17-3486

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

BIOCAD JSC,
Plaintiff-Appellant,

v.

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

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

BRIEF FOR PLAINTIFF-APPELLANT BIOCAD JSC
AND SPECIAL APPENDIX

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Plaintiff-Appellant Biocad JSC hereby states that it is owned by its parent corporation Biocad Holding Limited and that no publicly held company owns 10% or more of the stock of Biocad Holding Limited.

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JURISDICTIONAL STATEMENT

The district court had original subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1337 over the claims of Plaintiff-Appellant ("Biocad") arising under federal statutes (specifically, the Sherman Act, 15 U.S.C. §§ 1, 2; the Clayton Act, 15 U.S.C. §§ 15, 26; and the Robinson-Patman Act, 15 U.S.C. § 13). The court had supplemental jurisdiction under 28 U.S.C. § 1367 over Biocad's state-law claim.

The district court entered final judgment in favor of Defendants-Appellees ("Defendants") on September 30, 2017. SA1-16. Biocad filed a timely notice of appeal on October 27, 2017. A189. This Court has jurisdiction to review the district court's judgment under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Did Biocad plead antitrust injury by alleging that it created safe and effective pharmaceuticals, sold them worldwide, built a manufacturing facility compliant with U.S. Food and Drug Administration ("FDA") standards, and took specific, costly steps toward U.S. market entry until Defendants' anticompetitive conspiracy had its intended effect of causing Biocad to delay or abandon its entrance to the U.S. pharmaceutical market?

2. May Biocad's claims under the Sherman Act proceed under the Foreign Trade Antitrust Improvements Act of 1982 ("FTAIA") because Biocad alleges anticompetitive conduct, both in the United States and abroad, with the intended effect of preventing Biocad from importing pharmaceuticals into the United States?

3. If this Court allows Biocad's claims under the Sherman Act to proceed, should it also reinstate Biocad's claim for injunctive relief under the Clayton Act and its claim under New York's Donnelly Act, which the district court dismissed for the same reasons as the Sherman Act claims?

STATEMENT OF THE CASE

Biocad is a full-cycle drug manufacturing and development company based in St. Petersburg, Russia. Since 2010, Biocad has been preparing to enter the U.S. pharmaceutical market with biosimilar versions of three cancer drugs whose U.S. patents will expire in 2018 and 2019. Biocad is the only company to have successfully created biosimilars of all three drugs, and it currently sells, distributes, or licenses them in 47 countries worldwide. After making the enormous investment required to create the biosimilars themselves, Biocad further prepared for U.S. market entry by creating a U.S. subsidiary, transferring personnel to the United States, hiring multiple consulting firms to advise on U.S. regulatory approvals and market entry, leasing more than 4,000 square feet of laboratory space and production facilities in Boston, and investing millions of dollars in an FDA-compliant manufacturing facility in Eastern Europe.

Defendants are a group of entities affiliated with and controlled by Defendant Roche Holding AG ("Roche Holding"), a Swiss multinational healthcare corporation – including Defendant F. Hoffman-La Roche Ltd. ("FHL Roche"), a Swiss drug manufacturer, and Defendant Genentech, Inc. ("Genentech"), FHL Roche's U.S. affiliate. Roche Holding, FHL Roche, and Genentech (collectively, for convenience, "Roche") hold U.S. patent-protected monopolies for the three cancer treatments with which Biocad's drugs would compete. Defendant R-Pharm

JSC ("R-Pharm"), a Russian corporation, is Roche's official distributor in Russia for the drugs at issue. To extend Roche's monopoly power – and monopoly profits – beyond those patents' expiration, Defendants conspired to prevent Biocad from bringing cheaper biosimilars to the lucrative U.S. market. Their anticompetitive conduct had its intended effect: Biocad's entry into the U.S. import market has been delayed, and American consumers will continue to pay monopoly prices for life-saving medicine even after Defendants' patents expire.

Biocad filed this action in the Southern District of New York alleging violations of the federal and New York antitrust laws. According to Biocad's Complaint (as amended, A10-85), Defendants engaged in a concerted strategy to prevent Biocad from importing biosimilars into the United States. The Complaint describes Defendants' motive for conspiring (to protect Roche's U.S. monopoly, which alone accounts for nearly half its global profits for these drugs) and the methods used to carry out that conspiracy (corrupting hospitals and doctors, defrauding government ministries, and selling its drugs at a loss in Russia, where Biocad is already an active competitor). It also alleges that, as a result of the conspiracy's devastating effects on Biocad's business in its home market, Biocad has been forced to lay off employees in the United States and to delay its planned entry, and that it is in danger of being excluded from the U.S. market completely.

On Defendants' motions, the district court (Sullivan, J.) dismissed all claims with prejudice. The court ruled that Biocad had not sufficiently alleged antitrust standing because its Complaint provided too "little information from which the Court may assess the likelihood of [FDA] approval" of Biocad's biosimilars. SA6. In reaching that conclusion, the court acknowledged that Biocad had proffered "factual allegations relevant to its intent and preparedness to engage the U.S. pharmaceutical market," SA7, but found them insufficient. The court further ruled that Biocad's claims under the Sherman Act were barred by the FTAIA because Biocad had sought protection for "*anticipated* participation in *future* import commerce" rather than as an existing importer, and because the connection between Defendants' targeting of Biocad in its home market and its inability to enter the U.S. market was "too attenuated." SA10.

The district court also dismissed Biocad's claims under the Robinson-Patman Act and New York's Donnelly Act, as well as rejected Biocad's claim for injunctive relief under the Clayton Act. SA7-9, 13. It further denied leave to amend. SA13-15.

STATEMENT OF FACTS

This case arises from a conspiracy to keep a nascent competitor out of the U.S. pharmaceutical market. Roche is the sole U.S. seller of three key cancer drugs: bevacizumab, trastuzumab, and rituximab. So far, Biocad is the only pharmaceutical company in the world that has been able to create biosimilars of those three drugs. The drugs are the most valuable in Roche's portfolio. Together they bring in more than $20 billion annually. Roche obtains nearly half of its worldwide profits from the drugs from sales in the United States. But Roche will lose U.S. patent-based exclusivity rights for all three in 2018 and 2019. The expiration of Roche's patents created an opportunity for other pharmaceutical manufacturers, like Biocad, to bring cheaper, biosimilar versions of these medicines to the U.S. market – by far the largest oncology market in the world.

Starting in 2010, Biocad spent six years and millions of dollars developing its biosimilars, which gained regulatory approval in Russia and licensing and distribution agreements in 47 other countries before the Amended Complaint was filed in 2016. Biocad specifically prepared to import its biosimilars into the United States by hiring U.S. personnel and consultants, transferring existing employees to the United States, leasing operation space in Boston, and building a unique factory in Eastern Europe designed to meet the FDA's strict manufacturing requirements.

As Biocad prepared for U.S. market entry, Roche and R-Pharm conspired to prevent it by destroying Biocad's Russian business and raising obstacles to FDA-required testing. After Biocad entered the Russian market for bevacizumab, for instance, Roche and R-Pharm began to sell Roche's brand-name version of the drug at a loss in Russia while simultaneously raising the prices paid by U.S. cancer patients. Defendants also gave Russian doctors a $10 kickback for every prescription of Roche's medications; restricted U.S. distribution of Roche drugs to make it more difficult for competitors to acquire samples for testing; submitted fraudulent bids for Russian government contracts; and corrupted a network of state-owned hospitals to preclude Biocad from participating in a Russian government medical reimbursement program. Through those actions, Defendants sought "to . . . maintain Roche's monopoly position in the Relevant [U.S.] Markets and to block Plaintiff's entrance on the U.S. market." A173 (¶ 245). The conspiracy succeeded: Biocad's U.S. entry has been delayed or entirely prevented.

A. The U.S. Oncology Market, Biologics, And Biosimilars

The U.S. oncology market is the largest and most lucrative in the world. A123 (¶ 31). Of the $100 billion spent worldwide on cancer drugs in 2014, the U.S. spent $42.5 billion. *Id.* (¶¶ 30-31). The U.S. market for monoclonal antibodies ("mAbs"), the type of drug at issue here, is growing especially quickly. These mAbs – laboratory-produced antibodies that mimic natural antibodies – have

achieved considerable success at marking cancer cells, blocking growth signals, delivering chemotherapy toxins, and reducing new blood vessel growth. A123-24 (¶ 32). Industry-wide spending on targeted therapies (including mAbs) has grown at a compound average rate of 14.6% over the last five years, and the total market has increased from $24 billion in 2013 to a projected $34 billion in 2017. A124 (¶ 33). As a result, pharmaceutical companies are investing heavily in mAbs, hoping to make better drugs and cheaper versions of existing ones. *Id*.

Newly invented drugs typically enter the U.S. market under patent protection, giving the patent-holder a statutorily permitted monopoly for 20 years. *See* 35 U.S.C. § 154(a)(2). Because of the size of the U.S. market, and because there often are no adequate substitutes for a particular treatment, that period of exclusive rights is especially valuable for patentees of new cancer drugs. A117, 123 (¶¶ 13, 31). But it is expensive for U.S. patients, who are forced to pay monopoly prices and who benefit when competition is eventually permitted. A117 (¶¶ 12-13). When a patent exclusivity period ends – a point known as the "patent cliff," A136 (¶ 85) – generics and biosimilars enter the market at prices well below their brand-name equivalents. A135 (¶ 82). As more manufacturers enter the market, price competition accelerates, which drives prices even lower and reduces the profits that any manufacturer, including the original patent-holder, can expect from each sale. A136 (¶¶ 84-85).

"Biologics," the type of drugs at issue here, "differ from traditional drugs, which are typically synthesized from chemicals," because they are "derived from natural, biological sources such as animals or microorganisms." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669-70 (2017). "Because biologics come from living organisms, they are variable in nature and their structures are generally more complex and not as easy to define and characterize."[1] A biosimilar "is a biologic product that is highly similar to a biologic product that has already been approved by the [FDA]." *Id.* at 1669. The previously approved product is called the "reference product." *Id.* at 1670.

Assessing the structure and function of a biologic reference product poses significant challenges for developers of biosimilars. "Because the structure of a biologic and the process used to make it are typically complex, developing a biosimilar generally is not as easy as producing a generic drug."[2] A developer must have "[s]tate-of-the-art technology" to determine biosimilarity, which involves "extensively analyzing (i.e., characterizing) the structure and function of both the reference product and the proposed biosimilar" and then "compar[ing]

[1] FDA, *Biosimilars: More Treatment Choices and Innovation* (updated Oct. 23, 2017), https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm436399.htm (last visited Feb. 6, 2018).

[2] *Id.*

characteristics of the products, such as purity, chemical identity, and bioactivity."[3] The complexity of those problems leads to "a steep learning curve" for a biosimilar developer.[4]

The manufacturing process is a key part of creating a biosimilar (and indeed any biologic). *See* 1 James T. O'Reilly & Katharine A. Van Tassel, *Food and Drug Administration* § 13:154, at 1175 n.16 (4th ed. Nov. 2017) ("[W]ith traditional drug products, the process knowledge is less important than product knowledge, but for biologics, the product is the process."). A biosimilar developer typically has "no direct knowledge of the manufacturing process" used to create the reference product, and it must contend with the possibility that "[d]ifferent manufacturing processes may alter a protein product in a way that could affect the safety or effectiveness of the product."[5]

In creating a manufacturing process, a biosimilar manufacturer also must devise a way to avoid contamination reliably. The use of living cells to manufacture

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[3] FDA, *Biosimilar and Interchangeable Products* (updated Oct. 23, 2017), https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm (last visited Feb. 6, 2018).

[4] Erwin A. Blackstone & Joseph P. Fuhr Jr., *The Economics of Biosimilars*, 6 Am. Health & Drug Benefits 469, 472 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4031732/pdf/ahdb-06-469.pdf.

[5] U.S. Dep't of Health & Human Services et al., *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Guidance for Industry* 5-6 (Apr. 2015), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291128.pdf.

biologics means the process is "inherently more susceptible to contamination" than traditional drug manufacturing, and contaminations are "often difficult to detect and nearly impossible to remove in processing." *Id*. § 13:154, at 1175-76; *see also* W. Nicholson Price II & Arti K. Rai, *Manufacturing Barriers to Biologics Competition and Innovation*, 101 Iowa L. Rev. 1023, 1036 (2016) ("Manufacturing variation can lead to a plethora of . . . modifications and other alterations, with substantial clinical implications.").

Once a company overcomes these challenges, creates a biosimilar, and develops a reliable manufacturing process, the FDA approval process is considerably easier than for new biologics. In recognition of biosimilars' potential benefits to consumers and the complexity of independently demonstrating that a drug is "safe, pure, and potent," Congress acted in 2009 to create an abbreviated FDA approval pathway for biosimilars. *See* Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, tit. VII, subtit. A, § 7002(a)(2), (b)(3), (g)(1), 124 Stat. 119, 804-15, 819-20 (2010) ("BPCIA") (codified as amended at 42 U.S.C. § 262). Under the BPCIA, a biosimilar applicant "may piggyback on the showing made by the manufacturer (sponsor) of a previously licensed biologic (reference product)." *Sandoz*, 137 S. Ct. at 1670 (citing 42 U.S.C. § 262(k)(2)(A)(iii)). An applicant must show only "that its product is 'highly similar' to the reference product and that there are no 'clinically

meaningful differences' between the two in terms of 'safety, purity, and potency.'" *Id*. (quoting 42 U.S.C. § 262(i)(2)(A), (B)).

The Congressional Budget Office estimates that biosimilar entry leads to $140 million in U.S. consumer savings for every $1 billion spent on biological drugs; other studies place savings from biosimilar entry between $25 and $44 billion over 10 years. A135-36 (¶¶ 82-83).

B. Roche's Blockbuster Drugs And Expiring Patents

Roche is the largest oncology company in the world and holds the largest portfolio of FDA-approved mAbs. A124 (¶ 34). The three drugs at issue here – bevacizumab, trastuzumab, and rituximab – are its blockbusters. *Id*. Since their launch, the drugs collectively have brought Roche more than $170 billion. A125 (¶ 37). In 2013, drug purchasers spent $24 billion on all mAbs worldwide. A124-25 (¶ 36). Of that total, $21.2 billion (87.9%) was spent on Roche's three drugs – $9 billion (37.5%) within the United States alone. *Id.* Roche's sales remained steady through 2014 and 2015. A125 (¶ 37).

Roche's U.S. exclusivity rights to all three drugs will expire in 2018 and 2019. A126 (¶ 40). Exclusivity for rituximab, sold under the brand name Rituxan, will expire in 2018. A128 (¶ 54). Rituxan treats chronic lymphocytic leukemia and non-Hodgkin's lymphoma by seeking out a specific protein, CD20, found only on B-type white blood cells that are affected by certain types of lymphomas.

A127 (¶ 51). The molecule attaches itself to these cells, marking them and making them more visible to the immune system, which then can kill the infected cells. A127-28 (¶ 52). Although there are other FDA-approved drugs to treat leukemia and non-Hodgkin's lymphoma, none is a substitute for Rituxan. A140 (¶ 107). Rituxan has earned Roche $53.3 billion since its launch in 1998, including more than $7 billion a year in 2013, 2014, and 2015. A128 (¶¶ 53, 55).

Roche's patents for the other two drugs will expire in 2019. A126-27 (¶¶ 43, 48). Avastin, Roche's branded version of bevacizumab, inhibits new blood-vessel growth and stops cancer from spreading by intercepting the growth signals of the vascular endothelial growth factor. A126 (¶ 42). It is the only monoclonal antibody approved by the FDA for treatment of metastatic colon or rectal cancer, non-small cell lung cancer, glioblastoma multiform, and metastatic rectal cell carcinoma. A137 (¶ 88). It has earned $57.5 billion for Roche since its launch in 2004. A126 (¶ 44). Herceptin, Roche's branded version of trastuzumab, works by finding cancer cells with the HER2 protein and attaching itself to the surface, preventing the cancer from receiving new growth signals and signaling the immune system to destroy the cell to which it is attached. A127 (¶ 46). Although there are two other mAbs often prescribed to treat breast cancer, doctors typically prescribe them as complements to rather than substitutes for Herceptin. A138-39 (¶¶ 97-98). Herceptin is one of the most widely used breast-cancer treatments

currently on the market and continuously generates more than $6 billion in annual sales. A126-27 (¶ 45).

