17-3486

IN THE

United States Court of Appeals

FOR THE SECOND CIRCUIT

BIOCAD JSC,

Plaintiff-Appellant,

—against—

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

BRIEF FOR DEFENDANTS-APPELLEES

PAUL SPAGNOLETTI
ANDREW S. GEHRING
DAVIS POLK & WARDWELL LLP
450 Lexington Avenue
New York, New York 10017
(212) 450-4000

Counsel for Defendants-Appellees F. Hoffmann-La Roche Ltd and Roche Holding AG

CAITLIN J. HALLIGAN
ERIC J. STOCK
ALEJANDRO A. HERRERA
GIBSON, DUNN & CRUTCHER LLP
200 Park Avenue
New York, New York 10166
(212) 351-4000

Counsel for Defendant-Appellee R-Pharm JSC

DANIEL M. WALL
LATHAM & WATKINS LLP
505 Montgomery Street, Suite 2000
San Francisco, California 94111-6538
(415) 395-8240

AMANDA P. REEVES
ROMAN MARTINEZ
BENJAMIN W. SNYDER
LATHAM & WATKINS LLP
555 Eleventh Street, NW, Suite 1000
Washington, DC 20004
(202) 637-2207

LAWRENCE E. BUTERMAN
LATHAM & WATKINS LLP
885 Third Avenue
New York, New York 10022-4834
(212) 906-1264

Counsel for Defendant-Appellee Genentech, Inc.

ROCHE CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, defendants-appellees Roche Holding AG and F. Hoffmann-La Roche Ltd hereby state:

1. Roche Holding AG is a publicly held Swiss corporation and has no parent company. More than 10% of Roche Holding AG's voting shares are held either directly or indirectly by Novartis AG, a publicly held Swiss corporation.

2. F. Hoffmann-La Roche Ltd is a wholly owned subsidiary of Roche Holding AG, a publicly held Swiss corporation. More than 10% of Roche Holding AG's voting shares are held either directly or indirectly by Novartis AG, a publicly held Swiss corporation.

GENENTECH CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, defendant-appellee Genentech, Inc., hereby states that it is a wholly owned subsidiary of Roche Holdings, Inc. Roche Holdings, Inc.'s ultimate parent, Roche Holding AG, is a publicly held Swiss corporation. More than 10% of Roche Holding AG's voting shares are held either directly or indirectly by Novartis AG, a publicly held Swiss corporation.

R-PHARM CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, defendant-appellee R-Pharm JSC hereby states that 10% or more of its stock is held, directly or indirectly, by Mitsui & Co., Ltd., a publicly held Japanese company.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

PAGE(S)

BRIEFS

STATUTES & REGULATIONS

OTHER AUTHORITIES

STATEMENT OF THE ISSUES

This case presents two questions relating to the efforts of Biocad JSC ("Biocad") to use U.S. antitrust laws to punish alleged misconduct in Russia.

1. To plead that it has antitrust standing, Biocad must establish its "intention and preparedness" to enter the U.S. pharmaceuticals market for *bevacizumab*, *trastuzumab*, and *rituximab* (the "Drugs"). But Biocad does not currently participate, and has never participated, in the U.S. market. Nor has it alleged that it sought or obtained the requisite approvals from the Food and Drug Administration ("FDA").

The first question presented is whether Biocad's generalized allegations concerning preparatory steps to enter the U.S. market are sufficient to demonstrate "intention and preparedness," when Biocad has neither alleged a connection between those steps and any of the Drugs, nor alleged that it has even begun the process of applying for FDA approval for any of the Drugs.

2. The Foreign Trade Antitrust Improvements Act ("FTAIA") bars Sherman Act claims involving trade or commerce with foreign nations unless the alleged misconduct (1) involves import trade or import commerce, or (2) has a direct, substantial, and reasonably foreseeable effect on U.S. domestic or import commerce that gives rise to the claims at issue.

The second question presented is whether these narrow exceptions allow Biocad to invoke U.S. antitrust law and regulate competition in Russia, based merely on Biocad's allegation that harm to competition *in Russia* caused financial harm to Biocad's *Russian business* that, in turn, harmed its ability, years later, to enter the U.S. market.

INTRODUCTION

At its heart—and, for that matter, on its face—Biocad's complaint alleges that the competition it faces in Russia, from Russian competitors, is hurting its business (which is based in Russia). Although Biocad has never operated in the United States, it asserts that, through a nebulous chain of events, Defendants' conduct in Russia has dashed its hopes of one day selling pharmaceuticals here. This claim is nothing more than an improper attempt to shoehorn allegations about wholly foreign conduct affecting competition in a foreign market into the framework of American antitrust law. Indeed, in this action Biocad seeks to have a U.S. court make determinations as to, among other things, the legality of how drugs were priced, packaged, and sold *in Russia* (including to the Russian government).

Recognizing that Biocad's theory amounts to "a really fanciful application of the U.S. antitrust laws," the district court ultimately dismissed Biocad's claims with prejudice after giving it multiple opportunities to address the glaring flaws in its allegations. A110-11. Unhappy with that outcome, Biocad now tries to bolster its anemic Amended Complaint by making new assertions that are nowhere alleged in that complaint and mischaracterizing the allegations that do appear. But neither the Amended Complaint nor Biocad's brief establishes the kind of domestic nexus needed to sustain Biocad's claims. Biocad's allegations are fundamentally about

foreign conduct involving foreign companies in a foreign market, and its claims are foreclosed by two independent (but related) doctrines of U.S. antitrust law.

First, all of Biocad's claims fail because, in its zeal to use the U.S. legal system to redress its Russian grievances, Biocad filed suit without antitrust standing. Biocad cannot establish standing based on any injury that it allegedly incurred in the Russian market because, as a matter of law, foreign injuries do not confer antitrust standing in U.S. courts. To establish antitrust standing, a plaintiff must allege non-conclusory facts indicating that it has suffered a concrete injury of the sort that the American antitrust laws are intended to prevent—which means, at the very least, an injury related to competition in a U.S. market. But where, as here, suit is brought by a potential rather than actual entrant in the relevant U.S. market, it is blackletter law that the plaintiff must show its "intention and preparedness" to enter that market. *Am. Banana Co. v. United Fruit Co.*, 166 F. 261, 264 (2d Cir. 1908), *aff'd*, 213 U.S. 347 (1909).

Biocad is unable to do that. It filed this suit wanting to argue simply that Defendants' alleged conduct in Russia was a kind of "first cause" of its eventual exclusion from numerous other markets, including the United States. When faced with the "intention and preparedness" doctrine, Biocad then scrambled to argue that it was far enough along the path to U.S. entry to have standing. But that is plainly not true, and Biocad alleges no facts making such an allegation plausible. Among

other things, Biocad pleads no facts suggesting that it has ever sought, much less obtained, FDA approval to sell the Drugs at issue in the United States. *In fact, Biocad does not allege that it has ever interacted with the FDA with respect to any products, let alone with respect to the Drugs.* Its wholly conclusory allegation that "FDA approval is probable" cannot overcome the absence of any such supporting allegations. Nor can Biocad satisfy the pleading requirements by alleging that it has developed an FDA-compliant facility or leased space in the United States, because the complaint conspicuously fails to draw any connection between those allegations and the Drugs at issue here. Because Biocad has not alleged a link between the purported anticompetitive conduct and a domestic injury, it has failed to plead antitrust standing.

Second, Biocad's claims are barred by the plain statutory limits imposed on U.S. antitrust law by the Foreign Trade Antitrust Improvements Act (the "FTAIA"). The FTAIA generally excludes from the scope of the Sherman Act any conduct "involving trade or commerce . . . with foreign nations." 15 U.S.C. §6a. There is no dispute that Biocad's claims—stemming from allegations concerning competitive activities by non-U.S. companies in Russia that impacted Biocad's Russian operations—"involv[e] trade or commerce . . . with foreign nations." So Biocad's only option is to try to fit its claims into one of the narrow statutory exceptions to the FTAIA. That attempt fails.

The first exception Biocad claims—for conduct involving "import trade or import commerce," *id.*—applies only when a defendant's alleged conduct is itself import commerce (such as importing price-fixed goods) or acts directly upon import commerce (such as unlawfully refusing to deal with an importer). But Biocad asserts that Defendants directed their conduct at Biocad's *Russian* operations, not at its (nonexistent) American import business. Biocad claims that Defendants' conduct, by financially affecting those *Russian* operations, was intended to limit Biocad's ability to expand into the United States years later, but that theory fails to plead the direct interference with import commerce that the FTAIA requires.

The second FTAIA exception that Biocad invokes—after expressly waiving it below—is no more hospitable because it requires Biocad to show that both (1) Defendants' conduct had a direct, substantial, and reasonably foreseeable anticompetitive effect on domestic commerce, and (2) such domestic effect gave rise to Biocad's injury and Sherman Act claims. But Biocad's theory—that conduct directed at the Russian market had a downstream impact on prospective American operations it hoped to build years in the future—cannot establish the proximate causal nexus the FTAIA mandates. Moreover, the purported domestic effect of Defendants' alleged conduct did not give rise to Biocad's injury. Just the opposite: Biocad claims that its purported injury—exclusion from the U.S. market—will create a subsequent domestic effect by raising prices for consumers. As this Court

put it in a highly analogous context, "the direction of causation runs the wrong way." *Lotes Co. v. Hon Hai Precision Indus. Co.*, 753 F.3d 395, 414 (2d Cir. 2014). Because the alleged domestic anticompetitive effect did not cause Biocad's injury, its claims do not satisfy the second FTAIA exception, either.

This Court should reject Biocad's invitation to regulate the Russian pharmaceuticals market, and affirm Judge Sullivan's decision to dismiss Biocad's Amended Complaint with prejudice.

STATEMENT OF THE CASE

As Biocad's recitation of the facts makes clear, this case arises entirely from foreign conduct. Even drawing very generous inferences in Biocad's favor, the conduct by Defendants that allegedly affected Biocad occurred exclusively in Russia. Biocad points to certain peripheral allegations of U.S. conduct, but such conduct is not the basis of its alleged injury—indeed, Biocad does not claim that such conduct affected Biocad at all. A review of the actual allegations of Biocad's Amended Complaint confirms that this case constitutes an effort to invoke U.S. antitrust law to remedy Biocad's complaints about competition in the Russian marketplace.

