UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BIOCAD JSC	)	
	)	No. 1:16-cv-4226
Plaintiff,	)	
	)	
– against –	)	**COMPLAINT**
	)	
	)	
F. HOFFMAN LA-ROCHE LTD., GENENTECH, INC. AND R-FARM JSC,	)	**DEMAND FOR JURY TRIAL**
	)	
Defendants.	)	
	)	

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Plaintiff BIOCAD JSC ("Plaintiff"), by and through its attorneys Feinstein & Partners PLLC, brings this action for damages under the antitrust laws of the United States and other federal and state causes of action against Defendants F. Hoffman La-Roche Ltd., Genentech Inc., and R-Farm JSC (collectively, "Defendants") demanding a trial by jury. For the Complaint against the Defendants, Plaintiff alleges, upon knowledge as to itself, and otherwise upon information and belief, as follows:

NATURE AND SUMMARY OF THE ACTION

1. Plaintiff brings this action to recover damages that it sustained, and continues to sustain, as the direct and proximate result of Defendants' continuing pattern of anticompetitive and illegal conduct relating to the sale by Defendants of certain cancer drugs.

2. Defendant F. Hoffman La-Roche's ("Roche") manufactures and sells three blockbuster drugs used to treat cancer – *bevacizumab, trastuzumab* and *rituximab*, marketed and sold in the U.S. by Roche's fully-owned subsidiary, Defendant Genentech Inc. ("Genentech"), under the brand names Avastin®, Herceptin® and Rituxan®, respectively (collectively, "Drugs").

3. The Drugs bring Roche over US$ 20 Billion per year and remain the three best selling monoclonal antibodies used to treat cancer worldwide. Almost 50% of such profits come from the U.S., which remains the most lucrative market.

4. In fact, since their launch, the three star drugs brought Roche over US$ 170 Billion in sales. Roche's exclusivity rights to all three drugs in the U.S. are about to expire in 2018 and 2019.

5. Plaintiff, a private pharmaceutical company based in Russia, is the only pharmaceutical company in the world that was able to re-create biosimilars of all three of Roche's star drugs to date. As part of its global expansion plan, Plaintiff anticipated to enter the U.S. market with the generic alternatives at the time when Roche's exclusivity rights expire.

6. Knowing that generic entry would decimate its sales in the U.S., and that any delay in such entry would be highly profitable for Roche, even though very costly for consumers and cancer patients, Roche and other Defendants designed and implemented a scheme to destroy Plaintiff's competing business.

7. The scheme involved an astonishing array of illegal conduct that deliberately targeted, and severely burdened, not only Plaintiff, but also consumers and cancer patients in the United States, and included, among other things, registering a non-existent[1] drug , setting up tying arrangement for life-saving cancer drugs, and placing fraudulent bids at auctions and tenders.

8. To finance such predatory anti-competitive conduct, Roche used its monopoly position in the U.S. and its ability to charge U.S. consumers over-

[1] Reference throughout the document is made to the non-existent International Nonproprietary Name ("INN") and the Pharmaceutical Dosage Form.

inflated prices for oncology medication.

9. In 2014, shortly after Plaintiff recieved approval in Russia for its first biosimilar of Roche's star drug Rituxan® and announced that significant progress is being made to copy Avastin® and Herceptin®, Roche and Genentech implemented "a stealth price hike for three critical cancer drugs… Avastin, Herceptin and Rituxan" resulting in an estimated $300 Million profit overnight in the U.S.[2]

10. While Roche and Genentech keep raising prices in the U.S., they engage in predatory pricing in Russia, where Defendants sell such drugs at a loss – all to destroy Plaintiff and prevent it from entering the U.S. market with cheaper biosimilars.

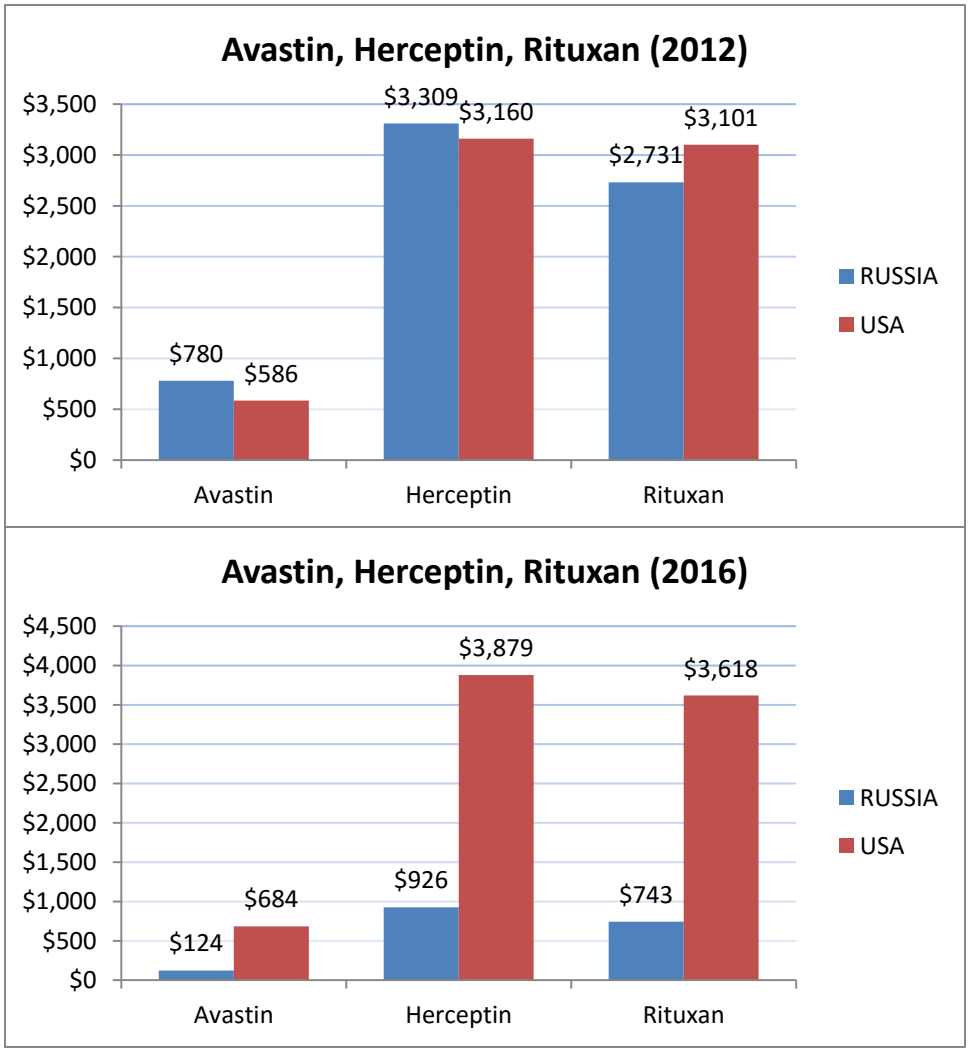
11. For example, Roche's officially declared price for bulk delivery of Avastin® 100mg upon entry to Russia is 20% higher than the price at which Avastin® 100mg is sold by Defendant R-Farm JSC ("R-Farm"), an independent exclusive distributor of the Drugs, after being packaged, distributed, taxes/duties paid, etc.

12. Thus, Roche is not only fully sponsoring the packaging, sales, marketing and distribution in Russia through an independent company, but does so at a loss. In the alternative, an independent Russian company, R-Farm (Roche's official distributor in Russia and a Russian pharmaceutical company),

[2] Saporito, Bill (2014, October 27). *"Hospitals Furious at Cancer-Drug Price Hikes"*. Time. Retrieved from http://time.com/3541484/cancer-drug-price-hikes/

is packaging Roche's drugs for free, pays all duties and taxes out of their own pocket and sells Roche's drugs at prices lower than the prices charged by Roche for such drugs.

13. In the meantime, Roche continues to increases prices in the U.S. for the same drugs. While Roche started selling its blockbuster drugs in Russia at prices higher than prices for the same drugs in the United States, the current disparity between prices for the same drugs is startling, with Avastin® currently costing four and a half (4.5) times cheaper in Russia than in the U.S., Herceptin® and Rituxan® - over three times cheaper.



14. Defendants managed to devise a scheme where the U.S. cancer patients are not only paying for Roche's anti-competitive and predatory conduct, but such conduct is aimed at preventing competition from entering the U.S. market with cheaper biosimilars – all so that Defendants can maintain its monopoly position in the U.S. and continue charging U.S. cancer patients exorbitant prices for Roche's cancer drugs.