C. Biocad's Global Business And Preparations To Enter The U.S. Market

Biocad is the only pharmaceutical company in the world that has created biosimilars of all three of Roche's star mAbs. A128 (¶ 56). It is the leading manufacturer of biosimilar mAbs and is Roche's primary competitor in the global mAbs market. A129-30 (¶ 63).

In 2010, Biocad began developing biosimilar mAbs, including biosimilars of Roche's blockbuster biologics. A128-29 (¶ 58). Biocad's drug development process involved creation of in-house mAbs manufacturing technology, a comprehensive characterization of developed biosimilars, and comparative clinical and nonclinical studies. *Id.* Biocad also built a 30,000 square-foot production facility – two-thirds of which consist of cleanrooms for safe manufacturing of biosimilars – with an annual output capacity of 3 million vials and 4 million pre-filled syringes. A130 (¶ 65). The Russian Ministry of Health approved Biocad's biosimilar of rituximab in 2014 and its biosimilars of bevacizumab and trastuzumab in 2015. A129 (¶¶ 59, 61-62).

Biocad now sells its biosimilars in Russia and worldwide. It has entered licensing and distribution agreements for its mAbs in 47 countries and has completed more than $200 million in sales contracts to partners in Indonesia,

Turkey, Armenia, Cambodia, Kenya, Kyrgyzstan, Morocco, Myanmar, Pakistan, South Africa, Ukraine, Uzbekistan, Sri Lanka, and Vietnam. A130-31 (¶¶ 66-67). Biocad produces the dominant biosimilar rituximab, accounting for 80% of non-Roche global sales and generating annual revenues of more than $155 million. A129 (¶ 60) (based on 2014 sales). In 2016, Biocad also began selling biosimilars of bevacizumab and trastuzumab. *Id.* (¶¶ 61-62).

In 2010 and 2011, Biocad began preparing to enter the U.S. market. A131 (¶¶ 68-69). It opened a U.S. subsidiary, started transferring and hiring business development personnel in the United States, and located premises for U.S.-based operations. *Id.* (¶ 69). In 2012, Biocad leased more than 4,000 square feet in Boston for materials handling and storage, research and development, product assembly, and office use. *Id.* (¶ 70). In 2013, Biocad drafted estimates and budgets for U.S. market entry, allotting between $60 and $100 million per molecule. *Id.* (¶ 71). It also hired William Blair, an outside consulting firm, to prepare a timeline and strategy for U.S. entry of Biocad's biosimilars. A132 (¶ 73).

In 2013, Biocad opened a new large-scale production site in Russia designed to conform to FDA standards for Current Good Manufacturing Practice and Current Good Laboratory Practice. A120, 132-33 (¶¶ 22, 74-76). On the advice of BioProcess, another leading U.S. consulting firm, Biocad developed and implemented a "Quality Improvement Plan" that involved extensive revisions of

its quality assurance systems, its laboratory quality control, its material controls, its validation and qualification systems, and its hygiene, pest control, and access control systems. A132-34 (¶¶ 75, 77). It verified its Russian facility's compliance through audits by other outside consultants. A134 (¶ 78).

To make those quality improvements for FDA compliance, Biocad invested (in addition to the general costs of the facility) more than $6 million on acquiring equipment, $1 million on incidental expenses, and 18,000 work hours. A132-33 (¶ 76). Biocad's facility is now the only one of its kind in Eastern Europe and one of only 50 facilities worldwide that specializes in producing the active pharmaceutical ingredients of monoclonal antibodies. A132 (¶ 74).

By 2016, after six years and millions of dollars of investments, Biocad considered FDA approval and U.S. entry to be within reach. It entered into several consulting agreements with Parexel, another U.S. life-sciences consulting firm, to help prepare documents for a Biological License Application to the FDA for its biosimilar trastuzumab. A134-35 (¶ 79). Biocad now had the necessary equipment and facilities. A132 (¶ 72). It had the financial resources. *Id.* And, alone in the world, it had manufacturing processes that reliably could produce biosimilars of all three of Roche's blockbuster mAbs in compliance with FDA standards. A128, 132 (¶¶ 56, 72).

D. Defendants' Conspiracy To Prevent Biocad's U.S. Entry

Recognizing the threat that Biocad's biosimilars posed to Roche's blockbuster drugs in its most lucrative market, Defendants organized a scheme to delay or altogether preclude Biocad's entry into the U.S. market. A143 (¶ 118). Because Roche still held patent-based monopolies in the United States, Biocad had no active U.S. business with which to interfere. Defendants therefore adopted a strategy of targeting Biocad's foreign operations to force it to delay or abandon the costly process of FDA approval and U.S. market entry. A135, 143 (¶¶ 81, 119). They pursued that goal through five main means.

1. Below-cost pricing in Russia

Defendants implemented a pricing scheme in which Roche sold mAbs at a loss in Russia while making up the difference in the U.S. market. A144-50 (¶¶ 121-135). When Roche first started selling its three blockbuster mAbs, prices in the United States and in Russia were comparable. In some instances, Russian prices were higher. A144-45 (¶¶ 122, 124). Even in 2012, before Biocad released its biosimilars, Avastin sold for $780 in Russia and $586 in the United States; Herceptin, for $3,309 in Russia and $3,160 in the United States; and Rituxan, for $2,731 in Russia and $3,101 in the United States. A145 (¶ 124).[6] By 2016, after

[6] The prices given for Avastin are per 100 mg. A146 (¶ 125). The Complaint does not set forth the quantity for Herceptin or Rituxan.

Biocad introduced all three biosimilars in Russia, Avastin's price fell to $124 in Russia but rose to $684 in the United States; Herceptin's price decreased to $926 in Russia but increased to $3,879 in the United States; and Rituxan's price declined to $743 in Russia but rose to $3,618 in the United States. *Id.* On average, these drugs grew 19% more expensive in the United States while becoming 76% cheaper in Russia. A144 (¶ 122). In some instances, Defendants sold Avastin in Russia for as little as $46 – less than one-fourteenth of the price in the United States. A145 (¶ 124 n.25).

That disparity in price cannot be explained only by the natural price decrease from increased competition, because Defendants sold at least one of Roche's drugs in Russia at a loss. When a pharmaceutical enters Russia, the importer is required to declare an "[e]ntry [p]rice," which refers to the bulk value of the drug before duties, taxes, and domestic costs of packaging, marketing, and distribution. A148 (¶ 130). Before Biocad's first sale of biosimilar bevacizumab, Roche declared an entry price of Avastin of $148, but the actual sale price of the drug in the country was $257. A149 (¶ 133). The $109 difference reflected taxes, duties, the costs of packaging and distribution, and presumably some profit for Roche's (theoretically independent) Russian distributor R-Pharm. After Biocad's biosimilar bevacizumab reached the market on February 15, 2016, Roche's declared entry price for Avastin was still $148, but the actual sale price plummeted to $124. *Id.* Thus, either

R-Pharm was bearing the costs of packaging and distribution and losing money on every sale of Avastin, or – as the Complaint alleges – Roche was secretly subsidizing R-Pharm to enable low prices that would destroy Biocad's business before Biocad could enter the U.S. market. A147-48 (¶ 129).

2. Restricted access to samples in the United States

Defendants also raised barriers to U.S. entry by restricting access to samples that competitors need to conduct bioequivalence testing. A161-62 (¶¶ 181-191). To receive FDA approval, a biosimilar or generic manufacturer must demonstrate that its formulation is therapeutically equivalent to the brand-name drug (the reference product). *Id.* (¶ 186). Doing so requires samples of the reference product, and that product's manufacturers therefore often slow competitors by limiting distribution networks and thwarting access to those samples. *Id.* (¶¶ 186-187). Roche did exactly that. In 2014, a few months after Biocad received its first Russian biosimilar approval and less than two weeks before the biosimilar's first sale, Genentech (Roche's U.S. subsidiary) sharply limited its distribution network for Avastin, Herceptin, and Rituxan. A161 (¶¶ 182, 184). What had been a network of 80 wholesalers became just six. *Id.* (¶ 183). That not only limited competitor access to samples, but also caused a surprise, overnight U.S. price-hike that netted Roche $300 million. *Id.* (¶ 184).

3. Payments to obtain business from Russian doctors, hospitals, clinics, and officials

Defendants also engaged in a systematic pattern of payoffs to influence Russian decisionmakers to take business from Biocad and give it to Roche and R-Pharm. A150-57 (¶¶ 136-170). Roche paid doctors and hospitals to submit formulary requests that specified non-essential drug characteristics (like packaging, product weight, and form) that matched only Roche's versions of these medications. A152 (¶¶ 146-147). By doing so, Roche circumvented a state-run auction system (intended to enable competition in the pharmaceutical system) and eliminated Biocad's biosimilars from those auctions. A151-52 (¶¶ 141-147).

In exchange for formulary requests that matched only Roche specifications, Roche spent tens of thousands of dollars renovating hospitals and clinics and buying them new equipment. A152-53 (¶¶ 149-150). The payoffs to individual doctors and government officials were even more expansive, consisting of both direct payments (disguised as fees for "lectures") and paying for doctors to attend conferences all over the world. A153-56 (¶¶ 152-163). The Complaint contains specific examples of doctors who received such payments, identifying them by name – though the examples given represent only a few of the many recipients. *Id.* (¶¶ 153-157, 162).

On an individual basis, Roche offered a $10-per-prescription kickback to doctors who could prove, with empty packaging, that they had prescribed Roche's

medications. A150, 156-57 (¶¶ 137, 164-169). As with the formulary-related payments, the kickbacks were disguised as payments for lectures. A157 (¶ 168). The kickbacks were so regular and accepted that some doctors who were not paid on time complained to Roche in writing. *Id.* (¶ 169).

Roche's system of payoffs was a deliberate corporate strategy. Roche's global compliance team received several complaints about the company's Russian business practices. A157-58 (¶ 172). As detailed in one of these complaints – from one of Roche's regional managers in Russia – Roche applied psychological pressure and harassed employees who would not participate in the bribery schemes while offering financial rewards to those who would. A158 (¶ 173). In 2013, Roche sent international compliance managers to investigate the complaints. Those managers gathered many more reports of corrupt conduct. A159 (¶¶ 174-176). Nothing changed except that the employees who had reported misconduct were pressured to quit. A159-60 (¶¶ 177-179). One of the investigators was quickly promoted from a regional compliance officer to head of business compliance for all of China, followed by another promotion to head of compliance for the entire Asia Pacific region. A160 (¶ 180).

4. Fraudulent auction bids

R-Pharm submitted fraudulent bids to Russian government auctions – bids Defendants knew R-Pharm could not fulfill – for the purpose of preventing Biocad

from claiming the business. A166 (¶ 209). On March 10, 2016, Ortat JSC, a wholly owned subsidiary of R-Pharm and the company responsible for secondary packaging of Avastin in Russia, announced that Avastin would not be available on the Russian market until the second half of 2016. *Id.* (¶ 210). At the same time, R-Pharm continued submitting bids in government auctions, offering to sell Avastin it did not have, again at prices below the bulk entry price declared at customs. R-Pharm's bids won, and it entered into and then defaulted on a number of government and municipal contracts. A167 (¶ 214). But it had accomplished its goal of preventing Biocad from winning those contracts.

5. Tying Herceptin with Perjeta

Defendants also employed monopoly power over a drug called Perjeta (pertuzumab, to which Biocad does not make a biosimilar) to force Russian breast-cancer patients to buy Herceptin from Roche instead of Biocad's biosimilar trastuzumab. A165 (¶¶ 203-205). When used together, trastuzumab and Perjeta have been shown to reduce risk of death from certain types of breast cancer by 34%. A163 (¶ 194). Shortly before Biocad brought its biosimilar trastuzumab to market, Roche stopped selling Perjeta separately in Russia and made it available only packaged with a vial of Herceptin under the new brand name Beyodaim. A163-64 (¶¶ 196-197). That classic tying scheme forced the many breast-cancer

patients who need both Perjeta and trastuzumab to buy both from Roche. A165 (¶ 203).

E. The Conspiracy's Intended And Actual Effects On Biocad

Most (but not all) of the conspiracy's anticompetitive conduct occurred in Russia, but was intended to "stabilize and maintain [Roche's] monopoly in the U.S. beyond the [patent-]permitted period, to destroy Plaintiff's competing business in the U.S., Russia and worldwide, and to foreclose the U.S. market to biosimilar alternatives to Roche's star drugs." A169 (¶ 226); *see id.* (¶¶ 223-224).

Defendants' objective of protecting Roche's U.S. monopoly explains their otherwise anomalous conduct in pricing mAbs to sell at a loss in Russia, *see supra* Part D.1, while at the same time paying doctors and tying products so that Defendants could sell more, *see supra* Parts D.3 and D.5, and lose more with every sale. It also explains R-Pharm's willingness to incur losses even without making sales, such as through fraudulent bidding designed to deny opportunities to Biocad. *See supra* Part D.4. Viewing the economic situation in Russia on its own, Defendants' behavior would appear irrational. But viewing that situation in light of Roche's desire to defend its hold on the U.S. market (and its anticompetitive tactics in that market as well, *see supra* Part D.2), R-Pharm's pursuit of money-losing sales makes sense as part of a global business strategy.

The conspiracy so far has had its intended effect. Defendants have lowered prices in Russia, A146-47 (¶¶ 125-127), cutting into Biocad's revenues; prevented Biocad from competing in important state-run auctions, A151-52 (¶¶ 145, 147), costing it business; taken sales from Biocad through unlawful payments to doctors, A156 (¶ 164); limited Biocad's access to samples needed for FDA applications, A162 (¶ 190); blocked Biocad from selling trastuzumab to Russian breast-cancer patients who also need Perjeta, A163-65 (¶¶ 192-205); and stopped Biocad from winning auctions through fraudulent bids on which R-Pharm could not deliver, A167 (¶ 214). Those actions were particularly damaging to Biocad because Russia is its home market, A130-31 (¶¶ 64-66), where it first obtained approval to sell biosimilar rituximab, bevacizumab, and trastuzumab, A129 (¶¶ 59-62).

The cumulative financial impact of Defendants' actions has forced Biocad to lay off personnel in the United States and delay its plans for U.S. market entry, and may prevent Biocad from entering at all. A135, 170-72 (¶¶ 81, 229-236). Patients in the United States will continue to pay monopoly prices for Avastin, Herceptin, and Rituxan for longer than they otherwise would – perhaps indefinitely. A118 (¶ 15).

F. Complaint And District Court Opinion

On June 7, 2016, Biocad filed a Complaint in the Southern District of New York for violations of the federal and state antitrust laws. A10-60. As amended on October 24, 2016, the Complaint raises claims under the Sherman Act, 15 U.S.C.

§§ 1, 2, for monopolization, attempted monopolization, conspiracy to monopolize, and conspiracy in restraint of trade; seeking treble damages and injunctive relief under the Clayton Act, 15 U.S.C. §§ 15, 26; and further alleging violations of the Robinson-Patman Act, 15 U.S.C. § 13, as well as New York's Donnelly Act, N.Y. Gen. Bus. L. § 340 *et seq*. The Complaint defined the "Relevant Markets" for antitrust purposes as the U.S. markets for the three drugs at issue (bevacizumab, trastuzumab, and rituximab). A136-37, 139, 141 (p. 24 n.19, ¶¶ 90, 100, 110). Biocad seeks damages solely for its inability to compete and for lost profits in those markets. A173-74, 176-77, 179, 182, 185-86 (¶¶ 246-249, 261-264, 276-279, 292-295, 309-310, 314, 321) (seeking relief only for harm in "Relevant Markets").

Defendants each moved to dismiss. The district court granted their motions and dismissed the suit with prejudice on the grounds that Biocad had not pleaded antitrust standing, that the foreign locus of the claims barred the suit, that Biocad was not entitled to injunctive relief under the Clayton Act, and that Biocad's requested leave to amend the complaint was unwarranted. SA15.

The district court determined that a nascent competitor in the U.S. pharmaceutical market must, to establish antitrust standing, plead "that FDA approval is probable." SA6. The court then asserted that,

> [a]lthough Plaintiff provides other factual allegations relevant to its intent and preparedness to engage the U.S. pharmaceutical market, including that it has created a subsidiary in the United States, leased space in Boston, Massachusetts, and taken steps to ensure

> that its new facility in Russia is FDA-compliant, none of these allegations overcome the paucity of facts set forth to demonstrate that FDA approval of Plaintiff's biosimilars is anywhere near likely or "probable."