A. Biocad Allegedly Creates Biosimilars of Roche's Products

Defendant F. Hoffmann-La Roche Ltd ("FHLR") manufactures and sells three cancer treatments: *bevacizumab*, *trastuzumab*, and *rituximab* (as previously defined,

the "Drugs"), which are marketed under the brand names Avastin, Herceptin, and Rituxan, respectively. A121, 124 (¶¶24, 35).[1] Each drug is approved for treatment of different types of cancers. A126-28 (¶¶41-42, 45-46, 51-52). FHLR sells the Drugs in Russia through an "independent distributor," defendant R-Pharm JSC ("R-Pharm"). A122 (¶26). FHLR's independent affiliate, defendant Genentech, Inc. ("Genentech"), markets and sells the Drugs in the United States. A121-22 (¶¶24-25). The Roche Group—a set of entities, including FHLR, within the corporate family of defendant Roche Holding AG ("Roche Holding" and, together with FHLR, "Roche")—has exclusive rights to sell the Drugs in the United States until its patents expire in 2018 and 2019. A120, 126 (¶¶23, 40). Biocad acknowledges that the relevant market is the U.S. market for the three Drugs. A136 (Section VIII, n.19); Br. for Pl.-Appellant Biocad JSC ("Biocad Br.") 25.

Biocad is a private pharmaceutical company based in Russia. A120 (¶22). It alleges that it has created biosimilars of the Drugs, which it first received approval to sell in Russia in 2014 and 2015. A129 (¶¶59, 61-62). Biocad claims that it "maintains a subsidiary and a facility in the U.S.," but it does not allege that its supposed U.S. subsidiary and facility have any connection to the Drugs, or even to manufacturing pharmaceuticals at all. A120 (¶22). Biocad further alleges that in

[1] Paragraph references are to Biocad's Amended Complaint.

2013—before Biocad had approval to sell the Drugs even in Russia—it opened "an FDA-compliant manufacturing facility in Russia for importation of biosimilars into the United State[s]." A120, 132 (¶¶22, 74).

Contrary to the implication in its opening brief, *see* Biocad Br. 15-16, Biocad's Amended Complaint lacks any allegation that its Russian manufacturing facility is equipped to produce any of the Drugs. Nor does Biocad allege that its Russian facility—or any other Biocad facility—was ever approved by the FDA as compliant with FDA standards. In fact, notwithstanding the litany of steps Biocad has supposedly taken to expand its operations, Biocad never actually alleges that it has the ability to manufacture the Drugs in a way that ensures they are highly similar to Roche's patented versions, per FDA requirements. A131-35 (¶¶68-81).

Biocad conclusorily alleges that it "anticipated FDA approval" and that "such FDA approval is probable." A120 (¶22). Entirely absent from the Amended Complaint, however, are any allegations that (1) Biocad has applied for FDA approval for any drugs, let alone the Drugs at issue; (2) Biocad has begun the clinical testing required to attain FDA approval; or (3) Biocad has ever interacted with the FDA at all.

B. Roche and R-Pharm Allegedly Engage in Conduct in Russia That Interferes with Biocad's Profitability

According to Biocad's Amended Complaint, Defendants orchestrated a convoluted conspiracy that financially harmed Biocad's business in Russia and

therefore somehow limited Biocad's ability to enter the U.S. market for the Drugs years in the future. Biocad claims that Defendants engaged in a variety of supposedly anticompetitive conduct.[2]

1. Biocad alleges that, *in Russia*, Roche engaged in a "[p]redatory and [d]iscriminatory [p]ricing [s]cheme" in which its independent distributor R-Pharm decreased the prices of the Drugs after Biocad received approval to sell one of the Drugs in Russia. A144-50 (¶¶121-35). Biocad also claims that Roche was able to fund that scheme because Genentech raised prices of the Drugs in the United States. A144-47 (¶¶123-27).

Nowhere does Biocad allege that the cost of producing and selling the Drugs (in either the United States or Russia) exceeds their price. Instead, it alleges that the price at which Avastin is sold in Russia is less than the "Entry Price." A149 (¶134). But the conclusion it draws from that allegation—that Roche therefore sells the Drug "at a loss," *id.*—does not follow: According to Biocad's own allegations, the Entry Price is the "value" declared at customs, not the *cost* of manufacturing the Drug. A148 (¶130).

[2] In many cases, Biocad's actual allegations improperly fail to distinguish among the Defendants, making it impossible to tell which allegations apply to each party. *See Atuahene v. City of Hartford*, 10 F. App'x 33, 34 (2d Cir. 2001) (court may disregard allegations that do not distinguish between defendants).

2. Biocad also alleges that, *in Russia*, Roche paid off Russian healthcare professionals to incentivize prescription of the Drugs. A150-60 (¶¶136-80). Despite devoting nearly 50 paragraphs of its Amended Complaint to these allegations, Biocad never claims that its own biosimilars would have been prescribed in the absence of these alleged payments or that Biocad ever challenged such conduct in Russia.

3. Biocad also alleges that, *in Russia*, R-Pharm sells one of the Drugs in a package with another drug, purportedly requiring Russian consumers to buy both drugs at the same time. A163-65 (¶¶192-205). The Amended Complaint lacks any allegation that this conduct injured Biocad or that any Russian authority viewed such alleged conduct as illegal.

4. Biocad also alleges that, *in Russia*, R-Pharm submitted bids for contracts with the Russian government that it had no ability to fill. A165-67 (¶¶206-14). Biocad never claims that it would have won the contracts in the absence of R-Pharm's bids or that anything prevented it from competing for those contracts after R-Pharm allegedly defaulted on them.

In addition to these *Russia*-based allegations, the Amended Complaint also included allegations—in a transparent attempt to manufacture a basis for asserting a U.S. claim—about some Defendants' conduct in the United States. But this conduct is entirely peripheral to the core theory of the Amended Complaint—that

Defendants' anticompetitive conduct in Russia injured Biocad's Russian business and thus indirectly harmed its ability to enter the U.S. market. Indeed, Biocad does not allege that it was affected in any way by the U.S. conduct it now points to on appeal. In particular, it alleges that Genentech limited the number of U.S. wholesalers that distributed the Drugs, and that Roche and Genentech packaged and labeled one of the Drugs in a way that encouraged patients to use more than they needed. A161-62, 167-68 (¶¶181-91, 215-22). Biocad does not allege that the changed method of distribution prevented Biocad from obtaining samples or otherwise affected Biocad's operations. Likewise, Biocad does not claim that the labeling of the Drug injured—or had any effect at all on—Biocad's operations, which, because Biocad does not operate in the United States, would be utterly implausible.

Based on this amalgam of alleged Russian conduct and irrelevant U.S. business decisions by certain Defendants in 2016 and earlier, Biocad claims that its hopes of selling the Drugs in the United States starting in 2018 and 2019 have been dashed. A143-44, 170 (¶¶120, 229-31). Biocad therefore asserted that Defendants had violated various U.S. antitrust laws, and it asked the district court to enjoin Defendants' price competition and other supposedly anticompetitive conduct in Russia (thereby increasing the price of the Drugs in the Russian market) and award it treble damages based on the sales that it claims it would have made starting later

this year if it had followed through on its hoped-for American expansion. A187 (Prayer for Relief).

C. The District Court Gives Biocad an Opportunity to Amend Its Complaint

After Biocad filed its initial complaint, Defendants informed the court that they intended to move to dismiss the case on the grounds that Biocad had failed to establish antitrust standing and had based its claims entirely on foreign conduct that does not implicate U.S. antitrust law. A61-72.

During a subsequent pre-motion conference, the district court indicated that it would likely dismiss the complaint, based on the issues raised by Defendants. The court repeatedly asked Biocad to articulate how it had suffered "more than a speculative injury," and to explain what "steps" it had "taken to enter the U.S. market." A88-90; *see also* A86, 91, 96-97 (questioning Biocad about its alleged injury). When the district court inquired whether Biocad had "even started" the "lengthy" FDA-approval process, Biocad admitted that it had not. A90. The district court described Biocad's complaint as "a really fanciful application of the U.S. antitrust laws" and noted that it did not state "a viable cause of action, at least as currently pled." A110-11.

Rather than dismiss the case, however, the district court invited Biocad to file an amended complaint. *Id.*

D. Biocad Files an Amended Complaint That Suffers from the Same Problems as Its Initial Complaint

In October 2016, Biocad filed an Amended Complaint that retained its focus on Russian conduct and still failed to allege that it had begun the FDA-approval process or that its supposedly FDA-compliant Russian facility was connected to any of the Drugs. Defendants filed motions to dismiss and, given Biocad's failure to correct the critical deficiencies previously identified in its complaint, a joint motion for sanctions. In September 2017, the district court reserved judgment on the motion for sanctions but dismissed Biocad's claims with prejudice on multiple grounds.

First, the district court held that Biocad had failed to establish antitrust standing. The court explained that a party asserting claims based on exclusion from a U.S. market must demonstrate its "intention and preparedness" to enter that market. SA5. In the case of the U.S. pharmaceuticals industry, that meant showing "a likelihood of FDA approval of the would-be competitive drug." *Id*. But, the district court noted, Biocad's Amended Complaint is utterly devoid of allegations concerning that process:

> Plaintiff provides no information about the expected timeline for approval, what clinical trials would be required, whether it has begun conducting clinical trials, its expected FDA application date, whether it has begun preparing an application, whether it has contacted the FDA, whether it has ever obtained approval for other biosimilar drugs from the FDA, or whether its contemplated approval would require a New Drug Application or an Abbreviated New Drug Application.

SA6. Because Biocad had "failed to supply any facts whatsoever regarding the FDA approval process for its biosimilars" and provided "little information from which the Court may assess the likelihood of approval of its biosimilars," it had not shown its intention and preparedness to enter the U.S. market and had not adequately pleaded antitrust standing. SA6-7.

As a second and independent basis for its decision, the district court also held that "the foreign locus" of Biocad's claims meant they were barred by the FTAIA and other statutory limitations. SA7. As to Biocad's Sherman Act claims, the court recognized that the FTAIA precludes such claims if they involve foreign commerce, unless a statutory exception applies. SA9.

The court first considered Biocad's argument that its claims fall within the so-called "Import Exclusion," which makes the U.S. antitrust laws applicable to a defendant's conduct "involving import trade or import commerce." SA9-12. The district court concluded that the Import Exclusion "require[s] a close connection between a defendant's alleged conduct and the import trade or import commerce at issue." SA10. Biocad, however, had alleged only "that Defendants' conduct has hampered its *anticipated* participation in *future* import commerce." *Id.* Moreover, "Defendants' alleged conduct was targeted at the domestic Russian pharmaceutical market, not a U.S. import market," rendering any connection between the Russian

conduct and the United States "too attenuated for Defendants' acts to be considered 'directed at' a U.S. import market." SA10-11).