15. More disturbing is the fact that Roche openly states that they do not expect to be affected by recent efforts in the U.S. to stabilize drug pricing, according to Roche's head of pharmaceuticals, Daniel O'Day. "Blockbusters Rituxan, Avastin and Herceptin won't be subject to 'short term' U.S. pricing pressure since the meds treat patients with few other options… it's generic drugmakers that'll take the hit"[3].

16. If Defendants continue their anti-competitive conduct to exclude generic competition and destroy Plaintiff, they will maintain their monopoly position in the U.S. beyond statutory exclusivity period and will earn billions of dollars more in profits than they would have otherwise. The immediate casualties of Defendants' manipulative conduct will be not only Plaintiff, but also the U.S. patients with cancer who will have to bear the unwarranted monopoly prices.

[3] Helfand, Carly (2016, February 1). *"Roche's pharma chief sees no 'short term' pricing pressure on its cancer blockbusters"*. FiercePharma. Retrieved from http://www.fiercepharma.com/sales-and-marketing/roche-s-pharma-chief-sees-no-short-term-pricing-pressure-on-its-cancer

JURISDICTION AND VENUE

17. Plaintiff brings this action under the Sherman Act, 15 U.S.C. §§ 1 and 2; the Clayton Act, 15 U.S.C. §§ 15 and 26; the Robinson-Patman Act, 15 USCA § 13; and related statutes and common law claims, to recover damages, including treble damages and the costs of suit, and reasonable attorneys' fees, against Defendants for the injuries sustained by Plaintiff.

18. This Court has original jurisdiction over Plaintiff's Complaint pursuant to 28 U.S.C. §§ 1331 and 1337 (federal question) and 15 U.S.C. §§ 1, 2, 15, 22 and 26 (antitrust).

19. This Court also has original diversity jurisdiction over all claims brought in this action pursuant to 28 U.S.C. § 1332(a)(1) and (2) because the amount in controversy exceeds the sum of $75,000, exclusive of interests and costs, and this the matter in controversy is between citizens of a state and citizen of a foreign state or citizens of different states.

20. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b), (d) and 15 U.S.C. §§ 15, 22 and 26 because at all times relevant to the bringing of this action, Defendants transacted business, did business, found, derived substantial revenue or resided in the Southern District of New York.

21. Each Defendant has transacted business in the United States, done an act in the United States, or caused a substantial anti-competitive effect in the United States by an act done elsewhere.

PARTIES

22. Plaintiff Joint Stock Company BIOCAD ("Plaintiff") is a Russian-based drug development and manufacturing company with a principal place of business at Ulitsa Svyazi, 34-A, Strelna, Saint-Petersburg, 198515. Plaintiff is a competitor of Defendants in manufacturing, distribution and sale of cancer treatment drugs.

23. Defendant F. Hoffman-La Roche Ltd. ("Roche") is a Swiss corporation based in Basel, Switzerland, with operations in the United States. Roche is a wholly-owned subsidiary of Roche Holding AG. Roche, through its affiliates, is engaged in the business of research, production, distribution and sale of oncological and other drugs, including Avastin®, Herceptin® and Rituxan®, worldwide, including in the United States and this District. Roche, directly and through affiliates that it controls, including the other Defendants in this lawsuit, and through actions in this country and internationally, has engaged in illegal and anti-competitive conduct designed to have a substantial and adverse impact within the United States.

24. Defendant Genentech, Inc. ("Genentech") is a Delaware corporation having a principal executive office at 1 DNA Way, South San Francisco, CA 94080. Genentech is also a registered foreign business corporation in New York and its agent is Corporation Service Company 80 State Street Albany, New York 12207. Genentech conducts business worldwide, including in the United States and this District. Genentech is an affiliate of

Roche, wholly owned subsidiary of Roche Holding AG and a member of the Roche Group. According to Genentech and Roche, Genentech "now serves as the headquarters for Roche pharmaceutical operations in the United States."[4] Upon information and belief, Roche, through Genentech, is engaged in business in the United States and this District generally and specifically with respect to its challenged conduct related to distribution and sale of cancer drugs, including Avastin®, Herceptin® and Rituxan®.

25. Upon information and belief, Roche also is engaged in business in this District through other wholly-controlled Roche's affiliates and subsidiaries of Roche Holding which, together with Genentech, comprise the Roche Group, including Genentech USA, Inc., a foreign business corporation (Delaware) registered to do business in New York; Roche Holdings Inc., a New York domestic business corporation; Roche TCRC, Inc., a foreign business corporation (Delaware) registered to do business in New York; Roche Molecular Systems, Inc., a foreign business corporation (Delaware) registered to do business in New York; and Roche Diagnostics Corporation, a foreign business corporation (Indiana) registered to do business in New York.

26. Upon information and belief, Defendant Joint Stock Company R-Farm ("R-Farm") is a Russian-based pharmaceutical company and an official distributor of Roche's drugs in Russia, including the drugs which are the subject of Plaintiff's complaint, with a principal place of business at Leninskiy

[4] Genentech, *About Us*, http://www.gene.com/about-us (last accessed April 21, 2016).

Prospect 111B, Moscow 119421, Russian Federation. R-Farm, with the help of the other Defenfants, engaged in illegal and anti-competitive conduct designed to have a substantial and adverse impact within the United States.

FACTUAL ALLEGATIONS RELEVANT TO ALL CAUSES OF ACTIONS

I. CANCER AND THE ONCOLOGY DRUGS MARKET

A. General Overview

27. Cancer is a devastating disease affecting over 8 million Americans today. According to the National Cancer Institute, an estimated 1,685,210 new cases of cancer will be diagnosed in the United States in 2016, and 595,690 people will die from the disease the same year.

28. While the survival rate has gone up in recent years, cancer remains a major public health concern. Patients and their loved ones depend on a handful of medications approved to treat the disease, hoping that the medications may be able to at least slow down the progression of cancer.

29. The global market for cancer drugs has reached $100 billion in annual sales in 2014, and could reach $147 Billion by 2018, according to a new report by the Institute for Healthcare Informatics ("IMS")[5].

30. Geographically, the United States dominates the market and

[5] IMS Institute for Healthcare Informatics, *"Developments in Cancer Treatments, Market Dynamics, Patient Access and Value: Global Oncology Trend Report 2015"*, http://www.imshealth.com/en/thought-leadership/ims-institute/reports/global-oncology-trend-2015

remains the most lucrative market for pharmaceutical companies – the United States alone spent $42.5 Billion on cancer drugs in 2014 according to IMS[6].

B. The Use Of Monoclonal Antibodies In Treating Cancer

31. The use of monoclonal antibodies for cancer therapy has achieved considerable success in recent years. Monoclonal antibodies are laboratory produced molecules that mimic naturally produced antibodies for oncology treatments and have a variety of applications, including cancer cell marking, growth signal blocking, the delivery of chemotherapy toxins, and the reduction of new blood vessel growth.

32. Some of the most common types of monoclonal antibodies ("mAbs") are:

a) Naked mAbs that work by themselves with no drug or radioactive material attached to them (*Ex*: *trastuzumab* is an antibody that binds to HER2 protein, commonly found in breast cancer, and stops it from becoming active);

b) Conjugated mAbs that are joined to a chemotherapy drug or to a radioactive particle and circulate throughout the body until they can find and hook onto the target antigen delivering the toxic substance;

c) Bispecific mAbs, which are made up of two different mAbs, meaning they can attach to two different proteins at the same time. By binding to both of these proteins, this drug brings the cancer cells and immune cells together, which is thought to cause the immune system to attack the cancer cells.

[6] *Id.*

C. Market for Cancer Monoclonal Antibodies

33. The dramatic increase in the size of the potential cancer market[7] has prompted pharmaceutical companies to invest in the oncology sector with major focus on monoclonal antibodies. Targeted therapies, including monoclonal antibodies, now account for almost 50% of total spending, and they have been growing at a compound average growth rate of 14.6% over the past five years.

34. According to the Research and Markets report, "Cancer Monoclonal Antibodies Market Forecast to 2017", the market for cancer mAbs was estimated at US$ 24 Billion in 2013, and is expected to grow to US$ 34 Billion by 2017[8].

II. ROCHE IS THE LARGEST ONCOLOGY COMPANY WORLDWIDE AND THE DOMINANT SELLER OF CANCER MONOCLONAL ANTIBODIES

35. Roche, the largest oncology company in the world, currently has the largest portfolio of approved monoclonal antibody treatments. Out of ten (10) best-selling cancer drugs worldwide, Roche produces the top three (3) selling monoclonal antibodies – *bevacizumab*, *trastuzumab* and *rituximab*, marketed in the U.S. by Roche's subsidiary Genentech under the brand names Avastin®, Herceptin® and Rituxan®, respectively.