SA7 (citation omitted). The court did not discuss or draw inferences from the Complaint's allegations that Biocad has in fact (and uniquely) created all three of these biosimilar mAbs, that it can reliably manufacture them up to FDA standards, and that they have been approved and sold in 15 other countries already. Nor did the court accept the Complaint's allegation that "FDA approval is probable" in light of Biocad's products and manufacturing capabilities. A120 (¶ 22).

The district court concluded in the alternative that Biocad's Sherman Act claims were barred by the FTAIA. Under that statute, the Sherman Act does not apply to conduct involving trade or commerce with foreign nations, except when the conduct involves import trade or commerce or when the conduct has a "'direct, substantial, and reasonably foreseeable effect'" on domestic or import commerce. SA9 (quoting 15 U.S.C. § 6a(1)). The exception for import trade did not apply, the court said, because Biocad had not yet begun importing to the United States and Roche was not an importer either. SA10-11. The court rejected as "conclusory" and "unfounded" the Complaint's "allegations that the Defendants' scheme 'specifically targeted U.S. import and domestic commerce' and 'did in fact produce some substantial effect on . . . interstate commerce.'" SA11 (quoting A138, 140, 169 (¶¶ 95, 105, 224)). Defendants' alleged conspiracy and attempt to monopolize

were not "directed at" the U.S. import market under the FTAIA because, the court asserted, the "alleged *intentions*" of Defendants' conspiracy could not provide a "sufficient causal nexus" to the United States. *Id.*

The district court also held that the FTAIA's exception for domestic effects did not apply. "Plaintiff's attenuated chain of causation is insufficient," the court said, "to establish a 'direct, substantial, and reasonably foreseeable effect' under the FTAIA." SA12. The court additionally held that, "even if it could be argued that Defendant[s'] foreign conduct caused a cognizable domestic effect" by excluding Biocad from the U.S. pharmaceutical market, "'the direction of causation runs the wrong way'" because "Plaintiff's injuries caused (or will cause) the domestic effect, not vice versa." *Id.* (quoting *Lotes Co. v. Hon Hai Precision Indus. Co.*, 753 F.3d 395, 414 (2d Cir. 2014)). The court reached that conclusion by construing Biocad's claims as seeking a remedy for the Russian effects of Defendants' conspiracy, rather than the U.S. effects of that conspiracy. *See id.* ("Plaintiff essentially alleges that Defendants' conduct in Russia harmed Plaintiff in Russia, which in turn prevented Plaintiff 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."). The court did not perceive that Biocad's Sherman Act claims seek a remedy for exclusion from the U.S. market itself, rather than for the earlier damages Biocad suffered in Russia. A172-82 (¶¶ 237-295).

Finally, the district court rejected Biocad's claim under New York's Donnelly Act for the sole reason that the Donnelly Act reaches only conduct within the scope of the Sherman Act and that the FTAIA therefore precluded the Donnelly Act claims just as it had barred the Sherman Act claims. SA13. It applied the same reasoning to reject Biocad's claim for injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26. SA13. And the court denied Biocad's request for leave to amend the Complaint as insufficiently developed.[7]

SUMMARY OF ARGUMENT

I.A. Biocad has properly pleaded antitrust injury and therefore antitrust standing. Exclusion from the U.S. markets for three cancer-fighting biologic drugs, as happened to Biocad here, is the kind of injury that the antitrust laws were intended to prevent. As a prospective competitor, Biocad must plead and ultimately prove that it intended and was prepared to enter the markets from which it was unlawfully excluded. Biocad has properly alleged that it has created and can reliably manufacture biosimilars of the drugs at issue; has successfully received approvals for and sold those drugs in other countries; and has become Roche's

[7] The district court also dismissed Biocad's claim under the Robinson-Patman Act and what it interpreted as a tying claim under the Clayton Act. SA7-9. Biocad does not appeal the dismissal of its Robinson-Patman Act claim. As for the Clayton Act, Biocad never intended to assert a separate substantive tying claim under that Act. It relies on the Clayton Act solely for its private cause of action based on Defendants' violations of the Sherman Act, including treble damages and injunctive remedies.

leading competitor globally. Biocad also has further alleged that it has taken particular steps directed at U.S. market entry, including creating a subsidiary, hiring personnel, and leasing premises in Boston.

B. Biocad also is prepared and ready to obtain FDA approval for its biosimilars in the United States, and will probably receive such approval if it overcomes the barriers created by Defendants' anticompetitive attacks. Although an allegation of probable approval is not always necessary to establish antitrust injury, such an allegation helps to support a showing of intent and preparedness for U.S. market entry. Biocad has alleged that FDA approval is probable, which the district court should have taken as true. It further has grounded that allegation in its successful efforts to bring its new Russian facility into compliance with FDA standards; to implement a quality control plan recommended by a leading U.S. consultant; and to verify compliance through multiple compliance audits. Combined with Biocad's previous success at growing a worldwide business, those allegations amply support its showing of antitrust injury.

C. The district court erred by refusing to credit Biocad's well-pleaded allegations on a motion to dismiss and by refusing to draw reasonable inferences in Biocad's favor. Disputes about whether FDA approval was in fact probable (as opposed to whether Biocad's allegations were concrete and plausible) cannot properly be resolved at the pleading stage. Further, the district court's demand for

a specific checklist of details about the status and expected progress of Biocad's FDA applications was inconsistent with the notice-pleading standard of Federal Rule of Civil Procedure 8 and with the principle that a plaintiff need not include evidence in its complaint.

II.A. The FTAIA does not bar Biocad's claims because Defendants' conduct involves import commerce. Where a defendant's conduct is directed at an import market, the FTAIA does not apply and the courts apply only pre-FTAIA law that requires a substantial intended effect on U.S. commerce. The conspiracy here was directed at the U.S. import market because it had the intent and effect of delaying or preventing Biocad's importation of biosimilar medications after Roche's exclusive rights expired. The district court's contrary conclusion rested on that court's disregard for Biocad's well-pleaded allegations and its erroneous belief that Defendants' intent did not matter to whether their conduct was directed at an import market.

B. In the alternative, Biocad's allegations also were sufficient to show that Defendants' conduct had a direct, substantial, and reasonably foreseeable effect on domestic commerce and import commerce. Preventing 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 that Defendants already had accomplished by the time Biocad's action was filed. Biocad's injuries

flow directly from that harm: but for Defendants' exclusionary conduct, Biocad would earn profits on sales it would be able to make in the U.S. market. Those lost profits are the only damages Biocad seeks to recover in this action. They are within the core purpose of the U.S. antitrust laws.

III. Biocad's claims under the Clayton Act for injunctive relief and under New York's Donnelly Act also should be reinstated. The district court's rationales for dismissing those claims depended entirely on its dismissal of Biocad's Sherman Act claims. Accordingly, all of those claims should be restored together if this Court reverses the district court's judgment.

STANDARD OF REVIEW

This Court "review[s] *de novo* a district court's dismissal of a complaint for failure to state a claim." *Starr v. Sony BMG Music Entm't*, 592 F.3d 314, 321 (2d Cir. 2010). "In so doing, [the Court] accept[s] as true the factual allegations of the complaint, and construe[s] all reasonable inferences that can be drawn from the complaint in the light most favorable to the plaintiff." *Arar v. Ashcroft*, 585 F.3d 559, 567 (2d Cir. 2009) (en banc).

ARGUMENT

I. BIOCAD HAS PLEADED ANTITRUST STANDING

To assert a claim under the antitrust laws, a plaintiff must establish antitrust standing by showing that it both (1) has "suffered antitrust injury" and (2) would be an "efficient enforcer[ ] of the antitrust laws." *Gelboim v. Bank of Am. Corp.*, 823 F.3d 759, 772 (2d Cir. 2016), *cert. denied*, 137 S. Ct. 814 (2017). The district court's ruling is based on the antitrust-injury component of that test.[8]

A. Biocad Has Pleaded Exclusion From A Market It Intends And Is Prepared To Enter, Which Constitutes Antitrust Injury

Biocad has antitrust injury because it is a prospective competitor in the U.S. market for cancer drugs that has been excluded from the market by Defendants' anticompetitive conduct. The antitrust laws provide relief for injuries stemming from anticompetitive conduct so long as the injury "is of the type that the antitrust statute was intended to forestall." *Associated Gen. Contractors of California, Inc. v. California State Council of Carpenters*, 459 U.S. 519, 540 (1983); *see Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977) (defining antitrust injury as "injury of the type the antitrust laws were intended to prevent and that

[8] Defendants did not raise in the district court any independent challenges to Biocad's ability to serve as an efficient enforcer of the antitrust laws below. Instead, they argued in footnotes that Biocad was not an efficient enforcer for the same reasons that it purportedly had not shown antitrust injury. *See* Dist. Ct. ECF No. 52, at 15 n.10; Dist. Ct. ECF No. 57, at 13 n.8. Accordingly, no separate efficient-enforcer analysis is required.

flows from that which makes defendants' acts unlawful"). Antitrust injury thus must "reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation." *Brunswick*, 429 U.S. at 489.

Biocad's exclusion from the U.S. markets for three cancer-fighting biologic drugs reflects the anticompetitive effect of Defendants' violations and qualifies as antitrust injury under settled precedent. Harm to "competitors whom the [antitrust] conspirators hoped to eliminate from the market," *Blue Shield of Virginia v. McCready*, 457 U.S. 465, 479 (1982), is one of the core forms of antitrust injury. *See id.* at 479-80 (acknowledging that such competitors have standing, and extending it to a patient of such a competitor); *Daniel v. American Bd. of Emergency Med.*, 428 F.3d 408, 439 (2d Cir. 2005) (a "would-be competitor can . . . demonstrate standing to challenge an exclusionary scheme that precludes him from entering a market [where] he sues to recover the profits that he otherwise would have earned"); *see also Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 123-25 (1969) (lost profits from market exclusion were "precisely the type of loss that the claimed violations of the antitrust laws would be likely to cause").

Because "it is as unlawful to prevent a person from engaging in business as it is to drive a person out of business," a prospective competitor may suffer antitrust harm just as surely as an established competitor. *American Banana Co.*

v. United Fruit Co., 166 F. 261, 264 (2d Cir. 1908), *aff'd*, 213 U.S. 347 (1909). The prerequisite for such claims is that the prospective competitor must plead and ultimately prove "facts showing an intention and preparedness to engage in business." *Id.*; *see also International Rys. of Cent. Am. v. United Brands Co.*, 532 F.2d 231, 248 (2d Cir. 1976) (describing the intent-and-preparedness standard as "well settled").[9] In making that showing,

> [i]ndicia of preparedness include adequate background and experience in the new field, sufficient financial capability to enter it, and the taking of actual and substantial affirmative steps toward entry, such as the consummation of relevant contracts and procurement of necessary facilities and equipment.

Andrx, 256 F.3d at 807; *see also Solinger v. A&M Records, Inc.*, 586 F.2d 1304, 1309-10 (9th Cir. 1978) (similar factors).

In this case, Biocad amply alleges intent and preparations to enter the relevant U.S. markets. Biocad alleges that it successfully has created biosimilars of the three drugs at issue, that it can manufacture those drugs reliably, that it already has received approvals for and sold its biosimilars in numerous other countries, and that it already is Roche's leading competitor in worldwide sales

[9] *See also Sanger Ins. Agency v. HUB Int'l, Ltd.*, 802 F.3d 732, 738 (5th Cir. 2015) (intent-and-preparedness standard); *Bourns, Inc. v. Raychem Corp.*, 331 F.3d 704, 710-12 (9th Cir. 2003) (same); *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 806-08 (D.C. Cir. 2001) (same); *Martin v. Phillips Petroleum Co.*, 365 F.2d 629, 633-34 (5th Cir. 1966) (same); IIA Phillip E. Areeda et al., *Antitrust Law* ¶ 349a, at 259-61 (4th ed. 2014) ("Areeda, *Antitrust Law*") (same).

of mAbs. A128-29 (¶¶ 56-62). In addition to a new, state-of-the-art Russian facility that complies with FDA manufacturing protocols, A132 (¶ 74), Biocad also has taken particular steps directed at U.S. market entry, including creating a U.S. subsidiary, transferring personnel to and hiring them in the United States, and leasing premises in Boston. A131 (¶¶ 68-70). It has hired consultants to support its efforts at U.S. entry, prepared a timeline and developed a strategy for that entry, and budgeted sums between $60 and $100 million for each product. A131-32 (¶¶ 71, 73). Those allegations are concrete, specific, and more than sufficient.

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

Because the U.S. pharmaceutical markets in which Biocad seeks to compete were regulated by the FDA, it ultimately must obtain FDA approval to sell its products here. Biocad's steps to prepare for obtaining that approval provide additional support for its showing of intent and preparedness to enter the market.

The D.C. Circuit's decision in *Andrx* provides instructive analysis of a related problem. In that case, the generic drug manufacturer Andrx allegedly had conspired with a brand manufacturer to keep other generics out of the market by indefinitely postponing the start of a statutory exclusivity period under the Hatch-Waxman Act. Biovail, one of the excluded generics, sought relief under the antitrust laws. Andrx argued that Biovail could not establish antitrust injury because it had not alleged that the FDA had approved its product. The D.C.

Circuit rejected that argument, holding that Biovail "could have alleged its intent and preparedness to enter the market by claiming that FDA approval was probable." *Andrx*, 256 F.3d at 808.

Andrx did not hold that an allegation of probable approval was necessary in all cases, nor has any other court (except the district court here) embraced such a categorical requirement. Some district courts have concluded that probable FDA approval, while potentially a "significant factor," is not a prerequisite to antitrust injury. *E.g.*, *Roxane Labs., Inc. v. SmithKline Beecham Corp.*, No. 09-CV-1638, 2010 WL 331704, at *3-4 (E.D. Pa. Jan. 26, 2010) (treating "the probability of FDA approval as one significant factor to recognize within the intent and preparedness standard," but refusing to dismiss merely because the plaintiff did not allege such probability in express terms).[10] Others have refused to find antitrust injury at least in part for lack of such an allegation. *See, e.g.*, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 207 (E.D.N.Y. 2003).

Whether it is necessary or optional, Biocad has alleged here that "FDA approval" of its biosimilars "is probable." A120 (¶ 22). Biocad also has averred that it "anticipates FDA approval to sell biosimilars in the U.S. and plans to compete head to head against Roche." A135 (¶ 80). Those are, in themselves,

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

properly pleaded allegations of fact that should be taken as true. And they are plausibly pleaded in view of the specific steps Biocad took to prepare for obtaining FDA approval. Those steps, which together cost Biocad millions of dollars and tens of thousands of work hours, consisted of bringing Biocad's new Russian facility into compliance with FDA manufacturing and laboratory standards, A132-33 (¶¶ 75-76); working with a leading U.S. consultant to implement a "Quality Improvement Plan," which involved extensive revisions of the facility's quality assurance systems, its laboratory quality control, its material controls, its validation and qualification systems, and its hygiene, pest control, and access control systems, A132-34 (¶¶ 75, 77); and verifying compliance through audits, A134 (¶ 78). Taking all of that into account, and in further light of its worldwide record of success at manufacturing biosimilars, achieving regulatory approvals, selling its products, and competing with Roche, A128-29 (¶¶ 56-62), Biocad had ample basis to say it likely will be able to obtain FDA approval – if it is not prevented by Defendants' anticompetitive conduct from being financially viable enough to compete in the U.S. market.

The weight of authority has found sufficient intent and preparedness for similarly situated or less-prepared plaintiffs. The court in *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 274 F. Supp. 2d 937 (N.D. Ill. 2003), found antitrust standing where a generic manufacturer had secured financing and negotiated development,

marketing, and supply agreements in "anticipation of the expiration of [a branded manufacturer's] five-year period of market exclusivity," but had not yet applied for FDA approval. *Id.* at 941-43. The court in *Tawfilis v. Allergan, Inc.*, 157 F. Supp. 3d 853 (C.D. Cal. 2015), found sufficient the plaintiff's "extensive experience selling drugs throughout the world" and regulatory approvals in numerous other countries – even though the plaintiff in that case was merely *planning* on building, but had not yet built, an FDA-compliant facility, much less applied for FDA approval. *Id.* at 866-67. The court in *Retrophin, Inc. v. Questcor Pharmaceuticals, Inc.*, 41 F. Supp. 3d 906 (C.D. Cal. 2014), accepted allegations of "expertise as a biopharmaceutical company focusing on rare diseases," even though the plaintiff had not yet (because of the defendant's conduct) acquired the rights to the drug it sought to market. *Id.* at 915.[11] Biocad is far better prepared to enter the market than were the plaintiffs in those cases.