The district court could have stopped there, for the Import Exclusion was the only basis Biocad offered for avoiding the FTAIA's bar. Indeed, Biocad affirmatively disclaimed its reliance on the FTAIA's other exception—the "Domestic Effects Exception" in 15 U.S.C. §6a(1)(A) and (2). Nonetheless, the district court briefly addressed that exception, too. The court explained that, as it understood Biocad's theory, "conduct in Russia harmed [Biocad] in Russia, which in turn prevented [Biocad] from entering the U.S. market, which in turn will have the eventual domestic effect of driving up the price of the Drugs in the United States." SA12. Under this Court's decision in *Lotes Co. v. Hon Hai Precision Industry Co.*, 753 F.3d 395 (2d Cir. 2014), however, this "attenuated chain of causation is insufficient to establish a 'direct, substantial, and reasonably foreseeable effect' under the FTAIA." SA12. Likewise, the court held that Biocad's "alleged injuries flow from Defendants' allegedly anticompetitive foreign conduct, not the domestic effect of that conduct." SA12-13. The court concluded that, under *Lotes*, Biocad's failure to show that its injury flows from a domestic anticompetitive effect bars its claims. *Id.* The district court dismissed Biocad's Clayton Act, Robinson-Patman Act, and Donnelly Act claims for similar reasons. SA7-9, 13.

The court concluded by denying Biocad leave to further amend its complaint. SA13-15. It noted that Biocad's Amended Complaint had failed to correct the deficiencies with its original pleading, "[n]otwithstanding" that Biocad had "the benefit of Defendants' pre-motion letter[s] and an extensive colloquy with the Court at the pre-motion conference, in which these very deficiencies were discussed." SA14. The district court never reached Defendants' remaining arguments.[3]

On appeal, Biocad has abandoned its claims under the Robinson-Patman Act and asserts that it is no longer relying on the Clayton Act as an independent source of substantive rights. Biocad Br. 28 n.7. In effect, that leaves only Biocad's Sherman Act claims (and its Donnelly Act claims, which it acknowledges rise or fall with its Sherman Act claims, *see id*. at 54).

STANDARD OF REVIEW

This Court reviews *de novo* a district court's grant of a motion to dismiss. *IBEW Local Union No. 58 Pension Tr. Fund & Annuity Fund v. Royal Bank of Scotland Grp., PLC*, 783 F.3d 383, 389 (2d Cir. 2015). In doing so, the Court need not accept conclusory allegations or unreasonable inferences. *Cantor Fitzgerald Inc. v. Lutnick*, 313 F.3d 704, 709 (2d Cir. 2002).

[3] R-Pharm, a Russian parent company with no presence in the United States, whose small U.S. subsidiary has absolutely no connection to Biocad's claims—and which has no financial or other interest in the Drugs in the United States—moved to dismiss Biocad's claims against it for lack of personal jurisdiction and improper service of process. A70. The district court did not rule on these grounds, but R-Pharm hereby fully preserves all such arguments.

SUMMARY OF ARGUMENT

The overarching problem with Biocad's claims in this case is that they center on alleged conduct by *foreign* companies *in Russia*. Unwilling or unable to pursue remedies under Russian law, Biocad is desperate to shoehorn its claims into U.S. antitrust law, where it can seek treble damages and an injunction that it hopes will allow it to win more business—and charge higher prices—in Russia. But American antitrust law is not designed to police alleged misconduct among foreign companies in foreign countries. As a result, Biocad's complaint runs headlong into two pillars of U.S. antitrust law—the antitrust standing doctrine and the FTAIA—that independently bar its extraterritorial claims. The district court correctly dismissed the Amended Complaint, and this Court should affirm.

I. The antitrust standing doctrine provides that a plaintiff can pursue claims under the antitrust laws only if it has suffered the specific sorts of injury that the antitrust laws are designed to prevent. Here, all of the concrete harm that Biocad describes in its Amended Complaint is harm *in Russia*. But as even Biocad acknowledges, the U.S. antitrust laws are not designed to prevent such harm.

Accordingly, Biocad pins its hopes for antitrust standing on the speculative injury it claims it will eventually suffer through exclusion from the U.S. pharmaceuticals market. Courts have consistently recognized that a plaintiff who claims such exclusion as the basis for antitrust standing must plausibly allege that,

but for the defendants' misconduct, the plaintiff's entry into the U.S. market was *probable*. Given the many natural barriers to entry into the U.S. pharmaceuticals market posed by FDA regulation, pharmacological uncertainty, and other perfectly legal sources, that is a high bar to clear—and Biocad falls well short. Apart from its bare claim that "FDA approval is probable," Biocad offers no specific facts from which to infer that it would receive approval to sell the Drugs in the United States. Indeed, it does not allege that it has even *begun* the FDA-approval process. Under any reasonable application of the antitrust standing doctrine, the district court's conclusion that Biocad's allegations were insufficient is clearly correct.

II. The Russian focus of Biocad's complaint is also dispositive under the FTAIA. Congress enacted the FTAIA to ensure that plaintiffs cannot draft the American courts into the role of global antitrust cop, regulating supposedly anticompetitive conduct by foreign companies in foreign markets. In order to bring a claim under the U.S. antitrust laws based on foreign conduct, therefore, a plaintiff must show either that (1) the conduct at issue *itself* involves import commerce (the "Import Exclusion"), or (2) the conduct has direct, substantial, and reasonably foreseeable effects on domestic or import commerce, and that those effects caused the plaintiff's injury (the "Domestic Effects Exception").

Neither exception applies. The conduct that allegedly injured Biocad occurred entirely in Russia, acting on Russian sales to Russian customers by a

Russian company. Biocad's suggestion that, but for its Russian injuries, it might eventually have started an import business to the United States years later is insufficient to establish that the conduct at issue here actually involved import commerce. The Import Exclusion therefore does not save Biocad's claims.

Nor has Biocad identified the direct and substantial link between overseas conduct and U.S. commerce that the Domestic Effects Exception requires. The connection between its reduced profits in the Russian market and its investment decisions years later in the American market is far too attenuated and indirect to support its claim. Moreover, the anticompetitive effects that Biocad claims will eventually be felt in the U.S. market—higher prices for the Drugs—would obviously not cause Biocad's injuries. They accordingly do not "give[] rise" to Biocad's claims, as the FTAIA and this Court's decision in *Lotes* require. 15 U.S.C. §6a(2).

The antitrust standing doctrine and the FTAIA offer separate and independent grounds for rejecting Biocad's claims but they illuminate the same underlying problem: Biocad's case is all about Russia, not the United States. The district court recognized that basic truth, and its decision should be affirmed.

ARGUMENT

POINT I

BIOCAD HAS NOT PLEADED ANTITRUST STANDING BECAUSE IT HAS NOT PROPERLY ALLEGED ANY INJURY SUFFERED IN THE UNITED STATES

To plead antitrust standing, "a plaintiff must show (1) an injury-in-fact; (2) that has been caused by the [alleged] violation; and (3) that is the type of injury contemplated by the [relevant antitrust] statute." *Blue Tree Hotels Inv. (Can.), Ltd. v. Starwood Hotels & Resorts Worldwide, Inc.*, 369 F.3d 212, 220 (2d Cir. 2004). Because U.S. law does not provide a remedy for every anticompetitive harm anywhere in the world, the last of the three standing requirements requires Biocad to allege an injury *in a U.S. market*. As courts have repeatedly held, injuries that "occurred exclusively in foreign markets" "are not of the type Congress intended to prevent" through the antitrust laws. *Turicentro, S.A. v. Am. Airlines Inc.*, 303 F.3d 293, 307 (3d Cir. 2002), *overruled in irrelevant part by Animal Sci. Prods., Inc. v. China Minmetals Corp.*, 654 F.3d 462 (3d Cir. 2011); *see* SA5 n.5.[4] Biocad must therefore allege that it suffered anticompetitive injury in the United States.

Biocad cannot satisfy that requirement here. Biocad does not claim that it is now participating—or ever participated—in the U.S. pharmaceuticals market, let

[4] *See also, e.g., Am. Ad Mgmt., Inc. v. Gen. Tel. Co. of Cal.*, 190 F.3d 1051, 1057 (9th Cir. 1999); *de Atucha v. Commodity Exch., Inc.*, 608 F. Supp. 510, 518 (S.D.N.Y. 1985); *In re Intel Corp. Microprocessor Antitrust Litig.*, 452 F. Supp. 2d 555, 563 (D. Del. 2006).

alone in the U.S. market for the Drugs. And Biocad has not plausibly alleged that it intended and was prepared to enter the U.S. market for the Drugs. Biocad therefore lacks standing to bring this extraterritorial claim.

A. To Establish a U.S.-Based Injury-in-Fact, Biocad Must Allege That FDA Approval of Its Drugs Was "Probable"

In attempting to establish that it suffered an injury in the United States, Biocad argues that, but for Defendants' conduct, it would have earned more profits in Russia and would have used those profits to enter the American market for the Drugs. Biocad Br. 32. But as Biocad concedes, to establish antitrust standing to bring a claim for exclusion from the U.S. market for the Drugs, it must plead "facts showing an intention and preparedness to engage in business" in that market. *Id.* at 34; *see Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 806-07 (D.C. Cir. 2001). As the district court correctly held, to establish "intention and preparedness" "[i]n the context of claims involving entrance into [a] U.S. pharmaceutical market," courts "require a plaintiff to allege that FDA approval of the potential drug is at least 'probable.'" SA5; *see, e.g.*, *Andrx*, 256 F.3d at 808; *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., Inc.*, No. Civ.A 03-232, 2004 WL 1427136, at *6 (E.D. Pa. June 21, 2004).

This probable-approval requirement reflects the reality that FDA approval is a prerequisite before any biological product can be sold in the United States. *See*

42 U.S.C. §262(a). Without the likelihood of such approval, a potential participant is simply not "prepared" to enter the U.S. market.

To receive FDA approval for biological products such as the Drugs, an applicant must demonstrate, "based upon data derived from" analytical studies, animal studies, and clinical studies, that "the biological product is biosimilar to a reference product." *Id.* §262(k)(2)(A)(i)(I). The applicant must also establish that the biosimilar relies on the same "mechanisms of action" and has the same "conditions of use" and "strength" as the reference product. *Id.* §262(k)(2)(A)(i)(II)-(IV). And it must show that "the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent." *Id.* §262(k)(2)(A)(i)(V).

Biocad recognizes that the process of bringing a biosimilar to market "poses significant challenges for developers of biosimilars." Biocad Br. 9. Indeed, Biocad quotes the FDA as saying that developing a biosimilar capable of FDA approval is more difficult than producing generic drugs. *Id.*[5] Other courts have recognized that

[5] The same source cited by Biocad explains that

> [t]he FDA rigorously and thoroughly evaluates a biologic's safety and effectiveness before granting it approval. . . . FDA experts must conclude, among other things, that there are no clinically meaningful differences between the biosimilar and its reference product—the already approved biologic—in terms of safety, purity and

obtaining FDA approval in the context of generics is a "significant hurdle[]" to entering the U.S. market. *Kos Pharm., Inc. v. Barr Labs., Inc.*, 242 F. Supp. 2d 311, 318 (S.D.N.Y. 2003); *see also, e.g.*, *In re Omeprazole Patent Litig.*, 490 F. Supp. 2d 381, 509 (S.D.N.Y. 2007) (noting the uncertainty in obtaining FDA approval for generics), *aff'd*, 281 F. App'x 974 (Fed. Cir. 2008).

