A.*, 542 U.S. 155, 169 (2004), the Supreme Court relied on prescriptive comity in construing the FTAIA to foreclose claims for foreign injuries independent of an antitrust violation's domestic effects. Here, Biocad's claims arise exclusively from domestic injuries. In *In re Vitamin C Antitrust Litigation*, 837 F.3d 175, 194 (2d Cir. 2016) *cert. granted in part sub nom. Animal Sci. Prods., Inc. v. Hebei Welcome Pharm. Co.*, 138 S. Ct. 734 (2018), this Court held that comity limited U.S. antitrust law because the Chinese government filed a formal statement in the district court asserting that Chinese law

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Biocad's opening brief showed (at 53-54) that the district court's reasons for dismissing its Clayton Act injunctive-relief claim and its Donnelly Act claim depended entirely on that court's ruling as to Biocad's Sherman Act claims. Defendants do not argue otherwise. Accordingly, if the Court reverses as to the Sherman Act claims, it should reinstate those other claims as well.

CONCLUSION

The judgment of the district court should be vacated, and this case should be remanded for further proceedings.

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required the alleged anticompetitive conduct. There is no similar statement from Russia here, nor any factual development of any kind. Comity thus cannot provide a basis for affirmance, even if this Court were to consider the issue.

Respectfully submitted,

/s/ *David C. Frederick*

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), the undersigned certifies that this brief complies with the applicable type-volume limitations of Local Rule 32.1(a)(4)(B) and Federal Rules of Appellate Procedure 32(a)(5)(A) and 32(a)(6). This brief was prepared using a proportionally spaced type (Times New Roman, 14 point). Exclusive of the portions exempted by Federal Rule of Appellate Procedure 32(f), this brief contains 6,837 words. This certificate was prepared in reliance on the word-count function of the word-processing system (Microsoft Word Office 2013) used to prepare this brief.

/s/ *David C. Frederick*
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June 7, 2018

CERTIFICATE OF SERVICE

I hereby certify that, on June 7, 2018, I electronically filed the foregoing Reply Brief for Plaintiff-Appellant Biocad JSC with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system. All participants are registered CM/ECF users and will be served by the appellate CM/ECF system.

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June 7, 2018