[11] *See also Amgen, Inc. v. F. Hoffmann-La Roche Ltd.*, 480 F. Supp. 2d 462, 466, 468 (D. Mass. 2007) (sufficient to allege personnel hiring, retention of outside consultants and vendors, contacting potential customers, and building an offshore facility, plus "imminent" FDA approval); *In re Metoprolol Succinate Direct Purchaser Antitrust Litig.*, Civil Nos. 06-52 (GMS) & 06-71 (GMS), 2010 WL 1485328, at *7-8 (D. Del. Apr. 13, 2010) (court could not conclude on motion to dismiss whether efforts to obtain approval were "slowed as a result of" anticompetitive conduct that caused plaintiff to "divert . . . resources" from FDA efforts); *BNLfood Invs. Ltd. SARL v. Martek Biosciences Corp.*, Civil No. WDQ-11-0446, 2011 WL 6439451, at *4 (D. Md. Dec. 14, 2011) (relying on plaintiff's experience in other countries, its actual development of the products involved, its foreign regulatory approvals, "the more than 10 million it has spent to build and expand its facilities . . . for U.S. customers," and "its contracts for staff and

Biocad's contention that it probably would obtain approval is further strengthened by its allegations that its plans to enter the U.S. market were the motive for Defendants to attack Biocad's business in Russia. For purposes of evaluating antitrust injury, this Court "assume[s] the alleged violation" occurred, *Daniel*, 428 F.3d at 437; here, the violation is alleged thoroughly and in detail. Taking Biocad's allegations as true, Roche and R-Pharm poured substantial resources into damaging Biocad's business, including tactics such as below-cost pricing and fraudulent bidding that cost money without helping Defendants' Russian business – for the sole purpose of blocking or delaying Biocad's entry into the U.S. market. Defendants' willingness to spend money for that goal permits a reasonable (indeed, strong) inference that they believed Biocad otherwise would succeed in entering the U.S. market and driving down Roche's prices.

C. The District Court Erred In Disregarding Biocad's Well-Pleaded Allegations Of Intent, Preparedness, And Probable FDA Approval

The district court here found a lack of intent and preparedness only by departing from the legal standard that governs a motion to dismiss. To begin with, Biocad's allegations about its preparations to enter the relevant U.S. markets

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equipment to enter the U.S. market"). *Bristol-Myers Squibb Co. v. Copley Pharmaceutical, Inc.*, 144 F. Supp. 2d 21 (D. Mass. 2000), on which the district court relied, is not to the contrary. That case turned on the plaintiff's failure to file first at the FDA, which the defendants' actions did not affect. *See id.* at 25.

and the probability of FDA approval based on those preparations were factual allegations that the district court was required to credit. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007) ("Rule 12(b)(6) does not countenance . . . dismissals based on a judge's disbelief of a complaint's factual allegations.") (alteration in original); *Anderson News, L.L.C. v. American Media, Inc.*, 680 F.3d 162, 184 (2d Cir. 2012) ("to present a plausible claim at the pleading stage, the plaintiff need not show that its allegations . . . are more likely than not true"). The district court's mistaken belief that it was required to assess at the pleading stage the "likelihood of [FDA] approval of [Biocad's] biosimilars," SA6, was contrary to those settled principles. At most, the district court's role was to assess whether it was plausible (not probable) that FDA approval was likely.

In making that assessment, the court should have kept in mind that "[t]he choice between two plausible inferences that may be drawn from factual allegations is not a choice to be made by the court on a Rule 12(b)(6) motion." *Anderson News*, 680 F.3d at 185; *see also Gelboim*, 823 F.3d at 782 ("[A]t the motion-to-dismiss stage, appellants must only put forth sufficient factual matter to plausibly suggest an inference . . . *even if* the facts are susceptible to an equally likely interpretation."). Here, Biocad's existing record of success in other countries combined with particular, identified preparations for entry into the relevant U.S. markets made it at least plausible that – absent delay caused by

Defendants' anticompetitive conduct – Biocad intended and was prepared to enter those markets at or around the time Roche lost exclusivity.

The district court also erred in reasoning that Biocad could not state a claim without providing a checklist of details about the FDA approval process, such as

> [the] expected timeline for approval, what clinical trials would be required, whether [Biocad] 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. The Complaint in this case was required to set forward only "a short and plain statement of [Biocad's] claim," Fed. R. Civ. P. 8(a)(2); this Court has "reject[ed]" the "contention that *Twombly* and [*Ashcroft v.*] *Iqbal*[, 556 U.S. 662 (2009),] require the pleading of specific evidence or extra facts beyond what is needed to make the claim plausible." *Arista Records, LLC v. Doe 3*, 604 F.3d 110, 120-21 (2d Cir. 2010); *see also In re Insurance Brokerage Antitrust Litig.*, 618 F.3d 300, 325 n.25 (3d Cir. 2010) (noting as to an antitrust complaint that "[i]t is not necessary to plead evidence") (alteration in original). Thus, even if Biocad were required (though it was not) to include an allegation that FDA approval was probable (as it did), the district court had no basis to demand a special list of allegations.

Finally, the district court also erred in stating that Biocad had "not explain[ed] the relevance of [its new] *facility* [in Russia] to the approval of its *drugs* in the United States." SA6. Biocad's successful construction of a new facility for manufacturing biosimilars – one of only 50 facilities worldwide in the specialized area of producing mAbs – was relevant to show its resources and capacity to enter the U.S. market as part of its plan to compete with Roche worldwide (as in many countries Biocad already does). That is especially so because – in the particular context of biosimilar production – a reliable manufacturing process is a key part of market readiness. And, if more were needed to link the facility to the U.S. market and FDA approval, Biocad's investments of resources and time to ensure that the new facility met FDA manufacturing and laboratory requirements further supported that connection.

II. THE FTAIA DOES NOT BAR BIOCAD'S CLAIMS

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

1. The FTAIA does not apply to, much less bar, Biocad's claims because it alleges and seeks a remedy for conduct directed at the U.S. import market. Under the FTAIA, the Sherman Act does not apply to "conduct involving trade or commerce (other than import trade or import commerce) with foreign nations." 15 U.S.C. § 6a. The parenthetical exclusion of "import trade or import commerce" generally is referred to as the "import exclusion" or the "import exception" to the

FTAIA. As this Court has explained, the FTAIA leaves the Sherman Act unaltered when "conduct by the defendants . . . was directed at an import market." *Kruman v. Christie's Int'l PLC*, 284 F.3d 384, 395 (2d Cir. 2002), *abrogated on other grounds by F. Hoffmann-La Roche Ltd. v. Empagran S.A.*, 542 U.S. 155 (2004).[12]

This Court explained how to apply the import exclusion in *Kruman*. "The relevant inquiry is whether the conduct of the defendants – not the plaintiffs – involves import trade or commerce." 284 F.3d at 395; *accord Carpet Grp. Int'l v. Oriental Rug Imps. Ass'n, Inc.*, 227 F.3d 62, 71-72 (3d Cir. 2000), *overruled on other grounds by Animal Sci. Prods., Inc. v. China Minmetals Corp.*, 654 F.3d 462 (3d Cir. 2011).[13] In assessing whether conduct "involves import trade or commerce," the FTAIA incorporates the "longstanding rule . . . that it is the effect and not the location of the conduct that determines whether the antitrust laws apply." *Kruman*, 284 F.3d at 395 (citing, *e.g.*, *United States v. Aluminum Co. of Am.*, 148 F.2d 416,

[12] The Supreme Court's decision in *Empagran* partially abrogated *Kruman* by holding that the FTAIA bars actions under the Sherman Act where: (1) anticompetitive conduct causes both domestic and foreign injuries; (2) the domestic and foreign injuries are independent of one another; and (3) the plaintiff seeks relief for the foreign injuries. *See Empagran*, 542 U.S. at 160-63. That holding is not relevant here because Biocad seeks relief solely for its domestic injuries. As the district court recognized, SA9-11, *Kruman* remains good law as to the present case (though that court erred in its reading of *Kruman*).

[13] *Animal Science Products* overruled *Carpet Group*'s holding that the FTAIA imposes a limit on federal subject matter jurisdiction, but reaffirmed its holding as to the substance of the import exception. *See* 654 F.3d at 470.

443-44 (2d Cir. 1945) (L. Hand, J.) ("*Alcoa*")). Thus, a defendant's conduct involves import commerce if it was "directed at an import market," *id.*, in the sense of being directed to produce an effect on such a market.

When a complaint alleges conduct directed at U.S. import commerce, courts apply the underlying Sherman Act standard that existed prior to the FTAIA to determine the reach of U.S. antitrust law. *See Minn-Chem, Inc. v. Agrium, Inc.*, 683 F.3d 845, 855 (7th Cir. 2012) (en banc) ("The FTAIA does not require any special showing in order to bring these transactions back into the Sherman Act, as *Empagran* put it, because they were never removed from the statute."). That traditional standard is that "the Sherman Act covers foreign conduct producing a substantial intended effect in the United States." *Hartford Fire Ins. Co. v. California*, 509 U.S. 764, 797 n.24 (1993) (applying *Alcoa,* 148 F.2d at 444).

In this case, Biocad alleges conspiratorial conduct that was directed at import commerce and was intended to (and did) have a substantial effect in the United States. Indeed, Defendants conspired for the "sole purpose" of preventing or delaying Biocad from entering the U.S. import market for pharmaceuticals. A173, 176, 179, 181-82 (¶¶ 245, 260, 275, 291). The Complaint supports that theory and renders it plausible with examples of anticompetitive conduct both in the United States and abroad, all to protect Roche's most lucrative market from the only company with biosimilars that will compete with all three of its blockbuster

mAbs. A123, 128 (¶¶ 31, 56); *see generally* A144-65 (¶¶ 122-205) (details of conduct). That conduct already has delayed Biocad's U.S. market entry. A169-70 (¶¶ 223-228). Whatever the result of this case, it is a foregone conclusion that U.S. cancer patients and their insurers will pay far higher prices for Roche's mAbs for at least some time because Biocad will not be importing its competing biosimilars.

In *Carpet Group*, the Third Circuit held that an alleged conspiracy to prevent foreign carpet manufacturers from selling directly to U.S. retailers was directed at the United States and so fell outside the FTAIA. A key fact was that the defendant had pressured others to refrain from doing business with the plaintiff's import business. That fact "alone," the court explained, "arguably should have been sufficient to remove the FTAIA as an obstacle." 227 F.3d at 72; *see also id.* at 73 (additional facts including prevention of sales by foreign manufacturers to U.S. retailers and efforts to stop trade fairs). Here, Biocad similarly alleges that Defendants conspired to prevent it from entering the U.S. import market and selling to their existing customers.

Maricultura Del Norte v. World Business Capital, Inc., 159 F. Supp. 3d 368 (S.D.N.Y. 2015), provides another useful illustration. In that case, a Mexican fish exporter claimed that it had been excluded from the U.S. import market for Bluefin tuna. *See id.* at 383 (explaining that plaintiffs "allege[d] that they . . . want[ed] to export Bluefin Tuna [from Mexico] into the United States and [we]re prevented

from doing so because of Defendants' allegedly anticompetitive conduct"). The court held that this type of claim "implicate[d] the FTAIA's import exception." *Id.* Here, Biocad has similarly alleged that it wants to export biosimilars from Russia and import them into the United States, but has been prevented from doing so by Defendants' anticompetitive conduct.

2. The district court's contrary ruling misconstrues the Complaint and misapplied longstanding antitrust principles. *First*, the court erred in stating that the Complaint "pleads no facts demonstrating . . . a substantial effect" on U.S. import or domestic commerce. SA11. Biocad pleaded facts demonstrating a causal connection between Defendants' attacks on its Russian business and the delay (and possible foreclosure) of its entry into the U.S. market. Those attacks resulted in less business and lost sales for Biocad in its home market of Russia. A146-47 (¶¶ 125-127) (lower prices); A151-52 (¶¶ 145, 147) (inability to bid on auctions); A156 (¶ 164) (lost sales from unlawful payments); A163-65 (¶¶ 192-205) (lost sales from Perjeta tying). Those losses damaged Biocad's financial position to the point where it has been required to lay off U.S. employees and otherwise delay expenditures needed for U.S. market entry. A135, 170-72 (¶¶ 81, 229-236). There is nothing conclusory or implausible about that scenario.

Second, the district court erred in finding "no authority for the proposition that Defendants' alleged *intentions* provide a sufficient causal nexus to satisfy the

import exception." SA11. This Court explained in *Kruman* that what matters is whether Defendants' conduct is "directed at an import market," 284 F.3d at 395, and whether "the object of the conspiracy was . . . [an] import market," *id.* at 396. Both of those tests – the "direct[ion]" of Defendants' conduct and the "object" of their conspiracy – plainly speak to their purposes in acting. *See also Maricultura Del Norte*, 159 F. Supp. 3d at 383 (both "intent and result" of conspiracy are relevant) (quoting *In re Vitamin C Antitrust Litig.*, 904 F. Supp. 2d 310, 317 (E.D.N.Y. 2012)). No other rule makes sense where, as here, the claims arise from an alleged conspiracy – what makes a conspiracy unlawful is always the intent of the conspirators. And, even aside from intent's inherent relevance, Defendants' aim to produce an anticompetitive effect on U.S. imports lends additional plausibility to Biocad's allegations that such an effect occurred.

Third, the district court erred in suggesting that the effect of Defendants' conspiracy "on U.S. import commerce was . . . attenuated by multiple intermediate steps." SA12 (attempting to distinguish *Maricultura Del Norte*). Attenuation that breaks a causal chain can occur where a plaintiff's injuries depend on the "conduct of persons who are not victims of the conspiracy" or where the damage it has suffered is "more remote than the harm allegedly suffered" by a more direct victim. *Associated Gen. Contractors*, 459 U.S. at 541 n.46; *see also Maricultura Del Norte*, 159 F. Supp. 3d at 383 (giving the example of "component manufacturers whose

products only reach the U.S. market after multiple iterations of incorporation into higher level products"). Here, Biocad's injuries stem directly from the actions of Defendants and their effect on Biocad's own financial health, and its goal to import its products directly into the United States.

Fourth, the district court misapplied *Kruman*. The court erroneously believed that here, "as in *Kruman*, the conduct alleged in the First Amended Complaint was 'directed at' manipulating prices in a foreign country," SA11, rather than the U.S. market. But the import exclusion did not apply in *Kruman* because the plaintiffs alleged *only* price-fixing at foreign auctions and failed to allege that "the object of the conspiracy was . . . [to deny] any import market for those goods." 284 F.3d at 396. The *Kruman* complaint therefore "did not describe conduct by the defendants that was directed at an import market." *Id.* at 395. Biocad's claims stand in sharp contrast. The Complaint repeatedly, plausibly alleges that the purpose of Roche's anticompetitive conduct was to prevent Biocad's entry into the lucrative U.S. pharmaceutical market. A173, 176, 179, 181-82 (¶¶ 245, 260, 275, 291).

Fifth, the district court erred in concluding that its decision found support in *Turicentro, S.A. v. American Airlines Inc.*, 303 F.3d 293 (3d Cir. 2002), *overruled on other grounds by Animal Science Products*, 654 F.3d 462, and *Animal Science Products* itself. Both decisions depended on the premise that the defendants' "actions did not directly increase or reduce imports into the United States."

Turicentro, 303 F.3d at 303; *see also Animal Sci. Prods.*, 654 F.3d at 470-71. But Biocad alleges that Defendants' actions had just that effect.

B. Biocad's Claims Also Arise From Direct, Substantial, And Reasonably Foreseeable Effects On U.S. Commerce[14]

1. The FTAIA brings conduct involving non-import foreign commerce back within the Sherman Act's reach provided that the conduct "has a direct, substantial, and reasonably foreseeable effect . . . on trade or commerce which is not trade or commerce with foreign nations, or on import trade or import commerce with foreign nations," 15 U.S.C. § 6a(1)(A), and provided that "such effect gives rise to a claim under the provisions of" the Sherman Act, *id.* § 6a(2). That provision is frequently referred to as the "domestic effects" exception (though it also covers effects on import commerce). It applies to conduct that

> (1) sufficiently affects American commerce, *i.e.*, it has a "direct, substantial, and reasonably foreseeable effect" on American domestic, import, or (certain) export commerce, *and* (2) has an effect of a kind that antitrust law considers harmful, *i.e.*, the "effect" must "giv[e] rise to a [Sherman Act] claim."