Because no party can introduce a drug into the U.S. market without securing FDA approval, no party can demonstrate "preparedness" to enter that market unless it alleges an actionable plan to file an FDA application, fulfill the arduous requirements for approval, and receive that approval in the foreseeable future. For that reason, courts around the country have held that FDA approval is required to plead antitrust standing when a plaintiff's allegations rest on exclusion from a U.S. pharmaceuticals market. *See, e.g.*, *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1368-69 (S.D. Fla. 2004) ("[W]ithout tentative FDA approval, a generic manufacturer cannot enter the marketplace, and thus there is no antitrust injury"); *Bristol-Myers Squibb Co. v. Copley Pharm., Inc.*, 144 F. Supp. 2d 21, 24-

---

> potency. This thorough evaluation helps to ensure that all biosimilar products . . . meet the Agency's high standards for approval.

FDA, *Biosimilars: More Treatment Choices and Innovation* (updated Oct. 23, 2017), https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm436399.htm (cited in Biocad Br. 9 n.1).

25 (D. Mass. 2000) (counterclaimant had not suffered antitrust injury when it "ha[d] not received the tentative regulatory approval required for market entry").[6]

B. Biocad Failed to Properly Allege Antitrust Injury in a U.S. Market Under Any Standard

Biocad's failure to allege any facts indicating that FDA approval is likely defeats its antitrust standing. Even after the district court specifically questioned Biocad about this shortcoming, Biocad's Amended Complaint still alleged no interaction whatsoever between itself and the FDA: Biocad does not claim that it has received approval to market *any* drug, filed an application to market *any* drug, or even notified the FDA that it intends to seek approval for *any* drug—let alone any of the three Drugs. This stands in stark contrast to the efforts of others who, based on public information, are demonstrating an "intention and preparedness" to enter these precise markets.[7] In fact, based on Biocad's allegations, FDA approval is not only

[6] Biocad grudgingly admits that probable FDA approval is "potentially a 'significant factor'" in establishing antitrust injury. Biocad Br. 36. That badly understates the required showing. But even under Biocad's test, the failure to plausibly allege FDA approval dooms its claims.

[7] For example, the FDA recently declined to approve Pfizer's proposed *trastuzumab* biosimilar, "highlight[ing] the need for additional technical information" about Pfizer's formulation of the Drug. Pfizer Inc., *Pfizer Provides Update on Proposed Trastuzumab Biosimilar* (Apr. 23, 2018), https://www.pfizer.com/news/press-release/press-release-detail/pfizer_provides_update_on_proposed_trastuzumab_biosimilar. The FDA has also declined Celltrion's applications for *rituximab* and *trastuzumab* biosimilars, *see* Celltrion, *Celltrion's Statement on CRLs from the U.S. FDA for Rituximab and Trastuzumab Biosimilar* (Apr. 6, 2018), https://www.celltrion.com/en/pr/newsDetail.do?seq=482, as well as Sandoz's application for a *rituximab* biosimilar, *see* Sandoz, *Sandoz Receives Complete Response Letter from the US FDA for Proposed Biosimilar Rituximab* (May 2, 2018), https://www.sandoz.com/news/media-releases/sandoz-receives-complete-response-letter-us-fda-proposed-biosimilar-rituximab. The Court may take judicial notice of this information because it is publicly available and "can be accurately and readily determined from

improbable at this juncture; it is *impossible*, given that Biocad has not even taken the minimal first steps necessary to start preparing an FDA application (which it could have submitted as far back as 2010, *see* 42 U.S.C. §262(k)(7)(B)). That cannot be sufficient to demonstrate the requisite intent and preparedness to sell the Drugs here. *See Andrx*, 256 F.3d at 807-08 (dismissing antitrust claim where plaintiff failed to adequately allege "that FDA approval was probable"); *Brotech*, 2004 WL 1427136, at *6 (dismissing antitrust claim where plaintiff had filed an FDA application but had not "allege[d] facts establishing . . . that FDA approval of said products is probable").

Instead of pleading facts that could plausibly establish antitrust standing, Biocad simply alleges, in conclusory fashion, that "FDA approval is probable." A120 (¶22); *see* Biocad Br. 36-37. That bare assertion should be given no weight if the intent-and-preparedness requirement is to have any meaning. Biocad's Amended Complaint contains no allegations about the FDA-approval process: how long it will take; how much progress (if any) Biocad has made in preparing an application; when it plans to submit any such application; what sorts of analytical, animal, or clinical trials it will need to perform; whether it has the capability of performing such trials; or how the Drugs will fare in those trials. If a party can

---

sources whose accuracy cannot reasonably be questioned." *See* Fed. R. Evid. 201(b); *see also Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 59-60 (2d Cir. 2016) (taking judicial notice of FDA guidance); *Island Software & Comput. Serv., Inc. v. Microsoft Corp.*, 413 F.3d 257, 261 (2d Cir. 2001) (taking judicial notice of federal copyright registrations).

overcome all of these pleading failures just by asserting that "FDA approval is probable," then the intent-and-preparedness standard is nothing more than a pleading formality. *See Pungitore v. Barbera*, 506 F. App'x 40, 43 n.1 (2d Cir. 2012) ("[G]iven the lack of any alleged facts supporting this conclusory assertion, we need not afford it the presumption of truth under *Iqbal* and *Twombly*."); *Brotech*, 2004 WL 1427136, at *6 (dismissing complaint because it "does not allege *facts* establishing . . . intent and preparedness to enter the market . . . or that FDA approval of said products is probable" (emphasis added)).[8]

Biocad spends pages of its Amended Complaint and brief emphasizing that it has created an FDA-compliant facility. A115, 132-34 (¶¶4, 6-7, 74-78); Biocad Br. 14-16, 35, 37, 42. But, as the district court recognized, SA6, Biocad *never* alleges any factual basis for crediting that assertion, and *never* alleges that the facility is capable of producing any of the Drugs—a failure that Biocad's opening brief ignores. And although Biocad claims that it has entered into agreements to license and distribute the Drugs in countries such as Indonesia, Turkey, and Armenia, *see* A130-31 (¶¶66-67), it nowhere alleges that it has obtained regulatory approvals to

[8] Contrary to Biocad's argument, the district court did not require Biocad to "provid[e] a checklist of details about the FDA approval process." Biocad Br. 41. Biocad pleaded *no* facts at all suggesting that it could obtain FDA approval for the Drugs. SA6. A straightforward application of the intent-and-preparedness standard thus requires dismissal of its claims. *See Solinger v. A&M Records, Inc.*, 586 F.2d 1304, 1309-10 (9th Cir. 1978) (to assess whether a party has met the intent-and-preparedness standard, courts "look[] for [v]arying combinations" of multiple elements, including "[a]ffirmative action on the part of plaintiff to engage in the proposed business").

begin distributing the Drugs there or that the regulatory approval processes in those countries are comparable to FDA procedures. *See Hack v. President & Fellows of Yale College*, 237 F.3d 81, 91 (2d Cir. 2000) (Pooler, C.J., concurring) ("We cannot read into [plaintiffs'] complaint the missing allegations crucial to [their] claim . . . , [particularly where] plaintiffs . . . filed one amended complaint and did not move to further amend when confronted with defendants' motion.").

Biocad's remaining allegations—that it has leased space in Boston, developed cost estimates for entering the U.S. market, and entered consulting and service agreements in preparation for U.S. market entry, A131-32, A134-35 (¶¶70-73, 79); *see* Biocad Br. 36-37—cannot cure those failings. None of those assertions demonstrates Biocad's ability to actually bring *bevacizumab*, *trastuzumab*, and *rituximab* to market in the United States. Despite acknowledging that the only relevant market is the U.S. market for those Drugs, A136 (Section VIII, n.19), Biocad's allegations essentially amount to generalized assertions that it is attempting to expand its business into other drugs (not necessarily the Drugs), *see, e.g.*, A128-29 (¶58) (noting that Biocad has developed biosimilar monoclonal antibodies apart from the Drugs). Given the drug-specific nature of the FDA-approval process, that sort of generic allegation about Biocad's hopes for future expansion is plainly insufficient.

In any event, Biocad's barebones allegation that it has taken certain minimal steps cannot paper over the gaping hole in its pleading: Even with these minor efforts in place, Biocad has pointed to no facts indicating that it is remotely prepared to overcome the hurdle of FDA regulatory approval. No court has ever held that a pharmaceutical company is prepared to enter the U.S. market in circumstances where (in the absence of anticompetitive conduct preventing it from submitting an FDA application) that company has not shown *any* efforts to actually seek FDA approval. This Court should not be the first.

Biocad attacks the district court's ruling by pointing to several cases in which, it claims, courts have "found sufficient intent and preparedness" for plaintiffs who were "similarly situated [to] or less-prepared" than Biocad itself. Biocad Br. 37-38. But in each of those cases, the plaintiffs established their intent and preparedness by pleading substantially more facts about the timing, mechanics, and likelihood of FDA approval than Biocad has pleaded here.

For instance, in *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 274 F. Supp. 2d 937, 944 (N.D. Ill. 2003), plaintiffs alleged that they were prepared to seek FDA approval for a generic version of a brand-name drug but that the defendant's anticompetitive conduct actively blocked them from doing so. Specifically, plaintiffs alleged that the defendant obtained several patents by fraudulent means, so plaintiffs could not make the certification required by the FDA-approval process that

their product would not infringe any applicable patents. *Id.* at 941-42. For that reason, plaintiffs were unable to apply for FDA approval. *See id.* at 944. Likewise, in *In re Metoprolol Succinate Direct Purchaser Antitrust Litigation*, Nos. 06-52 (GMS), 06-71 (GMS), 2010 WL 1485328, at *3 (D. Del. Apr. 13, 2010), plaintiffs alleged that the defendant obtained a monopoly on the sale of certain prescription drugs by "knowingly withh[olding] relevant information from the [Patent and Trademark Office] in order to fraudulently obtain . . . patents." The defendant also purportedly "fil[ed] sham patent-infringement lawsuits against generic manufacturers," which "trigger[ed] an automatic thirty month stay on final FDA approval of competitive generic drugs." *Id.* at *4.