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[7] Cancer, one of the leading causes of death worldwide, affected approximately 13 Million people in 2012, and this figure is expected to grow to 17 Million by 2020 according to the Research and Markets report "Cancer Monoclonal Antibodies Market Forecast 2017".

[8] Research and Markets, *"Cancer Monoclonal Antibodies Forecast 2017",* http://www.researchandmarkets.com/reports/2622783/cancer_monoclonal_antibodies_market_forecast_to

36. In 2013, out of US$ 24 Billion worth of profits from mAbs sold worldwide, Roche pocketed US$ 21.2 Billion according to Roche's financial statements - Avastin® (US$ 6.9 Billion), Herceptin® (US$ 6.7 Billion) and Rituxan® (US$ 7.6 Billion)[9]. More importantly, almost 50% of Roche's worldwide profits (US$ 9 Billion) came from the United States, which remains the most lucrative market for pharmaceutical companies.

37. Roche's profits from their three blockbuster drugs remained steady bringing the pharma giant over US$ 20 Billion in sales each year in 2014[10] and 2015[11]. In fact, since their launch, the three star drugs brought Roche over US$ 170 Billion.

III. ROCHE'S BLOCKBUSTER ONCOLOGY DRUGS

A. Avastin®

38. Roche's *bevacizumab*, marketed and sold in the U.S. by Genentech under the brand name Avastin®, is approved for the treatment of brain, colon, kidney and lung cancers. The drug generated US$ 6.7 Billion in annual sales last year[12].

39. Avastin® intercepts the vascular endothelial growth factor, or VEGF, growth signal, which is sent out by cancer cells to attract new blood

[9] Roche Finance Report 2013, available at http://www.roche.com/fb13e.pdf

[10] Roche Finance Report 2014, available at http://www.roche.com/fb14e.pdf

[11] Roche Finance Report 2015, available at http://www.roche.com/fb14e.pdf

[12] *Id.*

vessels to facilitate growth. By intercepting VEGF signals, Avastin® inhibits new blood vessel growth and stops cancer from spreading.

40. Roche's exclusivity rights in the U.S. for Avastin® expire in 2019.

41. Avastin® has brought Roche US$ 57.5 Billion since its launch in 2004.

C. Herceptin®

42. Roche's *trastuzumab*, marketed and sold in the U.S. by Genentech under the brand name Herceptin®, is one of the most widely used breast cancer treatments currently on the market and continuously generates over US$ 6 Billion in annual sales[13].

43. Herceptin® works by finding a cancer cell with HER2 protein and attaching itself to the surface, preventing the cancer from receiving new growth signals. In addition to blocking the growth signals, Herceptin® can alert the immune system to destroy the cancer cells to which it is attached.

44. Global sales of Herceptin® in 2013 topped US$ 6.7 Billion, and the drug, despite its age, remains a top three best seller after more than 15 years on the market.

45. Roche's exclusivity rights in the U.S. for Herceptin® expire in 2019.

46. Herceptin® has brought Roche US$ 58.2 Billion since its launch in

[13] Roche Finance Report 2013, available at http://www.roche.com/fb13e.pdf; Roche Finance Report 2014, available at http://www.roche.com/fb14e.pdf; and Roche Finance Report 2015, available at http://www.roche.com/fb14e.pdf

1998.

A. Rituxan®

47. Roche's *rituximab*, marketed and sold in the U.S. by Genentech under the brand name Rituxan®, was approved by the Food and Drug Administration ("FDA") in 1998 and was the first monoclonal antibody drug.

48. Used to treat chronic lymphocytic leukemia and non-Hodgkin's lymphoma, it seeks out a specific protein, CD20, only found on B-type white blood cells which are affected by certain types of lymphomas.

49. Rituxan® attaches itself to these cells, marking them and making them more visible to the immune system, which can then kill the infected cells.

50. Rituxan® continues to generate sales growth even after 15 years on the market with global sales in totaling US$7.6 Billion in 2013, US$ 7.9 Billion in 2014 and US$ 7.1 Billion in 2015[14]. This drug is considered the crowning jewel in a trio of cancer monoclonal antibodies developed by Roche, all of which are consistently big earners.

51. Roche's exclusivity rights in the U.S. for Rituxan® expire in 2018.

52. Rituxan® has brought Roche US$ 53.3 Billion since the launch in 1998.

[14] Roche Finance Report 2014, available at http://www.roche.com/fb13e.pdf; Roche Finance Report 2014, available at http://www.roche.com/fb14e.pdf; and Roche Finance Report 2015, available at http://www.roche.com/fb14e.pdf

IV. GENERIC ALTERNATIVES TO BRANDED PRESCRIPTION DRUGS, AND THE EFFECT OF THEIR ENTRY ON THE MARKET

53. Generic drugs are priced substantially below their brand-name drug equivalents. Typically, the first generic drug enters the market at a significant discount. As more generic competitors enter the market, price competition accelerates, and the prices continue to fall steeply.

54. According to an FDA study, entry of a second generic reduces the average generic price to nearly half of the branded price, and entry of additional generics reduces prices to 20% of the original branded price - in other words, an 80% discount[15].

55. Thus, once exclusivity is lost and generic entry occurs, an event known as the "patent cliff", the brand name manufacturer can expect a significant drop in profits and can lose 90% of its market share within 1 year.

56. Needless to say, confronted with an imminent loss of profits at the patent cliff, pharmaceutical companies often seek to stall or prevent altogether the entry of generic competition.

V. PLAINTIFF IS THE LEADING PRODUCER OF GENERIC MONOCLONAL ANTIBODIES, INCLUDING BIOSIMILARS OF ROCHE'S STAR DRUGS – *BEVACIZUMAB, TRASTUZUMAB* AND *RITUXIMAB*

57. Plaintiff is a full-cycle drug development and manufacturing company, doing everything from new molecule discovery and genetic

[15] FDA, *Generic Competition and Drug Prices* (Mar. 1, 2010)

engineering to large-scale commercial manufacturing and marketing support.

58. Plaintiff started development of generic monoclonal antibodies in 2010 in the context of a federal innovative project in Russia, including developing biosimilars of Roche's star drugs – Avastin®, Herceptin® and Rituxan®. The scope of the project included in-house development of mAbs manufacturing technology, comprehensive characterization of developed biosimilars, and comparative non-clinical and clinical studies.

59. In 2014, Plaintiff announced that a generic version of *rituximab*, AcellBia® (BCD-020), has been approved by the Russian Ministry of Health. The drug is a generic version of Roche's blockbuster *rituximab*, marketed and sold in the U.S. under the brand name Rituxan®.

60. Plaintiff is now the world leader in sales of biosimilar *rituximab*. Company's revenue from sales of AcellBia®, exceeded US$ 155 Million in 2014, representing more than 80% of global sales of non-originator *rituximab* biologicals.

61. Prior to 2014, Defendant Roche had a monopoly on the Russian market for *rituximab* products, just like it now has the monopoly in the United States.

62. In November of 2015, Plaintiff announced that the Russian Ministry of Health had approved Plaintiff's generic version of *bevacizumab*, BCD-021. The drug is a generic version of Roche's blockbuster *bevacizumab*,

marketed and sold in the U.S. under the brand name Avastin®.

63. Early in 2016, Plaintiff announced that the Russian Ministry of Health had approved Plaintiff's generic version of *trastuzumab*. The drug is a generic version of Roche's blockbuster *trastuzumab*, marketed and sold in the U.S. under the brand name Herceptin®.

64. By now, Plaintiff is the leading manufacturer of generic monoclonal antibodies and the biggest threat to Roche's star oncology drugs – Avastin®, Herceptin® and Rituxan®.

VI. PLAINTIFF'S GLOBAL EXPANSION AND ANTICIPATED ENTRY ON THE U.S. MARKET

65. As part of its global expansion plan, Plaintiff has concluded contracts for the sale and delivery of AcellBia®, valued at over US$ 200 Million, with distribution partners in Indonesia, Turkey, Armenia, Cambodia, Kenya, Kyrgyzstan, Morocco, Myanmar, Pakistan, South Africa, Ukraine, Uzbekistan, and Vietnam.

66. Plaintiff has also signed more than a dozen agreements with distribution and manufacturing companies in several countries of South-East Asia.

67. Since the U.S. market remains the largest oncology drugs market with US$ 42.5 Billion of cancer drugs sold in 2014, Plaintiff undertook a business development plan to enter the U.S. market.