[14] Biocad argued below that the FTAIA import exclusion, rather than the domestic-effects exception, applied to its claims. The domestic-effects exception argument is not barred on appeal, however, because the district court addressed the issue nonetheless. *See United States v. Williams*, 504 U.S. 36, 41 (1992) (review is "permitt[ed] . . . of an issue not pressed so long as it has been passed upon"); *United States v. Nursing Pers. Home Care*, 794 F.3d 232, 235 (2d Cir. 2015) ("we do not consider arguments waived when, although not raised below, they were nevertheless passed on").

Empagran, 542 U.S. at 162 (alterations in original). When applying that exception, this Court has explained that it requires two distinct inquiries: "one asking whether the defendants' foreign conduct caused a cognizable domestic effect, and the other asking whether that effect caused the plaintiff's injury." *Lotes Co. v. Hon Hai Precision Indus. Co.*, 753 F.3d 395, 414 (2d Cir. 2014).

The Complaint satisfies both inquiries. Preventing or delaying Biocad's U.S. market entry permits Roche to continue to charge monopoly prices or at the very least reduces competition after Roche's patents expire. That delay already has occurred. Even though the effect will not be felt in U.S. markets until Roche's patents expire, the cost to U.S. consumers is "direct, substantial, and reasonably foreseeable" – indeed, it is practically certain. That is all the statute requires.

Antitrust suits by prospective pharmaceutical competitors, where the injury is delayed market entry, are common and well-recognized. *See Xechem*, 274 F. Supp. 2d at 941-44 (approving delay theory of harm); *Amgen*, 480 F. Supp. 2d at 468 (same); *Retrophin*, 41 F. Supp. 3d at 910-15 (same); *Metoprolol Succinate*, 2010 WL 1485328, at *7-8 (same); *BNLfood*, 2011 WL 6439451, at *4 (same). In *Eon Laboratories, Inc. v. Smithkline Beecham Corp.*, 298 F. Supp. 2d 175 (D. Mass. 2003), Eon even lost its right to an antitrust counterclaim because the cause of action had accrued and therefore was compulsory before Eon's FDA approval and market entry – and before the expiration of the defendant's patents. *See id.*

at 182-83. Nothing in the FTAIA alters the ability of prospective competitors to bring suit merely because they seek to be importers rather than domestic producers.

The effect that Biocad challenges – delaying entry or entirely excluding Biocad from the market – also "gives rise," 15 U.S.C. § 6a(2), to Biocad's claims because Biocad's injury is the business (and profits) it has lost in the United States. Biocad's Sherman Act claims seek relief exclusively for Biocad's inability to enter the U.S. market on time and do not seek any damages for lost business or lost profits in Russia. A172-82 (¶¶ 237-295). Because being "delayed and excluded from entering the Relevant [U.S.] Markets," A174 (¶ 248), is the effect that "caused the plaintiff's injury," *Lotes*, 753 F.3d at 414, the domestic-effects exception applies.

2. The district court erroneously concluded that *Lotes* weighed against Biocad's claims, but the reasoning of *Lotes* supports Biocad. The plaintiff in *Lotes* allegedly had been excluded from the Chinese market for USB connectors by anticompetitive conduct involving certain Chinese patents. *See* 753 F.3d at 398-402. It sought damages for that exclusion under the Sherman Act, arguing that its exclusion from the Chinese market had forced up prices in the United States and so harmed U.S. consumers. *See id.* at 414. This Court held that the FTAIA's requirement that a domestic effect "'give[] rise to' a plaintiff's claim" means that "the domestic effect must proximately cause the plaintiff's injury." *Id.* (alteration

in original). The plaintiff in *Lotes* did not meet that standard because the first alleged injury – exclusion from the market in *China* – causally preceded the higher prices later charged by the alleged monopolists in the United States. *See id*. The other identified injury in *Lotes* was that the defendants' refusal to license its patents "foreclose[ed] competition in the United States." *Id*. That second argument failed because any such refusal was neither a but-for nor a proximate cause of the plaintiff's exclusion from the Chinese market. *See id.* at 415.

Here, Biocad alleges that the Roche conspiracy has delayed or entirely precluded its entry into the U.S. market – that is, Defendants have "foreclos[ed] competition in the United States." *Id*. at 414. Unlike in *Lotes*, that effective exclusion from the U.S. market is the proximate cause of every injury for which Biocad seeks a remedy under the Sherman Act. Biocad is not seeking a Sherman Act remedy for injuries it suffered in the Russian marketplace; rather, it is seeking a remedy exclusively for the damage it has suffered as a result of having its entry into the U.S. market delayed or prevented.

The Complaint covers Defendants' conduct in Russia not because Biocad seeks an independent remedy for its Russian injuries in U.S. courts, but instead to illustrate the particulars of Roche's anticompetitive scheme. "The means of illicit exclusion, like the means of legitimate competition, are myriad." *United States v. Microsoft Corp.*, 253 F.3d 34, 58 (D.C. Cir. 2001) (en banc) (per curiam). In this

case, Roche's means of illicit exclusion involved numerous acts aimed at crushing Biocad's Russia-based business before it could enter the U.S. market. Biocad's lost profits in the United States are proximately linked to those exclusionary acts.

The district court's rule also would impose a novel, significant, and erroneous restriction on the domestic-effects exception. If the chain of causation runs the wrong way in this case, then exclusion from competition can never itself "give[] rise to a claim." 15 U.S.C. § 6a(2). That would mean that excluded competitors could *never* bring claims within the FTAIA. Excluded competitors, of course, long have had an antitrust cause of action. *See American Banana*, 166 F. at 264; *Martin*, 365 F.2d at 633; *International Rys.*, 532 F.2d at 248; *Andrx*, 256 F.3d at 806; *Bourns*, 331 F.3d at 711; *Sanger Ins.*, 802 F.3d at 738; IIA Areeda, *Antitrust Law* ¶ 349a. If Congress had wanted to bar such claims under the FTAIA, it would have said so expressly. And we are aware of no court – except the district court here – that has ever approved such a result.

III. DISMISSAL OF BIOCAD'S CLAYTON ACT INJUNCTIVE RELIEF CLAIM AND ITS DONNELLY ACT CLAIM ALSO SHOULD BE REVERSED

Biocad's claims for injunctive relief under the Clayton Act and for relief under New York's Donnelly Act also should be reinstated.

Section 16 of the Clayton Act confers a private right of action, and permits injunctive relief, for plaintiffs who allege "threatened loss or damage by a violation

of the antitrust laws." 15 U.S.C. § 26. Section 16 injunctive relief is therefore "characteristically available even though the plaintiff has not yet suffered actual injury." *Zenith Radio*, 395 U.S. at 130. To state a claim for injunctive relief under Section 16, a plaintiff must merely "demonstrate a significant threat of injury from an impending violation of the antitrust laws or from a contemporary violation likely to continue or recur." *Id.* Here, the district court rejected Biocad's request for injunctive relief under the Clayton Act only because it believed that the FTAIA pushed Biocad's claims outside the reach of U.S. antitrust law. SA13. For the reasons given in Parts I and II, neither antitrust standing doctrine nor the FTAIA bars Biocad's claims, and it therefore should be permitted to pursue injunctive relief under Section 16.

The district court also dismissed Biocad's Donnelly Act claim on the sole basis that the Donnelly Act does not permit claims that are barred by the FTAIA. *Id.* Because Biocad's claims are not barred by the FTAIA, the Donnelly Act claim should be reinstated as well.

CONCLUSION

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

Respectfully submitted,

/s/ *David C. Frederick*

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February 8, 2018

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), the undersigned certifies that this brief complies with the applicable type-volume limitations of Local Rule 32.1(a)(4)(A) and Federal Rules of Appellate Procedure 32(a)(5)(A) and 32(a)(6). This brief was prepared using a proportionally spaced type (Times New Roman, 14 point). Exclusive of the portions exempted by Federal Rule of Appellate Procedure 32(f), this brief contains 12,699 words. This certificate was prepared in reliance on the word-count function of the word-processing system (Microsoft Word Office 2013) used to prepare this brief.

/s/ *David C. Frederick*
David C. Frederick

February 8, 2018

CERTIFICATE OF SERVICE

I hereby certify that, on February 8, 2018, I electronically filed the foregoing Brief for Plaintiff-Appellant Biocad JSC and the following Special Appendix with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system. All participants are registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/ *David C. Frederick*
David C. Frederick

SPECIAL APPENDIX

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

No. 16 Civ. 4226 (RJS)

BIOCAD, JSC,

Plaintiff,

VERSUS

F. HOFFMAN-LA-ROCHE, LTD., *ET AL.*,

Defendants.

OPINION AND ORDER
September 30, 2017

RICHARD J. SULLIVAN, District Judge:

Plaintiff Biocad JSC brings this action against Defendants Roche Holding AG, F. Hoffman-La Roche Ltd., Genentech, Inc., and R-Pharm JSC, alleging that Defendants engaged in anti-competitive conduct to preclude Plaintiff from entering the market for oncological drugs in the United States. Now before the Court are Defendants' motions to dismiss the First Amended Complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). (Doc. Nos. 51, 53, 56.) For the reasons set forth below, the motions are GRANTED.

I. BACKGROUND

A. Facts

Plaintiff is a Russian drug development and manufacturing company with its principal place of business in St. Petersburg, Russia.[1] Defendants Roche Holding AG and F. Hoffman-La Roche ("FHL Roche") are Swiss corporations based in Basel, Switzerland engaged in the research, production, distribution, and sale of pharmaceuticals. Defendant Genentech, Inc. is a Delaware corporation affiliated with FHL Roche and Roche Holding AG (together, the "Roche Group") with its principal place of business in San Francisco, California. Defendant R-Pharm JSC is a Russian pharmaceutical company with its

[1] The following facts are taken from the First Amended Complaint (Doc. No. 37 ("FAC")) and are accepted as true for the purpose of deciding this motion. The Court has also considered Defendants' memoranda in support of dismissal (Doc. Nos. 52, 55, 57), Plaintiff's opposition (Doc. No. 63 ("Opp'n")), and Defendants' reply memoranda (Doc. Nos. 65–67).

principal place of business in Moscow, Russia.

The First Amended Complaint alleges an elaborate conspiracy whereby the Defendants[2] engaged in illegal anti-competitive behavior in Russia in order to sabotage Plaintiff's nascent efforts to enter the U.S. market for oncology drugs. Plaintiff alleges that Defendants maintain a monopoly in the United States over certain treatments called monoclonal antibodies, and in particular, over three drugs: bevacizumab (Avastin), trastuzumab (Herceptin), and rituximab (Rituxan) (collectively, the "Drugs"). Plaintiff further alleges that it is the only pharmaceutical company in the world able to manufacture biosimilars of the Drugs and thus compete directly with Defendants in the United States and in other countries. (FAC ¶¶ 56, 63.) Biosimilars are drugs sold at prices lower than their brand-name equivalents. (*Id.* ¶¶ 82–84.)

Plaintiff alleges that it began developing biosimilar monoclonal antibodies in 2010, including biosimilars of the Drugs, and received approval from the Russian Ministry of Health for its biosimilars of the Drugs in late 2014 and 2015. (*Id.* ¶¶ 58–62.) Plaintiff has two production sites for its drugs in Russia, one in St. Petersburg and one in Moscow, and has "contracts for the sale and delivery of its biosimilars valued at over U.S. $200 million, with distribution partners in Indonesia, Turkey, Armenia, Cambodia, Kenya, Kyrgyzstan, Morocco, Myanmar, Pakistan, South Africa, Ukraine, Uzbekistan, [Sri] Lanka, and Vietnam." (*Id.* ¶¶ 64, 67.) Plaintiff alleges that it has begun taking steps to market its biosimilars in the United States by opening a subsidiary and hiring personnel in the United States, securing a lease for space to be used as a laboratory, budgeting the cost of entry into the U.S. market, opening a new manufacturing site in Eastern Europe, hiring consultants to help ensure that the new site meets U.S. Food and Drug Administration ("FDA") and European Union regulations, developing a Quality Improvement Plan to meet FDA requirements, and spending over $7 million on equipment and incidental fees. (*Id.* ¶¶ 68–71, 74–80.) Plaintiff "anticipates FDA approval to sell biosimilars in the U.S. and plans to compete head to head against [Defendants] by dramatically undercutting" Defendants' prices for the Drugs. (*Id.* ¶ 80.)

However, according to the First Amended Complaint, Defendants' illegal and anti-competitive conduct in Russia has hampered Plaintiff's plans to enter the U.S. market for the Drugs. Plaintiff alleges that Defendants perpetrated an assortment of illegal, anticompetitive schemes, including:

- Engaging in predatory pricing by increasing the prices of the Drugs in the United States and decreasing the prices of the Drugs in Russia by 72% to 84% (*id.* ¶¶ 121–27);
- Selling the Drugs in Russia through a distributor (Defendant R-Pharm) at a loss (*id.* ¶¶ 128–35);
- Bribing doctors, pharmacies, and hospitals in Russia to prescribe and request the Drugs from state-sponsored insurance programs (*id.* ¶¶ 136–80);
- Limiting distribution of the Drugs in order to thwart testing of biosimilars (*id.* ¶¶ 181–91);

[2] The First Amended Complaint rarely distinguishes between the acts of each Defendant, and frequently refers to all four Defendants simply as "Defendants," or to the Roche Group as "Roche." (*See, e.g.*, FAC ¶ 4 n.1, 9, 11, 13.)

- Illegally tying and bundling the drug Herceptin to another cancer drug, Perjeta, in Russia (*id.* ¶¶ 192–205);

- Making fraudulent bids for and misrepresenting the availability of Avastin in Russia (*id.* ¶¶ 206–14); and

- Packaging Herceptin in a way that forced patients to buy, and eventually discard, more of the drug than they would if it was packaged differently (*id.* ¶¶ 215–22).

The First Amended Complaint alleges that the above-described anti-competitive conduct was part of an effort "to foreclose the U.S. market to biosimilar alternatives" to the Drugs. (*See, e.g.*, *id.* ¶ 226.) Plaintiff alleges that, because of Defendants' actions, it has been "deprived of the ability to realize its substantial investments into the preparations undertaken to import biosimilars in[to] the U.S." (*Id.* ¶ 230.)

B. Procedural History

Plaintiff commenced this action by filing a complaint against Defendants FHL Roche Ltd., Genentech, Inc., and R-Pharm JSC on June 7, 2016. (Doc. No. 1.) On October 24, 2016, Plaintiff filed the First Amended Complaint, adding Roche Holding AG as a Defendant and asserting claims under the Sherman Act, 15 U.S.C. §§ 1, 2, the Clayton Act, 15 U.S.C. §§ 15, 26, the Robinson-Patman Act, 15 U.S.C. § 13, and the Donnelly Act, N.Y. Gen. Bus. Law § 340 *et seq.* (Doc. No. 37.) On December 12, 2016, each Defendant filed a motion to dismiss the First Amended Complaint (Doc. Nos. 51–58) arguing, among other things, that Plaintiff did not allege an antitrust injury and therefore lacks antitrust standing to bring a claim,[3] that the Court lacks subject-matter jurisdiction over Plaintiff's Clayton Act and Robinson-Patman Act claims, and that the Foreign Trade Antitrust Improvements Act of 1982 ("FTAIA") bars Plaintiff's Sherman Act and Donnelly Act claims.[4] The motions were fully briefed by February 15, 2017.

II. Legal Standard

On a Rule 12(b)(1) motion to dismiss, the party seeking to invoke the Court's jurisdiction bears the burden of proving that subject matter jurisdiction exists. *Robinson v. Overseas Military Sales Corp.*, 21 F.3d 502, 507 (2d Cir. 1994). "A case is properly dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) when the district court lacks the statutory or constitutional power to adjudicate it." *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000). In deciding a motion to dismiss a complaint pursuant to Rule 12(b)(1), "[t]he court must take all facts alleged in the [pleading] as true and draw all reasonable inferences in favor of [the claimant]." *Morrison v. Nat'l Australia Bank Ltd.*, 547 F.3d 167, 170 (2d Cir. 2008) (citation and quotation marks omitted).