Unlike the plaintiffs in those cases, Biocad has made no allegations suggesting that Defendants' conduct constituted regulatory roadblocks or otherwise impeded its ability to file an FDA-approval application (or affected its likelihood of obtaining approval). To the contrary, Biocad has not alleged that Defendants directed any actions at all toward the FDA. Instead, it has pointed only to an opaque chain of financial consequences that allegedly denied it capital needed to enter the U.S. market. That is not remotely analogous to *Xechem* and *Metoprolol*.

Biocad's other cases are equally unavailing. In each of them, the plaintiffs had offered detailed allegations about the probability of FDA approval that are missing from Biocad's Amended Complaint. *See Tawfilis v. Allergan, Inc.*, 157 F.

Supp. 3d 853, 857-58 (C.D. Cal. 2015) (plaintiffs provided a detailed description of the FDA-approval process and alleged that their product "could have been approved for sale in the U.S. in less than two years following its obtaining regulatory approval abroad"); *Retrophin, Inc. v. Questcor Pharm., Inc.*, 41 F. Supp. 3d 906, 915 (C.D. Cal. 2014) (plaintiff alleged that it had "prepar[ed] a plan to obtain regulatory approvals" and had established "an apparatus to conduct clinical trials to obtain FDA approval" for the relevant products); *Amgen, Inc. v. F. Hoffmann-La Roche Ltd.*, 480 F. Supp. 2d 462, 468 (D. Mass. 2007) (counterclaim-defendant conceded, in its own allegations, that "FDA approval . . . is imminent" and that the counterclaimant "is making meaningful preparations" to market the relevant drug); *BNLfood Invs. Ltd. SARL v. Martek Biosciences Corp.*, Civil No. WDQ-11-0446, 2011 WL 6439451, at *4 (D. Md. Dec. 14, 2011) (plaintiff notified the FDA "that it intended to market [its product] for use in food" and "pursu[ed] . . . FDA review").

Biocad's Amended Complaint is missing precisely the allegations that were necessary to sustain the complaints in each of these cases—allegations indicating that FDA approval for the product at issue was imminent or that the parties had taken meaningful, concrete steps in pursuit of it. Biocad has not alleged that it has ever been in contact with the FDA about *anything*.

Biocad cites no case supporting its theory that it can state a claim by alleging that interference with its foreign operations deprived it of funds that it may have used

to further its ambitions to one day sell the Drugs in the United States. At bottom, Biocad's assertion that the district court did not draw every possible inference in its favor, Biocad Br. 39-41—and, indeed, its argument as a whole—fundamentally misunderstands the *Iqbal* and *Twombly* pleading standards. Although courts must "accept as true all factual allegations and draw from them all reasonable inferences," they "are not required to credit conclusory allegations or legal conclusions couched as factual . . . allegations." *Nielsen v. Rabin*, 746 F.3d 58, 62 (2d Cir. 2014). Biocad attempts to pin an entire theory of antitrust standing on four words: "FDA approval is probable." But that conclusory and hollow assertion is not enough. Biocad has utterly failed to allege that Defendants' conduct has caused (or will cause) it to suffer any harm in the U.S. market. This Court should affirm the dismissal of Biocad's Amended Complaint because it has not pleaded antitrust standing.

POINT II

THE SHERMAN ACT DOES NOT APPLY TO THE EXTRATERRITORIAL CONDUCT ALLEGED IN BIOCAD'S COMPLAINT

Just as Biocad cannot establish antitrust standing based on an alleged extraterritorial injury, it cannot establish that the antitrust laws reach such injuries at all. The allegedly anticompetitive conduct was undertaken by *foreign* defendants against a *foreign* plaintiff in *Russia*—all as part of a conspiracy, Biocad claims, to undermine Biocad's Russian operations so that years later it could not afford to

expand its operations into the U.S. market. But Congress enacted the FTAIA specifically to ensure that the American antitrust laws would not reach such obviously extraterritorial conduct. Indeed, Biocad's claims here would, absurdly, require a U.S. court sitting thousands of miles away to pass judgment on whether the pricing, packaging, and related sales conduct by a Russian company (R-Pharm) selling drugs in Russia constituted lawful competition under the standards of the U.S. antitrust laws.

Biocad argues that, FTAIA notwithstanding, U.S. courts can regulate foreign business practices that are alleged to have deprived a company of foreign revenues that the company could have used to fund its entry into the U.S. market. But allowing U.S. judicial interference in foreign markets based on such an extraordinarily attenuated chain of causation is plainly not what Congress intended. Biocad's failure to satisfy the requirements of the FTAIA provides an independent basis for dismissing the complaint.[9]

In the FTAIA, Congress expressly excluded certain conduct from the scope of the American antitrust laws. As relevant here, the FTAIA provides that

[9] Because Biocad's claim under the Clayton Act depends on establishing anticompetitive conduct prohibited by U.S. antitrust laws, to the extent Biocad's Sherman Act claims are barred by the FTAIA, its Clayton Act claim would also be barred. *See* 15 U.S.C. §15. Likewise, New York's Donnelly Act reaches no further than the Sherman Act, *see Global Reins. Corp.-U.S. Branch v. Equitas Ltd.*, 18 N.Y.3d 722, 735 (2012), and so the FTAIA also bars Biocad's claim under that statute.

> [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.

In *Lotes Co. v. Hon Hai Precision Industry Co.*, 753 F.3d 395 (2d Cir. 2014), this Court offered a succinct explanation of how the FTAIA operates. First, the opening "chapeau" paragraph "'initially lays down a general rule placing *all* (nonimport) activity involving foreign commerce outside the Sherman Act's reach.'" *Id.* at 404 (quoting *F. Hoffmann-La Roche Ltd. v. Empagran S.A.*, 542 U.S. 155, 162 (2004)). The chapeau creates an exception to this general rule for "import trade or import commerce," 15 U.S.C. §6a—the "Import Exclusion." That exception applies to "import transactions" and "import restraints," but not to "wholly foreign transactions." H.R. Rep. No. 97-686, at 9-10 (1982).

Next, Sections 6a(1) and (2) then "bring[] . . . back within the Sherman Act's reach" conduct that meets two express requirements: "(1) the foreign conduct has a

'direct, substantial, and reasonably foreseeable effect' on U.S. domestic [or] import . . . commerce, [15 U.S.C] § 6a(1); and (2) that effect 'gives rise to a claim under' the Sherman Act, [15 U.S.C.] § 6a(2)." *Lotes*, 753 F.3d at 404, 413-14 (quoting FTAIA and *Empagran*, 542 U.S. at 162). The purpose of this "Domestic Effects Exception" is to ensure that the Sherman Act covers only extraterritorial conduct with a close nexus to U.S. commerce.

Here, the conduct at issue indisputably "involv[es] trade or commerce . . . with foreign nations." 15 U.S.C. §6a. Biocad's claim turns entirely on harms allegedly inflicted on Biocad (a *Russian* company), by Roche (a *Swiss* company) and R-Pharm (a *Russian* company), in *Russia*. This case is therefore presumptively subject to the FTAIA's exclusion of extraterritorial conduct from the Sherman Act. Biocad's claim is, as this Court said in *Lotes*, "precisely the type of 'independently caused foreign injury' that . . . falls outside of Congress's intent." 753 F.3d at 414 (quoting *Empagran*, 542 U.S. at 173).

To establish otherwise, Biocad must show that the challenged conduct falls within either the Import Exclusion or the Domestic Effects Exception. As the district court recognized, however, these narrow exceptions do not encompass Biocad's foreign allegations. SA9-13. The FTAIA therefore provides an alternative and independent basis for affirming the decision below.

A. The FTAIA's Import Exclusion Does Not Apply to Allegations of Conduct Interfering with Biocad's Domestic Russian Operations

Biocad's lead argument is that its claims fall within the FTAIA's Import Exclusion for "conduct involving . . . import trade or import commerce," 15 U.S.C. §6a, because it has alleged that Defendants' conduct in Russia deprived Biocad's Russian business of capital with an intent to exclude Biocad, years later, from importing its biosimilars into the United States. *See* Biocad Br. 42-49. But the text, history, and policy of the Import Exclusion all establish that it applies only to conduct that itself either *constitutes* or *directly acts upon* import commerce. Biocad's interpretation would convert the Import Exclusion's black-and-white, threshold inquiry about what type of conduct is alleged into an open-ended, future effects-based test that turns on the defendant's alleged scienter. It would also render the Domestic Effects Exception essentially superfluous, subjecting a claim like this one—concerning *foreign* transactions for *foreign* products sold by *foreign* companies to *foreign* consumers in *foreign* markets—to regulation in the U.S. courts, merely because a plaintiff alleges that the defendants hoped that eventually the ripple effects would reach American shores. This Court should reject that implausibly loose reading of the Import Exclusion.

1. *The Import Exclusion Applies Only to Conduct That Itself Constitutes or Directly Acts Upon Import Commerce*

By its terms, the Import Exclusion applies only to "conduct involving . . . import trade or import commerce." 15 U.S.C. §6a. The parties agree that "conduct" refers to the *defendant's* conduct, *see Kruman v. Christie's Int'l PLC*, 284 F.3d 384, 398 (2d Cir. 2002), and it plainly encompasses that defendant's "actions," "behavior," or "way of acting," *see* SA10; *Random House Webster's Unabridged Dictionary* 426 (2d ed. 1997) (*Random House*). There is no dispute that "import trade or import commerce" refers to the movement of goods into the United States from a foreign country. *See, e.g.*, *id.* at 961; *Minn-Chem, Inc. v. Agrium, Inc.*, 683 F.3d 845, 855 (7th Cir. 2012) (en banc). Thus, for the Import Exclusion to apply, Defendants' alleged conduct must be actions "involving" the movement of goods into the United States. It is not.

The ordinary meaning of the term "involving" encompasses "includ[ing] as a necessary circumstance, condition, or consequence," "contain[ing] . . . within itself or its scope," and "requir[ing] as a necessary accompaniment." *Random House* at 1005; *Webster's Third New International Dictionary Unabridged* 1191 (1993). As a matter of plain text, therefore, an antitrust defendant's conduct only *involves* import trade or commerce if the defendant's actions themselves either (1) directly constitute such commerce (in which case the conduct "contains" or "includes" that

commerce), or (2) directly act upon such commerce (in which case the commerce is a "necessary circumstance" of, or "accompaniment" to, such conduct).

The FTAIA's legislative history confirms that the Import Exclusion is narrowly limited to conduct that itself constitutes or directly acts upon import commerce. As the House Report explained, Congress added the Import Exclusion to clarify that, while "wholly foreign transactions as well as export transactions are covered by the [FTAIA]," "import transactions are not." H.R. Rep. No. 97-686, at 10 (1982). Those excluded "import transactions" include only "imports" themselves (*i.e.*, conduct constituting import commerce) and "import restraints" (*i.e.*, conduct directly restraining import commerce). *Id.* at 9-10.