68. In anticipation of its entry on the U.S. market with generic monoclonal antibodies, Plaintiff has opened a subsidiary in the U.S., has established and grown operations in the U.S. in the past several years, hired new people in the U.S. and transferred business development personnel from Russian office to the U.S.

69. Plaintiff had invested a substantial amount of time, funds and resources to establish operations in the U.S.

70. However, Defendants' illegal and anti-competitive conduct has thwarted Plaintiff's business development, caused serious damages, and is threatening Plaintiff's viability as a business.

VII. RELEVANT MARKETS FOR ANTITRUST PURPOSES

A. Relevant Market for Bevacizumab

71. *Bevacizumab*, branded and marketed by Roche worldwide and by Genentech in the U.S. under the name Avastin®, is a monoclonal antibody that intercepts the vascular endothelial growth factor, or VEGF, growth signal, which is sent out by cancer cells to attract new blood vessels to facilitate growth. By intercepting VEGF signals, Avastin® inhibits new blood vessel growth and stops a cancer from spreading.

72. Avastin® is the only monoclonal antibody approved by the FDA for treatment of metastatic colon or rectal cancer, non-small cell lung cancer, glioblastoma multiform, metastatic rectal cell carcinoma.

73. Thus, the relevant product market in which to assess the anti-competitive effects of Defendants' conduct is the market for *bevacizumab* and its equivalents.

74. The relevant geographic market is the United States. While *bevacizumab* is produced and sold elsewhere, only Genentech has FDA approval to market the drug in the United States.

75. Currently, Roche and Genentech hold a monopoly in the relevant market because they are the exclusive sellers of *bevacizumab* in the United States.

76. Entry of generic *bevacizumab* products will significantly and immediately decrease Roche/Genentech's *bevacizumab* sales and market share, and will lead to a substantial reduction in the average market price paid for *bevacizumab* products.

77. At all times relevant to this complaint, Defendants' exclusionary acts restricted entry of Plaintiff's generic drugs into the relevant market and protected Roche/Genentech's monopoly.

B. Relevant Market for Trastuzumab

78. *Trastuzumab*, branded and marketed by Roche worldwide and by Genentech in the U.S. under the name Herceptin®, is a monoclonal antibody that interferes with the HER2/neu receptor and is used to treat breast cancer.

79. Herceptin® is approved by the FDA for treatment of breast

cancer, metastatic gastric or gastroesophageal junction adenocarcinoma. The other two monoclonal antibodies used as supplements to Herceptin® are Perjieta® and Kadcyla®, both manufactured and sold by Roche and Genentech.

80. Perjeta® and Kadcyla® are not generally prescribed as substitutes for Herceptin®. Instead, the drugs can be prescribed together, or at different stages as complementing each other. The fact that these drugs are prescribed as complements, not substitutes, evidences that they do not compete head to head.

81. Thus, the relevant product market in which to assess the anti-competitive effects of Defendants' conduct is the market for *trastuzumab* and its equivalents.

82. The relevant geographic market is the United States. While *trastuzumab* is produced and sold elsewhere, only Genentech has FDA approval to market the drug in the United States.

83. Currently, Roche and Genentech hold a monopoly in the relevant market because they are the exclusive sellers of *trastuzumab* in the United States.

84. Entry of generic *trastuzumab* products will significantly and immediately decrease Roche/Genentech's *trastuzumab* sales and market share, and will lead to a substantial reduction in the average market price paid for *trastuzumab* products.

85. At all times relevant to this complaint, Defendants' exclusionary acts restricted entry of Plaintiff's generic drugs into the relevant market and protected Roche/Genentech's monopoly.

C. Relevant Market for Rituximab

86. *Rituximab*, branded and marketed by Roche worldwide and by Genentech in the U.S. under the name Rituxan®, is a chimeric monoclonal antibody against the protein CD20, which is primarily found on the surface of immune system B cells. The drug destroys B cells and is therefore used to treat diseases which are characterized by excessive, overactive or dysfunctional B cells, such as leukemia and non-Hodgkin's lymphoma.

87. While Rituxan® is not the only FDA-approved drug to treat leukemia and non-Hodgkin's lymphoma, there are currently no drugs that can be used to substitute Rituxan®.

88. Other monoclonal antibodies approved by FDA and used to treat leukemia and non-Hodgkin's lymphoma are Zevalin® (manufactured and sold by Biogen Idec, part of Roche Group) and Campath® (manufactured and sold by Millennium Pharmaceuticals and Genzyme). These drugs are not generally prescribed as substitutes for Rituxan®. Instead, the drugs can be prescribed together, or at different stages as complementing each other. The fact that these drugs are prescribed as complements, not substitutes, evidences that they do not compete head to head.

89. Thus, the relevant product market in which to assess the anti-competitive effects of Defendants' conduct is the market for *rituximab* and its equivalents.

90. The relevant geographic market is the United States. While *rituximab* is produced and sold elsewhere, only Genentech has FDA approval to market the drug in the United States.

91. Currently, Roche and Genentech hold a monopoly in the relevant market because they are the exclusive sellers of *rituximab* in the United States.

92. Entry of generic *rituximab* products will significantly and immediately decrease Roche/Genentech's *rituximab* sales and market share, and will lead to a substantial reduction in the average market price paid for *rituximab* products.

93. At all times relevant to this complaint, Defendants' exclusionary acts restricted entry of Plaintiff's generic drugs into the relevant market and protected Roche/Genentech's monopoly.

94. It is worth noting that in February of this year, the FDA approved Gazyva® for the treatment of non-Hodgkin lymphoma. Gazyva® has the same indicators as Rituxan® and is expected to compete with Rituxan® head to head. Gazyva® is manufactured and sold by Roche.

VIII. ROCHE ENGAGED IN ILLEGAL AND ANTI-COMPETITIVE CONDUCT TO MAINTAIN AND ADVANCE ITS MONOPOLY POSITION IN THE U.S. AND TO DESTROY PLAINTIFF – ALL AT THE EXPENSE OF AMERICAN CANCER PATIENTS

95. At some point after Plaintiff started working on biosimilars to Roche's star drugs, Roche and Genentech began preparing for the inevitable competition from Plaintiff in Roche's most profitable market - the United States.

96. Plaintiff's biosimilars directly compete with Roche's three star drugs that bring Roche over US$ 20 Billion annually. Recognizing the growing threat of competition from Plaintiff's biosimilars to the monopoly achieved by Roche/Genentech in the U.S. market, Roche and other Defendants willfully and purposefully hatched a scheme to secure and maintain Roche's monopoly in the U.S. beyond the exclusivity timeline.

97. To perpetuate its monopoly profits for several more years and to continue charging U.S. consumers supra competitive prices, Roche knew that Plaintiff's business had to be destroyed before Plaintiff's cheaper generic versions of Roche's star drugs could become available in the U.S. Defendants started with Plaintiff's main and largest market – Russia.

98. The scheme involved an astonishing array of illegal conduct that has deliberately targeted, and severely burdened, not only Plaintiff, but also consumers and cancer patients both in the United States and abroad, including:

a) Predatory and discriminatory pricing;

b) Limiting output followed by illegal tying arrangements;

c) Registration of a non-existent drug through a third party;

d) Participation in auctions and contests with fraudulent bids;

e) Limiting the distribution network in the U.S. in anticipation of generic entry and with the intent to restrain trade.

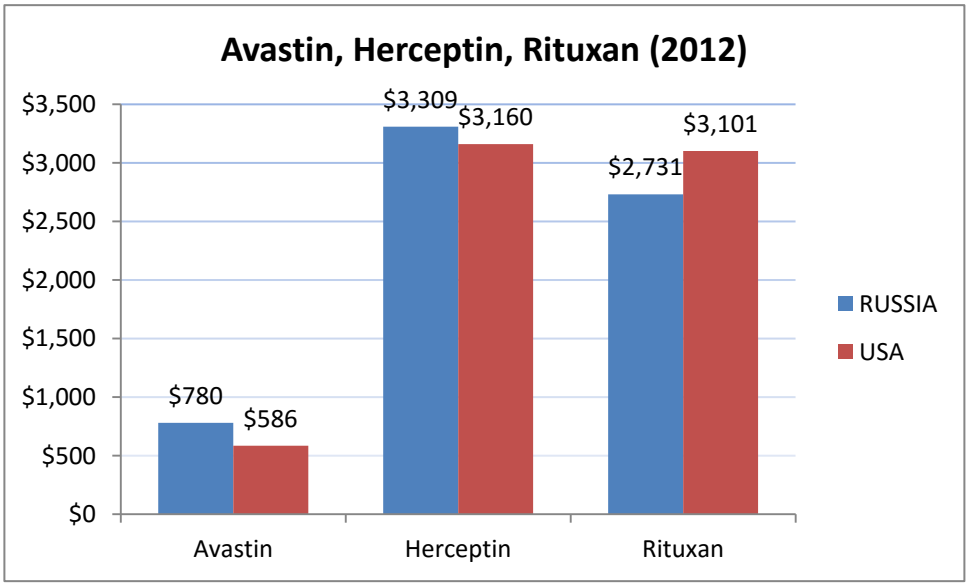
99. Roche used its monopoly position in the U.S. and its ability to charge American cancer patients supra competitive prices to finance its illegal scheme to destroy Plaintiff's business both in the U.S. and Russia, and to foreclose the U.S. market to generic alternatives to Roche's blockbuster drugs.