[3] Although Defendant Genentech, Inc.'s brief makes reference to Plaintiff's constitutional standing, its arguments and analysis reflect that it is only challenging Plaintiff's antitrust standing.

[4] The Court does not reach Defendants' arguments that Plaintiff failed to state a claim for each of its causes of action, that Plaintiff R-Pharm was not properly served, that the Court lacks personal jurisdiction over R-Pharm, and that the case should be dismissed under the doctrine of forum non conveniens. The Court notes that it may dismiss a complaint without addressing personal jurisdiction in cases "with multiple defendants – over some of whom the court indisputably has personal jurisdiction – in which all defendants collectively challenge the legal sufficiency" of the complaint. *Chevron Corp. v. Naranjo*, 667 F.3d 232, 246 n.17 (2d Cir. 2012).

To survive a motion to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, a complaint must "provide the grounds upon which [the] claim rests." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007); *see also* Fed. R. Civ. P. 8(a)(2) ("A pleading that states a claim for relief must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief . . . ."). To meet this standard, plaintiffs must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In reviewing a Rule 12(b)(6) motion to dismiss, a court must accept as true all factual allegations in the complaint and draw all reasonable inferences in favor of the plaintiff. *ATSI Commc'ns*, 493 F.3d at 98. However, that tenet "is inapplicable to legal conclusions." *Iqbal*, 556 U.S. at 678. Thus, a pleading that offers only "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. If the plaintiff "ha[s] not nudged [its] claims across the line from conceivable to plausible, [its] complaint must be dismissed." *Id*. at 570.

III. Discussion

A. Plaintiff Has Not Pleaded Antitrust Standing

An antitrust plaintiff must show both constitutional standing and antitrust standing. *Gelboim v. Bank of Am. Corp.*, 823 F.3d 759, 770 (2d Cir. 2016). Although constitutional standing is not implicated here, antitrust standing is "a threshold, pleading-stage inquiry and when a complaint by its terms fails to establish this requirement [a court] must dismiss it as a matter of law." *Gatt Commc'ns Inc. v. PMC Assocs. L.L.C.*, 711 F.3d 68, 75 (2d Cir. 2013) (affirming district court's dismissal of complaint for lack of antitrust standing pursuant to Rule 12(b)(6)).

In order to demonstrate antitrust standing, a plaintiff must allege "(a) that it suffered a special kind of 'antitrust injury,' and (b) that it is a suitable plaintiff to pursue the alleged antitrust violations and thus is an 'efficient enforcer' of the antitrust laws." *Gatt Commc'ns, Inc. v. PMC Assocs., L.L.C.*, 711 F.3d 68, 76 (2d Cir. 2013) (quoting *Port Dock & Stone Corp. v. Oldcastle Ne., Inc.*, 507 F.3d 117, 121 (2d Cir. 2007)). In order to establish antitrust injury, "the plaintiff must demonstrate that its injury is of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *In re Aluminum Warehousing Antitrust Litig.*, 833 F.3d 151, 157 (2d Cir. 2016) (quotation marks omitted).

Courts employ a "three-step process for determining whether a plaintiff has sufficiently alleged antitrust injury." *Gatt Commc'ns*, 711 F.3d at 76. First, the plaintiff must identify the anticompetitive practice of which it complains. *See id.* Next, the Court must "identify the actual injury the plaintiff alleges." *Id.* (quotation marks omitted). Finally, because "[i]t is not enough for the actual injury to be causally linked to the asserted violation," the Court must "compare the anticompetitive effect of the specific practice at issue to the actual injury the plaintiff alleges" in order to determine whether the injury alleged is "of the type the antitrust laws were intended to prevent and that flows from that which makes or might make defendants' acts

unlawful." *Id.* (alterations and quotation marks omitted).

Plaintiff contends that its antitrust injury arises from its exclusion from the U.S. pharmaceutical market caused by Defendants' anticompetitive conduct in Russia.[5] However, Plaintiff acknowledges that it does not currently participate, and has *never* participated, in the U.S. market, arguing instead that Defendants illegally "prevent[ed] [it] from engaging in business" there. *Am. Banana Co. v. United Fruit Co.*, 166 F. 261, 264 (2d Cir. 1908), *aff'd*, 213 U.S. 347 (1909). A competitor that has not yet entered a market may also suffer antitrust injury if it was illegally prevented from doing so. *See id*. However, at the very least, such a would-be competitor must demonstrate its "intention and preparedness" to enter the relevant market. *Reaemco, Inc. v. Allegheny Airlines*, 496 F. Supp. 546, 553 (S.D.N.Y. 1980) (quoting *Am. Banana Co.*, 166 F. at 264).

In the context of claims involving entrance into the U.S. pharmaceutical market – a highly regulated industry – Plaintiffs alleging intention and preparedness must demonstrate a likelihood of FDA approval of the would-be competitive drug, since such approval is a prerequisite for any drug to enter the U.S. pharmaceutical market. *See* 21 U.S.C. § 355(a); *Kos Pharm., Inc. v. Barr Labs., Inc.*, 242 F. Supp. 2d 311, 318 (S.D.N.Y. 2003) (FDA approval presents a "significant hurdle" for plaintiff's "prospects for actual sales" of its drug). Courts thus require a plaintiff to allege that FDA approval of the potential drug is at least "probable." *See, e.g., Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 808 (D.C. Cir. 2001), *cert. denied*, 535 U.S. 931 (2002) (plaintiff "could have alleged its intent and preparedness to enter the market by claiming that FDA approval was probable"); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 207 (E.D.N.Y. 2003) (finding no antitrust standing when the complaint "does not allege that [plaintiffs] filed an ANDA or that FDA approval was probable") (citing *Andrx Pharm., Inc.*, 256 F.3d at 806–808).

To be sure, not all courts have required that a plaintiff allege that it has received or applied for FDA approval in order establish preparedness to enter the pharmaceutical industry with a particular drug. *Compare Bristol–Myers Squibb Co. v. Copley Pharm., Inc.*, 144 F. Supp. 2d 21, 25 (D. Mass. 2000) (intention and preparedness not demonstrated when plaintiff had not obtained the "tentative regulatory approval required for market entry"), *with Xechem, Inc. v. Bristol-Myers Squibb Co.*, 274 F. Supp. 2d 937, 943 (N.D. Ill. 2003) (declining to find a per se rule requiring a new drug filing with the FDA), *and Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 546 (D.N.J. 2000) (party "need not demonstrate that the FDA has first approved its product" to have standing). However, many of the cases holding that an application for FDA approval is not required to plead preparedness involve claims that FDA applications were delayed or obstructed as a result of allegedly fraudulent

[5] To the extend the FAC can be read to allege injuries in Russia, those injuries do not give rise to an antitrust injury for the reasons set forth in Part B of this opinion. *See, e.g., In re Intel Microprocessor Litig.* 452 F. Supp. 2d. 555, 557 (D. Del. 2006) (dismissing complaint for lack of antitrust standing when it alleged "foreign injuries that occurred in foreign markets" that were "not the type of injury that Congress intended to prevent through the [FTAIA] or the Sherman Act"); *de Atucha v. Commodity Exch., Inc.*, 608 F. Supp. 510, 518 (S.D.N.Y. 1985) ("Congress did not contemplate recovery under the antitrust laws by an individual who traded, and was injured entirely outside of United States commerce.")

patent applications or sham litigation by the defendants – something that is not alleged here. *See, e.g.*, *Rochester Drug Co-op., Inc. v. Braintree Labs.*, 712 F.Supp.2d 308, 317 (D. Del. 2010) (plaintiff alleged that "as a result of [the patent holder]'s scheme, the ANDA approval process was delayed by the FDA"); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 757 (E.D. Pa. 2003) (plaintiffs "alleged that [d]efendants filed frivolous lawsuits" that "directed resources away from FDA approval and toward the defense of the infringement actions . . . result[ing] in a delay of FDA approval").

But even assuming that a formal application for FDA approval is not required to establish preparedness to engage in the U.S. pharmaceutical market, an antitrust plaintiff must still demonstrate that FDA approval is probable. Consequently, plaintiffs alleging intent and preparedness to enter a pharmaceutical market typically include facts regarding the stage of the FDA-approval process their product has reached or the steps the plaintiff has taken (or plans to take) to secure approval. *See, e.g.*, *Andrx Pharm., Inc.*, 256 F.3d at 807 (approving district court's dismissal of complaint alleging only that plaintiff had filed an Abbreviated New Drug Application, but reversing because the court erred in dismissing with prejudice when the plaintiff may have been able to cure the deficiency); *Retrophin, Inc. v. Questcor Pharm., Inc.*, 41 F. Supp. 3d 906, 915 (C.D. Cal. 2014) (finding sufficient intent and preparedness when plaintiff alleged to have "a plan to obtain regulatory approvals" and an "apparatus to conduct clinical trials to obtain FDA approval") (internal quotation marks omitted); *cf. 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) (dismissing counterclaim that failed "to include any allegations regarding how far [plaintiff] has gone in the process of obtaining FDA approval of products . . . [or] when such approval may be anticipated").

Here, Plaintiff has not merely failed to allege that it filed for FDA approval – it has failed to supply any facts whatsoever regarding the FDA approval process for its biosimilars. 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. And while Plaintiff alleges that it has audited and inspected one of its facilities in Russia in contemplation of FDA approval, it does not explain the relevance of that *facility* to the approval of its *drugs* in the United States. In sum, Plaintiff has provided little information from which the Court may assess the likelihood of approval of its biosimilars, and has thus failed to allege more than "a hope or expectation" of engaging in the U.S. pharmaceutical market. *Reaemco, Inc.*, 496 F. Supp. at 554 (quoting *Image & Sound Serv. Corp. v. Altec Serv. Corp.*, 148 F. Supp. 237, 239 (D. Mass. 1956)).

Plaintiff places great emphasis on *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 274 F. Supp. 2d 937, for the proposition that it has sufficiently alleged its preparedness to engage the U.S. pharmaceutical market. In that case, like the instant case, the plaintiffs alleged that they had taken various steps to prepare for entry into the U.S. market, including obtaining production and distribution agreements in other parts of the

world. *Id.* at 941–42. However, in *Xechem*, the plaintiffs also alleged that the defendant's anti-competitive conduct – filing fraudulent patents – directly prevented them from applying for FDA approval during the relevant time period. *Id.* at 944 ("Plaintiffs may have been in the position to file for FDA approval with the ANDA as early as 1998, but for Defendant's purportedly fraudulently-obtained patents."). Here, Plaintiff makes no allegation that any of the Defendants' anticompetitive conduct has prevented it from applying for FDA approval, and in fact provides no explanation for its failure to take any steps toward applying for FDA approval to sell its biosimilars in the United States. Plaintiff's emphasis on *Kos Pharm., Inc. v. Barr Labs., Inc.*, 242 F. Supp. 2d at 311, is also unavailing, as that case involved a declaratory judgment for a patent infringement claim, not an antitrust claim, and in any event involved a party that had already applied for FDA approval of the potentially-infringing generic medicine. *See id.* at 317–18.

Although Plaintiff provides other factual allegations relevant to its intent and preparedness to engage the U.S. pharmaceutical market, including that it has created a subsidiary in the United States, leased space in Boston, Massachusetts, and taken steps to ensure that its new facility in Russia is FDA-compliant (FAC ¶¶ 68–71, 75–80), none of these allegations overcome the paucity of facts set forth to demonstrate that FDA approval of Plaintiff's biosimilars is anywhere near likely or "probable." Indeed, Plaintiff's other factual allegations relate principally to its business in Russia and in other parts of the world, not efforts to enter the U.S. market, and in fact underscore its lack of background and experience in the U.S. pharmaceutical market and the absence of contracts to enter the business of selling its biosimilars in the United States.

For these reasons, the Court finds that Plaintiff has failed to set forth facts demonstrating its intention and preparedness to engage the U.S. pharmaceutical market, and thus has failed to allege that it has suffered an antitrust injury. Defendants' motions to dismiss for lack of antitrust standing are therefore granted.

B. The Foreign Locus of Plaintiff's Claims Also Bars This Lawsuit

But even if the First Amended Complaint could clear the bar for antitrust standing, the foreign locus of Plaintiff's allegations would still defeat each of its causes of action. Put simply, (1) the Clayton Act and Robinson-Patman Act do not confer subject-matter jurisdiction over Plaintiff's claims, (2) the FTAIA excludes Plaintiff's allegations from the reach of the Sherman Act, and (3) the Donnelly Act does not extend to claims that are beyond the reach of the Sherman Act. The Court will address each of these conclusions in turn.

1. Plaintiff's Clayton Act and Robinson-Patman Act Claims

The Clayton Act and Robinson-Patman Act provide a private cause of action for illegal tying, price discrimination, and other anticompetitive conduct. However, both acts contain parallel, jurisdiction-limiting language that confines their reach to persons and activities within U.S. commerce, extending only to conduct involving commodities sold for "use, consumption, or resale within the United States," 15 U.S.C. §§ 13 (Robinson-Patman Act), 14 (Clayton Act), and to persons "engaged in commerce," *id.*, a phrase the Supreme Court has determined is "a term of art indicating a limited assertion of federal jurisdiction,"

Circuit City Stores, Inc. v. Adams, 532 U.S. 105, 121 (2001). Specifically, the Supreme Court has held that the reach of both acts is limited "to persons and activities that are themselves 'in commerce,'" *Gulf Oil Corp. v. Copp Paving Co.*, 419 U.S. 186, 194 (1974), as opposed to "anticompetitive acquisitions and activities [that] *affect* commerce," *id*. at 195 (emphasis added); *see also Rotec Indus., Inc. v. Mitsubishi Corp.*, 348 F.3d 1116, 1122 (9th Cir. 2003) ("The reach of the [Robinson-Patman Act] extends only to persons and activities which are themselves within the flow of commerce among the states or with foreign nations, but does not extend to all activities which affect such commerce.").

Plaintiff's illegal tying claim under the Clayton Act, which alleges that Defendants tied and bundled the drug Herceptin to another cancer drug, Perjeta, in Russia, unambiguously pertains only to conduct involving commodities sold in Russia. (*See* FAC ¶ 193 ("[Defendants] organized and orchestrated a classic tying and bundling scheme, where [Defendants] forced Russian cancer patients in need of Perjeta . . . to purchase [Defendants'] Herceptin.")). This claim is not actionable under the Clayton Act, even broadly construed, because it does not involve the purchase or sale of products bound for "use, consumption, or resale within the United States." *See, e.g., Boyd v. AWB Ltd.*, 544 F. Supp. 2d 236, 247 (S.D.N.Y. 2008) (Lynch, J.) (dismissing Clayton Act claim when "[n]othing in the complaint remotely suggests that the transactions . . . involved the purchase or sale of any . . . commodity that was bound 'for consumption, use, or resale within the United States'").

Similarly, Plaintiff's predatory and discriminatory pricing claim under the Robinson-Patman Act, which alleges that Defendants charged prices of 72% to 84% less in Russia than in the United States, likewise depends explicitly upon products sold in Russia. (FAC ¶¶ 124–27). Although one leg of the alleged price discrimination scheme took place in the United States, "no cause of action arises under the [Robinson-Patman] Act unless both commodities involved in the alleged price discrimination are 'sold for use, consumption, or resale within the United States.'" *Zenith Radio Corp. v. Matsushita Elec. Indus. Co.*, 402 F. Supp. 244, 248 (E.D. Pa. 1975) (quoting 15 U.S.C. § 13(a)) (dismissing claims when "one 'leg' of the price discrimination alleged by plaintiffs involves commodities that are 'sold for use, consumption, or resale,' not within the United States, but within a foreign country, Japan"); *see also C.E.D. Mobilephone Commc'ns, Inc. v. Harris Corp.*, No. 81-cv-4651 (JFK), 1985 WL 193, at *2 (S.D.N.Y. Jan. 14, 1985) ("The Robinson-Patman Act, 15 U.S.C. § 13(a), makes it unlawful to discriminate in price between purchasers of like commodities only where such commodities 'are sold for use, consumption, or resale <u>within</u> the United States.'") (emphasis in original).