As the Seventh Circuit has noted, Congress had a "pragmatic reason" for excluding import trade from the FTAIA's particular requirements: "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." *Minn-Chem*, 683 F.3d at 854. It is unsurprising, then, that Congress would limit categorical exclusion from the FTAIA to only that conduct with an immediate connection to import commerce, leaving other extraterritorial conduct to be analyzed under the FTAIA's Domestic Effects Exception.

This Court's precedent further confirms that the Import Exclusion applies only to conduct that constitutes or directly acts upon import commerce. In *Lotes*, 753 F.3d at 411, this Court addressed the meaning of the Import Exclusion when interpreting the FTAIA's Domestic Effects Exception, under which a plaintiff must prove that the foreign conduct on which it bases its claims had a "direct, substantial, and reasonably foreseeable effect" on import commerce. 15 U.S.C. §6a(1). The Court recognized that the two provisions must be construed *together*, and so it rejected the defendants' view that the effects necessary to come within the Domestic Effects Exception must follow as an "immediate consequence" of the foreign conduct. *Lotes*, 753 F.3d at 411. The Court explained that requiring such an "immediate consequence" for the Domestic Effects Exception would "all but collapse the FTAIA's domestic effects exception into its separate import exclusion." *Id.* The Court's analysis confirmed that the Import Exclusion requires an "immediate consequence" on U.S. import trade or commerce, while foreign conduct that lacks this "immediate consequence" must satisfy the test established by the Domestic Effects Exception.[10]

[10] In adopting this view, the *Lotes* Court largely agreed with the position urged by the United States as *amicus curiae* that the Import Exclusion does not apply merely because "the challenged conduct proximately causes an *effect* on import commerce," but only "when the challenged conduct *itself* involves import commerce." Br. for the U.S. and Federal Trade Commission as Amici Curiae in Supp. of Defs.-Appellees, *Lotes Co. v. Hon Hai Precision Indus. Co.*, No. 13-2280, 2013 WL 5587239, at *31 (2d Cir. Oct. 7, 2013) (emphases added). In other words, to fall within the Import

This Court also addressed the Import Exclusion in *Kruman v. Christie's International PLC*, 284 F.3d 384 (2d Cir. 2002). There, the Court emphasized that "[t]he relevant inquiry is whether the conduct of the defendants . . . involves import trade or commerce." *Id.* at 395. The Court applied that test by analyzing the nature of the challenged conduct at issue—a price-fixing conspiracy under which rival auction houses agreed on "the prices they charged for their services in foreign auctions." *Id.* It concluded that the Import Exclusion clearly did not apply because the fixed commissions at issue were not "directed at an import market" but rather applied to transactions between foreign sellers and foreign purchasers. *Id.* at 395-96.

Notably, the *Kruman* Court explained that it made no difference that "the goods purchased in those auctions may ultimately have been imported by individuals in the United States." *Id.* The Import Exclusion simply did not apply, because the alleged conduct—price-fixing in foreign auctions—was "not the trade in and subsequent movement of the goods that were purchased and sold [at those auctions]." *Id.* The Court thus recognized that what matters is whether the defendant's conduct *itself* constitutes or acts upon import commerce, not any eventual downstream effects on such commerce.

Exclusion, "there can be no subsequent sales or other steps" between the alleged conduct and a product's sale or delivery "into the United States." *Id.* at *30.

2. *The Import Exclusion Does Not Turn on the Defendant's Subjective Intent*

In Biocad's view, there is no requirement that the conduct at issue constitute or directly act upon import commerce. Instead, Biocad claims that the Import Exclusion applies whenever the conduct at issue is "'directed at an import market' . . . in the sense of being directed to produce an effect on such a market." Biocad Br. 44. Under Biocad's test, the "causal nexus" necessary to satisfy the Import Exclusion depends merely on the defendant's subjective "intentions." *Id.* at 46-47. Unsurprisingly, no court has adopted that construction—and this Court has rejected it. *See Lotes*, 753 F.3d at 411.

It is no accident that Biocad's brief never meaningfully attempts to reconcile its intent-based test with the text of the Import Exclusion. That text is clear that what matters is whether the defendant's conduct itself "involv[es] . . . import commerce"—not whether the defendant undertakes that conduct with a particular subjective motivation or state of mind. Nothing in the FTAIA's language points to subjective intent as the analytical lodestar.

Quite the contrary: In ordinary parlance, it is wrong to say that a person's conduct "involves" a thing merely because the person hopes that her conduct will eventually affect that thing. A child may clean her plate in the hope that she will get dessert—but that hardly means eating broccoli is "conduct involving ice cream." And legal usage is no different: A defendant who files a false tax return surely has

not committed an "offense involv[ing] a . . . semiautomatic firearm," U.S.S.G. Guidelines Manual §2k2.1(a)(1), just because he intends to use his undeserved refund to purchase a new gun.

Biocad's atextual interpretation of the Import Exclusion also renders a significant portion of the FTAIA superfluous. The FTAIA contemplates that certain conduct will initially be *excluded* from the Sherman Act by Section 6a's chapeau language, but then *brought back* into the Sherman Act by the Domestic Effects Exception because the conduct has a "direct, substantial, and reasonably foreseeable effect . . . on import trade or import commerce." *See Empagran*, 542 U.S. at 162. Biocad's broad interpretation of the Import Exclusion, however, would make that category of conduct a null set: Any conduct having a direct, substantial, and reasonably foreseeable effect on import trade or import commerce would *already be* excluded from the FTAIA (and thus included in the Sherman Act). Biocad thus commits the very error this Court warned about in *Lotes*, "collaps[ing] the FTAIA's domestic effects exception into its separate import exclusion." 753 F.3d at 411.[11]

The Third Circuit has condemned such expansive conceptions of the Import Exclusion as well. It has explained that "the FTAIA differentiates between conduct

[11] The Government made the same point in its *amicus* brief in *Lotes*: The Import Exclusion and the Domestic Effects Exception should be interpreted to "fit comfortably together," such that "the former applies when the challenged conduct *itself involves* import commerce, while the latter applies when the challenged conduct *proximately causes an effect on* import commerce." U.S. *Lotes* Amicus, 2013 WL 5587239, at *31 (emphases added).

that 'involves' [import] commerce [in the Import Exclusion], and conduct that 'directly, substantially, and foreseeably' affects such commerce [in the Domestic Effects Exception]. To give the latter provision meaning, the former must be given a relatively strict construction." *Carpet Grp. Int'l v. Oriental Rug Importers Assoc., Inc.*, 227 F.3d 62, 72 (3d Cir. 2000), *overruled in irrelevant part by Animal Sci. Prods.*, 654 F.3d 462; *see also Minn-Chem*, 683 F.3d at 857 (similar).

In the face of all this, Biocad seeks support for its intent-based effects test from this Court's decision in *Kruman*, which it claims announced a general rule that "the FTAIA leaves the Sherman Act unaltered when 'conduct by the defendants . . . was directed at an import market.'" Biocad Br. 43; *see also id.* at 42-44, 46-47. But Biocad's quoted language from *Kruman*—which it both takes out of context and misunderstands—does not support its broad, intent-based approach.

As discussed above, *Kruman* refused to apply the Import Exclusion because the defendant/auction-house's price-fixing conduct directly involved the prices charged in foreign auctions. 284 F.3d at 395. The Court explained that this conduct "was [not] *directed at an import market*" because "'[t]he commerce that is the focus of this case is . . . not the trade in and subsequent movement of the goods that were purchased and sold.'" *Id.* (emphasis added). Biocad interprets the "directed at an import market" language as establishing an affirmative rule that the Import Exclusion applies whenever the conduct was "directed to produce an effect on such

a market." Biocad Br. 44. But that is not what the *Kruman* Court said, nor is it consistent with what the Court did: To determine whether the conduct was "directed at an import market," the Court evaluated the nature of the specific conduct at issue, not the defendant's subjective intent in undertaking the conduct. Specifically, the Court emphasized that the conduct was "directed at" foreign commerce—not at import commerce—because that conduct consisted of fixing the prices charged in "foreign auctions." 284 F.3d at 395. Nothing in *Kruman* addressed subjective intent or supports Biocad's view that the exact same price-fixing of foreign transactions would have "involv[ed] import commerce" if the defendants had subjectively hoped to influence the re-sale of the auctioned goods into the United States.[12]

The Third Circuit's decision in *Carpet Group*, on which Biocad also relies, presents a helpful contrast. There, the plaintiffs' business involved facilitating import transactions between foreign manufacturers and American rug retailers. *See* 227 F.3d at 70. The plaintiffs accused the defendants of threatening to retaliate against their business partners for participating in the rug imports plaintiffs had arranged. *See id.* at 70, 72. The Third Circuit held that such conduct—specifically penalizing

[12] For similar reasons, Biocad is wrong to assert that *Kruman* establishes a test centering on "whether 'the object of the conspiracy was . . . [an] import market.'" Biocad Br. 47. In context, the quoted language merely states that the defendant's conduct directly involved foreign auctions rather than import commerce: "While some of the goods purchased in those auctions may ultimately have been imported by individuals in the United States, the *object of the conspiracy* was the price that the defendants charged for their auction services, not any import market for those goods." *Kruman*, 284 F.3d at 395-96 (emphasis added).

businesses for participating in import transactions—"directly involved both import and domestic commerce" and triggered the Import Exclusion. *Id.* at 72. That is worlds away from Biocad's theory of the Import Exclusion, under which it is enough for a plaintiff simply to plead that defendants hoped their conduct involving foreign transactions would eventually produce effects in the United States.

3. *The Conduct Alleged Here Does Not Involve Import Commerce*

Under the test laid out above, Biocad's claims do not come within the Import Exclusion because they involve "wholly foreign transactions," between foreign companies, in a foreign country. H.R. Rep. No. 97-686, at 10.