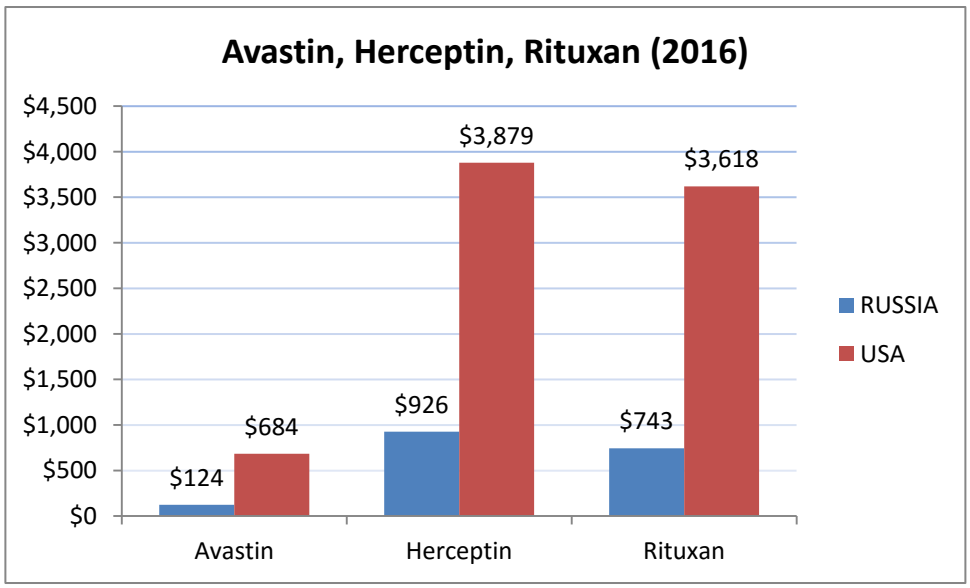
100. While Roche started selling its blockbuster drugs in Russia at prices higher than prices for the same drugs in the United States, over the past several years, Roche continued increasing the prices in the U.S. on average 19%, while dropping the prices in Russia on average 76%. In addition, shortly after Plaintiff received approval in Russia for its first biosimilar to Roche's star drug Rituxan® and announced that significant progress is being made to copy Avastin® and Herceptin®, Roche and Genentech implemented "a stealth price hike for three critical cancer drugs… Avastin, Herceptin and Rituxan"[16] resulting in an estimated $300 Million profit overnight in the U.S.[17]

[16] Saporito, Bill (2014, October 27). *"Hospitals Furious at Cancer-Drug Price Hikes"*. Time. Retrieved from http://time.com/3541484/cancer-drug-price-hikes/

[17] *Id.*

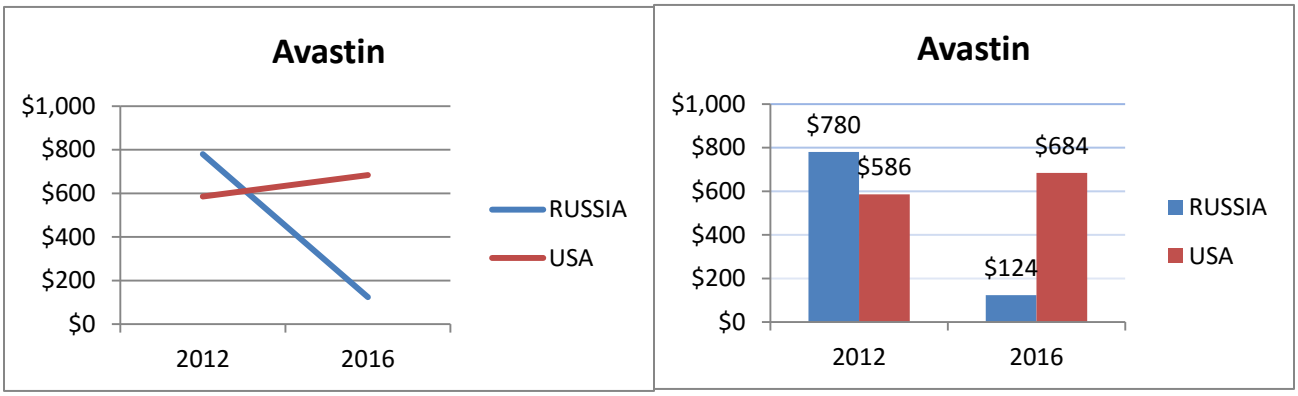
101. The graphs below demonstrate the current price disparity with Avastin® costing 5.5 times cheaper in Russia than in the U.S.[18], Herceptin® – and Rituxan® – over 4 times cheaper.



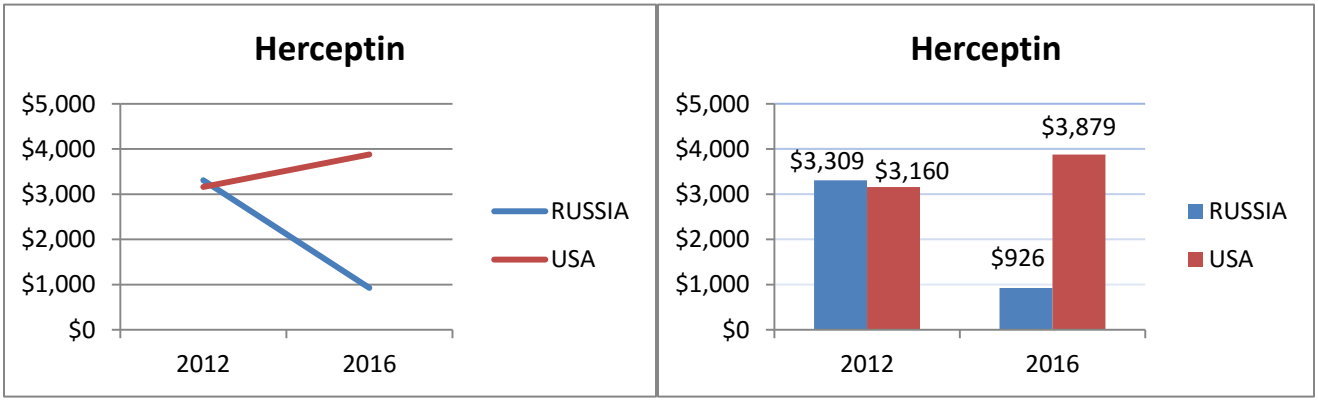


[18] The price disparity for Avastin® reached 14 times at certain auctions and tenders, with Avastin® sold by Roche for as low as US$ 46.

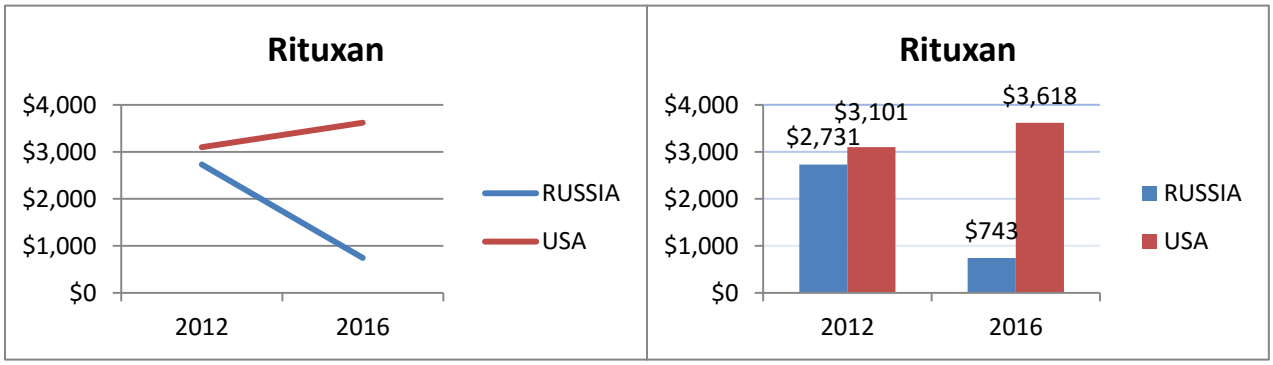
102. The average sales price of Avastin® 100mg increased substantially from 2012 to 2016 in the U.S. At the same time, the supra competitive pricing in the U.S. allowed Roche to finance predatory pricing in Russia, where Roche dropped the prices for Avastin® 100mg since 2012 84% or over 6 times.