Plaintiff devotes just three sentences in its 50-page opposition brief to the Robinson-Patman Act, conclusorily asserting that price discrimination between purchasers in different geographic markets may violate the Robinson-Patman Act. (*See* Opp'n at 49–50.) But the cases cited by Plaintiff all involve price discrimination schemes taking place *entirely* within the United States. *See, e.g., Utah Pie Co. v. Cont'l Baking Co.*, 386 U.S. 685, 697, (1967) (discussing price discrimination for frozen pies primarily in Salt Lake City, Utah); *Porto Rican Am. Tobacco Co. of Porto Rico v. Am. Tobacco Co.*, 30 F.2d 234, 235 (2d Cir. 1929) (addressing price discrimination in cigarette sales in Puerto Rico); *Checker Motors Corp.*

v. Chrysler Corp., 283 F. Supp. 876, 881 (S.D.N.Y. 1968), *aff'd*, 405 F.2d 319 (2d Cir. 1969) (discussing legality of rebate program for taxicab purchases in the United States and primarily in New York City). These cases do not address the jurisdictional bar created by the plain language of the Clayton Act and Robinson-Patman Act against suits involving foreign conduct.

Accordingly, the foreign locus of Plaintiff's claims excludes them from the Court's subject-matter jurisdiction under the Clayton Act and Robinson-Patman Act. Those claims are therefore properly dismissed.

2. Plaintiff's Sherman Act Claims

The FTAIA provides that 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. Thus, according to the plain terms of the FTAIA, two types of foreign commerce remain subject to the Sherman Act: conduct involving import trade or import commerce, and "conduct involving *nonimport* trade or *nonimport* commerce when that conduct (1) has a direct, substantial, and foreseeable effect on import trade or import commerce, and (2) the Sherman Act claim arises out of that effect." *In re Vitamin C Antitrust Litig.*, 904 F. Supp. 2d 310, 317 (E.D.N.Y. 2012). Courts refer to the first category as the "import exception" and the second as the "domestic effects exception." *See, e.g.*, *id.* at 316.

a. Plaintiff's Claims Do Not Fall Within the Import Exception

When assessing whether allegations fall within the scope of the import exception to the FTAIA, "[t]he relevant inquiry is whether the conduct of the defendants – not the plaintiffs – involves import trade or commerce." *Kruman v. Christie's Int'l PLC*, 284 F.3d 384, 395 (2d Cir. 2002) *abrogated on other grounds by F. Hoffmann-La Roche Ltd. v. Empagran S.A.*, 542 U.S. 155 (2004). Here, the First Amended Complaint alleges foreign acts conducted by one domestic and three foreign Defendants that caused foreign injuries to the Plaintiff and compromised its future plans to import biosimilars of the Drugs to the United States. To the extent the First Amended Complaint makes reference to conduct that allegedly occurred in the United States, it does not allege that those activities caused an injury in the United

States or involved U.S. import commerce.[6] Rather, Plaintiff acknowledges that Defendants' alleged conduct occurred almost exclusively in Russia, but argues that its allegations fall within the import exception because the exception extends to anticompetitive behavior that is "directed at the U.S. import market.'" *In re Vitamin C Antitrust Litig.*, 904 F. Supp. 2d at 316–17.

But while Plaintiff is correct that the import exception does not require "that the defendants function as the physical importers of goods," *id.* (quoting *Animal Sci. Prod., Inc. v. China Minmetals Corp.*, 654 F.3d 462, 470 (3d Cir. 2011), *as amended* (Oct. 7, 2011)), a complaint must still describe conduct that "target[ed] import goods or services." *Animal Sci. Prod., Inc.*, 654 F.3d at 470. Because the import exception is "given a relatively strict construction," *Carpet Grp. Int'l v. Oriental Rug Importers Ass'n, Inc.*, 227 F.3d 62, 72 (3d Cir. 2000), *overruled on other grounds by Animal Sci. Prod., Inc.*, 654 F.3d 462, courts require a close connection between a defendant's alleged conduct and the import trade or import commerce at issue. The import exception thus applies only to foreign anticompetitive conduct "with an immediate impact on U.S. markets." *Maricultura Del Norte v. World Business Capital, Inc.*, 159 F. Supp. 3d 368, 383 (S.D.N.Y. 2015)

Here, Plaintiff has not alleged that Defendants are involved in import commerce, that Plaintiff is importing or has ever imported any product into the United States, or that import commerce for biosimilars of the Drugs even exists in the United States. Instead, Plaintiff argues that its allegation that Defendants' conduct has hampered its *anticipated* participation in *future* import commerce for biosimilars of the Drugs is sufficient. But none of the cases cited in Plaintiff's brief support that proposition, and in fact each case cited by Plaintiff involved at least one party who was engaged in *actual* import commerce. *See, e.g.*, *Eskofot A/S v. E.I. Du Pont De Nemours & Co.*, 872 F. Supp. 81, 83 (S.D.N.Y. 1995) ("[Plaintiff] has average annual sales of approximately $75 million, $12 million of which is derived from sales in the United States."); *In re Vitamin C Antitrust Litig.*, 904 F. Supp. 2d at 317 ("The sale contracts provided by the parties show that defendants specifically contracted for the delivery of vitamin C to locations within the U.S.").

But even if Plaintiff could allege that it was in the business of importing its biosimilars into the United States, which it has not, Plaintiff has not alleged a sufficient nexus between Defendants' conduct and the domestic effects of that conduct to satisfy a "strict construction" of the FTAIA's import exception. That is, the relationship between Defendants' acts and their effect on U.S. import commerce is too attenuated for Defendants' acts to be considered "directed at" a U.S. import market. Rather, Plaintiff's allegations indicate that Defendants' alleged conduct was targeted at the domestic Russian pharmaceutical market, not a U.S.

[6] The First Amended Complaint alleges that Defendants packaged Herceptin "worldwide" in a manner that misrepresents how much patients need to buy or use (FAC ¶ 216), but not that those misrepresentations affected Plaintiff's sales of its biosimilars in the United States, since Plaintiff does not sell drugs in the United States. The First Amended Complaint also alleges that Defendants reduced the number of wholesalers it uses for the Drugs in order to limit the availability of samples necessary for its rivals to obtain FDA approval for competitive drugs, but as noted above, Plaintiff does not allege that it has begun – or even contemplated – clinical trials that require those samples or otherwise attempted to obtain such samples from Defendants. (*See id.* ¶¶ 181–91.)

import market, which is not enough to invoke the FTAIA's import exception.

The Second Circuit's opinion in *Kruman* is particularly instructive in this regard. In *Kruman*, a class of plaintiffs alleged that the defendants participated in a price-fixing scheme for foreign auctions. 284 F.3d at 395. The Second Circuit held that the import exception did not apply, even though some of the items purchased at the foreign auctions were eventually imported into the United States, because "[t]he plaintiffs did not describe conduct by the defendants that was directed at an import market." *Id.* Noting that "the defendants' conspiracy appears to have been directed at controlling the prices they charged for their services in *foreign* auctions," the Circuit concluded that such conduct did not implicate the import exception. *Id.* (emphasis added); *see also id.* at 396 ("[T]he object of the conspiracy was the price that the defendants charged for their auction services, not any import market for those goods."). Here, 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.

Plaintiff's conclusory allegations that the Defendants' scheme "specifically targeted U.S. import and domestic commerce" (FAC ¶¶ 95, 105) and "did in fact produce some substantial effect on the interstate commerce" (*id.* ¶ 224) are unfounded and do not compel a different conclusion. Plaintiff pleads no facts demonstrating such a substantial effect and provides no authority for the proposition that Defendants' alleged *intentions* provide a sufficient causal nexus to satisfy the import exception. On the contrary, *Kruman* clearly requires that action "targeted" or "directed" at import markets for the purposes of the FTAIA must directly affect those import markets, not merely reflect an intention to affect them. *See also Animal Sci. Prod., Inc.*, 654 F.3d at 470 ("Defendants were allegedly involved only in unlawfully setting extra-territorial commission rates. Their actions did not directly increase or reduce imports into the United States.") (quotation marks and citation omitted); *Turicentro, S.A. v. Am. Airlines Inc.*, 303 F.3d 293, 303 (3d Cir. 2002) *overruled on other grounds by Animal Sci. Prod., Inc.*, 654 F.3d at 462 (holding that the import exception was not met when defendant's extraterritorial "actions did not directly increase or reduce imports into the United States"). Here, the only market that Defendants allegedly "targeted" was the Russian market for the Drugs and biosimilars for the Drugs.

Plaintiff's reliance on *Maricultura Del Norte v. World Business Capital, Inc.*, 159 F. Supp. 3d 368, is equally unavailing. In that case, a bank foreclosed upon the plaintiffs' fishing vessels after the plaintiffs, who were bluefin tuna fishers, defaulted on a loan. *Id.* at 372–73. The bank reassigned the loan to the plaintiffs' direct competitor in the fishing industry, which refused to provide the information required to release the vessels in an attempt to eliminate its competition. *Id.* On defendant's motion to dismiss, Judge McMahon held that, because the plaintiffs alleged "an immediate impact on the U.S. bluefin tuna market," the allegations fell within the import exception to the FTAIA. *Id.* at 383. But unlike Plaintiff here, the plaintiffs in *Maricultura Del Norte* were importers who alleged that they "were, are, and intend to continue being sellers of bluefin tuna into the United States market." *Maricultura Del Norte v. World Bus. Capital, Inc.*, 14-cv-10143 (CM) (S.D.N.Y. October 29, 2014), Doc. No. 1 at ¶ 393. In fact, Judge McMahon

distinguished the facts of that case from other cases where the alleged impact on U.S. import commerce was, as here, attenuated by multiple intermediate steps. *Maricultura Del Norte*, 159 F. Supp. 3d at 383.

Unlike the plaintiffs in *Maricultura Del Norte*, and like the plaintiffs in *Kruman*, Plaintiff here does not and cannot allege that Defendants' acts had a direct effect on imports in the United States. Accordingly, Plaintiff's claims do not fall within the import exception to the FTAIA.

b. Plaintiff's Claims Do Not Fall Within the Domestic Effects Exception

Although Plaintiff does not even argue the point, the Court also finds that Plaintiff's claims fail to meet the FTAIA's domestic effects exception because any domestic effect resulting from Defendant's alleged behavior did not "give rise to" Plaintiff's claim under the Sherman Act.[7] Conduct falls within the domestic effects exception when (1) it has a "direct, substantial, and reasonably foreseeable effect" on U.S. domestic, import, or certain export commerce, 15 U.S.C. § 6a(1), and (2) that effect "gives rise to a claim under" the Sherman Act, *id.* § 6a(2). The Supreme Court has held that the statutory phrase "gives rise to a claim" means "gives rise to the *plaintiff's* claim." *See Empagran S.A.*, 542 U.S. at 173 (concluding that "Congress would not have intended the FTAIA's exception to bring independently caused foreign injury within the Sherman Act's reach"). Thus, the domestic effects exception requires two distinct inquiries, "one asking whether the defendants' foreign conduct caused a cognizable domestic effect, and the other asking whether that effect caused the plaintiff's injury." *Lotes Co. v. Hon Hai Precision Indus. Co.*, 753 F.3d 395, 414 (2d Cir. 2014).

Plaintiff essentially alleges that Defendants' conduct in Russia harmed Plaintiff in Russia, which in turn prevented Plaintiff 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. For the reasons discussed above, Plaintiff's attenuated chain of causation is insufficient to establish a "direct, substantial, and reasonably foreseeable effect" under the FTAIA. But even if it could be argued that Defendant's foreign conduct caused a cognizable domestic effect, Plaintiff has not alleged that *this* effect (*i.e.*, increase in the price of the Drugs in the United States) caused *Plaintiff's* injuries as required under the second prong of the domestic effect test. Rather, to the extent there is a causal connection between Plaintiff's injuries and the alleged domestic effect of Defendants' conduct, "the direction of causation runs the wrong way." *Lotes Co.*, 753 F.3d at 414. That is, Plaintiff's injuries caused (or will cause) the domestic effect, not vice versa.

The Second Circuit's opinion in *Lotes* helps to explain the operation of the domestic effects exception in this case. Like Plaintiff here, the plaintiff in *Lotes* alleged that the defendants' foreign anticompetitive conduct excluded it from the U.S. market, which would have the eventual effect of reducing competition and driving up prices. However, the Second Circuit held that the domestic effects exception did not apply because "those higher prices did not cause [plaintiff's] injury of being excluded from the market for USB 3.0 connectors – that injury flowed directly from the defendant's

[7] (*See* Opp'n at 22 ("the relevant inquiry is not the domestic effects exception, but the import exception") (quoting *Maricultura*, 159 F. Supp. 3d at 316).)

exclusionary foreign conduct." *Id.* at 414. The Second Circuit thus clarified that the exception applies only when the domestic effects of a defendant's anticompetitive foreign conduct causes a plaintiff's injury, not when defendant's conduct causes plaintiff's injury, which also results in domestic effects.

Here, Plaintiff's alleged injuries flow from Defendants' allegedly anticompetitive foreign conduct, not the domestic effect of that conduct, and is therefore the type of "independently caused foreign injury" that falls outside of the reach of the domestic effects exception. *Id.* at 414 (quoting *Empagran*, 542 U.S. at 173.)

3. Plaintiff's Donnelly Act Claims

Because Plaintiff's claims are beyond the reach of the Sherman Act, its state-law claim under the Donnelly Act must also be dismissed. The Donnelly Act does not reach foreign conduct deliberately placed by Congress "beyond the Sherman Act's reach." *In re Foreign Exch. Benchmark Rates Antitrust Litig.*, 74 F. Supp. 3d 581, 601 (S.D.N.Y. 2015) (citing *Global Reins. Corp. U.S. Branch v. Equitas Ltd.*, 18 N.Y.3d 722, 735 (2012) (holding that a claim barred by the FTAIA cannot be brought under the Donnelly Act because, among other reasons, "[t]he established presumption is . . . against the extraterritorial operation of New York law . . . and we do not see how it could be overcome in a situation where the analogue federal claim would be barred by congressional enactment")). For the reasons set forth above, Plaintiff's claims are beyond the reach of the Sherman Act. Accordingly, Plaintiff's Donnelly Act claim is also properly dismissed.

C. Plaintiff Is Not Entitled to Injunctive Relief

In an apparent last-ditch effort to secure relief from the Court, Plaintiff makes the conclusory argument that it is entitled to injunctive relief under Section 16 of the Clayton Act because, "[a]t the very least, Plaintiff demonstrated threatened injury of direct exclusion from the U.S. market." (Opp'n at 18.) Section 16 of the Clayton Act confers a private right of action on plaintiffs who allege "threatened loss or damage by a violation of the antitrust laws." 15 U.S.C. § 26. Section 16 injunctive relief is therefore "characteristically available even though the plaintiff has not yet suffered actual injury." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 130 (1969) (citation omitted). Instead, to state a claim for injunctive relief under Section 16, a plaintiff must merely "demonstrate a significant threat of injury from an impending violation of the antitrust laws or from a contemporary violation likely to continue or recur." *Id.*

But, for the reasons set forth above, Plaintiff has not alleged a "significant threat of injury from an impending violation of the antitrust laws" since it has failed to allege conduct that falls within the reach of U.S. antitrust law. Because the foreign locus of its claims excludes Plaintiff's claims from coverage under that law, there is no "threatened loss of damage" from a violation of those laws alleged here.

D. Plaintiff's Request for Leave to Amend Is Denied

Finally, the Court considers Plaintiff's request for leave to amend. (Opp'n 50.) Although "Rule 15(a) of the Federal Rules of Civil Procedure provides that leave to amend 'shall be freely given when justice so requires,' it is within the sound discretion of

the [Court] to grant or deny leave to amend." *McCarty v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007) (quoting Fed. R. Civ. P. 15(a)). In addition, the Second Circuit has consistently stated that district courts may deny leave to amend when plaintiffs request such leave in a cursory sentence on the last page of an opposition to a motion to dismiss, without any justification or an accompanying suggested amended pleading. *See, e.g.*, *City of Pontiac*, 752 F.3d at 188 (affirming denial of leave to amend where plaintiffs already had one opportunity to amend their complaint and had "identified no additional facts or legal theories" to support their request to amend); *Food Holdings Ltd. v. Bank of Am. Corp*., 423 F. App'x 73, 76 (2d Cir. 2011) (affirming district court's denial of leave to amend where plaintiff requested leave to amend "on the final page of their brief in opposition to defendants' motion to dismiss, in boilerplate language and without any explanation as to why leave to amend was warranted"); *Porat v. Lincoln Towers Cmty. Ass'n*, 464 F.3d 274, 275–76 (2d Cir. 2006).