Biocad alleges that Defendants conspired to lower the prices of their drugs in Russia and take other actions in Russia to encourage the use of their drugs over Biocad's drugs in the Russian market. SA2-3. But as the district court explained, those "allegations indicate that Defendants' alleged conduct was targeted at the domestic Russian pharmaceutical market, not a U.S. import market." SA10-11. When the allegations finally turn to Defendants' supposedly unlawful conduct (starting at paragraph 117 of the Amended Complaint), they consist entirely of accusations about attempts to monopolize the *Russian* market. Biocad claims that, in response to its introduction in Russia of biosimilar competitors to the Drugs, Defendants worked with their distributor to lower the prices for the Drugs in the Russian market. *See* A146-48 (¶¶125-27). And it alleges that, starting in 2010, four

years before Biocad even introduced its first biosimilar of one of the Drugs in the Russian market, Defendants were attempting to influence "doctors, pharmacies, hospitals and other healthcare professionals, *employed by Russian government*" to purchase the Drugs. *See* A150 (¶¶136-39). All those allegations, however, deal with Defendants' sales of the Drugs in Russia.[13]

None of the conduct identified by Biocad's Amended Complaint was itself import commerce. Nor did the alleged conduct act directly upon or otherwise have immediate consequences on import commerce: Biocad does not operate in U.S. import commerce. Just "as in *Kruman*, the conduct alleged in the First Amended Complaint was 'directed at' manipulating prices in a foreign country, Russia, and would affect import trade and import commerce into the United States only by a series of indirect and attenuated steps." SA11. Accordingly, the Import Exclusion does not apply.[14]

[13] Biocad also alleges that Defendants increased the prices of the Drugs in the United States, A144-47 (¶¶121-27), but that allegation provides no basis for an antitrust claim because Defendants hold a *lawful* monopoly over the Drugs in the United States by virtue of their patents.

[14] Even if the Import Exclusion did apply, Biocad acknowledges (at 44) that the Sherman Act limits the scope of antitrust liability to extraterritorial acts producing a "substantial intended effect in the United States." *Hartford Fire Ins. Co. v. California*, 509 U.S. 764, 797 n.24 (1993) (relying on *United States v. Aluminum Co. of Am.*, 148 F.2d 416 (2d Cir. 1945) (L. Hand, J.)); *see also Minn-Chem*, 683 F.3d at 855; *Carpet Grp.*, 227 F.3d at 73-75. Both before and after adoption of the FTAIA, Congress, courts, and commentators have understood that test to embody a "*direct* effects" requirement. *See, e.g.*, 4 Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶277 at 363 (2d ed. 2000). As explained further below, Biocad has failed to identify any such direct effects. *See infra* at 47-52.

B. Biocad's Claims Do Not Satisfy the FTAIA's Domestic Effects Test

Below, Biocad affirmatively waived any reliance on the Domestic Effects Exception.[15] Nonetheless, the district court addressed—and rejected—that exception as a basis for allowing this case to proceed. The court held that Biocad could show neither (1) that Defendants' conduct had a "direct, substantial, and reasonably foreseeable effect" on domestic commerce in the form of higher prices, *see* 15 U.S.C. §6a(1)(A); nor (2) that any such effect on domestic prices caused Biocad's injuries, *see id.* §6a(2). SA12-13. That is hardly surprising, given the tenuous causal chain Biocad has had to conjure up in an attempt to connect conduct in the Russian biosimilars market back in 2016 and earlier to effects that even *Biocad* acknowledges have yet to materialize in the United States years later. Both of the district court's holdings on this point were correct, and each provides a sufficient basis for rejecting the applicability of the Domestic Effects Exception.

1. *The Alleged Conduct Does Not Have a "Direct" Anticompetitive Effect on Domestic Commerce*

To come within the Domestic Effects Exception, Biocad must first demonstrate "a direct, substantial, and reasonably foreseeable effect" on U.S. commerce caused by the conduct it alleged. 15 U.S.C. §6a(1)(A). This Court has

[15] SA12 ("Plaintiff does not even argue the [Domestic Effects Exception] point . . . ."); Pl.'s Opp. to Mots. to Dismiss at 22 (arguing that "the relevant inquiry is not the domestic effects exception, but the import exception").

interpreted that statutory provision to require a "reasonably proximate causal nexus" between the overseas conduct and its alleged domestic effects, reflecting "antitrust law's classic aversion to remote injuries." *Lotes*, 753 F.3d at 411. Mere "ripple effect[s]" are not enough. *Latino Quimica-Amtex S.A. v. Akzo Nobel Chems. B.V.*, No. 03-cv-10312, 2005 WL 2207017, at *12 (S.D.N.Y. Sept. 8, 2005) (citation omitted).

Moreover, the domestic "effect" in question must be the type of "*anticompetitive* effect" that is traditionally the focus of antitrust law. H.R. Rep. 97-686, at 11 (1982) (emphasis added)). Anticompetitive effects on commerce typically encompass "increases in price, or decreases in output or quality." *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 238 (2d Cir. 2003). Where an antitrust plaintiff claims "simply that it has been harmed as an individual competitor," without demonstrating "any adverse impact on price, quality, or output" that would establish "a showing of actual adverse effect on competition," the plaintiff has failed to allege the requisite anticompetitive effect on commerce. *Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., Inc.*, 996 F.2d 537, 547 (2d Cir. 1993); *see also Tops Mkts., Inc. v. Quality Mkts., Inc.*, 142 F.3d 90, 96 (2d Cir. 1998); *K.M.B. Warehouse Distribs., Inc. v. Walker Mfg. Co.*, 61 F.3d 123, 128 (2d Cir. 1995).

Here, Biocad alleges that Defendants' conduct in Russia will one day result in domestic anticompetitive effects in the United States, in the form of higher drug

prices charged to American consumers. As the district court explained, Biocad "essentially alleges that Defendants' conduct in Russia harmed [Biocad] in Russia, which in turn prevented [Biocad] from entering the U.S. market, which in turn will have the eventual domestic effect of driving up the price of the Drugs in the United States." SA12; *see also* Biocad Br. 30 ("[p]reventing or delaying Biocad's U.S. market entry will permit Roche to continue to charge monopoly prices—a direct, harmful effect on domestic or import commerce"); *id.* at 50 (identifying "cost to U.S. consumers" as relevant domestic effect).

Any connection between the conduct alleged in the Amended Complaint and higher prices that might one day be charged to American consumers is speculative, remote, and distant. It is undisputed that the allegedly monopolistic conduct alleged in the Amended Complaint in 2016 has produced *no* such effects in the United States to date, because Roche's patent protection for all three Drugs remains in effect. *See* Biocad Br. 50 (conceding that "the effect will not be felt in U.S. markets until Roche's patents expire"). That by itself forecloses Biocad's claim.

Even if Roche's patents had expired by the time of the foreign conduct alleged in the Amended Complaint, that conduct in Russia would only produce anticompetitive effects in the United States through a highly attenuated chain of causation. Such effects would arise only if:

- Biocad actually suffered lost profits in Russia (meaning, for example, that customers did not turn to Biocad to fill contracts after R-Pharm defaulted on deliveries, *see* A167 (¶214)).
- The harm from lost sales in that single country became so severe that Biocad lost its ability to self-fund entry into the United States, even though it claims that it has licensing and distribution contracts for its biosimilars in 46 other countries and has hundreds of millions of dollars in sales outside of Russia, *see* A130-31 (¶¶66-67).
- Biocad was unable to secure funding for its entry into the multi-billion dollar U.S. market from commercial lenders or other sources, despite its alleged position as the "leading manufacturer of biosimilar mAbs," "leading . . . direct competitor of Roche," and "biggest threat to Roche's star oncology drugs." A129-30 (¶63).
- Biocad's inability to self-fund, rather than some other cause (such as lack of experience in Western pharmaceutical regulatory regimes), prevented it from obtaining FDA approval to market its biosimilars in the United States.
- Other established biosimilar manufacturers likewise failed to bring to market biosimilar competitors to Roche's biologics, such that Biocad's absence from the U.S. market meant that Roche maintained

> a practical monopoly on those biologics even after its patent protection expired.

That is an exercise in fanciful speculation, not the "reasonably proximate causal nexus" required by Section 6a(1)(A). *Lotes*, 753 F.3d at 411; *see also Associated Gen. Contractors v. Cal. State Council of Carpenters*, 459 U.S. 519, 540-41 (1983) (noting that a chain of causation that "contains several somewhat vaguely defined links" is indicative of an indirect effect). There is simply no reason for this Court to assume—contrary to common sense—that each of Biocad's dominos would have fallen just right. *See* SA12.[16]

Meanwhile, the policy consequences of such an expansive interpretation of the FTAIA are difficult to overstate. A decision authorizing Biocad's claims to go forward would give American antitrust law an outsized (and unsought) role in the regulation of foreign commerce. It would mean that a foreign company unhappy with its competitor's conduct *anywhere in the world* could seek an injunction from a U.S. court ordering the competitor to cease that foreign conduct, based entirely on the foreign company's allegation that, if its overseas profits were greater, it might eventually (years later) try to enter the American market. That would be true, moreover, even if the conduct in question were perfectly legal in the place where it

[16] That is especially true given that, in fact, other biosimilar manufacturers have already indicated their intent to introduce competitors to the Drugs once Roche's patent protections expire. *See infra* at 57 n.18.

occurred. Such a regime is almost certain to provoke international ire, which is not what Congress signed up for. *See Empagran*, 542 U.S. at 165; *McCulloch v. Sociedad Nacional de Marineros de Hond.*, 372 U.S. 10, 21-22 (1963) (declining to construe federal law to apply to foreign activities where doing so would create "the possibility of international discord").

This case illustrates the radical nature of Biocad's proximate-causation theory. The whole purpose of the FTAIA's proximate-cause requirement is to impose sensible policy limits on the extraterritorial application of U.S. antitrust law. The statute's goal is to avoid a judicial free-for-all in which the United States and potentially dozens of other countries around the world are simultaneously adjudicating the same claims involving foreign companies, foreign conduct, and a primary and direct effect on foreign commerce. In this case, for instance, that free-for-all would require American courts to oversee discovery into, among other things, alleged conspiracies among Russian entities; pricing and costs of pharmaceuticals in Russia; marketing and prescription practices for Russian drugs; bidding for government contracts in Russia; and kickbacks to doctors and healthcare institutions in Russia—an industrywide review of the retail and distribution practices of the Russian markets. Biocad's theory directly undermines Congress's objective by seeking to have a U.S. court regulate activity in Russia, affecting Russian competition, that has never been found illegal in Russia.

2. *The Alleged Anticompetitive Effect on Domestic Commerce Is Not the Proximate Cause of Biocad's Injury*

Biocad has another, independent, causation problem. To qualify for the Domestic Effects Exception, Biocad must show not only (1) that the foreign conduct it complains of was the direct cause of substantial anticompetitive effects in the United States, but also (2) that those same effects "give[] rise" to its claim. 15 U.S.C. §6a(2). As the district court recognized, it cannot satisfy this second (and distinct) causation requirement, either. SA12-13.

The FTAIA's text is perfectly clear that the *same* domestic effect that satisfies Section 6a(1)'s "direct, substantial, and reasonably foreseeable" requirement must *also* "give[] rise to [the plaintiff's] claim" under Section 6a(2). *See* 15 U.S.C. §6a(2) (using phrase "*such* effect" to refer back to the "effect" addressed in Section 6a(1)). In *Lotes*, this Court recognized that Section 6a(2)'s "gives rise to" requirement means that the "domestic effect must proximately cause the plaintiff's injury." 753 F.3d at 414; *see also Empagran*, 542 U.S. at 173.