103. The average sales price of Herceptin® increased substantially from 2012 to 2016 in the U.S. At the same time, the supra competitive pricing in the U.S. allowed Roche to finance predatory pricing in Russia, where Roche dropped the prices for Herceptin® 72% since 2012 or almost 4 times.



104. The average sales price Rituxan® increased substantially from 2012 to 2016 in the U.S. At the same time, the supra competitive pricing in the U.S. allowed Roche to finance predatory pricing in Russia, where Roche dropped the prices for Rituxan® 73% since 2012 or almost 4 times.



A. Predatory And Discriminatory Pricing Scheme

105. Roche is abusing its monopoly position in the U.S. and the ability to charge U.S. consumers inflated prices in order to finance predatory pricing in Russia and destroy Plaintiff's business and anticipated entry on the U.S. market with generic alternatives to Roche's blockbuster drugs.

106. While the price disparity itself is apparent from the graphs above, Roche went further than just dropping prices below any justifiable level. Roche is fully financing operations and profits of a third party distributor in Russia to put Plaintiff out of business.

107. Roche's conduct in connection with sales of Avastin® in Russia is a good example of Roche's discriminatory and predatory pricing scheme

financed by the price hikes in the U.S.

108. Prior to generic version of *bevacizumab* entering the market, Roche sold Avastin® 100mg at auctions and government tenders at about 16% over the MOH Price[19], sometimes as high as 120%.

109. However, once Plaintiff's generic *bevacizumab* was approved and became available for sale on the market, Roche started dropping prices at auctions on average 85% of the MOH Price, sometime as low as 94%, or US$ 46 for Avastin® 100mg (compared to US$ 684 in the U.S.).

110. More importantly, the price of Avastin® 100mg declared by Roche upon entry to Russia is US$ 148. This is the bulk price, not including taxes, duties, fees, secondary packaging in Russia, and distributor's share and profits. Thus, Roche is currently not only selling Avastin® 100mg at a loss, but also fully sponsors a third party independent company to operate, make profits and sell Roche's drugs in Russia – all while raising prices for the same drug in the United States.

111. More disturbing is that hundreds of thousands of cancer patients

[19] Here the reference is made to the highest manufacturer's price registered with the Russian Minstry of Health ("MOH"). Russian Law requires that the maximum manufacturer's price for a vital and essential drug be registered with MOH as a prerequisite for placing such drug on the market. This price does not include taxes, special fees or distributor's profit margins. Manufactureres can reduce prices during actual auction and tenders.

The actual prices of pharmaceutical products supplied by private companies to public health-care providers are determined in the course of state procurement procedures carried out by the respective authorities. A reverse tender or auction mechanism is normally used for determining the ultimate purchase price where the MOH price plus taxes, fees, duties and distributor's share of profits is the starting point, and the bidder who offers the lowest price wins the auction. For the purposes of this Complaint , the manufacturer's maximum registered price is referred to as "MOH Price", and the actual price of a drug sold at auctions and tenders is referred to as "Actual Price".

taking Roche's Drugs in the U.S. are forced to cover the costs of Roche's anti-competitive conduct that is aimed to prevent cheaper drugs from entering the U.S. market. The Drugs currently cost U.S. cancer patients hundreds of thousand of dollars, while extending life by only several months.

B. Registration Of Non-Existent Drug And Illegal Tying and Bundling Scheme

112. Shortly after Plaintiff obtained approval for generic *trastuzumab*, Roche, with the help of Defendants R-Farm and Genentech, hatched a scheme to prevent Plaintiff from sellig generic *trastuzumab,* maintain its monopoly position and destroy Plaintiff's business.

113. In addition to severely dropping prices, Roche organized and orchestrated a classic tying and bundling scheme, where Roche forced Russian cancer patients in need of another cancer drug produced by Roche, to purchase Roche's Herceptin®.

114. Roche's drugs, Herceptin® and Perjeta® have been registered in Russia in the name of Roche and supplied by Roche and Genentech since 2010 and 2013, respectively.

115. Perjeta® is a monoclonal antibody used for the treatment of breast cancer, and, if used in combination with Herceptin®, has been shown to reduce the risk of death by 34% in certain types of breast cancer[20]. Thus, patients often

[20] Genentech, *Genentech's Perjeta Significantly Extends Survival in People With HER2-Positive Metastatic Breast Cancer,* available at

require both drugs.

116. First, Roche stopped selling Perjeta® in Russia.

117. Then, on October 10, 2014, R-Farm, at the direction and full knowledge of Roche and Genentech, registered with the Russian Ministry of Health, a new drug under the name "Beyodaim"[21].

118. However, "Beyodaim" is not a new drug, a new compound or combination of two drugs, but merely separate vials of Herceptin® and Perjeta® included in one box.

119. Beyodaim is not recognized as an active ingredient by the World Health Organization[22] and is not listed as a product on Roche's or Genentech's global websites or product lists. The only reference to "Beyodaim" can be found on Roche's Russian version of the website.

120. Moreover, "Beyodaim" was registered as a new drug with the Ministry of Health in the name of Defendant R-Farm, who does not manufacture either of the drugs included in the package but acts as Roche's official distributor in the Russian market. Prior to registration of this "new" drug, several managers from Roche migrated to R-Farm.

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http://www.gene.com/media/press-releases/14267/2012-12-07/genentechs-perjeta-significantly-extends

[21] Transliteration from Russian "Бейодайм", registration No. ЛП-002670.

[22] The World Health Organization uses Anatomical Therapeutic Chemical (ATC) Classification System for the classification of active ingredients of drugs according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties.

121. The trademark "Beyodaim", however, was registered by Roche in its own name.

122. Until this day, Perjeta® is not available in Russia and can only be purchased inside "Beyodaim" together with Roche's Herceptin®.

123. As mentioned above, Herceptin® and Perjeta®, even though two distinct products, are frequently used together in treatment of breast cancer. The only way for patients and consumers to buy Perjeta® now is in combination with Herceptin®.

124. Patients are thus forced to purchase Herceptin® from Roche and R-Farm in order to obtain the necessary Perjeta®.

125. As the only seller of Perjeta® on the Russian market[23], Roche has monopoly power and has exercised such power to force patients fighting with cancer to buy Herceptin® from Defendants[24].

126. Defendants' anti-competitive conduct has foreclosed and will continue to foreclose competition and prevent cancer patients from obtaining the benefit of competing products. Specifically, it will prevent patients from enjoying the benefit of Plaintiff's high-quality generic alternative to Herceptin®.

127. Moreover, the Russian Anti-monopoly Service had issued a

[23] Roche's exclusivity for Perjeta in the Russian market expires in 2019.

[24] "Beyodaim" is registered in the name of Defendant R-Farm, with Herceptin manufactured and shipped to Russia by Genentech, and Perjeta manufactured and shipped to Russia by Roche.

decision on December 17, 2015 holding that the registration and sale of "Beyodaim" is in violation of antitrust laws and principles.

C. Dosage of Herceptin®

128. In addition to forcing cancer patients in Russia to buy Roche's expensive Herceptin® as part of "Beyodaim" when a much cheaper generic version is already available on the market, Defendants' packaging and dosage of the drug raises serious concerns as well.

129. Herceptin® is marketed and sold worldwide in vials containing 440 mg of the drug.

130. Depending on the purpose of the treatment, patients are to be given a dose of 2 to 8 mg Herceptin/Kg weight. For a person weighing about 150 lbs., that translates to an amount of Herceptin ranging from 136 mg to 544 mg. Herceptin is administered weekly or three-weekly.

131. Each vial contains 440 mg of Heceptin® as a lyophilized sterile powder[25]. Before Herceptin can be administered, it must be mixed with a liquid contained in the package and also provided by Roche and Genentech.