Here, in the final sentence of its opposition to Defendants' motions to dismiss, Plaintiff, without any legal or other support, states in a single sentence that "[e]ven if, *arguendo*, the Court finds any deficiencies in Plaintiff's pleadings in the Amended Complaint, Plaintiff should be afforded the right to correct such deficiencies." (Opp'n 50.) Significantly, Plaintiff offers no basis for its request for leave to amend nor does it attach a proposed amended complaint. *See Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 190 (2d Cir. 2015) (noting that a court may deny leave to amend, on notice grounds, "where the request gives no clue as to how the complaint's defects would be cured" (quoting *Porat*, 464 F.3d at 276)). Moreover, this is not Plaintiff's first attempt at re-pleading in this action. To the contrary, on October 24, 2016, after the parties had exchanged pre-motion letters and the Court had held a pre-motion conference concerning Defendants' contemplated motions to dismiss (Doc. Nos. 22, 32), Plaintiff sought and received leave to amend for the purpose of addressing deficiencies in the complaint that the Court and Defendants addressed at some length. Notwithstanding the benefit of Defendants' pre-motion letter and an extensive colloquy with the Court at the pre-motion conference, in which these very deficiencies were discussed (*see* Doc. No. 33 at 12:15–31:14), Plaintiff's amended pleading still fails to allege facts sufficient to withstand a motion to dismiss.

As Judge Lynch aptly noted when he was on the district court, "[w]hile pleading is not a game of skill in which one misstep may be decisive to the outcome, neither is it an interactive game in which plaintiffs file a complaint, and then bat it back and forth with the Court over a rhetorical net until a viable complaint emerges." *In re Refco Capital Mkts., Ltd. Brokerage Customer Sec. Litig*., Nos. 06-cv-643, 07-cv-8686, 07-cv-8688 (GEL), 2008 WL 4962985, at *2 (S.D.N.Y. Nov. 20, 2008) (citations and internal quotation marks omitted); *see also Ruotolo v. City of New York*, 514 F.3d 184, 191 (2d Cir. 2008) (noting that courts can deny leave to amend where there has been "repeated failure to cure deficiencies by amendments previously allowed" (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)); *NRW, Inc. v. Bindra*, No. 12-cv-8555 (RJS), 2015 WL 3763852, at *1 (S.D.N.Y. June 16, 2015) ("To grant leave to amend after a plaintiff has had ample opportunity to amend would be condoning a strategy whereby plaintiffs hedge their bets . . . in the hopes of having another bite at the

proverbial apple." (internal quotation marks omitted)). Accordingly, because Plaintiff has failed to attach a proposed amended complaint or even attempted to explain why an additional opportunity to amend would cure the First Amended Complaint's deficiencies, and because Plaintiff's past efforts provide no comfort in this regard, the Court denies Plaintiff's request for leave to amend.

IV. CONCLUSION

Because Plaintiff has failed to plead an antitrust injury, because the foreign locus of Plaintiff's claims place them outside the reach of U.S. antitrust law, and because Plaintiff has not demonstrated a significant threat of injury from an impending violation of the antitrust laws, Defendants' motions to dismiss the First Amended Complaint are GRANTED, and Plaintiff's request for leave to amend the First Amended Complaint is DENIED. The Clerk of Court is respectfully directed to terminate the motions pending at docket numbers 51, 53, and 56, and to close this case.[8]

SO ORDERED.

RICHARD J. SULLIVAN
United States District Judge

Dated: September 30, 2017
New York, New York

* * *

Biocad JSC is represented by Albert Feinstein and Arevik Khurdayan of Feinstein & Partners PLLC, 54 E. 66th Street, New York, NY, 10065.

F. Hoffman La-Roche Ltd. and Roche Holding AG are represented by Paul Spagnoletti and Andrew S. Gehring of Davis Polk & Wardwell LLP, 450 Lexington Avenue, New York, NY, 10017.

Genentech, Inc. is represented by Amanda P. Reeves, Daniel M. Wall, Lawrence E. Buterman, and Thomas J. Giblin of Latham & Watkins LLP. 555 Eleventh Street, Nw, Suite 1000, Washington, DC, 20004.

R-Pharm JSC is represented by Eric J. Stock of Gibson, Dunn & Crutcher, LLP, 200 Park Avenue, 48th Floor, New York, NY, 10166.

[8] Closing this action will not affect Defendants' motion for sanctions (Doc. No. 71), which is still pending before the Court. *See Covanta Onondaga Ltd. P'ship v. Onondaga County Res. Recovery Agency*, 318 F.3d 392, 396 (2d Cir. 2003) ("[A] court that has concluded its adjudication of the merits of a case within its jurisdiction by entering a final judgment retains authority to take action with respect to some collateral matters related to the case, such as attorney's fees and costs.").

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----------X

BIOCAD, JSC,

Plaintiff,

-against-

16 **CIVIL** 4226 (RJS)

JUDGMENT

F. HOFFMAN-LA-ROCHE, LTD., et al.,

Defendants.

----------X

Before the Court are Defendants' motions to dismiss the First Amended Complaint pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6), and the matter having come before the Honorable Richard J. Sullivan, United States District Judge, and the Court, on September 30, 2017, having rendered its Opinion and Order granting Defendants' motions to dismiss the First Amended Complaint, denying Plaintiff's request for leave to amend the First Amended Complaint , and directing the Clerk of Court to close this case, and dismissing the complaint, it is,

ORDERED, ADJUDGED AND DECREED: That for the reasons stated in the Court's Opinion and Order dated September 30, 2017, Defendants' motions to dismiss the First Amended Complaint are granted and Plaintiff's request for leave to amend the First Amended Complaint is denied; accordingly, the case is closed.

Dated: New York, New York
September 30, 2017

RUBY J. KRAJICK

Clerk of Court

BY: Kmango

Deputy Clerk

15 U.S.C. § 6a

§ 6a. Conduct involving trade or commerce with foreign nations

Sections 1 to 7 of this title 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.

If sections 1 to 7 of this title apply to such conduct only because of the operation of paragraph (1)(B), then sections 1 to 7 of this title shall apply to such conduct only for injury to export business in the United States.

15 U.S.C. § 1

§ 1. Trusts, etc., in restraint of trade illegal; penalty

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 2

§ 2. Monopolizing trade a felony; penalty

Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 15

§ 15. Suits by persons injured

(a) Amount of recovery; prejudgment interest

Except as provided in subsection (b), any person who shall be injured in his business or property by reason of anything forbidden in the antitrust laws may sue therefor in any district court of the United States in the district in which the defendant resides or is found or has an agent, without respect to the amount in controversy, and shall recover threefold the damages by him sustained, and the cost of suit, including a reasonable attorney's fee. The court may award under this section, pursuant to a motion by such person promptly made, simple interest on actual damages for the period beginning on the date of service of such person's pleading setting forth a claim under the antitrust laws and ending on the date of judgment, or for any shorter period therein, if the court finds that the award of such interest for such period is just in the circumstances. In determining whether an award of interest under this section for any period is just in the circumstances, the court shall consider only—

(1) whether such person or the opposing party, or either party's representative, made motions or asserted claims or defenses so lacking in merit as to show that such party or representative acted intentionally for delay, or otherwise acted in bad faith;

(2) whether, in the course of the action involved, such person or the opposing party, or either party's representative, violated any applicable rule, statute, or court order providing for sanctions for dilatory behavior or otherwise providing for expeditious proceedings; and

(3) whether such person or the opposing party, or either party's representative, engaged in conduct primarily for the purpose of delaying the litigation or increasing the cost thereof.

(b) Amount of damages payable to foreign states and instrumentalities of foreign states

(1) Except as provided in paragraph (2), any person who is a foreign state may not recover under subsection (a) an amount in excess of the actual damages sustained by it and the cost of suit, including a reasonable attorney's fee.

(2) Paragraph (1) shall not apply to a foreign state if—

(A) such foreign state would be denied, under section 1605(a)(2) of Title 28, immunity in a case in which the action is based upon a commercial activity, or an act, that is the subject matter of its claim under this section;

(B) such foreign state waives all defenses based upon or arising out of its status as a foreign state, to any claims brought against it in the same action;

(C) such foreign state engages primarily in commercial activities; and

(D) such foreign state does not function, with respect to the commercial activity, or the act, that is the subject matter of its claim under this section as a procurement entity for itself or for another foreign state.

(c) Definitions

For purposes of this section—

(1) the term "commercial activity" shall have the meaning given it in section 1603(d) of Title 28, and

(2) the term "foreign state" shall have the meaning given it in section 1603(a) of Title 28.

15 U.S.C. § 26

§ 26. Injunctive relief for private parties; exception; costs

Any person, firm, corporation, or association shall be entitled to sue for and have injunctive relief, in any court of the United States having jurisdiction over the parties, against threatened loss or damage by a violation of the antitrust laws, including sections 13, 14, 18, and 19 of this title, when and under the same conditions and principles as injunctive relief against threatened conduct that will cause loss or damage is granted by courts of equity, under the rules governing such proceedings, and upon the execution of proper bond against damages for an injunction improvidently granted and a showing that the danger of irreparable loss or damage is immediate, a preliminary injunction may issue: *Provided*, That nothing herein contained shall be construed to entitle any person, firm, corporation, or association, except the United States, to bring suit for injunctive relief against any common carrier subject to the jurisdiction of the Surface Transportation Board under subtitle IV of Title 49. In any action under this section in which the plaintiff substantially prevails, the court shall award the cost of suit, including a reasonable attorney's fee, to such plaintiff.

15 U.S.C. § 13

§ 13. Discrimination in price, services, or facilities

(a) Price; selection of customers

It shall be unlawful for any person engaged in commerce, in the course of such commerce, either directly or indirectly, to discriminate in price between different purchasers of commodities of like grade and quality, where either or any of the purchases involved in such discrimination are in commerce, where such commodities are sold for use, consumption, or resale within the United States or any Territory thereof or the District of Columbia or any insular possession or other place under the jurisdiction of the United States, and where the effect of such discrimination may be substantially to lessen competition or tend to create a monopoly in any line of commerce, or to injure, destroy, or prevent competition with any person who either grants or knowingly receives the benefit of such discrimination, or with customers of either of them: *Provided*, That nothing herein contained shall prevent differentials which make only due allowance for differences in the cost of manufacture, sale, or delivery resulting from the differing methods or quantities in which such commodities are to such purchasers sold or delivered: *Provided, however*, That the Federal Trade Commission may, after due investigation and hearing to all interested parties, fix and establish quantity limits, and revise the same as it finds necessary, as to particular commodities or classes of commodities, where it finds that available purchasers in greater quantities are so few as to render differentials on account thereof unjustly discriminatory or promotive of monopoly in any line of commerce; and the foregoing shall then not be construed to permit differentials based on differences in quantities greater than those so fixed and established: *And provided further*, That nothing herein contained shall prevent persons engaged in selling goods, wares, or merchandise in commerce from selecting their own customers in bona fide transactions and not in restraint of trade: *And provided further*, That nothing herein contained shall prevent price changes from time to time where in response to changing conditions affecting the market for or the marketability of the goods concerned, such as but not limited to actual or imminent deterioration of perishable goods, obsolescence of seasonal goods, distress sales under court process, or sales in good faith in discontinuance of business in the goods concerned.

(b) Burden of rebutting prima-facie case of discrimination

Upon proof being made, at any hearing on a complaint under this section, that there has been discrimination in price or services or facilities furnished, the burden of rebutting the prima-facie case thus made by showing justification shall be upon the person charged with a violation of this section, and unless justification shall be affirmatively shown, the Commission is authorized to issue an order terminating the discrimination: *Provided, however,* That nothing herein contained shall prevent a seller rebutting the prima-facie case thus made by showing that his lower price or the furnishing of services or facilities to any purchaser or purchasers was made in good faith to meet an equally low price of a competitor, or the services or facilities furnished by a competitor.

(c) Payment or acceptance of commission, brokerage, or other compensation

It shall be unlawful for any person engaged in commerce, in the course of such commerce, to pay or grant, or to receive or accept, anything of value as a commission, brokerage, or other compensation, or any allowance or discount in lieu thereof, except for services rendered in connection with the sale or purchase of goods, wares, or merchandise, either to the other party to such transaction or to an agent, representative, or other intermediary therein where such intermediary is acting in fact for or in behalf, or is subject to the direct or indirect control, of any party to such transaction other than the person by whom such compensation is so granted or paid.

(d) Payment for services or facilities for processing or sale

It shall be unlawful for any person engaged in commerce to pay or contract for the payment of anything of value to or for the benefit of a customer of such person in the course of such commerce as compensation or in consideration for any services or facilities furnished by or through such customer in connection with the processing, handling, sale, or offering for sale of any products or commodities manufactured, sold, or offered for sale by such person, unless such payment or consideration is available on proportionally equal terms to all other customers competing in the distribution of such products or commodities.

(e) Furnishing services or facilities for processing, handling, etc.

It shall be unlawful for any person to discriminate in favor of one purchaser against another purchaser or purchasers of a commodity bought for resale, with or

without processing, by contracting to furnish or furnishing, or by contributing to the furnishing of, any services or facilities connected with the processing, handling, sale, or offering for sale of such commodity so purchased upon terms not accorded to all purchasers on proportionally equal terms.

(f) Knowingly inducing or receiving discriminatory price

It shall be unlawful for any person engaged in commerce, in the course of such commerce, knowingly to induce or receive a discrimination in price which is prohibited by this section.

N.Y. Gen. Bus. L. § 340

§ 340. Contracts or agreements for monopoly or in restraint of trade illegal and void

1. Every contract, agreement, arrangement or combination whereby

A monopoly in the conduct of any business, trade or commerce or in the furnishing of any service in this state, is or may be established or maintained, or whereby

Competition or the free exercise of any activity in the conduct of any business, trade or commerce or in the furnishing of any service in this state is or may be restrained or whereby

For the purpose of establishing or maintaining any such monopoly or unlawfully interfering with the free exercise of any activity in the conduct of any business, trade or commerce or in the furnishing of any service in this state any business, trade or commerce or the furnishing of any service is or may be restrained, is hereby declared to be against public policy, illegal and void.

2. Subject to the exceptions hereinafter provided in this section, the provisions of this article shall apply to licensed insurers, licensed insurance agents, licensed insurance brokers, licensed independent adjusters and other persons and organizations subject to the provisions of the insurance law, to the extent not regulated by provisions of article twenty-three of the insurance law; and further provided, that nothing in this section shall apply to the marine insurances, including marine protection and indemnity insurance and marine reinsurance, exempted from the operation of article twenty-three of the insurance law.

3. The provisions of this article shall not apply to cooperative associations, corporate or otherwise, of farmers, gardeners, or dairymen, including live stock farmers and fruit growers, nor to contracts, agreements or arrangements made by such associations, nor to bona fide labor unions.

4. The labor of human beings shall not be deemed or held to be a commodity or article of commerce as such terms are used in this section and nothing herein

contained shall be deemed to prohibit or restrict the right of workingmen to combine in unions, organizations and associations, not organized for the purpose of profit.

5. An action to recover damages caused by a violation of this section must be commenced within four years after the cause of action has accrued. The state, or any political subdivision or public authority of the state, or any person who shall sustain damages by reason of any violation of this section, shall recover three-fold the actual damages sustained thereby, as well as costs not exceeding ten thousand dollars, and reasonable attorneys' fees. At or before the commencement of any civil action by a party other than the attorney-general for a violation of this section, notice thereof shall be served upon the attorney-general. Where the aggrieved party is a political subdivision or public authority of the state, notice of intention to commence an action under this section must be served upon the attorney-general at least ten days prior to the commencement of such action. This section shall not apply to any action commenced prior to the effective date of this act.

6. In any action pursuant to this section, the fact that the state, or any political subdivision or public authority of the state, or any person who has sustained damages by reason of violation of this section has not dealt directly with the defendant shall not bar or otherwise limit recovery; provided, however, that in any action in which claims are asserted against a defendant by both direct and indirect purchasers, the court shall take all steps necessary to avoid duplicate liability, including but not limited to the transfer and consolidation of all related actions. In actions where both direct and indirect purchasers are involved, a defendant shall be entitled to prove as a partial or complete defense to a claim for damages that the illegal overcharge has been passed on to others who are themselves entitled to recover so as to avoid duplication of recovery of damages.