As noted above, the allegedly "direct, substantial, and reasonably foreseeable effect" on which Biocad relies is an increase in U.S. drug prices and the attendant "cost to U.S. consumers." Biocad Br. 50; *see also id*. at 30 (stating that the "direct, harmful effect[s] on [U.S.] commerce" at issue here are the "monopoly prices" that Defendants' conduct "will permit Roche to continue to charge"). But the higher prices charged to American consumers are plainly *not* the "proximate cause" of

Biocad's asserted injuries (its anticipated lost profits from U.S. sales). *Lotes*, 753 F.3d at 414. On the contrary, any increase in the price of those drugs provides more room for price-cutting competitors to enter the market profitably, thus making it easier for Biocad and any other potential entrants to compete in the United States. As the district court rightly recognized, "[Biocad] has not alleged that *this* effect (*i.e.*, increase in the price of the Drugs in the United States) caused [*Biocad's*] injuries as required under the second prong of the domestic effect test." SA12. Biocad's theory of causation thus "runs the wrong way" because its injury—lost profits flowing from its alleged exclusion from the U.S. market—"*precedes* any domestic effect [on U.S. drug prices] in the causal chain." *Lotes*, 753 F.3d at 414; *see also* Biocad Br. 50 (describing causal chain that *starts* with "[p]reventing or delaying Biocad's U.S. market entry" and *ends* with an "effect . . . felt in U.S. markets"). The domestic effect therefore cannot be the cause of Biocad's claim, as both Section 6a(2) and *Lotes* demand.

Biocad tries to avoid its Section 6a(2) causation problem through sleight-of-hand. As noted above, for purposes of Section 6a(1)(A), Biocad claims that the "direct, substantial, and reasonably foreseeable effect" supporting extraterritorial application of the U.S. antitrust laws is the increase in drug prices charged to American consumers. Biocad Br. 24, 50. But when it comes time to address Section 6a(2)'s separate causation requirement, Biocad pivots and asserts that a *different*

"effect"—its own delayed entry or exclusion from the U.S. market—is the proximate cause of its injuries. *Id.* at 51.

Under the FTAIA, Biocad cannot rely on different "effects" to satisfy the distinct requirements of Section 6a(1)(A) and Section 6a(2). The text of the FTAIA is clear: Section 6a(1)(A) requires that the foreign conduct have a direct, substantial, and reasonably foreseeable "effect" on domestic commerce, and Section 6a(2) requires that "*such* effect"—*i.e.*, the *same* "effect" used to satisfy Section 6a(1)(A)—give rise to the plaintiff's claim. Having relied on higher prices as the relevant "effect" for purposes of Section 6a(1)(A), Biocad must show that those higher prices also gave rise to its claim for purposes of Section 6a(2). For the reasons explained above, it cannot do so—and, indeed, Biocad hardly even makes the effort, preferring to swap out effects instead.

On reply, Biocad might try to salvage its claims by arguing that its exclusion from the U.S. market—as opposed to higher consumer prices—is capable of satisfying *both* Section 6a(1)(A) and Section 6a(2). That argument is waived twice over: Biocad did not make it in its opening brief, nor was it pressed or passed upon below.[17]

[17] As Biocad acknowledges, it told the district court that it was not relying on the Domestic Effects Exception *at all*. Biocad Br. 49 n.14; SA12 & n.7. Biocad asserts that it can avoid that waiver on appeal because the district court "nevertheless passed on" the Domestic Effects Exception. Biocad Br. 49 n.14. But the district court *never* "passed on" Biocad's brand-new assertion that the relevant "effect" for purposes of the Domestic Effects Exception is its delayed entry into, or exclusion from,

Even if the Court opted to overlook those waivers, such an argument would be doomed on the merits (which is presumably why it was not offered in the first place). A competitor's exclusion from a market is not itself an anticompetitive effect on commerce for purposes of antitrust law. Exclusion might harm a competitor, but it is not itself necessarily a harm to *competition*, because it does not constitute an increase in price or reduction in output or quality. *See supra* at 48; *Tops Mkts.*, 142 F.3d at 96 ("[T]he fact that Tops may have been prevented from competing in the Jamestown market does not alone prove an adverse effect on competition as a whole," because "even if plaintiff were hindered from competing, nothing changed in the relevant product market from the consumer's perspective."); *K.M.B. Warehouse*, 61 F.3d at 128 ("The fact that KMB was not permitted to compete in this market does not alone prove an adverse effect on intrabrand competition."); *Capital Imaging Assocs.*, 996 F.2d at 546-47 (an excluded competitor had not established "detrimental effects" because the competitor "ha[d] not shown that defendant's activities have had any adverse impact on price, quality, or output of medical services offered to consumers in the relevant market").

---

the U.S. market. On the contrary, the *only* domestic "effect" the district court addressed in its discussion of the Domestic Effects Exception was the increase in drug prices. *See* SA12-13 (variously describing the relevant domestic effect as "driving up the price of the Drugs in the United States," "[the] increase in the price of the Drugs in the United States," and "driving up prices"). This Court should not be the first to address Biocad's newly minted Section 6a(2) argument. *See, e.g.*, *Prabhudial v. Holder*, 780 F.3d 553, 555 (2d Cir. 2015).

Here, so long as *other* competitors may enter the U.S. market for the Drugs, any exclusion of Biocad would not harm competition or consumers. And Biocad has not alleged that Defendants' alleged efforts to hurt Biocad's profitability in Russia would have prevented other biosimilar manufacturers from introducing their own versions of the Drugs in the United States. Nor could it, given that—as judicially noticeable materials make clear—multiple other companies with significant experience with the FDA-approval process have already indicated their intent to introduce such competitor products.[18] This just confirms that Biocad's exclusion, by itself, cannot qualify as a domestic anticompetitive "effect" under Section 6a(1)(A).

Finally, Biocad argues (at 53) that if the district court's Section 6a(2) holding is correct, "excluded competitors could *never* bring claims within the FTAIA." But that is true only to the extent that those competitors' injuries do not flow from domestic anticompetitive effects and instead arise from foreign conduct that does not act directly on imports into the United States. It is hardly surprising that Congress would have wanted to keep the U.S. courts out of such disputes. Indeed, the text and history of the FTAIA mandate that result and reflect the statute's core premise that foreign commerce and conduct with only tangential or speculative

[18] *See supra* at 25 n.7; *see also, e.g.*, FDA, *FDA Approves First Biosimilar for Cancer Treatment* (updated Dec. 21, 2017), https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm576096.htm; FDA, *FDA Approves Ogivri as a Biosimilar to Herceptin* (updated Dec. 1, 2017), https://www.fda.gov/drugs/informationondrugs/approveddrugs/ucm587404.htm. The Court may take judicial notice of these publicly available items. *See, e.g.*, *Apotex*, 823 F.3d at 59-60.

effects on the United States is appropriately regulated by the country in which it occurred—not through the extraterritorial application of American antitrust laws.

The implications of Biocad's rule, by contrast, would be truly startling: If exclusion from a U.S. market caused by aggressive price competition abroad is itself an "effect" capable of satisfying both Section 6a(1)(A) and Section 6a(2), then *Russian* conduct, in *Russia*, that harms a *Russian* company's profitability and thereby prevents it from importing goods to the United States would be actionable under the U.S. antitrust laws *even if there is no effect on prices, output, or quality in the U.S. market*. That is exactly the sort of extraterritorial claim based on indirect, downstream consequences that the FTAIA was enacted to eliminate.[19]

CONCLUSION

For these reasons, this Court should affirm the judgment of the district court dismissing Biocad's Amended Complaint with prejudice.

[19] For similar reasons, another basis for this Court to affirm the district court's dismissal of Biocad's claim is the doctrine of comity. *See, e.g.*, *Empagran*, 542 U.S. at 169. Here, because Biocad's claims would require this Court to police, according to U.S. antitrust principles, the conduct of Russian companies engaged in the pricing, packaging, and sale of pharmaceuticals in Russia—conduct that is more properly regulated by the Russian authorities—dismissal of the action is justified on comity grounds. *See, e.g.*, *In re Vitamin C Antitrust Litig.*, 837 F.3d 175, 194 (2d Cir. 2016), *cert. granted*, 138 S. Ct. 734 (2018) ("[W]e conclude that China's 'interests outweigh whatever antitrust enforcement interests the United States may have in this case as a matter of law.'").

Dated: New York, New York
May 10, 2018

RESPECTFULLY SUBMITTED,

DAVIS POLK & WARDWELL LLP

By: */s/ Paul Spagnoletti*
Paul Spagnoletti
Andrew S. Gehring
450 Lexington Avenue
New York, New York 10017
Tel.: (212) 450-4000
Fax: (212) 450-4800
paul.spagnoletti@davispolk.com
andrew.gehring@davispolk.com

Counsel for Defendants-Appellees Roche Holding AG and F. Hoffmann-La Roche Ltd

GIBSON, DUNN & CRUTCHER

By: */s/ Eric J. Stock*
Caitlin J. Halligan
Eric J. Stock
Alejandro A. Herrera
200 Park Avenue
New York, New York 10166-0193
Tel.: (212) 351-4000
Fax: (212) 351-4035
challigan@gibsondunn.com
estock@gibsondunn.com
aherrera@gibsondunn.com

Counsel for Defendant-Appellee R-Pharm JSC

LATHAM & WATKINS LLP

By: */s/ Daniel M. Wall*
Daniel M. Wall
505 Montgomery Street, Ste. 2000
San Francisco, California 94111
Tel.: (415) 395-8240
Fax: (415) 395-8095
dan.wall@lw.com

Lawrence E. Buterman
885 Third Avenue
New York, New York 10022
Tel.: (212) 906-1200
Fax: (212) 751-4864
lawrence.buterman@lw.com

Amanda P. Reeves
Roman Martinez
Benjamin W. Snyder
555 Eleventh Street, NW
Suite 1000
Washington, DC 20004
Tel.: (202) 637-2183
Fax: (202) 637-2201
amanda.reeves@lw.com
roman.martinez@lw.com
benjamin.w.snyder@lw.com

Counsel for Defendant-Appellee Genentech, Inc.

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the applicable type-volume word count limitation, containing 13,999 words. This certificate was prepared in reliance on the word processing system used to prepare the motion, inclusive of headings, footnotes, and quotations, and exclusive of the parts of the brief exempted from the type-volume limitation by Federal Rule of Appellate Procedure 32(f).

Dated: May 10, 2018

DAVIS POLK & WARDWELL LLP

By: */s/ Paul Spagnoletti*
Paul Spagnoletti

450 Lexington Avenue
New York, New York 10017
Telephone: (212) 450-4000
Facsimile: (212) 701-5800