132. According to Roche and Genentech, the mixed solution should have a concentration of Herceptin® of 21mg/mL[26]. However, as described in a

[25] Genentech, *Herceptin Full Prescribing Information*, available at http://www.gene.com/download/pdf/herceptin_prescribing.pdf (last accessed June 3, 2016).

[26] *Id.*

recent Class Action Suit filed against Roche and Genentech in California, Genetech and Roche either misrepresent the amount if Herceptin® in the vial , or misrepresent the concentration of the solution resulting in patients buying and using more drug than they would otherwise need[27].

133. More importantly, once dissolved as a solution, Herceptin® can lose its potency and must be discarded after 28 days[28].

134. Some patients are allergic to the liquid solution provided in the package, requiring Herceptin® to be mixed with sterile water. Once Herceptin® is mixed with water, it must be discarded immediately after single use[29].

135. The current packaging and dosage of Herceptin® forces patients to use more drug than they would otherwise need and/or discard the drug they could not use[30].

D. Fraudulent Bids For Avastin®

136. At the end of 2015, Biocad obtained approval for the manufacturing and sale of generic *bevacizumab*. Until that time, *bevacizumab*

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[27] See Complaint, *Comanche County Memorial Hospital v. Genentech et al*, Docket No. 3:16-cv-02498 (N.D. Cal. May 9, 2016).

[28] *Id.*

[29] *Id.*

[30] Harris, Gardiner (March 1, 2016). *Waste in Cancer Drugs Costs $3 Billion a Year, a Study Says.* New York Times, http://www.nytimes.com/2016/03/01/health/waste-in-cancer-drugs-costs-3-billion-a-year-a-study-says.html?_r=0 (Last accesed, June 3, 2016).

was sold in Russia exclusively by Roche under the brand name Avastin®.

137. Avastin® was launched in Russia in 2009 and, thus, since 2009 and until the end of 2015, Roche had monopoly position and fully controlled price and output in the Russian market, leading to supra competitive pricing. In fact, in 2012, the price for Avastin® in Russia was 28% higher than the price for Avastin® in the U.S.

138. In addition to engaging in predatory pricing as discussed above, Defendants engaged in fraudulent bidding to win government contracts and tenders for Avastin® in order to retain monopoly position and destroy Plaintiff's competing business.

139. On March 10, 2016, Ortat JSC, a fully owned subsidiary of Defendant R-Farm and the official packaging company responsible for secondary packaging of Avastin® in Russia, distributed a letter addressed "To All Interested parties" announcing that Avastin® will not be available on the Russian market until the second half of 2016.

140. Despite knowing that the drug will not be available, Defendant R-Farm, with full knowledge and at the direction of Roche, continued participating in government auctions and tenders and submitting bids for Avastin® at prices lower than the cost of drug declared by Roche upon entry to Russia.

141. With full knowledge that Defenfants will not be able to perform,

R-Farm entered into numerous government and municipal contracts that called for delivery of Avastin® before the second half of 2016.

142. R-Farm, knowingly and intentionally misrepresented the availability of Avastin® and participated in auctions based on such misrepresentations, with the purpose and intention to maintain Roche's leading position on the market for Avastin® and to prevent Plaintiff from securing any contract for generic equivalent of Avastin®.

143. R-Farm and Roche did succeed in winning the fraudulent bids with no intention of delivering the drug pursuant to the contracts. Defendants did in fact default on numerous contracts and did not deliver the drug, yet prevented Platiniff from offering this much needed drug to cancer patients in Russia.

D. Limiting Distribution Networks In The U.S.

144. In 2014, Genentech, Roche's subsidiary in the U.S. and the seller of Roche's star drugs in the U.S., announced substantial limitation of its distribution network for three drugs – Avastin®, Herceptin® and Rituxan®.

145. Roche and Genentech shifted distribution from 80 wholesalers who had handled the drugs to just six.

146. Such distribution change resulted in "a stealth price hike for three critical cancer drugs... Avastin, Herceptin and Rituxan" resulting in an

estimated $300 Million profit overnight in the U.S.[31]

147. However, limiting distribution network in the U.S. did not only helped Defendants finance their illegal conduct in Russia, but was also designed to slow down the entry of generic alternatives on the U.S. market.

148. To receive approval from the FDA, generic firms are required to conduct bioequivalence testing to demonstrate that a generic formulation is therapeutically equivalent to the brand drug. This testing requires access to a limited amount of the brand product.

149. Thus, distribution restrictions can be used by pharmaceutical companies to prevent generic firms from obtaining samples of the brand product for testing purposes with the FDA.

150. Roche's plan to limit distribution network to a few specialty distributors not only limits generic manufacturer's access to reference drugs, but it also increases costs for patients and hospitals and forces hospitals to increase inventory and buy more drugs that they would normally order.

151. When hospitals contract with wholesalers, drugs are delivered daily from distributors at specific times. But with specialty distributors, drugs are shipped via other courier services such as FedEx Corp., potentially at later times, compelling hospitals to increase the inventory of drugs they have on hand to ensure patient needs are met. This, again, leads to increased costs to

[31] Saporito, Bill (2014, October 27). *"Hospitals Furious at Cancer-Drug Price Hikes"*. Time. Retrieved from http://time.com/3541484/cancer-drug-price-hikes/

the cancer patients.

IX. ANTI-COMPETITIVE EFFECT ON THE U.S. MARKET AND INJURY TO PLAINTIFF

152. Avastin®, Herceptin® and Rituxan® have been the most valuable drugs in Roche's portfolio earning over US$ 20 Billion per year. Rather than lose much of this revenue stream, Roche embarked on a strategy to inhibit generic competition and unlawfully maintain its monopoly in the relevant markets for monoclonal antibodies.

153. Using its monopoly position and supra pricing allowed Roche to finance destruction of Plaintiff's business in Russia and in the U.S. More specifically, Roche severely dropped prices on Plaintiff's main and largest market - Russia, engaged a third party to register a non-existent drug to effectuate an illegal tying scheme, and submitted fraudulent bids to win government auctions and contracts.

154. As a direct and proximate result of Defendants' anti-competitive and unlawful tactics, competition in the sale of monoclonal antibodies in the United States was improperly diminished and restrained.

155. As a result of these anti-competitive acts, Defendants thwarted low-cost generic competition to these monopolies for many months or years, forcing consumers to overpay by hundreds of millions of dollars for vital prescription drugs.

156. As a direct and proximate result of the foregoing anti-competitive effects, Plaintiff has suffered injury to their business and property, including by being deprived of the ability to effectively compete in the United States.

157. Defendants' anti-competitive conduct was aimed to stabilize and maintain the monopoly in the U.S., to destroy Plaintiff's competing business in the U.S., Russia and worldwide, and to foreclose the U.S. market to generic alternatives to Roche's star drugs.

X. ROCHE'S ANTI-COMPETITIVE CONDUCT IN RUSSIA IS IN LINE WITH ROCHE'S WORLDWIDE POLICY TO DESTROY ANY GENERIC COMPETITION AND PREVENT CHEAPER DRUGS FROM ENTERING THE U.S. MARKET

158. The scheme to destroy Plaintiff, producer of biosimilar drugs, was established and implemented with the full knowledge and at the direction of Roche and Roche's corporate management.

159. In recent years, Roche has made several other attempts to thwart generic competition.

160. In 2014, Biocon and the local arm of Mylan launched copies of *trastuzumab* in India under the brands CanMab and Hertraz, posing the first challenge against Roche's blockbuster drugs.

161. Roche sued Biocon and successfully precluded any sales of generic *trastuzumab*.

162. Similarly, Roche first attempted to sue Plaintiff in Russia to preclude

production and sale of generic *rituximab*. When Roche's attempt to sue Plaintiff in Russia failed – Roche hatched a scheme to make sure that Plaintiff does not survive to see its generic alternatives on the U.S. market, despite investing substantial funds, time and resources into building and developing the foundation for selling its products in the U.S.

163. Currently, Roche is also trying to block Plaintiff's sale of generic alternatives not only in Russia but also in Shri Lanka[32], Ecuador and other countries.

164. As a leading participant in the global market for oncology drugs and the exclusive seller of Avastin®, Herceptin® and Rituxan® in the U.S., Roche understands the danger of generic alternatives to Roche's extraordinary profits, the effect generic entry can have on Roche's market share and monopoly position in the U.S., and the fact that the foreclosure of the U.S. market to generic drugs would result in higher profits for Roche and the ability to continue charging American consumers and cancer patients inflated prices for oncology prescription medications.

165. When threatened with imminent generic competition to its blockbuster drugs, Roche designed and implemented a scheme with the help and active participation of the other Defendants aimed to destroy Plaintiff's competing business, maintain Roche's monopoly in the United States and continue inflating prices of various cancer drugs sold to consumers and cancer

[32] Roche filed a lawsuit in Shri Lanka to prevent Plaintiff from selling generic *trastuzumab* (Roche's Herceptin®).

patients within the United States and abroad.

FIRST CLAIM FOR RELIEF

Violation of Section 2 of the Sherman Act

166. Plaintiff realleges and incorporates by reference each and every allegation set forth in the paragraphs above.

167. At all times relevant, Defendants Roche and Genentech were engaged in the manufacturing, marketing, distribution, and sale of monoclonal antibodies in the global market, including in the U.S.

168. Defendants' activities, and the sale of their products, have both taken place, and have had a substantial anti-competitive effect upon, interstate commerce within the United States and foreign commerce.

169. At all relevant times Defendants' business activities and anti-competitive conduct that are the subject of this Complaint were within the flow of and had a direct, substantial and reasonably foreseeable effect on interstate and foreign trade and commerce.

170. Defendants' anti-competitive activities and their effects have caused injury to the Plaintiff both inside the United States and in foreign nations.

171. At all relevant times, Roche imported drugs, parts of drugs or drug compounds into the U.S. commerce.

172. At all relevant times, Roche possessed monopoly power in each relevant drug market for monoclonal antibodies in the U.S.: *rituximab*, *trastuzumab* and *bevacizumab*.

173. Through the anti-competitive conduct described herein, Defendants have willfully acquired and/or maintained monopoly power in the relevant markets. Defendants acted with an intent to acquire and/or maintain monopoly, and their anti-competitive conduct described herein enabled them to do so, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

174. There are no legitimate business justifications for Defendants' conduct, and any purported legitimate business justifications are mere pretexts.

175. The purpose and effect of Defendants' actions was to block generic drugs from entering the relevant markets for *bevacizumab, trastuzumab* and *rituximab*.

176. Defendants' conduct had direct effect of foreclosing the U.S. market to generic producers and Plaintiff were injured in their business or property as a direct and foreseeable result of Roche's monopoly and predatory practices.

177. Plaintiff had been injured in their business and property in an amount to be established at trial.

178. Plaintiff is also entitled to an award of treble damages.

SECOND CLAIM FOR RELIEF

Violation of Section 1 of the Sherman Act

179. Plaintiff realleges and incorporates by reference each and every allegation set forth in the paragraphs above.

180. At all relevant times, Defendants sold and shipped substantial quantities of cancer drugs in a continuous and uninterrupted flow of interstate and foreign commerce. Defendants received payment for such products across state and national boundaries.

181. Defendants' activities, and the sale of their products, have both taken place, and have had a substantial anti-competitive effect upon, interstate commerce within the United States and foreign commerce.

182. Beginning at least as early as 2014, Roche hatched a scheme and engaged in predatory conduct with the intention to restrain trade in the U.S. This scheme was an unreasonable restraint of trade and commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. §1

183. Defendants' anti-competitive activities and their effects have caused injury to Plaintiff both inside the United States and in foreign nations.

184. There are no legitimate business justifications for Defendants' conduct, and any purported legitimate business justifications are mere pretexts.

185. Defendants' conduct had direct effect of foreclosing the U.S. market to generic producers, and Plaintiff was injured in their business or property as a direct and foreseeable result of Roche's monopoly and Defendants' predatory practices.

186. Plaintiff had been injured in their business and property in an amount to be established at trial.

187. Plaintiff is also entitled to an award of treble damages.

THIRD CLAIM FOR RELIEF

Violation of the Clayton Act 15 U.S.C. § 14

188. Plaintiff realleges and incorporates by reference each and every allegation set forth in the paragraphs above.

189. At all relevant times, Defendants sold and shipped substantial quantities of cancer drugs in a continuous and uninterrupted flow of interstate and foreign commerce. Defendants received payment for such products across state and national boundaries.

190. Defendants' activities, and the sale of their products, have both taken place, and have had a substantial anti-competitive effect upon, interstate commerce within the United States and foreign commerce.

191. Defendants' anti-competitive activities and their effects are in violation of the Clayton Act.

192. Defendants have engaged in price discrimination, illegal tying and bundling, and other anti-competitive conduct in violation of Section 3 of the Clayton Act, 15 U.S.C. § 14.

193. The effect of these arrangements has been to substantially lessen competition in the relevant markets.

194. There are no legitimate business justifications for Defendants' conduct, and any purported legitimate business justifications are mere pretexts.

195. Defendants' conduct had direct effect of foreclosing the U.S. market to generic producers and Plaintiff were injured in their business or property as a direct and foreseeable result of Roche's monopoly and predatory practices.

196. Plaintiff had been injured in their business and property in an amount to be established at trial.

197. Plaintiff is also entitled to an award of treble damages.

FOURTH CLAIM FOR RELIEF

Violation of the Robinson-Patman Act 15 U.S.C. § 13

198. Plaintiff realleges and incorporates by reference each and every allegation set forth in the paragraphs above.

199. Defendants have engaged in price discrimination, illegal tying and

bundling, and other anti-competitive conduct in violation of the Robinson-Patman Act 15 U.S.C. § 13.

200. There is no reasonable justification for Defendants' conduct.

201. The effect of such conduct is to substantially lessen and harm competition.

202. The sales by Defendants Roche and Genentech were and are being made in commerce on an interstate basis.

203. The differences in prices charged by Defendants and other anti-competitive conduct as alleged herein have caused the loss of Plaintiff's customers, sales, profits and earnings, resulting in the predictable and systematic destruction of Plaintiff's businesses and injuring competition within the relevant markets.

204. The injuries suffered by Plaintiff by reason of Defendants' actions described above are the type of injuries which the Robinson-Patman Act was enacted to prevent and are "antitrust injuries" under that Act.

205. As a direct and proximate result of Defendants wrongful actions, Plaintiff has suffered damages and, therefore, is entitled to and request special and consequential damages in amounts according to proof at the time of trial.

206. Plaintiff is also entitled to an award of treble damages.

FIFTH CLAIM FOR RELIEF

Violation of Donnely Act – N.Y. General Busines Law §§340 *et seq*.

207. Plaintiff realleges and incorporates by reference each and every allegation set forth in the paragraphs above.

208. Defendants have engaged in anticompetitive conduct as alleged in this Complaint that unreasonably restrained trade.

209. Defendants have violated and continue to violate General Business Law §§340 *et seq*. in that they are restraining competition in New York for the purposes of establishing or maintaining a monopoly in the market for monoclonal antibodies, specifically markets for *bevacizumab, trastuzumab* and *rituximab*.

SIXTH CLAIM FOR RELIEF

Tortious Interference With Business Relationships

210. Plaintiff realleges and incorporates by reference each and every allegation set forth in the paragraphs above.

211. Plaintiff expended considerable resources to develop and manufacture monoclonal antibodies and had a long standing business relationships with healthcare providers, hospitals and authorities responsible for buying essential drugs.

212. Defendants had full knowledge of Plaintiff's business

relationships and tortiously interfered with such business relationships when they intentionally diverted the sales by submitting fraudulent bids and arranging tying scheme to prevent Plaintiff from selling Plaintiff's products, including generic *trastuzumab* and *bevacizumab*.

213. Defendants acted through the use of wrongful means by executing an illegal and anticompetitive scheme, improperly diverting sales of certain cancer drugs, as well as by making misrepresentations at the auctions and tenders.

214. By registering a non-existent drug, participating in auctions based on misrepresetnations, illegally tying products and engaging in predatory pricing, Defendants intentionally interfered with Plaintiff's advantageous business relationships so as to deprive Plaintiff of profits.

215. As a result of Defendants' conduct, Plaintiff was deprived of profits from the sale of its monoclonal antibodies after expending considerable resources, time and fund to develop and manufacture the drugs.

216. As a direct and proximate result of Roche's wrongful actions, Plaintiff has suffered damages and, therefore, is entitled to and request special and consequential damages in amounts according to proof at the time of trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. On the FIRST, SECOND, THIRD, FORTH, FIFTH and SIXTH claims for relief, for damages to be determined at trial;

B. For treble damages pursuant to 5 U.S.C. § 15(a);

C. For pre-judgment and post-judgment interest;

D. For any and all costs of suit herein incurred, including, but not limited to attorneys' fees and costs; and

E. For such other and further relief that the Court may deem just and proper.

JURY DEMAND

Plaintiff respectfully demands a trial by jury on all issues raised herein.

Dated: June 6, 2016
New York, New York

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